

Interessenerklärungen – Tabellarische Zusammenfassung

- 1 Berater- bzw. Gutachtertätigkeit oder bezahlte Mitarbeit in einem wissenschaftlichen Beirat eines Unternehmens der Gesundheitswirtschaft (z. B. Arzneimittelindustrie, Medizinproduktindustrie), eines kommerziell orientierten Auftragsinstituts oder einer Versicherung
- 2 Mitarbeit in einem Wissenschaftlichen Beirat (advisory board)
- 3 Honorare für Vortrags- und Schulungstätigkeiten im Auftrag eines Unternehmens der Gesundheitswirtschaft, eines kommerziell orientierten Auftragsinstituts oder einer Versicherung
- 4 Bezahlte Autoren-/oder Coautorenschaft im Auftrag eines Unternehmens der Gesundheitswirtschaft, eines kommerziell orientierten Auftragsinstituts oder einer Versicherung
- 5 Forschungsvorhaben/ Durchführung klinischer Studien: finanzielle Zuwendungen (Drittmittel) für Forschungsvorhaben oder direkte Finanzierung von Mitarbeitern der Einrichtung vonseiten eines Unternehmens der Gesundheitswirtschaft, eines kommerziell orientierten Auftragsinstituts oder einer Versicherung
- 6 Eigentümerinteressen (Patent, Urheberrecht, Aktienbesitz): Besitz von Geschäftsanteilen, Aktien, Fonds mit Beteiligung von Unternehmen der Gesundheitswirtschaft
- 7 Indirekte Interessen: Mitglied von in Zusammenhang mit der Leitlinienentwicklung relevanten Fachgesellschaften/Berufsverbänden, Mandatsträger im Rahmen der Leitlinienentwicklung

Stand November 2021

	Berater-/ Gutachter- tätigkeit	Mitarbeit in einem Wissenschaft- lichen Beirat (advisory board)	Bezahlte Vortrags-/oder Schulungs- tätigkeit	Bezahlte Autoren- /oder Coautoren- schaft	Forschungs- vorhaben/ Durchfüh- rung klinischer Studien	Eigentümer- interessen (Patent, Urheberrecht, Aktienbesitz)	Indirekte Interessen	Bewertung
Allescher, Hans-Dieter	Bayer	Bayer	keine	keine	keine	keine	Mitglied: DGVS DGEVB DGIM DKG BDI AGA Schwerpunkt: - Federführung: Endoudate Persönlich: -	keine Col, keine Konsequenz
Behrens, Angelika	Nein	Nein	abbvie Falk Norgine Falk Norgine medupdate	Nein	E&L medical GmbH	Nein	Mitglied: Arbeitsgemeinschaft leitender Gastroenterologen im Krankenhaus e. V. , Vorstandstätigkeit Schwerpunkt: Durchführung einer multizentrischen Studien zum Thema Sedierung Federführung: - Persönlich: -	gering, keine Konsequenz
Beilenhoff, Ulrike	keine	keine	Tätigkeit als Fachdozentin in Hygiene- Sachkundekur sen, in	Autor von ESGE- ESGENA Guidelines zum Thema	keine	keine	Mitglied: Vorsitzende der Deutschen Gesellschaft für Endoskopiefachberufe (DEGEA)	keine Col, keine Konsequenz

									Schwerpunkt: verschiedene Publikationen zum Thema Hygiene Federation: Organisation von Kongressen, Fortbildungen und Webinaren der DEGEA und ESGENA Persönlich: nein	
Bitter, Horst	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Mitglied: Nein Schwerpunkt: Nein Federation: Nein Persönlich: Nein	keine Col, keine Konsequenz
Eckardt, Alexander	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Mitglied: Keine Schwerpunkt: Keine Federation: Keine Persönlich: Keine	keine Col, keine Konsequenz
Fischer, Nadine	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Mitglied: Nein, Wissenschaftliche Tätigkeit: Nein, Wissenschaftliche Tätigkeit: Nein, Beteiligung an Fort-/Ausbildung: Nein, Persönliche Beziehung: Nein	keine Col, keine Konsequenz
Heidemann, Peggy	Nein	Nein	Nein	KV-Journal MV	1. Stadtverwaltung Schwerin bng dgvs	Nein	Nein	Nein	Mitglied: bng bund niedergelas, Gastroenterologen Deutschlands Regionalvors. MV Mitglied: dgvs	keine Col, keine Konsequenz

						Labor Schwerin Kompetenznetz Darmkrankungen Hausarztstammisch SN							Mitglied: dgp dt. Gesell. für Pneumologie und Beatmungsmedizin Mitglied: Gesellsch. der Internisten MV Schwerpunkt: Darmkrebsvorsorge Federführung: - Persönlich: -	
In der Smitten, Susanne	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Mitglied: Mitgliedschaft in der Deutschen Morbus Crohn / Colitis ulcerosa Vereinigung (DCCV), Inselstraße 1, 10179 Berlin Schwerpunkt: - Federführung: - Persönlich: -	keine Col, keine Konsequenz
Jung, Michael	Ärztelkam mer rheinland - pfalz Niedersac hsen	nein				Falk Pharma Wassenburg olympus					keine	keine	Mitglied: Mitglied der KRINKO Schwerpunkt: Hygiene in der Endoskopie Diagnostische und therapeutische Endoskopie Federführung: Unterricht an der Schule für ärztliches Assistenzpersonal in der Endoskopie Heidelberg Trainingskurse der EndoAkademie Persönlich: keine	keine Col, keine Konsequenz

Klare, Peter	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Mitglied: - Schwerpunkt: - Federführung: - Persönlich: -	keine Col, keine Konsequenz
Kopp, Ina	Deutsche Akkreditier- ungs- stelle (DAkkS)	Wissenschaftliche r Beirat des Instituts für Qualitäts- sicherung und Transparenz im Gesundheitswe- sen (IQTIG)	EBM Frankfurt, Arbeitsgruppe des Instituts für Allgemeinmedi- zin am FB Medizin der Johann Wolfgang Goethe- Universität Frankfurt	Schattauer Verlag	Deutsche Krebshilfe (DKH)	Nein	Nein	Mitglied: Lenkungsausschuss für das Leitlinienprogramm Onkologie von Deutscher Krebsgesellschaft, Deutscher Krebshilfe und AWMF (Mitglied) Schwerpunkt: Leitlinien, Qualitätsmanagement, Versorgungsforschung Federführung: Seminare Leitlinien der AWMF für Leitlinienentwickler und das Curriculum Leitlinienberater - Aufbaueminare Leitlinien der AWMF für Leitlinienberater - Workshops des Leitlinienprogramms Onkologie Persönlich: --	keine Col, keine Konsequenz	
Lorenz, Pia	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Mitglied: keine Schwerpunkt: nein Federführung: nein Persönlich: nein	keine Col, keine Konsequenz	

PD Dr. Lynen Jansen, Petra	keine	keine	Nein	keine	keine	keine	Mitglied: keine, Wissenschaftliche Tätigkeit: Leitlinien, Wissenschaftliche Tätigkeit: entfällt, Beteiligung an Fort-/Ausbildung: Leitlinienakademie, Persönliche Beziehung: keine	keine Col, keine Konsequenz
Riphaus, Andrea	Nein	DGVS Beirat Sektion Endoskopie Sektionsvorsitzen de 2018 DGE-BV Beiratsmitglied	Falk Foundation Endoscopy Campus	Springer Medizin Verlag GmbH	Nein	Nein	Mitglied: - Schwerpunkt: - Federführung: - Persönlich: -	keine Col, keine Konsequenz
Rosien, Ulrich	Bundesministerium für Arzneimittel und Medizinprodukte Arzneimittelkommission der deutschen Ärzteschaft Bundesärztekammer	Arzneimittelkommission der deutschen Ärzteschaft der Bundesärztekammer	Kursleiter an der Endoclub Academy bei Kursen, die nach den inhaltlichen Vorgaben der Fachgesellschaft durchgeführt werden Med-Update	Verlag Elsevier Verlag Elsevier	Falk Pharma	keine	Mitglied: Berufsverband deutscher Internisten, kein Mandat Mitglied: Berufsverband Gastroenterologie, keine Mandat Schwerpunkt: Medizinische Fachbücher: Facharztwissen Gastroenterologie, Facharztprüfung Gastroenterologie Schwerpunkt: Efficacy of Budesonide Orodispersible Tablets as Induction Therapy for Eosinophilic Esophagitis in a	keine Col, keine Konsequenz

Bundesärz tekammer	<p>Randomized Placebo-Controlled Trial. Lucendo AJ, Miehke S, Schlag C, et al. Schoepfer A, Straumann A; International EOS-1 Study Group. <i>Gastroenterology</i>. 2019 Jul;157(1):74–86.e15. doi: 10.1053/j.gastro.2019.03.025</p> <p>Schwerpunkt: Consensus report: faecal microbiota transfer - clinical applications and procedures. König J, Siebenhaar A, Högenauer C, et al. <i>Aliment Pharmacol Ther</i>. 2017 Jan;45(2):222–239. doi: 10.1111/apt.13868</p> <p>Schwerpunkt: The impact of technical and clinical factors on fecal microbiota transfer outcomes for the treatment of recurrent <i>Clostridioides difficile</i> infections in Germany. Peri R, Aguilar RC, Tüffers K, Erhardt A, Link A, Ehlermann P, Angeli W, Frank T, Storr M, Glück T, Sturm A, Rosien U, Tacke F, Bachmann O, Solbach P, Stallmach A,</p>
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Goesser F, Vehreschild MJ;
German Clinical Microbiome
Study Group (GCMMSG). United
European Gastroenterol J. 2019
Jun;7(5):716-722. doi:
10.1177/2050640619839918.
Schwerpunkt: Multicenter,
randomized comparison of the
diagnostic accuracy of 19-gauge
stainless steel and nitinol-based
needles for endoscopic
ultrasound-guided fine-needle
biopsy of solid pancreatic masses.
Hann A, Epp S, Veits L, Rosien U,
Siegel J, Möscher O, Bohle W,
Meining A. United European
Gastroenterol J. 2020
Apr;8(3):314-320. doi:
10.1177/2050640619887580.
Schwerpunkt: Sustained response
after remdesivir and convalescent
plasma therapy in a B-cell
depleted patient with protracted
COVID-19. Malsy J, Veletzky L,
Heide J, Hennigs A, Gil-Ibanez I,
Stein A, Lütgehetmann M, Rosien

U, Jasper D, Peine S, Hiller J, Haag F, Schmiedel S, Huber S, Jordan S, Addo MM, Schulze Zur Wiesch J. Clin Infect Dis. 2020 Oct 26;ciaa1637. doi: 10.1093/cid/ciaa1637. Schwerpunkt: Patient radiation dose in percutaneous biliary interventions: recommendations for DRLs on the basis of a multicentre study. Schmitz D, Vogl T, Nour-Eldin NA, Radeleff B, Kröger JC, Mahnken AH, Ittrich H, Gehl HB, Plessow B, Böttcher J, Tacke J, Wispler M, Rosien U, Schorr W, Joerdens M, Glaser N, Fuchs ES, Tal A, Friesenhahn-Ochs B, Leimbach T, Höpner L, Weber M, Gölder S, Böhmig M, Hetjens S, Rudi J, Schegerer A. Eur Radiol. 2019 Jul;29(7):3390-3400. doi: 10.1007/s00330-019-06208-6. Schwerpunkt: [The revised version of standard terminology in gastroenterological endoscopy -

result of a consensus project of the german society for gastroenterology, digestive and metabolic diseases]. Meinung A, Schmidbauer W, Schumacher B, Toerner T, Keuchel M, Baltes P, Denzer U, Götz M, Hochberger J, Jakobs R, Klaus J, Moog G, Rosien U, von Delius S, Wehrmann T, Lerch MM, Lammert F. *Z Gastroenterol*. 2018 Jan;56(1):e1. doi: 10.1055/s-0035-1567241

Schwerpunkt: [The revised version of standard terminology in gastroenterological endoscopy - result of a consensus project of the german society for gastroenterology, digestive and metabolic diseases]. Meinung A, Schmidbauer W, Schumacher B, Toerner T, Keuchel M, Baltes P, Denzer U, Götz M, Hochberger J, Jakobs R, Klaus J, Moog G, Rosien U, von Delius S, Wehrmann T, Lerch MM,

Schaible, Anja	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Nein	keine Col, keine Konsequenz
Schilling, Dieter	Firma Storz Endoskop e	Nein	Firma Falk Firma Vifor	Nein	Nein	Nein	Nein	Nein	keine Col, keine Konsequenz

Lammert F. Z Gastroenterol. 2017
Nov;55(11):1119-1126. doi:
10.1055/s-0043-121167.
Federführung: CIRS Endoskopie
der DGVS
Federführung: Best of DGVS
Federführung: Viszeralmedizin
2021
Persönlich: nein
Mitglied: Sekretärin Endoskopie
der Chirurgischen
Arbeitsgemeinschaft Endoskopie
und Sonografie (CAES) der
Deutschen Gesellschaft für
Allgemein-und Viszeralchirurgie
(DGAV)
Schwerpunkt:
Anastomoseninsuffizienz
Federführung: -
Persönlich: -
Mitglied: Arbeitsgemeinschaft
leitender gastroenterologischer
Krankenhausärzte
Schwerpunkt: Sedierung in der
Endoskopie,

Seifert, Hans	Nein	Nein	Falk- Foundation	ERBE- Instrumente	Nein	Nein	Nein	<p>Pankreaszystemmanagement, DElegation ärztlicher leistung Federführung: - Persönlich: -</p> <p>Mitglied: DGVS Vorsitz der Sektion Endoskopie Schwerpunkt: Mitglied in DGVS, ASGE, AGA, BDI, DGEVB Federführung: - Persönlich: -</p> <p>keine Col, keine Konsequenz</p>
Tonner, Peter H.	Nein	Nein	Nein	Nein	Nein	Nein	Nein	<p>Mitglied: Deutsche Gesellschaft für Anästhesiologie und Intensivmedizin American Society of Anesthesiologists International Anesthesia Research Society European Society of Anaesthesiology Wissenschaftlicher Verein zur Förderung der klinisch angewendeten Forschung in der Intensivmedizin Deutsche Gesellschaft für interdisziplinäre Intensivmedizin Schwerpunkt: Intensivmedizin, Anästhesiologie Federführung: -</p> <p>keine Col, keine Konsequenz</p>

Voigtländer, Torsten	Nein	Nein	Nein	Olympus	Olympus	Nein	Nein	Nein	<p>Persönlich: - Mitglied: - Schwerpunkt: Gallengangserkrankungen, Stenttherapie, Biomarker in Gallenflüssigkeit, endoskopische Techniken, Sedierung bei ERCP Federführung: Endoskopische Ausbildung, Hepatologie</p> <p>Persönlich: -</p>	keine Col, keine Konsequenz
von Delius, Stefan	Nein	Medtronic	Nein	Takeda AstraZeneca Olympus Medwork Boston Erbe Falk Ovesco Norgine Abbvie	Nein	Nein	Nein	Nein	<p>Mitglied: DGVS Schwerpunkt: - Federführung: - Persönlich: -</p>	Moderat, Enthaltung bei Empfehlung 3.4.2
Wappler, Frank	Nein	Nein	Braun Melsungen Sourcia	Mitherausge ber AINS Mitherausge ber Anästhesiolo gie &	Nein	Nein	Nein	<p>Mitglied: Präsident DGAI Schwerpunkt: MH, Sepsis, Begleiterkrankungen, Analgesiedierung Federführung: Deutscher Anästhesie Congress,</p>	keine Col, keine Konsequenz	

Wehrmann, Till	Nein	Nein	Falk Foundation	Nein	Nein	Nein	Hauptstadtkongress Anästhesiologie und Intensivtherapie, Regionaltagungen DGAI Persönlich: --- Mitglied: DGVS, Mitglied des Vorstands Mitglied: DGE-BV, Mitglied des Vorstands (Generalsekretär) Schwerpunkt: - Federführung: - Persönlich: -	keine Col, keine Konsequenz
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Literatursammlung:

AG 1 - Literatur 2013 - 2014

Inhalt: 16 Literaturstellen

Literaturstelle	Evidenzlevel	Studientyp
Arakawa, H. 2013	1	RCT
Bastaki, M. 2013	3	Randomized controlled double blind study
Boguradzka, A. 2014	3	RCT with statistical analysis based on patient self reports
Eberl, S. 2014	1	RCT with 180 patients in 3 arms (60 patients in each group)
Falt, P. 2013	1	Prospective, randomized, single-center trial
Glomsaker, T. B. 2013	2	prospective data were recorded
Hafner, S. 2015	1	systematic review of 16 randomised controlled trials consisting of 2933 colonoscopies
Hammami, Muhammad B. 2019	3	RCT
Jover, R. 2013	4	Case Controll ist am ehesten zutreffend
Kim, Hyunil 2020	1	RCT
Knuth, J. 2013	4	RCT
Lee, S. J. 2015	3	RCT
Lin, S. 2013	2	Metaanalyse
Shavakhi, A. 2014	3	prospektiv, randomisiert
Töx, U. 2013	3	Prospektiv randomisiert.
Xu, C. X. 2013	3	RCT

OXFORD (2011) Appraisal Sheet: Systematic Reviews: 2 Bewertung(en)

Hafner, S. et al. Water infusion versus air insufflation for colonoscopy. Cochrane Database Syst Rev. . CD009863. 2015				
Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References	
<p>Evidence level: 1</p> <p>Study type: systematic review of 16 randomised controlled trials consisting of 2933 colonoscopies</p> <p>Databases: Cochrane</p>	<p>Population: 2933 colonoscopies with male and female participants, regardless of the indication (screening, surveillance,</p>	<p>Primary: 1. Cecal intubation rate 2. Adenoma detection a. Number of participants with at least one adenoma detected (adenoma detection rate) b. Number of adenomas detected per participant</p>		

<p>Colorectal Cancer Group Specialized Register (searched February 2014)</p> <ul style="list-style-type: none"> • Cochrane Central Register of Controlled Trials (CENTRAL; 2014, Issue 1); • Ovid MEDLINE (1950 to February 2014); • Ovid EMBASE (1974 to February 2014); • ClinicalTrials.gov (1999 to February 2014) <p>In addition: the references from all identified studies as well as review articles on this topic for more eligible trials screening of published meeting abstracts of international scientific conferences such as the Digestive Disease Week, the United European Gastroenterology Week, the European Crohn's and Colitis Organisation meeting, and the annual meeting of the American College of Gastroenterology to identify studies published in abstract form only</p> <p>Ovid EMBASE (1974 to February 2014), ClinicalTrials.gov (1999 to February 2014)</p> <p>Search period: 1950 to 2014</p> <p>Inclusion Criteria: Randomised controlled trials comparing water infusion (water exchange or water immersion methods) against standard air insufflation during the insertion phase of the colonoscopy were included. RCTs irrespective of language and publication status no discrimination between water immersion and water exchange methods</p> <p>Exclusion Criteria: Studies with water-related methods as adjuncts to usual air insufflation were excluded.</p>	<p>symptoms).</p> <p>Intervention: water infusion (water exchange or water immersion methods) against standard air insufflation during the insertion phase of the colonoscopy</p> <p>Comparison: comparison of 16 RCT with regard to cecal intubation rate, adenoma detection, and pain in 2933 colonoscopies performed either with water infusion (water exchange or water immersion methods) or with standard air insufflation</p>	<p>Secondary: 1. The time needed to reach the cecum 2. Maximum pain score reported by the participants 3. Completing cecal intubation without sedation/analgesia 4. Adverse events (side effects from sedatives/analgesics used or procedure-related complications)</p> <p>Results: Completeness of colonoscopy (cecal intubation rate) was similar between water infusion and standard air insufflation (risk ratio 1.00, 95% confidence interval (CI) 0.97 to 1.03, P = 0.93). Adenoma detection rate was slightly improved with water infusion (risk ratio 1.16, 95% CI 1.04 to 1.30, P = 0.007). With water infusion participants experienced significantly less pain (mean difference in pain score on a 0 to 10 scale: -1.57, 95% CI -2.00 to -1.14, P < 0.00001) and a significantly lower proportion of participants requested on-demand sedation or analgesia, or both (risk ratio 1.20, 95% CI 1.14 to 1.27, P < 0.00001)</p> <p>Author's Conclusion: Improved adenoma detection might be due to the cleansing effects of water infusions on the mucosa. Detection of premalignant lesions during standard colonoscopy is suboptimal, and so improvements in adenoma detection by water infusion colonoscopy, although small, may help to reduce the risk of interval colorectal carcinoma. The most obvious benefit of water infusion colonoscopy was reduction of procedure-related abdominal pain, which may enhance the acceptance of screening/surveillance colonoscopy.</p>
<p>Methodical Notes</p>		

Funding Sources: not mentioned

COI: none

Study Quality: heterogeneity and reporting biases systematically assessed and transparently dealt with

Heterogeneity: huge between-study variability, outliers excluded

Sensitivity analysis revealed that the result was heavily determined by one trial that had a particularly long procedure time (at least three times longer than the other trials) (Leung FW 2010). Exclusion of this study reduced heterogeneity markedly

Publication Bias: investigation of potential publication bias using the funnel plot. As inspection of funnel plots did not reveal signs of asymmetry, no additional tests such as Egger's linear regression test were performed

Notes:

systematic review of 16 randomised controlled trials consisting of 2933 colonoscopies

Lin, S. et al. Water intubation method can reduce patients' pain and sedation rate in colonoscopy: a meta-analysis. Dig Endosc. 25. 231-40. 2013

Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 2</p> <p>Study type: Metaanalyse</p> <p>Databases: PubMed, Embase, Cochrane CENTRAL Register, China National Knowledge Information</p> <p>Search period: n. d.</p> <p>Inclusion Criteria: water, colonoscopy, random, trial, metaanalysis, age > 18, RCT, no history of colorectal disease.</p> <p>Exclusion Criteria: ASA III-IV, fehlende Daten, vorherige Chirurgie des Colons</p>	<p>Population: s. o.</p> <p>Intervention: Colonoscopy</p> <p>Comparison: Wsser vs. Luft</p>	<p>Primary: n. d.</p> <p>Secondary: n. d.</p> <p>Results: 15 Artikel mit 1414 PATienten ausgewählt. Wassermethode reduziert den Bedarf an Sedierung und ist weniger schmerzhaft bei gleichen Erfolgsraten der Prozedur.</p> <p>Author's Conclusion: Die Wassermethode sollte im Rahmen der Colonoscopy bevorzugt werden.</p>	<p>adäquat</p>

Methodical Notes

Funding Sources: n. d.

COI: keine

Study Quality: adäquat

Heterogeneity: moderat (s. o.)

Publication Bias: n. d.

Notes:

Eingeschlossen wurden nur RCTs. Limitation ergeben sich aus 1.5.

OXFORD (2011) Appraisal Sheet: RCT: 10 Bewertung(en)

Arakawa, H. et al. Does pulse oximetry accurately monitor a patient's ventilation during sedated endoscopy under oxygen supplementation?. Singapore Med J. 54. 212-5. 2013

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 70 (35 in each group)</p> <p>Recruiting Phase:</p> <p>Inclusion Criteria: The eligibility criteria included an age of 20–75 years and American Society of Anesthesiologists (ASA) class I–II (class I: healthy; class II: single controlled disease state).</p> <p>Exclusion Criteria: Exclusion criteria were ASA class III–V, therapeutic or emergency colonoscopy, SpO₂ < 90% when breathing room air, a history of cardiopulmonary diseases or major abdominal operations, allergy to meperidine or flunitrazepam, alcoholism, use of psychotropic drugs, and pregnant or breastfeeding women.</p>	<p>Intervention: sedated diagnostic colonoscopy with either oxygen supplementation or room air breathing</p> <p>Comparison: Patients were randomised into two study groups: (a) oxygen supplementation group (oxygen supplementation was administered routinely prior to and during the procedure at a rate of 2 L/min); and (b) room air breathing group (room air was breathed during the procedure; oxygen supplementation was administered if SpO₂ fell below 90% for more than 20-second intervals during the procedure).</p>	<p>Primary: SpO₂ and etCO₂ levels before and after sedation</p> <p>Secondary:</p> <p>Results: The rise of etCO₂ caused by alveolar hypoventilation was comparable in the two groups after sedation. SpO₂ was significantly higher in the oxygen supplementation group than in the room air breathing group (98.6% ± 1.4% vs. 93.1% ± 2.9%; p < 0.001) at peak etCO₂, and oxygen supplementation caused SpO₂ to be overestimated by greater than 5% when compared with room air. SpO₂ at peak etCO₂ was reduced from the baseline before sedation for the oxygen supplementation and room air breathing groups by 0.5% ± 1.1% and 4.1% ± 3.1%, respectively (p < 0.001)</p> <p>Author's Conclusion: SpO₂ alone is not adequate for monitoring alveolar ventilation during sedated endoscopy under oxygen supplementation due to possible delays in detecting alveolar hypoventilation in patients. Even if SpO₂ decreases by only 1% during the procedure and its level remains near 100%, physicians should consider the onset of severe alveolar hypoventilation, which requires immediate intervention.</p>

Methodical Notes

Funding Sources: not mentioned

COI: not mentioned

Randomization: Patients were randomised into two study groups: (a) oxygen supplementation group (oxygen supplementation was administered routinely prior to and during the procedure at a rate of 2 L/min); and (b) room air breathing group (room air was breathed during the procedure; oxygen supplementation was administered if SpO₂ fell below 90% for more than 20-second intervals during the procedure).

Blinding: no

Dropout Rate/ITT-Analysis:

Notes:

RCT with small sample size (70 patients, 35 in each group) and relatively healthy state of our patients

Bastaki, M. et al. A randomized double-blind trial of anesthesia provided for colonoscopy by university-degreed anesthesia nurses in Greece: safety and efficacy. Gastroenterol Nurs. 36. 223-30. 2013

Population	Intervention - Comparison	Outcomes/Results
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<p>Evidence level: 3</p> <p>Study type: Randomized controlled double blind study</p> <p>Number of Patient: n=100</p> <p>Recruiting Phase:</p> <p>Inclusion Criteria: Adults patients undergoing colonoscopy</p> <p>Exclusion Criteria:</p>	<p>Intervention: Colonoscopy with sedation and bispectral imaging</p> <p>Comparison: Comparison of the Bispectral imaging</p>	<p>Primary: Bispectral imaging index</p> <p>Secondary: Patient memory during procedure Satisfaction score</p> <p>Results: Significantly lower BIS index in the nurse sedated group compared to control Also patient memory during the procedure and satisfactions score were significantly better in the Nurse sedated group</p> <p>Author's Conclusion: Sedation offered be an university deegred nurse anaesthesia provider was absolutely safe and effective, offering perticular comfort to the patient durch the intervention</p>
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Methodical Notes

Funding Sources: none

COI:

Randomization: yes

Blinding: blinded to bispectral imaging

Dropout Rate/ITT-Analysis:

Notes:

Different sedation protocoll between the groups

Boguradzka, A. et al. The effect of primary care physician counseling on participation rate and use of sedation in colonoscopy-based colorectal cancer screening program--a randomized controlled study. Scand J Gastroenterol. 49. 878-84. 2014

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: RCT with statistical analysis based on patient self reports</p> <p>Number of Patient: 600</p> <p>Recruiting Phase:</p> <p>Inclusion Criteria: consecutive subjects 50–65 years of age visiting PCP group practice for routine medical consultation</p> <p>Exclusion Criteria:</p>	<p>Intervention: discuss CRC screening with primary care physician's (PCP) or to receive an information leaflet on colorectal cancer (CRC) screening only</p> <p>Comparison: The outcome measures were the participation rate and the proportion of unsedated colonoscopies assessed on subjects' self-reports collected six months after the intervention.</p>	<p>Primary: Participation rate in colonoscopy</p> <p>Secondary: proportion of unsedated colonoscopies</p> <p>Results: Participation rate was 47.0% (141 subjects) in the counseling group and 13.7% (41 patients) in the information leaflet group. The rates of unsedated colonoscopies were 77.0% and 39.0%, respectively. In a multivariate analyses, PCP's counseling was associated with higher participation in CRC screening (adjusted odds ratio [OR] 5.33, 95% confidence intervals [95% CI] 3.55–8.00) and higher rate of unsedated colonoscopies (OR 7.75, 95% CI 2.94–20.45).</p> <p>Author's Conclusion: In opportunistic primary colonoscopy screening, PCP's counseling significantly increases participation rate and decreases demand for sedation compared to recruitment with information materials only.</p>

Methodical Notes

Funding Sources: not mentioned

COI:

Randomization: randomly assigned in a 1:1 ratio to PCP's counseling or CRC screening leaflet

Blinding: none

Dropout Rate/ITT-Analysis:

Notes:

RCT with statistical analysis based on patient self reports

Eberl, S. et al. Is "really conscious" sedation with solely an opioid an alternative to every day used sedation regimes for colonoscopies in a teaching hospital? Midazolam/fentanyl, propofol/alfentanil, or alfentanil only for colonoscopy: a randomized trial. Tech Coloproctol. 18. 745-52. 2014

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT with 180 patients in 3 arms (60 patients in each group)</p> <p>Number of Patient: 180 patients</p> <p>Recruitment Phase: Randomly selected 55 colonoscopy days within a 5-month period at one of three colonoscopy suites</p> <p>Inclusion Criteria: Patients 18 years of age, American Society of Anesthesiologists (ASA) class I-III, scheduled for elective colonoscopy</p> <p>Exclusion Criteria: Patients with a history of allergic reaction to any drugs in the three regimens, unregulated hypertension, bradycardia, arrhythmia, or serious COPD were excluded.</p>	<p>Intervention: M (midazolam/fentanyl), A (alfentanil), and P (propofol/alfentanil) in elective colonoscopy</p> <p>Comparison: M (midazolam/fentanyl) versus A (alfentanil) versus P (propofol/alfentanil) with regard to endoscopist and patient satisfaction and respiratory events</p>	<p>Primary: gastroenterologist and patient satisfaction measured by validated questionnaires modified from the Patient Satisfaction with Sedation Instrument (PSSI) and Clinician Satisfaction with Sedation Instrument (CSSI)</p> <p>Secondary: respiratory and hemodynamic events</p> <p>Results: A high level of satisfaction was found in all groups, with patients in group P being more satisfied with their sedation experience (median 1.75, p<0.001). Gastroenterologist satisfaction varied not significantly between the three alternatives. Patients in group A felt less drowsy, could communicate more rapidly than patients in both other groups, and met discharge criteria immediately after the end of the procedure. Respiratory events associated with sedation were observed in 43 % patients in group M, 47 % in group P, but only 13 % in group A (p<0.001).</p> <p>Author's Conclusion: Alfentanil could be an alternative for sedation in colonoscopy even in the setting of a teaching hospital. It results in satisfied patients easily taking up information, and recovering rapidly. Respiratory events were also less frequent than when other methods were used.</p>

Methodical Notes

Funding Sources: not mentioned

COI: none

Randomization: 180 eligible patients were randomized per working day to one of the following study arms: midazolam/fentanyl (group M, n=60), alfentanil (group A, n=60), and propofol/alfentanil (P, n=60).

Blinding: Patients were blinded to the sedation regimen. Observer, endoscopist, endoscopic and anesthesia nurse could not be blinded.

Dropout Rate/ITT-Analysis: 408 patients were eligible. Due to overlap in time between the procedures, 242 patients were asked for participation and 62 patients refused.

Notes:

RCT with 180 patients in 3 arms, three colonoscopy suites involved

Falt, P. et al. Cap-assisted water immersion for minimal sedation colonoscopy: prospective, randomized, single-center trial. Dig Endosc. 25. 434-9. 2013

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: Prospective, randomized, single-center trial</p> <p>Number of Patient: 208 randomized in 2 groups, 98 finally analysed in each arm</p> <p>Recruiting Phase: recruited between March and May 2012</p> <p>Inclusion Criteria: Men and women older than 18 years referred to the unit for diagnostic outpatient colonoscopy</p> <p>Exclusion Criteria: history of colorectal surgery, known inflammatory bowel disease, chronic benzodiazepine use, refusal of sedation</p>	<p>Intervention: cap-assisted water immersion (Cap Water) compared to water immersion colonoscopy (Water) in minimal sedation colonoscopy</p> <p>Comparison: cecal intubation time in minimal sedation colonoscopy with cap-assisted water immersion (Cap Water) compared to water immersion colonoscopy (Water)</p>	<p>Primary: cecal intubation time</p> <p>Secondary: success rate of minimal sedation colonoscopy patient discomfort during the colonoscopy</p> <p>Results: Cecal intubation time was 6.9 +/- 2.9 min in Cap Water and 7.4 +/- 4.2 min in the Water arm (P = 0.73). Success rate of minimal sedation colonoscopy was equal in both groups (92.9%, P = 1.00). From the endoscopist's point of view, there were nonsignificant trends towards lower discomfort (P = 0.06), less need for abdominal compression (P = 0.06) and lower difficulty score (P = 0.05) during Cap Water colonoscopy. Adenoma detection rate was similar in both arms (44% in Cap Water vs 45% in the Water group, P = 0.88). There were no complications recorded in the present study.</p> <p>Author's Conclusion: In comparison with water immersion without cap, cap-assisted water immersion colonoscopy was not able to shorten the cecal intubation time. However, it has the possibility of reducing patient discomfort and difficulty of colonoscope insertion. Potential impact on improved detection of neoplastic lesions has to be evaluated by further studies.</p>

Methodical Notes

Funding Sources: not mentioned

COI: none

Randomization: stratified block randomization with a special regard to sex (men/women) and age (older/younger than 60 years)

Blinding: The patients were blinded, the endoscopist and the assisting nurse were not blinded.

Dropout Rate/ITT-Analysis: 12 subjects were excluded from the analysis: five patients due to poor bowel preparation, three due to malignant obstruction, two due to newly diagnosed inflammatory bowel disease, one due to severe ischemic colitis and one because of protocol deviation

Notes:

Prospective, randomized, single-center trial

Hammami, Muhammad B. et al. Sequence of same-day upper and lower gastrointestinal endoscopy does not affect total procedure' time or medication use: A randomized trial. JGH Open. 3. 488-493. 2019

Population	Intervention Comparison	Outcomes/Results
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<p>Evidence level: 3</p> <p>Study type: RCT</p> <p>Number of Patient:</p> <p>Recruitment Phase: July 2016 to November 2017</p> <p>Inclusion Criteria: nicht kritisch kranke Erwachsenen zwischen 18 und 90 Jahren mit geplanter Doppeluntersuchung mit Sedierung/Anästhesie innerhalb der Endoskopieabteilung</p> <p>Exclusion Criteria: Untersuchung außerhalb der Endoskopieabteilung, Schwangere, "no decision-making capacity"</p>	<p>Intervention: ÖGD gefolgt von Koloskopie</p> <p>Comparison: Koloskopie gefolgt von ÖGD</p>	<p>Primary: nicht adjustierte mittlere Untersuchungszeit</p> <p>Secondary: mittlere Differenz in der Medikamentendosis.</p> <p>Results: kein signifikanter Unterschied in primärem und in sekundären Endpunkten</p> <p>Author's Conclusion: The sequence of same-day double gastrointestinal endoscopy does not affect total procedure time or medication use.</p>
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<p>Methodical Notes</p>
<p>Funding Sources: k.A.</p> <p>COI: keine</p> <p>Randomization: ja: website Randomization.com (http://randomization.com).</p> <p>Blinding: nein</p> <p>Dropout Rate/ITT-Analysis: 0; ITT</p> <p>Notes: Ein signifikanter Unterschied war nicht zu erwarten. Es wurde Raumluft insuffliert und kein CO2 verwendet</p>

<p>Kim, Hyunil et al. Oxygenation before Endoscopic Sedation Reduces the Hypoxic Event during Endoscopy in Elderly Patients: A Randomized Controlled Trial. Journal of Clinical Medicine. 9. . 2020</p>		
<p>Population</p>	<p>Intervention - Comparison</p>	<p>Outcomes/Results</p>
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 70 (Studiengröße wurde zuvor berechnet)</p> <p>Recruitment Phase: 1 Jahr 8/2018/2019</p> <p>Inclusion Criteria: Alter 65 oder höher; ASA unter 3; ÖGD oder orale EUS</p> <p>Exclusion Criteria: ASA 3 oder höher, Alter unter 65</p>	<p>Intervention: Oxygenisierung vor und während der Endoskopie mit 2 l O₂/min</p> <p>Comparison: keine prophylaktische O₂-Gabe</p>	<p>Primary: Hypoxämie mit O₂-Sättigung unter 90%</p> <p>Secondary: differences in demographic factors between the hypoxia and non-hypoxia groups and compare the underlying disease and endoscopy-related factors</p> <p>Results: hypoxia occurred in 28 (80%) patients in the non-oxygenated group versus no patient in the oxygenated group</p> <p>Author's Conclusion: The incidence of hypoxia during sedation endoscopy is high in patients over 65 years, but oxygenation during endoscopic sedation in elderly people can significantly reduce the incidence of intraprocedural hypoxic events</p>
<p>Methodical Notes</p>		
<p>Funding Sources: grant from the Korea Health Technology R&D Project through the Korea Health Industry Development Institute (KHIDI), funded by the Ministry of Health & Welfare, Republic of Korea (grant number: HI19C0062).</p>		
<p>COI: The authors declare no conflict of interest</p>		

Randomization: ja: sequential sealed opaque envelope method

Blinding: nein (aber O2-Saettigung als objektiver Parameter)

Dropout Rate/ITT-Analysis: 0

Notes:

Knuth, J. et al. Is the transnasal access for esophagogastroduodenoscopy in routine use equal to the transoral route? A prospective, randomized trial. Z Gastroenterol. 51. 1369-76. 2013

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 4</p> <p>Study type: RCT</p> <p>Number of Patient: 183</p> <p>Recruitment Phase: k.A.</p> <p>Inclusion Criteria: Patienten zur diagnostischen ÖDG ohne Sedierung in 2 Endoskopieeinheiten</p> <p>Exclusion Criteria: Patienten, bei denen die nasale Route zu eng waren, wurde nicht ausgewertet</p>	<p>Intervention: transnasale ÖGD</p> <p>Comparison: transorale ÖGD</p>	<p>Primary: es gibt keine Definition eines primary outcomes in dieser Studien</p> <p>Secondary:</p> <p>Results:</p> <p>Author's Conclusion:</p>

Methodical Notes

Funding Sources:

COI: keiner

Randomization: ja

Blinding: nein

Dropout Rate/ITT-Analysis: Patienten, bei denen die nasale Route zu eng waren, wurde nicht ausgewertet

Notes:

Abgesehen von Nasenblutung, einer spezifischen Nebenwirkung des nasalen Zugangs, die bei 28% auftrat, wurde ausschließlich subjektive Parameter verglichen. Keine Aussagen zur diagnostischen Ausbeute

Lee, S. J. et al. Efficacy of carbon dioxide versus air insufflation according to different sedation protocols during therapeutic endoscopic retrograde cholangiopancreatography: prospective, randomized, double-blind study. Dig Endosc. 27. 512-521. 2015

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: RCT</p> <p>Number of Patient: 160</p> <p>Recruitment Phase: Mai 2013 - Februar 2014</p> <p>Inclusion Criteria: therapeutische ERCP bei Patienten mit naiver Papille</p>	<p>Intervention: Insufflation von CO2-Gas anstelle von Raumluft bei Patienten mit BPS (balanced propofol sedation, Midazolam + Opioid) oder PS (Propofol + Opioid)</p> <p>Comparison: Insufflation von Raumluft</p>	<p>Primary: immediate post-ERCP abdominal pain after recovery</p> <p>Secondary: abdominal pain at 3 h and 24 h, abdominal distension, nausea, overall satisfaction with sedation, abdominal radiography, sedation efficacy, endoscopic procedure outcomes procedure-related</p>

<p>Exclusion Criteria: inability to provide informed consent, age under 18 years, abdominal pain with a severity of >2 on a 10-point visual analogue scale (VAS) ASA V, neurological impairment, narcotic use during the previous 12 h, uncontrolled chronic obstructive pulmonary disease (COPD), severe acute pancreatitis, acute exacerbation of chronic pancreatitis, pregnancy, poor general status (performance status 4), early completion of procedure for anatomical reasons prior to attempted cannulation.</p>		<p>complications.</p> <p>Results: signifikant weniger Schmerz (VAS) nach Erholung in der CO2-BPS-Gruppe (p=0,002)</p> <p>Author's Conclusion: CO2 with BPS showed the lowest VAS score for early abdominal pain, distension and GVS, and had a higher score for overall satisfaction for sedation.</p>
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Methodical Notes

Funding Sources: Soonchunhyang University Research Fund (No.20130619).

COI: keine

Randomization: ja

Blinding: ja

Dropout Rate/ITT-Analysis: 0

Notes:

Die statistische Abgrenzung von BPS und PS geht aus den Daten nicht hervor. Der Einfluss der unterschiedlichen Erholungszeit nach Midazolam im Vergleich zu Propofol wird nicht diskutiert

Xu, C. X. et al. Stepwise sedation for elderly patients with mild/moderate COPD during upper gastrointestinal endoscopy. World J Gastroenterol. 19. 4791-8. 2013

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: RCT</p> <p>Number of Patient: s. o.</p> <p>Recruitment Phase: 2011 - 2012</p> <p>Inclusion Criteria: Alter > 70 Jahre, milde-moderate COPD, ÖGD</p> <p>Exclusion Criteria: Hypertonus, Hypotonus, SSS, neurologische oder psychiatrische Vorerkrankung, metabolische Erkrankung, ASA III-IV, schwere COPD, ASA IV-V</p>	<p>Intervention: stufenweise Sedierung mit Propofol im Vergleich zu einer kontinuierlichen Sedierung?</p> <p>Comparison: ältere Patienten mit oder ohne COPD</p>	<p>Primary: Pharyngeale Mißempfindungen</p> <p>Secondary: Vitalparameter, Prozesszeiten, Propofolverbrauch</p> <p>Results: signifikant häufiger Hypoxämie bei COPD-Patienten mit kontinuierlicher vs. stufenweiser Sedierung. Gleiches gilt für die Rate von AEs. Der Propofolverbrauch war höher bei kontinuierlicher Sedierung, die Prozesszeiten länger.</p> <p>Author's Conclusion: Stufenweise Sedierung mit Propofol ist sicher und effektiv bei älteren Patienten mit COPD.</p>

Methodical Notes

Funding Sources: National Grant.

COI: n. d.

Randomization: RCT

Blinding: s. o.

Dropout Rate/ITT-Analysis: s. o.

Notes:

OXFORD (2011) Appraisal Sheet: Diagnostic Studies: 1 Bewertung(en)

Töx, U. et al. Propofol sedation for colonoscopy with a new ultrathin or a standard endoscope: a prospective randomized controlled study. Endoscopy. 45. 439-44. 2013

Evidence level/Study Types	Population	Outcomes/Results
Evidence level: 3 Study type: Prospektiv randomisiert.	Number of patients / samples: 203 Reference standard: n. d. Validation: n. d. Blinding: der für die Sedierung verantwortliche Arzt war geblendet. Inclusion of clinical information: Studie liegt nur als Abstrakt vor, Frage daher nicht valide zu klären. Dealing with ambiguous clinical findings: Studie liegt nur als Abstrakt vor, Frage daher nicht valide zu klären.	Results: Bei Verwendung eines ultradünnen Endoskops (UTC) ist der Sedierungsbedarf signifikant reduziert. Die Zeit bis zur Ileocacalintubation war verlängert. Author conclusions: Entspricht exakt den Resultaten

Methodical Notes

Funding Sources: n. d.

COI: n. d.

Notes: Studie prospektiv randomisiert. Deitallierte Angaben liegen nicht vor (s. o.).

NEWCASTLE - OTTAWA Checklist: Case Control: 1 Bewertung(en)

Jover, R. et al. Modifiable endoscopic factors that influence the adenoma detection rate in colorectal cancer screening colonoscopies. Gastrointest Endosc. 77. 381-389.e1. 2013

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 4 Study type: Case	Funding sources: Asociación Española de Gastroenterología, Asociación	Total no. patients: 5059 Patient characteristics:	Interventions: Analyse der Einflussfaktoren auf die Adenomdetektionsrate

<p>Controll ist am ehesten zutreffend</p>	<p>Española contra el Cáncer (Fundación Científica and Junta de Barcelona), the Instituto de Salud Carlos III (PI08/90717, PI08/0726, INT-09/208, PI11/2630), FEDER funds, and Agència de Gestió d'Ajuts Universitaris i de Recerca (2009SGR849). CIBERehd is funded by the Instituto de Salud Carlos III. In the Basque Country, the study received additional support with grants from Obra Social de Kutxa, Diputación Foral de Gipuzkoa (DFG 07/5), Departamento de Sanidad del Gobierno Vasco, EITB-Maratoia (BIO 07/CA/19) y Acción Transversal contra el Cáncer del CIBERehd (2008). In Galicia, this work was supported by Dirección Xeral de Innovación e Xestión da Saúde Pública, Consellería de Sanidade, Xunta de Galicia.</p> <p>Conflict of Interests: keiner</p> <p>Randomization: keine</p> <p>Blinding: keine</p> <p>Dropout rates: keine</p>	<p>Juni 209 bis Juni 2011</p> <p>Inclusion criteria: asymptomatische Personen von 50 bis 69 Jahren zur Screeningkoloskopie</p> <p>Exclusion criteria: personal history of CRC, adenoma or inflammatory bowel disease, family history of hereditary or familial CRC (ie, >2 first-degree relatives with CRC or 1 diagnosed before age 60 years), severe comorbidity previous colectomy previous CRC screening test within the recommended intervals symptoms requiring additional work-up</p>	<p>Comparison: nicht zutreffend</p>
<p>Notes:</p>	<p>es handelt sich um eine Analyse einer für eine andere Studie rekrutierten Patientengruppe, somit formal nicht um eine Fall-Kontroll-Studien (auch der Begriff Kohortenstudie wäre nicht zutreffend, da es keine Vergleichskohorte gibt)</p> <p>Author's conclusion: Withdrawal time was the only modifiable factor related to the ADR in colorectal cancer screening colonoscopies associated with an increased detection rate of overall, advanced, proximal, and distal adenomas</p>		
<p>Outcome Measures/results</p>	<p>Primary Hospital, Geschlecht, Altersgruppe, Rückzugszeit, Zoekumintubationsrate, Abstand zum Ende der Vorbereitung, gesplittete Vorbereitung, Art und Qualität der Vorbereitung, Sedierung durch den Endoskopiker, Sedierung mit Propofol</p> <p>Secondary</p>	<p>Results: in der multivarianten Analyse bleibt nur die Rückzugszeit während der Koloskopie als signifikanter Faktor. Der in der univarianten Analyse zugunsten einer durch den Endoskopiker durchgeführten Sedierung signifikant höheren Detektionsrate, war in der multivarianten Analyse nicht mehr signifikant.</p>	

NEWCASTLE - OTTAWA Checklist: Cohort: 2 Bewertung(en)

Glomsaker, T. B. et al. Patient-reported outcome measures after endoscopic retrograde cholangiopancreatography: a prospective, multicentre study. Scand J Gastroenterol. 48. 868-76. 2013

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 2 Study type: prospective data were recorded	Funding sources: n.a. Conflict of Interests: n.a. Randomization: none Blinding: none Dropout rates: n.a.	Total no. patients: 2808 patients data Recruiting Phase: 2007 till 2009 in 11 hospitals Inclusion criteria: Patients for ERCP Exclusion criteria: -	Interventions: Patient-reported outcome measures (PROMs) in ERCP Comparison:
Notes:	Abstractbewertung ! Author's conclusion: Female gender, the performance of EST and longer procedure times were independent predictors for increased procedure-related pain. The individual hospital and sedation regimen predicts the patient's pain experience.		
Outcome Measures/results	Primary Patient-reported pain, discomfort and general satisfaction with the ERCP Secondary Procedure time, sedation regimen	Results: Data from 2808 ERCP procedures were included in this study. Patient questionnaires were returned for 52.6% of the procedures. Moderate or severe pain was experienced in 15.5% and 14.0% of the procedures during the ERCP and in 10.8% and 7.7% of the procedures after the ERCP, respectively. In addition, female gender, endoscopic sphincterotomy (EST), and longer procedure times served as independent predictors of increased pain during the ERCP. The performing hospitals and sedation regimens were independent predictors of the procedural pain experience. In 90.9% of the procedures, the patients were satisfied with the information overall, and in 98.3% of the procedures, the patients were satisfied with the treatment provided. Independent predictors of dissatisfaction with the treatment included the occurrence of specific complications after ERCP and pain during or after the procedure.	

Shavakhi, A. et al. Premedication with sublingual or oral alprazolam in adults undergoing diagnostic upper gastrointestinal endoscopy. Endoscopy. 46. 633-9. 2014

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: prospektiv, randomisiert	Funding sources: n. d. Conflict of Interests: n. d. Randomization: keine genauen Informationen Blinding: n. d. Dropout rates: n. d.	Total no. patients: 220 Recruiting Phase: n. d. Inclusion criteria: diagnostische ÖDG in Sedierung Exclusion criteria: n. d.	Interventions: Alprazolam per os oder sl sowie Plazebo oral und sl. Comparison: Angst, Schmerz, Discomfort, Sedierung

Notes:	<p>Die Studie liegt nur als Abstrakt vor, ein download der vollständigen Literaturstelle war nicht möglich.</p> <p>Author's conclusion: Keine spezifischen; lediglich Wiederholung der Ergebnisse.</p>	
Outcome Measures/results	<p>Primary n. d.</p> <p>Secondary n. d.</p>	<p>Results: DAs Angstlevel war unter Alprazolam sl signifikant niedriger als mit Plazebo oral oder sl. Schmerz- und Diskomfortscores waren nach Alprazolam oral und sl nidriger als nach Placebo oral und sl. Gleiches galt für die allgemeine Toleranz seitens der Patienten. In Bezug auf die intravenöse Sedierung bestanden keine Gruppenunterschiede. Die Bereitschaft die Endoskopie zu wiederholen war nach Alprazolam höher als bei Placebo.</p>

Literatursammlung:

AG 1 - Literatur 2015 - 2020

Inhalt: 71 Literaturstellen

Literaturstelle	Evidenzlevel	Studientyp
Adams, M. A. 2017	3	Retrospective cohort study analyzed with multiple logistic regression
Adams, M. A. 2016	4	Systematic Review
Agrawal, D. 2015	5	survey
Andrade, C. M. 2017	2	systematic review and meta-analysis of seven studies (prospective and retrospective) of moderate to low quality
Aravapalli, A. 2015	4	Retrospective analysis
Ball, A. J. 2015	3	database analysis
Behrens, A. 2016	3	subgroup analysis of a registry study (database)
Benson, M. 2020	3	retrospective, age and sex-matched, casecontrol study comparing 132 super obese patients (BMI \geq 50 kg/m ²) to 132 control patients with normal BMIs (18.5–25 kg/m ²)
Bielawska, B. 2018	2	Retrospective population-based cohort study analyzed from coding data (demographic data, diagnostic and procedure codes) in the Ontario region.
Borgaonkar, M. R. 2016	1	a retrospective study of all the colonoscopies performed in one of two hospitals in the city of St. John's, NL, between January 1, 2012, and June 30, 2012
Bugajski, M. 2018	2	no, cross-sectional analysis based on database records from 23 centres participating in a population-based colonoscopy screening programme in Poland plus Gastronet questionnaires
Buxbaum, J. 2017	4	
Cabadas Avión, R. 2019	4	yes
Cabadas Avion, R. 2018	5	Unclear, retrospectiv analysis
Cadoni, S. 2020	5	expert suggestions for an action plan of how to resume endoscopy activity after the peaks of the Covid-19 pandemic lockdowns
Campbell, J. A. 2017	3	RCT of moderate quality, prospective design
Conway, A. 2016	1	Systematic review and meta-analysis.
Daza, J. F. 2018	2	Metaanalysis
de Paulo, G. A. 2015	2	Prospective non-randomized trial in outpatients who underwent gastroscopy or colonoscopy or both
Dumonceau, J. M. 2015	1	Guideline-could not be censored

Ferreira, A. O. 2016	1	RCT
Gedeon, M. 2019	1	RCT in a community hospital endoscopy suite
Grilo-Bensusan, I. 2018	4	a prospective, single-center, descriptive study of 300 patients undergoing ambulatory colonoscopy under conscious sedation
Gürbulak, B. 2018	3	case-control study
Harvin, G. 2016	4	prospective, single centre study
Hung, A. 2016	4	case controll
Jin, E. H. 2017	5	
Jirapinyo, P. 2015	1	Case Controll
Khoi, C. S. 2015	3	Case Controll
Kim, S. Y. 2020	4	Case Controll. Es gibt aber eigentlich eine Kontrollgruppe, außer man sieht Sedierung/nicht-Sedierung und die Altersgruppen als "Kontrollen"
Klare, P. 2015	1	RCT
Kollmann, C. M. 2018	3	Case controll
Kothari, D. 2016	4	Cohort study, prospektive design
Kudaravalli, P. 2020	5	
Laffin, A. E. 2020	2	Case Controll. Eigentlich wird die untersuchte Gesamtgruppe nur in 4 BMI-Klassen unterteilt
Lauriola, M. 2019	5	
Lee, S. P. 2017	5	tetrospektive Fallstudie ohne Kontrolle
Lee, S. S. 2015	5	
Lee, S. 2015	4	Case controll
Leffler, D. A. 2015	4	diagnostic study
Leslie, K. 2017	3	prospektive Kohortenstudie, wobei eine eigentlichen Kontrollkohorte fehlt sondern eine Differenzierung innerhalb der Beobachtungsgruppe erfolgt
Leslie, K. 2016	4	cohort study
Lieber, S. R. 2020	3	Retrospective analysis of national data on anesthesia services of 428947 procedures
Lim, S. 2019	4	systematischer Review von RCTs
Liou, S. C. 2018	1	prospektive Kohortenstudie
McCain, J. D. 2020	1	
Mudambi, L. 2016	1	Retrospective case-control study
Nonaka, S. 2015	4	Prospective cohort study
Parker, S. 2018	2	RCT
Perbtani, Y. B. 2016	3	Datenbankanalyse, retrospektiv.
Pérez-Cuadrado Robles, E. 2016	4	Datenbankanalyse, retrospektiv.

Predmore, Z. 2017	1	
Protopapas, A. A. 2020	3	Kohortenstudie
Quinn, L. 2016	4	Umfrage
Ra, Y. S. 2016	3	Fragebogen
Sargin, M. 2016	3	Prospektiv
Shin, S. 2017	2	RCT
Shingina, A. 2016	3	Retrospektiv, Auswertung der Krankenunterlagen, Einzelzentrum.
Smith, I. 2018	4	Observational study
Smith, Z. L. 2019	5	review
Smith, Z. L. 2019	2	RCT
Sun, X. 2018	1	RCT, doppelblind
Theivanayagam, S. 2017	4	Retrospektive Datenanalyse
Thornley, P. 2016	4	Prospektive, nicht-randomisierte Vergleichsstudie
Tsou, M. Y. 2018	3	Pharmakologische MOdellentwicklung
Turse, E. P. 2019	3	Retrospektive monozentrische Studie
Vaessen, H. H. 2016	1	Umfrage
van de Ven, S. 2019	3	retrospektive Kohortenstudie
Xue, M. 2018	2	Meta-Analyse
Yurtlu, D. A. 2016	3	Retrospective analysis
Zakeri, N. 2015	3	retrospektiv

OXFORD (2011) Appraisal Sheet: Systematic Reviews: 8 Bewertung(en)

Adams, M. A. et al. A Systematic Review of Factors Associated With Utilization of Monitored Anesthesia Care for Gastrointestinal Endoscopy. Gastroenterol Hepatol (N Y). 12. 361-70. 2016				
Evidence Types	level/Study	P - I - C	Outcomes/Results	Literature References
Evidence level: 4 Study type: Systematic Review Databases: Pubmed, Embase, Cinahl Search period: 01/1980 - 03/2015 Inclusion Criteria: observational study or		Population: American Intervention: None Comparison: None	Primary: Utilization of MAC in gastrointestinal endoscopy Secondary: - time periods -geographic aspects -patient-related factors -procedural factors -income and insurance status -provider and facility related factors. Results: The review describes differences in the utilization of MAC regarding to time periods,	Inadomi JM, 2010, Gastrointest Endosc. 2010 Alharbi O, 2009, Anesthesiology Anderson JC, 2012, Gastrointest Endosc. 2012 Aravapalli A, 2013, Am J Gastroenterol. Campo R, 2004, Gastroenterol

<p>randomized, controlled trial primarily examining utilization or factors associated with utilization of MAC for EGD and/or colonoscopy</p> <ul style="list-style-type: none"> - analysis of more than 10,000 procedures - original data not duplicated in another abstract or manuscript <p>Exclusion Criteria: - data duplicated in another abstract or manuscript</p>		<p>geographic aspects, patient-related factors, procedural factors, income and insurance status, provider and facility related factors.</p> <p>Author's Conclusion: MAC utilization for gastrointestinal endoscopic sedation has increased markedly over the past decade, leading to significant additional health care expenditures. MAC use appears to be driven by a complex interplay of economic and noneconomic factors, rather than being easily explained by financial drivers alone.</p> <p>MAC.</p>	<p>Hepatol. Ciofoaia V, 2012, Gastroenterology Cooper GS,, 2013, JAMA Intern Med. Dominitz JA, 2013, Gastroenterology George S, 2013, Gastroenterology Hoda KM, 2009, Gastrointest Endosc. Khiani VS, 2012, Clin Gastroenterol Hepatol. Liu H, 2012, JAMA Vargo JJ, 2004, Gastrointest Endosc</p>
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<p>Methodical Notes</p>
<p>Funding Sources: None</p> <p>COI: None</p> <p>Study Quality: - Methodologic quality of each study was assessed using the Newcastle-Ottawa scale</p> <ul style="list-style-type: none"> - Because of significant heterogeneity among studies, quantitative pooling of data was not possible. - Studies were reviewed in a qualitative synthesis, with effect estimates and 95% CI included when available. <p>Heterogeneity: High heterogeneity in study results (due to long searching period: 1980 - 2015)</p> <p>Publication Bias: low</p> <p>Notes:</p>

<p>Agrawal, D. et al. Contrasting Perspectives of Anesthesiologists and Gastroenterologists on the Optimal Time Interval between Bowel Preparation and Endoscopic Sedation. Gastroenterol Res Pract. 2015. 497176. 2015</p>			
Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 5</p> <p>Study type: survey</p> <p>Databases: 109 anesthesiologists and 112 gastroenterologists (chiefs and/or directors of anesthesiology and gastroenterology at academic hospitals in the United States)</p> <p>Search period: not mentioned</p> <p>Inclusion Criteria: chief and/or director of anesthesiology and gastroenterology at academic hospital.</p>	<p>Population: chiefs and/or directors of anesthesiology and gastroenterology at academic hospitals in the United States</p> <p>Intervention: survey</p> <p>Comparison: Data were summarized using descriptive statistics. Comparisons between groups were measured with the</p>	<p>Primary:</p> <p>Secondary:</p> <p>Results: Anesthesiologists and gastroenterologists do not agree on the optimal interval for sedation after last drink of bowel prep. 96% of the anesthesiologists, but only 26% of the gastroenterologists prefer to wait longer than the recommended 2 hours for clear liquids.</p> <p>Author's Conclusion: The data suggest a need for clearer guidelines regarding the optimal time</p>	<p>A. A. Siddiqui, K. Yang, S. J. Spechler et al., "Duration of the interval between the completion of bowel preparation and the start of colonoscopy predicts bowel-preparation quality," Gastrointestinal Endoscopy, vol.69, no.3, pp.700-706, 2009.</p>

the United State		interval for sedation after last ingestion of bowel prep.	
Exclusion Criteria: none			

Methodical Notes
Funding Sources: not mentioned
COI: The authors declare that there is no conflict of interests regarding the publication of the paper.
Study Quality: The survey was distributed to 130 gastroenterologists and responses were received from 112, for a response rate of 86%. For the anesthesiologists, the questionnaire was sent to 120 anesthesiologists and responses were received from 109, for a response rate of 91%.
Heterogeneity:
Publication Bias:
Notes: survey study with clear limitations: sample size comprizes 221 persons, expert opinions of the chiefs and directors of gastroenterology and anesthesiology at academic institutions

Andrade, C. M. et al. Safety of gastrointestinal endoscopy with conscious sedation in obstructive sleep apnea. World J Gastrointest Endosc. 9. 552-557. 2017			
Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 2</p> <p>Study type: systematic review and meta-analysis of seven studies (prospective and retrospective) of moderate to low quality</p> <p>Databases: A comprehensive electronic search of MEDLINE and EMBASE, search strategy well-defined</p> <p>Search period: from inception until March 1, 2015.</p> <p>Inclusion Criteria: Studies performed on patients with obstructive sleep apnea undergoing endoscopy with conscious sedation and at least one the following variables of interest were considered for inclusion: Incidence of hypoxia, hypotension, tachycardia, and bradycardia.</p> <p>Exclusion Criteria: no OSA patients, not conscious sedation, pediatric population, editorial/book/case report, duplicates</p>	<p>Population: patients with obstructive sleep apnea (OSA)</p> <p>Intervention: conscious sedation</p> <p>Comparison: number of incidents (hypoxia, hypotension, tachycardia, bradycardia) in OSA patients compared to other patients undergoing the same endoscopic procedure with conscious sedation (controls)</p>	<p>Primary:</p> <p>Secondary:</p> <p>Results: No significant differences between OSA patients and controls were identified among any of the study variables: Incidence of hypoxia (7 studies, 3005 patients; OR = 1.11; 95%CI: 0.73-1.11; P = 0.47; I2 = 0%), incidence of hypotension (4 studies, 2125 patients; OR = 1.10; 95%CI: 0.75-1.60; P = 0.63; I2 = 0%), incidence of tachycardia (3 studies, 2030 patients; OR = 0.94; 95%CI: 0.53-1.65; P = 0.28; I2 = 21%), and incidence of bradycardia (3 studies, 2030 patients; OR = 0.88; 95%CI: 0.63-1.22; P = 0.59; I2 = 0%).</p> <p>Author's Conclusion: For patients undergoing endoscopic procedures with conscious sedation, OSA does not appear to be risk factor for cardiopulmonary complications.</p>	
Methodical Notes			

Funding Sources: nor mentioned

COI: The authors deny any conflict of interest.

Study Quality: Continuous data were summarized as odds ratio (OR) and 95%CI and pooled using generic inverse variance under the randomeffects model. Heterogeneity between pooled studies was assessed using I² statistic and categorized as low (< 30%), moderate (30%-50%), or high (> 50%). All analyses were performed using Review Manager 5.1 software.

Heterogeneity: The heterogeneity among the studies was low (I² = 0%).

Publication Bias:

Notes:

Conway, A. et al. Depth of anaesthesia monitoring during procedural sedation and analgesia: A systematic review and meta-analysis. Int J Nurs Stud. 63. 201-212. 2016

Evidence Types	level/Study	P - I - C	Outcomes/Results	Literature References
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<p>Evidence level: 1</p> <p>Study type: Systematic review and meta-analysis.</p> <p>Databases: published, unpublished and ongoing studies found by searching the following databases: The Cochrane Central Register of Controlled Trials (CENTRAL) (1999 (established) to 1st May 2015); MEDLINE (OvidSP) (1966 to 1st May 2015); CINAHL (EBSCOhost) (1982 to 1st May 2015); ClinicalTrials.gov; World Health Organization International Clinical Trials Registry Platform.</p> <p>Search period: up to 1st May 2015.</p> <p>Inclusion Criteria: Randomized controlled trials that compared use of a depth of anaesthesia monitoring device to a control group who received standard monitoring during procedural sedation and analgesia were included.</p> <p>Exclusion Criteria: studies that included patients who received general or regional anaesthesia were excluded from the review</p>	<p>Population: A total of 16 trials (2138 participants) were included. patients (adults or children) who received procedural sedation and analgesia (with or without local anaesthesia) in any inpatient or outpatient setting where procedural sedation and analgesia was used in a hospital</p> <p>Intervention: Depth of anaesthesia monitoring, such as Bispectral Index™, E-Entropy and Narcotrend, was used in addition to clinical judgement and/or a specified clinical sedation assessment tool to monitor consciousness</p> <p>Comparison: study arm with depth of anaesthesia monitoring vs. control group where depth of anaesthesia monitoring was not used to monitor consciousness (only clinical judgement and/or a specified clinical sedation assessment tool was used)</p>	<p>Primary: Safety outcomes were hypoxaemia, hypotension and adverse events. Efficacy outcomes were amount of sedation used, duration of sedation recovery and rate of incomplete procedures.</p> <p>Secondary:</p> <p>Results: Meta-analysis of 8 trials (766 participants) found no difference in hypoxaemia (RR 0.87; 95% CI=0.67 to 1.12). No statistically significant difference in hypotension was observed in meta-analysis of 8 trials (RR 0.96; 95% CI=0.54 to 1.7; 942 participants). Mean dose of propofol was 51mg lower for participants randomised to depth of anaesthesia monitoring (95% CI=-88.7 to -13.3mg) in meta-analysis of results from four trials conducted with 434 participants who underwent interventional endoscopy procedures with propofol infusions to maintain sedation. The difference in recovery time between depth of anaesthesia and standard monitoring groups was not clinically significant (8 trials; 809 participants)</p> <p>Author's Conclusion: Depth of anaesthesia monitoring did impact sedation titration during interventional procedures with propofol infusions. For this reason, it seems reasonable for anaesthetists to utilise a depth of anaesthesia monitoring device for select populations of patients if it is decided that limiting the amount of sedation would be beneficial for the individual patient. However, there is no need to invest in purchasing extra equipment or training staff who are not familiar with this technology (e.g. nurses who don't routinely use a depth of anaesthesia monitoring device during</p>	
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general anaesthesia) because there is no high quality evidence suggestive of clear clinical benefits for patient safety or sedation efficacy.

Methodical Notes

Funding Sources: not mentioned

COI: none

Study Quality: previously defined search strategy bias assessment

Heterogeneity: wide range of clinical settings, not limited to gastroenterology

Publication Bias: risk of bias assessment (Cochrane risk of bias tool) performed by two reviewers

Notes:
Systematic review and meta-analysis.

Daza, J. F. et al. Propofol administration by endoscopists versus anesthesiologists in gastrointestinal endoscopy: a systematic review and meta-analysis of patient safety outcomes. Can J Surg. 61. 226-236. 2018

Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 2</p> <p>Study type: Metaanalysis</p> <p>Databases: Medline, CINAHL, Embase, Web of Science, Central</p> <p>Search period: till may 2016</p> <p>Inclusion Criteria: Studies with adult population unergoing upper GI endoscopy. Administration of propofol by endoscopist or nurse under guidance of endoscopists. Control group propofol administred by anesthetist or nurse abesthetist.</p> <p>Exclusion Criteria: Advanced endoscopic procedures ERCP, EUS, enteroscopy, endoscopic surgery</p>	<p>Population: 606 articles screened, 5 articles for inclusion, 2 RCT, 2 prospective cohorts and retrospective cohort study. Studies from 1998 till 2015</p> <p>Intervention: Administration of propofol by gastroenterologist or anesthetist</p> <p>Comparison: Safety and SRAEs</p>	<p>Primary: SREAs Aitway intervention, Hypotension, Bradycardia, cardiopulmonary events, gastrointestinale complications, death</p> <p>Secondary: Awareness with recall, total propofol administredtotal procedure time, patient satisfaction, time to recovery, pain during procedure, cecal intubation and Polyp detection.</p> <p>Results: No increased rate of airway intervention or hypotension. Higher rate of bradycardia and awareness of recall in the gastroenterologist sedation. Anesthetists sedation with higher use of propofol and with longer time to recovery. No effect on cardiopulomnary events, procedure time, death, patients satisfaction, pain during procedure, endoscopic parameters</p> <p>Author's Conclusion: Endoscopist may safely administer propofol without compromising procedural quality in patients classified as ASA I and II.</p>	<p>31. Citations, only 5 Studies used</p> <p>De Paolo G.A. et al. 2015, Endosc. Int. Open</p> <p>Vargo J.J. et al., 2006, Aliment. Pharmacol. Ther.</p> <p>Nathan J.H et al. 2015, J. Digest. Endosc.</p> <p>Poincloux, et al., 2011, Dig. L liver Dis.</p> <p>Ferreira AO et al., 2016, Endoscopy</p>

Methodical Notes

Funding Sources: none

COI: none

Study Quality: only 5 out of 602 articles

Heterogeneity: medium

Publication Bias: possible

Notes:

Lim, S. et al. Moderate versus deep sedation in adults undergoing colonoscopy: systematic review and meta-analysis. Curr Med Res Opin. 35. 879-885. 2019

Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 4</p> <p>Study type: systematischer Review von RCTs</p> <p>Databases: Die Abfrage in Medline, Embase, Central und Google scholar erbrachte 172 Studien, zu denen 2 handausgeählt ergänzt wurden. Am Ende des Auswahlprozesses blieben 3 Studien übrig</p> <p>Search period: bis Mai 2018</p> <p>Inclusion Criteria: (1) RCT; (2) studies that compared deep sedation with moderate sedation, regardless of administration route or agent administered; and (3) studies performed on patients who underwent colonoscopy under sedation. Kommentar: "Colonoscopy" war nicht teil der Suchstrategie</p> <p>Exclusion Criteria: Review articles, case reports, case series, letters to the editor, commentaries, proceedings, laboratory science studies and any other nonrelevant studies were excluded.</p>	<p>Population: 919 Patienten aus 3 Studien (davon 520 aus einer der 3 Studien)</p> <p>Intervention: tiefe Sedierung</p> <p>Comparison: moderate Sedierung</p>	<p>Primary: patient satisfaction, physician satisfaction, incidence of recall and incidence of desaturation</p> <p>Secondary: Recovery time</p> <p>Results: incidence of desaturation was higher in the deep group than in the moderate group (RR=0.18; 95% CI: 0.01 to 0.99; NNTB=56.7; 95% CI: 31.6 to 273.1)</p> <p>Author's Conclusion: moderate sedation showed comparable safety and effectiveness to deep sedation with respect to patient satisfaction, physician satisfaction, incidence of recall and recovery time; the incidence of desaturation was higher in deep sedation than in moderate sedation. However, additional larger-scale studies of better quality may be needed to confirm these results.</p>	<p>Allen M, 2015 Can J Anaesth. VanNatta ME, 2006 Am J Gastroenterol. Paspatis GA, 2001, Colorectal Dis.</p>

Methodical Notes

Funding Sources: kein funding

COI: kein Konflikt

Study Quality: wie bereits ausgeührt, ist der Auswahlprozess der Studien unzureichend transparent und die Studien untereinander bei unterschiedlichen Fragestellungen (z.B. Patientenzufriedenheit vs. Adenomdetektionsrate) eingeschränkt vergleichbar.

Heterogeneity: s.o

Publication Bias: unklar, da nicht bekannt, welche Rolle die "handausgewählten" Studien haben.

Notes:

der in die Auswertung eingegangenen Studienpool erscheint für die Fragestellung nicht geeignet.

Smith, Z. L. et al. Anesthesia-administered sedation for endoscopic retrograde cholangiopancreatography: monitored anesthesia care or general endotracheal anesthesia?. Curr Opin Anaesthesiol. 32. 531-537. 2019

Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
Evidence level: 5 Study type: review Databases: Search period: Inclusion Criteria: Exclusion Criteria:	Intervention: Comparison:	Primary: Secondary: Results: Author's Conclusion: Persuing managed anesthesia care (MAC) or general endotracheal anesthesia (GEA) for patients undergoing ERCP is best approached on an individual basis. Patients at high risk for sedation-related adverse events likely benefit from GEA.	
Methodical Notes			
Funding Sources: COI: Study Quality: not very good Heterogeneity: Publication Bias: yes Notes:			

Xue, M. et al. No increased risk of perforation during colonoscopy in patients undergoing propofol versus traditional sedation: A meta-analysis. Indian J Gastroenterol. 37. 86-91. 2018			
Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
Evidence level: 2 Study type: Meta-Analyse Databases: MEDLINE, CBM, VIP, CNKI Search period: keine Angabe Inclusion Criteria: alle Studien mit Propofolsedierung und Colonoscopy Exclusion Criteria: Überempfindlichkeit gegen Studienmedikation, Vergleichsstudien Propofol vs. Propofol + Zusatzmedikation, Konferenzpaper	Population: s. oben Intervention: Colonoscopy Comparison: Propofol versus Standardsedierung	Primary: Rate an Kolonperfoationen Secondary: Results: Keine Gruppenunterschiede Author's Conclusion: Propofol erhöht das Risiko für Kolonperforationen während Colonoscopy nicht. Randomisierte Studien gefordert.	
Methodical Notes			
Funding Sources: Nein. COI: Nein. Study Quality: Meta-Analyse			

Heterogeneity:

Publication Bias:

Notes:

OXFORD (2011) Appraisal Sheet: RCT: 7 Bewertung(en)

Ferreira, A. O. et al. Non-anesthesiologist administration of propofol sedation for colonoscopy is safe in low risk patients: results of a noninferiority randomized controlled trial. Endoscopy. 48. 747-53. 2016

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 277</p> <p>Recruiting Phase: 1/2014 and 2/2015</p> <p>Inclusion Criteria: patients 18-80 years . ASA I and II , elective colonoscopy</p> <p>Exclusion Criteria: ASA > II, pregnancy, patients with intravenous drug use, predicted difficult airway and ventilation, as defined</p>	<p>Intervention: sedation non-anaesthesiologist administered / NAAP</p> <p>Comparison: comparing NAAP (group A) with anaesthesiologist administered sedation group (group B)</p>	<p>Primary: incidence of adverse events, minor an de sentinel. to evaluate sedation safety, colonoscopy quality and patient satisfaction with NAAP.</p> <p>Secondary: propofol dose, patient satisfaction, pain, colonoscopy quality indicators, and procedure and recovera times.</p> <p>Results: there were no differences in mean propofol dose, withdral time, painless colonoscopy, satisfaction, and amnesia. There were no sentinel adverse events. There were no differences in cecal intubation and adenom dwetetection rate.</p> <p>Author's Conclusion: NAAP is equivalent to anaesthesiologist-administered sedation in the rate of adverse events in a lowe risk population</p>

Methodical Notes

Funding Sources:

COI: none

Randomization: www.randomization .com

Blinding: single blinded , only patients were kept blinjd

Dropout Rate/ITT-Analysis: none attendance n-5, respiratory infection n-3 at the time of procedure

Notes:

Gedeon, M. et al. Use of noninvasive positive pressure ventilation in patients with severe obesity undergoing esophagogastroduodenoscopy: a randomized controlled trial. Surg Obes Relat Dis. 15. 1589-1594. 2019

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT in a community hospital endoscopy suite</p> <p>Number of Patient: 56 (A total of 208 patients were screened</p>	<p>Intervention: EGD</p> <p>Comparison: treatment (NIPPV) and control (nasal cannula, NIPPV for rescue) groups.</p>	<p>Primary: Primary endpoints were oxygen desaturation events !94% and oxygen desaturation events ,90% requiring intervention.</p> <p>Secondary: A secondary endpoint was the use of NIPPVas a rescue maneuver</p> <p>Results: A statistically significant difference was noted between the</p>

between April 2017 to April 2018 and 56 patients completed the procedure (28patients per study arm)

Recruiting Phase: Participants were identified from 3 physician practices from April 2017 to April 2018.

Inclusion Criteria: EGD
Obesity (body mass index of 40 to 60)

Exclusion Criteria: The exclusion criteria were as follows: pregnancy, BMI >60 or <40, active substance abuse (alcohol, benzodiazepines, and illicit drugs), previous weight loss or gastric surgery, current tobacco use, lung disease (chronic obstructive pulmonary disease, asthma), history of upper respiratory tract infection within 2 weeks of the procedure, baseline oxygen saturation <94%, and patients undergoing combined EGD and colonoscopy

groups for desaturation events !94% (14.3% of treatment and 57.1% of control groups, P 5.002). There was also a statistically significant difference in the risk of a desaturation event ,90% requiring intervention (3.5% of treatment and 28.6% of control groups, P 5.025). All patients in the control group who developed desaturation events requiring intervention were rescued with NIPPV.

Author's Conclusion: This study demonstrated the successful use of NIPPV as an adjunct to decrease the incidence of desaturation events in patients with severe obesity undergoing EGD. It also suggests that NIPPV can be used as a rescue maneuver.

Methodical Notes

Funding Sources: not mentioned

COI: The authors have no commercial associations that might be a conflict of interest in relation to this study.

Randomization: yes

Blinding: none

Dropout Rate/ITT-Analysis: 152 patients (of 208) did not complete the procedure

Notes:
RCT in a community hospital endoscopy suite

Klare, P. et al. Patient position and hypoxemia during propofol sedation for colonoscopy: a randomized trial. Endoscopy. 47. 1159-66. 2015

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 412</p> <p>Recruiting Phase: k.A.</p> <p>Inclusion Criteria: Outpatients and inpatients aged</p>	<p>Intervention: colonoscopy in the left lateral decubitus position</p> <p>Comparison: patients placed in the supine position</p>	<p>Primary: incidence of hypoxemic events, defined as a reduction of SaO2<90%</p> <p>Secondary: (i) number of oxygen desaturations; (ii) apnea; (iii) further vital parameters, such as hypotension (systolic blood pressure <90mmHg) and bradycardia (heart rate <50/min);</p>

>18 years who were scheduled for colonoscopy

Exclusion Criteria: Exclusion criteria were emergency examinations, ASA risk classes V and VI, pregnancy, and pre-existing hypotension (systolic blood pressure <90mmHg), bradycardia (heart rate <50/min), or hypoxemia (SaO₂<90%) before the start of the endoscopy

(iv) procedural parameters, in particular sedative dosage, cecal intubation rate, cecal intubation time, frequency of patient repositioning, and frequency of abdominal hand-pressure maneuvers;
(v) patient satisfaction, as rated by the patients, and patient cooperation, as rated by the endoscopist, and
(vi) colonoscopy outcome parameters, such as polyp and adenoma detection rates.

Results: ITT: Oxygen desaturation (SaO₂<90%) was detected in 25 patients in the supine group (12.1 %) and in 14 patients in the left lateral group (6.8 %; P=0.064)
PP: Oxygen desaturation (SaO₂<90%) was detected in 18 patients in the supine group (11.2 %) and two patients (1.8 %) in the left lateral group (OR 0.14, 95%CI 0.03–0.62; P=0.003)

Author's Conclusion: The positioning of patients in the left lateral position during propofol sedation for colonoscopy results in lower desaturation rates provided the position can be maintained throughout endoscopy.

Ergänzend:

incidence of hypoxemia did not differ significantly between the study groups with respect to the intention-to-treat analysis (P=0.064).

when adjusting for propofol dosage, hypoxemia occurred more frequently in the supine group (OR 0.48, 95%CI 0.24–0.96; P=0.040).

87% of all patients suffering from hypoxemia experienced desaturation exclusively in a supine position.

In per-protocol analysis, in which patients who were repositioned

for technical reasons were excluded lower frequency of oxygen desaturation in the left lateral group than in the supine group was found (P=0.004).

Methodical Notes

Funding Sources: k.A.

COI: keine

Randomization: ja (Rancode 3.6 with a 1:1 allocation using a prespecified block size)

Blinding: nein

Dropout Rate/ITT-Analysis: A total of 137 patients had to be excluded from per-protocol analysis because of protocol violations. Most of these patients (121/137, 88.3 %) had to be excluded because of repositioning in order to ease passage of the endoscope

Notes:

Parker, S. et al. A Web-based Multimedia Program Before Colonoscopy Increased Knowledge and Decreased Anxiety, Sedation Requirement, and Procedure Time. J Clin Gastroenterol. 52. 519-523. 2018

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: RCT</p> <p>Number of Patient: 51 vs. 52</p> <p>Recruitment Phase: n. d.</p> <p>Inclusion Criteria: > 18 Jahre, elektive ambulante Kolonoskopie.</p> <p>Exclusion Criteria: Kein Internet, vorherige Kolonoskopie, mangelnde Sprachkenntnisse, Notfälle</p>	<p>Intervention: Anwendung des interaktiven Multimedia Colonoscopy EMMI Programms (Emmi Solutions) zur Information und Aufklärung der Patienten mit anschließender Fragebogenuntersuchung vs. Standardverfahren</p> <p>Comparison: s. o</p>	<p>Primary: Messung der präprozeduralen Angst und Kenntnisse zum Verfahren.</p> <p>Secondary: Behandlungsqualität, erfolgreiche Kolonoskopie, Sedativa-Verbrauch.</p> <p>Results: EMMI-Gruppe höherer Informationsgrad und Selbsteinschätzung geringerer Angst als in der konventionellen Gruppe. EMMI-Gruppe mit geringerem Verbrauch an Sedativa und kürzeren Prozedurenzeiten.</p> <p>Author's Conclusion: Multimediale Aufklärung verbessert das Verständnis der Patienten und bietet besseren Komfort und Erfolg.</p>

Methodical Notes

Funding Sources: EMMI Solutions

COI: Ein Mitarbeiter der EMMI Solutions war beteiligt. Andere Autoren: nein.

Randomization: RCT

Blinding: ja

Dropout Rate/ITT-Analysis: s. o.

Notes:
 RCT, hohe Ausschlussrate in der Untersuchungsgruppe. Dies ist begründet durch technische Schwierigkeiten bei der Kontaktaufnahme, Nichtvorhandensein von e-mail oder Internet beim Patienten, und das die Patienten das Trainingsprogramm vor der Endoskopie verpassten.

Shin, S. et al. Patient satisfaction after endoscopic submucosal dissection under propofol-based sedation: a small premedication makes all the difference. Surg Endosc. 31. 2636-2644. 2017

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: RCT</p> <p>Number of Patient: 72 von 81</p> <p>Recruitment Phase: 2014 - 2015</p> <p>Inclusion Criteria: Patienten mit Magenkarzinom oder Adenom mit Indikation zur ESD. ASA I - III, ECOG 0 oder 1.</p> <p>Exclusion Criteria: Vorherige Magenresektion oder ESDs. Allergie. 3 oder mehr Läsionen (unklar welche gemeint sind), Sedierung innerhalb</p>	<p>Intervention: Midazolam vs. Placebo, ESD unter Sedierung mit Propofol und Fentanyl b. Bed. unter Bestimmung der Sedierungstiefe mit MOAA/S (Ziel 3 oder 4).</p> <p>Comparison: Vergleich von Prämedikation mit Midazolam vs. Placebo anhand Satisfaction-Scores NRS, VAS und Wong-Baker FACES</p>	<p>Primary: Patienten- und Untersucherzufriedenheit.</p> <p>Secondary: Untersuchungsvariablen (Medikamentenverbrauch etc.), Medikamentenverbräuche, Akzeptanz der Patienten, die gleiche Sedierungsmethode erneut zu erhalten.</p> <p>Results: Nach Interimsanalyse abgebrochen, da Patienten hochsignifikant die Sedierung mit Midazolam bevorzugten. Alle anderen Parameter ohne Gruppenunterschiede.</p> <p>Author's Conclusion: Eine Prämedikation mit einer geringen Dosis von Midazolam steigert den Patientenkomfort ohne die Prozedurqualität</p>

Methodical Notes**Funding Sources:** nein**COI:** nein**Randomization:** ja**Blinding:** ja**Dropout Rate/ITT-Analysis:** 9 von 81**Notes:**

Smith, Z. L. et al. A randomized controlled trial evaluating general endotracheal anesthesia versus monitored anesthesia care and the incidence of sedation-related adverse events during ERCP in high-risk patients. Gastrointest Endosc. 89. 855-862. 2019

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: RCT</p> <p>Number of Patient: 200 von 231</p> <p>Recruitment Phase: 2016 - 2017</p> <p>Inclusion Criteria: Alter > 18 Jahre, Hochrisiko-ERCP (mind. 1 SRAE Risikofaktor; ASA IV, BMI > 35, Mallampati IV, STOP-BANG > 3, COPD, Alkoholabusus)</p> <p>Exclusion Criteria: Notfall-ERCP, unsicherer Atemweg (?), Magenausgangsstenose, Schwangerschaft</p>	<p>Intervention: ERCP unter Sedierung bzw. Allgemeinanästhesie</p> <p>Comparison: Sedierung ohne (MAC) bzw. Allgemeinanästhesie mit endotrachealer Intubation (GEA)</p>	<p>Primary: SRAEs (Hypoxämie < 90%, Atemwegsmanipulationen, KOnversion zu Allgemeinanästhesie, Hypotension, Herzrhythmusstörungen, respiratorische Probleme.</p> <p>Secondary: ERCP-Zeiten, Zeit bis Kanülierung des Duktus, Erfolg der Prozedur, PRAEs.</p> <p>Results: Inzidenz in der MAC Gruppe höher (51,5% vs. 9,9%). ERCP Abbruch in 10,1% in der MAC Gruppe. Prozesszeiten zwischen den Gruppen nicht signifikant unterschiedlich. Keine PRAEs unmittelbar. 10 traten verzögert auf, jedoch ohne Gruppeunterschieden.</p> <p>Author's Conclusion: GEA sollte für Hochrisiko ERCP indiziert werden.</p>

Methodical Notes**Funding Sources:** keine Angabe**COI:** keine**Randomization:** ja**Blinding:** nein**Dropout Rate/ITT-Analysis:** 200 von 231**Notes:**

Anästhesie- bzw. Sedierungskonzept korrekt geplant und durchgeführt.
Studienplanung und -durchführung adäquat.

Sun, X. et al. Topical pharyngeal anesthesia provides no additional benefit to propofol sedation for esophagogastroduodenoscopy: a randomized controlled double-blinded clinical trial. Sci Rep. 8. 6682. 2018

Population **Intervention - Comparison** **Outcomes/Results**

<p>Evidence level: 1</p> <p>Study type: RCT, doppelblind</p> <p>Number of Patient: 636</p> <p>Recruitment Phase: 2017</p> <p>Inclusion Criteria: Patienten mit Indikation für ÖGD in Sedierung</p> <p>Exclusion Criteria: keine Angaben</p>	<p>Intervention: ÖGD in Sedierung mit Propofol</p> <p>Comparison: Topische Anästhesie des Larynx versus Plazebo</p>	<p>Primary: Umittelbarer Diskomfort des Halses (VAS) sowie Patientenzufriedenheit.</p> <p>Secondary: Diskomfort des Halses nach einem Tag (VAS), orale Medikation sowie AEs.</p> <p>Results: Propofoldosierungen in beiden Gruppen nicht unterschiedlich. Untersuchungszeiten vergleichbar. Diskomfort unmittelbar sowie 1 Tag nach Endoskopie nicht unterschiedlich. Keine UNterschied in Bezug auf den Bedarf einer oralen Medikation.</p> <p>Author's Conclusion: Topische Anästhesie mit Lidocain reduziert den pharyngealen Diskomfort nicht und steigert auch nicht die Zufriedenheit.</p>
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<p>Methodical Notes</p>
<p>Funding Sources: Institutionell</p> <p>COI: keine</p> <p>Randomization: RCT</p> <p>Blinding: doppelblind</p> <p>Dropout Rate/ITT-Analysis: 626 von 636</p> <p>Notes: Adäquates Studiendesign sowie korrekte Durchführung der Studie</p>

OXFORD (2011) Appraisal Sheet: Diagnostic Studies: 10 Bewertung(en)

<p>Bugajski, M. et al. Modifiable factors associated with patient-reported pain during and after screening colonoscopy. Gut. 67. 1958-1964. 2018</p>		
<p>Evidence level/Study Types</p>	<p>Population</p>	<p>Outcomes/Results</p>
<p>Evidence level: 2</p> <p>Study type: no, cross-sectional analysis based on database records from 23 centres participating in a population-based screening programme in Poland plus Gastronet questionnaires</p>	<p>Number of patients / samples: Of 35216 screening colonoscopies in 2014 and 2015 included in the study, 22725 (64.5%) patients returned valid Gastronet questionnaires.</p> <p>Reference standard:</p> <p>Validation:</p> <p>Blinding: no</p> <p>Inclusion of clinical information: Gastronet results for question on pain during and after colonoscopy</p> <p>Patient factors: age, sex, previous abdominal surgery, previous colonoscopy and BMI.</p> <p>Sedation type: no sedation, benzodiazepine-opioid sedation, or propofol sedation</p>	<p>Results: The proportion of examinations described as causing pain during (after) the procedure was 22.5% (14.2%) for unsedated, 19.9% (13.5%) for benzodiazepine-opioid sedation and 2.5% (7.5%) for propofol sedation. Propofol sedation, higher case volume of endoscopists, newest endoscope generation and adequate bowel preparation were significantly associated with lower odds of painful colonoscopy. Pain scores after colonoscopy showed similar associations. Adjusted pain rates during and after colonoscopy varied 11 and over 23-fold, respectively, between endoscopists.</p> <p>Author conclusions: We identified several independent, modifiable factors associated with pain during and after colonoscopy, of which individual endoscopist was the most important. Dedicated training should be considered to</p>

	<p>Procedure factors: bowel preparation for procedure, procedure completed to the caecum, most advanced lesion categorisation and endoscope generation</p> <p>Endoscopist factors: proportion of examinations with caecum intubation (CIR), proportion of examinations with at least one adenoma detected (ADR), specialty of endoscopist (gastroenterology, surgery or other (Polish Society of Gastroenterology certificate of competence in colonoscopy was obligatory)), endoscopist's age and sex and recent screening colonoscopy case volume (number of colonoscopies in screening setting during 2012–2014).</p> <p>Dealing with ambiguous clinical findings:</p>	<p>decrease variability among endoscopists.</p>
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<p>Methodical Notes</p>
<p>Funding Sources: funded by grant Pol-Nor/204233/30/2013 from the Polish-Norwegian Research Programme through the National Centre for Research and Development of Poland.</p> <p>COI: MFK is on the advisory board of Alfa Wasserman and has spoken and taught for Olympus Poland. JR is on the advisory boards of Alfa Wasserman, Ipsen Pharma, Polpharma and Takeda and has a travel grant from Abbvie. The other authors have no competing interests.</p> <p>Notes: cross-sectional analysis based on database records from 23 centres participating in a population-based colonoscopy screening programme in Poland plus Gastronet questionnaires</p>

<p>Cabadas Avi3n, R. et al. Effectiveness and safety of gastrointestinal endoscopy during a specific sedation training program for non-anesthesiologists. Rev Esp Enferm Dig. 111. 199-208. 2019</p>		
<p>Evidence level/Study Types</p>	<p>Population</p>	<p>Outcomes/Results</p>
<p>Evidence level: 4</p> <p>Study type: yes</p>	<p>Number of patients / samples: n=3475</p> <p>Reference standard: Gastroenterologists with and without training program for sedation</p> <p>Validation:</p> <p>Blinding: no</p> <p>Inclusion of clinical information: no</p> <p>Dealing with ambiguous clinical findings:</p>	<p>Results: The training group had higher rate of completed procedures and lower rate of excessive sedation (1.35 vs 8.61%) hypoxiaemia (0.72% vs 2.49%) and port procedure-related pain (1.8% vs. 4.3%). There was no difference in patients satisfaction</p> <p>Author conclusions: Sedation training program improved effectiveness and safe outcomes of sedation for endoscopy when compared to gastroenterologists without training program.</p>

<p>Methodical Notes</p>
<p>Funding Sources: no</p>
<p>COI: none Lorenz P et al. Leitlinienreport der aktualisierten... Z Gastroenterol 2023; 61: e628–e653 © 2023. Thieme. All rights reserved.</p>

Notes: Sedation with midazolam and fentanyl

Cabadas Avion, R. et al. Prospective analysis of the complications, efficacy, and satisfaction level on the sedation performed by anaesthetists in gastrointestinal endoscopy. Rev Esp Anesthesiol Reanim. 65. 504-513. 2018

Evidence level/Study Types	Population	Outcomes/Results
<p>Evidence level: 5</p> <p>Study type: Unclear, retrospectiv analysis</p>	<p>Number of patients / samples: 3746</p> <p>Reference standard: no</p> <p>Validation: not given</p> <p>Blinding: no</p> <p>Inclusion of clinical information: not learly stated, consecutive patients ?</p> <p>Dealing with ambiguous clinical findings:</p>	<p>Results: Incidence of major complications was low Incidence of hypoxemia of 3.0% ins scheduled endoscopy and 5.7% in urgent endoscopy</p> <p>Author conclusions: The participation of the anesthetist has shown excelent results in this study</p>

Methodical Notes

Funding Sources: not given, Department of anesthesiology

COI: Department of anesthesiology

Notes:

Campbell, J. A. et al. Endoscopic ultrasound sedation in the United Kingdom: Is life without propofol tolerable?. World J Gastroenterol. 23. 560-562. 2017

Evidence level/Study Types	Population	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: RCT of moderate quality, prospective design</p>	<p>Number of patients / samples: 200, 100 in the endoscopic ultrasound (EUS) arm and 100 in the oesophago-gastroduodenoscopy (OGD) arm</p> <p>Reference standard:</p> <p>Validation:</p> <p>Blinding: no</p> <p>Inclusion of clinical information: A visual analogue scale (0-10) was used to record patients' expected pain pre-procedure and the actual pain perceived post-procedure. Subsequent willingness to repeat the procedure was also noted. Procedure duration, sedation dosages and sedation complications were recorded for each patient.</p> <p>Dealing with ambiguous clinical findings:</p>	<p>Results: EUS procedures lasted significantly longer than OGDs (15 min vs 6 min, $P < 0.0001$), however, there was no difference in anticipated pain scores between the groups (EUS 3.37/10 vs OGD 3.47/10, $P = 0.46$). Pain scores indicated EUS was better tolerated than OGD (1.16/10 vs 1.88/10, $P = 0.03$) although higher doses of sedation were used for EUS procedures. There were no complications identified in either group.</p> <p>Author conclusions: Although propofol has been shown to be a superior sedation agent the mandatory anaesthetic support required in the United Kingdom makes its unfeasible to be used for all EUS procedures. We feel our study demonstrates that the tolerability of EUS with opiate and benzodiazepine sedation is acceptable.</p>

Methodical Notes

Funding Sources: No funding was required for this study

COI: no competing interests

Notes: RCT, but the study arms (EUS vs. OGD) do not reflect the underlying question of interest to what extent opiate and benzodiazepine sedation causes more patient discomfort than propofol sedation

Grilo-Bensusan, I. et al. Prospective study of the factors associated with poor tolerance to ambulatory colonoscopy under conscious sedation. Rev Esp Enferm Dig. 110. 223-230. 2018

Evidence level/Study Types	Population	Outcomes/Results
<p>Evidence level: 4</p> <p>Study type: a prospective, single-center, descriptive study of 300 patients undergoing ambulatory colonoscopy under conscious sedation</p>	<p>Number of patients / samples: A total of 343 patients were included, of which 337 had a full colonoscopy indication. Of these, 319 were performed under conscious sedation, and finally 300 colonoscopies (94%) were deemed valid for the study</p> <p>Reference standard:</p> <p>Validation: to determine the factors which are related to poor tolerance to colonoscopy under conscious sedation since it could permit an a priori selection of patients who might require deep sedation with propofol</p> <p>Blinding: no The endoscopist and the nurse also assessed the patients' pain during the procedure "blindly", without knowing the response of the others.</p> <p>Inclusion of clinical information: Patients' general variables (age, gender, weight, height, BMI, comorbidity and reason for examination) were recorded. If a colonoscopy had been previously performed, the pain experienced by the patient was assessed quantitatively by means of a 0 to 100 mm VAS, as well as qualitatively as "bad" or "good".</p> <p>Dealing with ambiguous clinical findings: The correlation between the variables was studied using the Spearman's correlation coefficient</p>	<p>Results: Tolerance was good in 273 cases (91%). The median value of tolerance was 13 (p25-p75: 4-33). Pain was considered as mild in 215 (71.7%), moderate in 57 (19%) and intense in 28 (9.3%). In the univariate study, greater pain was associated with females, anxiety, the indication for the procedure, the length of time and difficulty of the examination, and the doses of sedatives. In the multivariate study, both the indication (OR 2.92, 95% CI = 1.03-8.2, p < 0.05) and the difficulty of the examination (OR 4.68, 95% CI = 1.6-13.6, p < 0.01) were significant. Complications were found in 16 patients (5.3%), although all of them were insignificant.</p> <p>Author conclusions: Conclusions: tolerance of patients undergoing ambulatory colonoscopy under conscious sedation is good in most cases and complications are infrequent and minor. A worse tolerance to the test is associated with women patients, individuals with anxiety prior to colonoscopy, indication, difficult and longer exploration and lower doses of sedatives.</p>

Methodical Notes
Funding Sources: not mentioned
COI: not mentioned
Notes: a prospective, single-center, descriptive study of 300 patients undergoing ambulatory colonoscopy under conscious sedation

Harvin, G. et al. Patients presenting for colonoscopy: A great opportunity to screen for sleep apnea. World J Gastrointest Endosc. 8. 697-700. 2016		
Evidence level/Study Types	Population	Outcomes/Results
Evidence level: 4 Study type: prospective, single centre study	Number of patients / samples: 60 Reference standard: yes: Berlin questionnaire Validation: no Blinding: no Inclusion of clinical information: BMI, ASA, age, Mallampati, neck circumference, height, weight, BMI, indications for procedure Dealing with ambiguous clinical findings: No	Results: 26/60 (43,3%): Positive Berlin questionnaire 9/57 (15,8%): snoring > 10 s 13/ 57 (22.8%): drop in oxygen saturation < 92%. Author conclusions: Screening patients for sleep apnea at the time of a colonoscopy offers a unique opportunity not only to screen for colon cancer but also to identify patients at high risk for OSA who should undergo further testing.

Methodical Notes
Funding Sources: No
COI: No
Notes: Screening for OSA is a substantial element before performing a sedation independent of indication for a colonoscopy or other examination under sedation.

Kothari, D. et al. An open-access endoscopy screen correctly and safely identifies patients for conscious sedation. Gastroenterol Rep (Oxf). 4. 281-286. 2016		
Evidence level/Study Types	Population	Outcomes/Results
Evidence level: 4 Study type: Cohort study, prospektive design	Number of patients / samples: 8063 Reference standard: yes Validation: no Blinding: no Inclusion of clinical information: Dealing with ambiguous	Results: 78 patientes =0.97% of patients were identified as needing anesthesiologist-assisted sedation. 44 booked through open-access Author conclusions: < 1 % of patients inappropriately booked for sdations using a multit-tiered screening process. Most common reasons for anesthesiologist-assisted-sedation were chronic opiod, benzodiazepine and/or alcohol use.This suggests that these entities could be included in screening processes for open-access scheduling

Methodical Notes**Funding Sources:** none**COI:** none**Notes:** Determine ealiability of open-access scheduling system for approprate use of conscious sedation**Leffler, D. A. et al. Development and validation of the PROcedural Sedation Assessment Survey (PROSAS) for assessment of procedural sedation quality. Gastrointest Endosc. 81. 194-203.e1. 2015****Evidence level/Study Types****Population****Outcomes/Results****Evidence level:** 4**Number of patients / samples:** 900/ nein**Results:** 91.6% of patients reported minimal discomfort; 8.4% of patients reported significant discomfort**Study type:** diagnostic study**Reference standard:** nein

2.4% of patients experienced hemodynamic and/or respiratory instability.

There was a high correlation between patient reported intraprocedure discomfort and clinician assessments of procedural discomfort and patient recall of procedural pain 24 to 48 hours postprocedure (p<0.001 for all)

Validation: k.A.**Blinding:** keine Verblindung**Author conclusions:** The PROSAS is a clinically relevant, patient-centered, easily administered instrument that allows for standardized evaluation of procedural sedation quality. The PROSAS may be useful in both research and clinical settings**Inclusion of clinical information:** ja**Dealing with ambiguous clinical findings:** nein**Methodical Notes****Funding Sources:** Clinical Innovation Award from the center for Disease and Healthcare at Beth Israel Deaconess Medical Center.**COI:** keine**Notes:** Auswahl der Patienten, aus denen das Messtool abgeleitet wurde und Auswahl der Patienten im nachfolgenden Anwendungstool ist unklar. Die Bewertung der Sedierung durch den Patienten ist aufgrund der Anamnese fragwürdig.**Lieber, S. R. et al. Complications Associated with Anesthesia Services in Endoscopic Procedures Among Patients with Cirrhosis. Hepatology. . . 2020****Evidence level/Study Types****Population****Outcomes/Results****Evidence level:** 3**Number of patients / samples:** n=428947**Results:** Complications 4441 (1.09%), Serious complications 1349 (0.34%)**Study type:** Retrospective analysis of national data on anesthesia services of 428947 procedures**Reference standard:**

Risk factors american society class 4 +5, ÖGD, general anasthesia, cases after night shift, longer duration cases

Validation: 4441 complications (1.09 %), 1349 serious complications (0.34%)**Author conclusions:** Anesthesia directed sedation was found to be safe, with few serious complications (<1%). Risk of ADS complications increase with older age, more severe disease, procedure type and case complexity**Blinding:** not applicable

	Inclusion of clinical information: Analysis of risk factors Dealing with ambiguous clinical findings:	
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Methodical Notes

Funding Sources:

COI:

Notes: Retrospective analysis of complication rates of 428947 anesthesiological procedures (national data on anaesthesia)

Smith, I. et al. Establishing an anaesthetist-delivered propofol sedation service for advanced endoscopic procedures: implementing the RCA/BSG guidelines. Frontline Gastroenterol. 9. 185-191. 2018

Evidence level/Study Types	Population	Outcomes/Results
Evidence level: 4 Study type: Observational study	Number of patients / samples: 1000 Reference standard: yes Validation: not given Blinding: no Inclusion of clinical information: Patienten undergoing endoscopy, anethesia was provided by one single experiance anesthesis Dealing with ambiguous clinical findings:	Results: Is not clear. Propofol gives excellnt procedueal conditions Author conclusions: Guideline facilitated propofol sedation

Methodical Notes

Funding Sources: not given

COI: no given

Notes: This study is of no use

OXFORD (2011) Appraisal Sheet: Prognostic Studies: 2 Bewertung(en)

Bielawska, B. et al. Anesthesia Assistance in Outpatient Colonoscopy and Risk of Aspiration Pneumonia, Bowel Perforation, and Splenic Injury. Gastroenterology. 154. 77-85.e3. 2018

Population	Intervention	Outcomes/Results
Evidence level: 2 Study type: Retrospective population-based cohort study analyzed from coding data (demographic data, diagnostic and procedure codes) in the Ontario region.	Intervention: Colonoscopy performed under endoscopist-directed sedation with midazolam plus opiates vs. Anesthesists-directed sedation with propofol analyzed by propensity-matched cohorts Comparison: Outcome of	Primary: Coding of bowel perforation, splenic injury or aspiration pneumonia in both groups. Secondary: Results: AA was provided in 862.817 cases (28,2 %) of the cohort. After propensity-matching 793.073 pts were analyzed for each group. The risk for perforation (OR 0,99) and for splenic injury (OR 1,09) did not differ

<p>Number of Patient: 3.834.927 pts. underwent outpatient colonoscopy</p> <p>Recruiting Phase: 1/2005 until 12/2012</p> <p>Inclusion Criteria: Patients underwent outpatient colonoscopy in the Ontario region either under sedation with benzo's and narcotics by the endoscopist or with propofol by an anesthetist (AA-group).</p> <p>Exclusion Criteria: Patients < 18 years, inpatient colonoscopy, concurrent EGD additionally performed.</p>	<p>Anesthesia-assisted colonoscopy vs. unassisted colonoscopy</p>	<p>significantly between both groups. However, AA was associated with an increased risk of aspiration pneumonia (OR 1,63).</p> <p>Author's Conclusion: In a population-based cohort study, AA for outpatient colonoscopy was associated with a significantly increased risk for aspiration pneumonia, but not for bowel perforation or splenic injury. Endoscopists should warn patients, especially those with respiratory compromise, of this risk.</p>
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<p>Methodical Notes</p>
<p>Funding Sources: partially funded by Physicians Services Inc.</p> <p>COI: none</p> <p>Randomization: Pseudo-randomization by propensity matching.</p> <p>Blinding: none</p> <p>Dropout Rate/ITT-Analysis: n/a</p> <p>Notes:</p>

<p>Cadoni, S. et al. Covid-19 pandemic impact on colonoscopy service and suggestions for managing recovery. Endosc Int Open. 8. E985-e989. 2020</p>		
<p>Population</p> <p>Evidence level: 5</p> <p>Study type: expert suggestions for an action plan of how to resume endoscopy activity after the peaks of the Covid-19 pandemic lockdowns</p> <p>Number of Patient: none</p> <p>Recruiting Phase:</p> <p>Inclusion Criteria:</p> <p>Exclusion Criteria:</p>	<p>Intervention</p> <p>Intervention:</p> <p>Comparison:</p>	<p>Outcomes/Results</p> <p>Primary:</p> <p>Secondary:</p> <p>Results:</p> <p>Author's Conclusion: The practice of on-demand sedation with benzodiazepines and/or opiates will allow most patients to complete a water-aided examination with minimal or no sedation. Other methods reported to minimize patient discomfort during colonoscopy can be used, in addition to water-aided techniques. Unsedated or minimally sedated patients who do not require recovery or require a shorter one allow rapid turnaround. Trainee education in water-aided colonoscopy has been demonstrated to confer benefits.</p>

<p>Methodical Notes</p>
<p>Funding Sources: not mentioned</p> <p>COI: The authors declare that they have no conflict of interest</p> <p>Randomization: none</p> <p>Blinding: none</p>

Dropout Rate/ITT-Analysis: none

Notes: expert suggestions for an action plan of how to resume endoscopy activity after the peaks of the Covid-19 pandemic lockdowns

not assessed in detail

NEWCASTLE - OTTAWA Checklist: Case Control: 16 Bewertung(en)

Benson, M. et al. Safety and Efficacy of Moderate Sedation in Super Obese Patients Undergoing Lower and Upper GI Endoscopy: a Case-Control Study. *Obes Surg.* 30. 3466-3471. 2020

Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 3</p> <p>Study type: retrospective, age and sex-matched, casecontrol study comparing 132 super obese patients (BMI ≥ 50 kg/m²) to 132 control patients with normal BMIs (18.5–25 kg/m²)</p>	<p>Funding sources: not mentioned</p> <p>Conflict of Interests: none</p> <p>Randomization: no (reviewed the electronic medical record)</p> <p>Blinding: o</p> <p>Dropout rates:</p>	<p>Total no. patients: 264 (132 super obese patients, 132 controls with normal BMIs)</p> <p>Patient characteristics: July 1, 2016 and October 31, 2017</p> <p>Inclusion criteria: Inclusion criteria were clinically stable patients who received moderate conscious sedation for outpatient general endoscopic procedures (EGD, colonoscopy). Controls were matched to cases for age, sex, type of procedure performed, and for similar indications. All of the general endoscopic procedures were completed by the same group of endoscopists in an ambulatory setting within a tertiary care academic center. All of the evaluated procedures were completed with CO₂ insufflation. Moderate conscious sedation was defined as midazolam, fentanyl, and diphenhydramine administered intravenously by a sedating registered nurse with supervision by the endoscopist performing the procedure and titrated to a goal sedation score of 3 on the Richmond Agitation-Sedation Scale (RASS).</p> <p>Exclusion criteria: Patients who were admitted to the hospital, monitored anesthesia care (MAC) or general anesthesia, advanced endoscopic procedures (e.g. ERCP, endoscopic ultrasound,</p>	<p>Interventions: moderate conscious sedation in Esophagogastroduodenoscopy (EGD) and colonoscopy</p> <p>Comparison: Safety and efficacy of moderate sedation in super obese patients undergoing lower and upper GI endoscopy (colonoscopy, EGD) compared to controls with normal BMIs</p>

		endoscopic mucosal resection, or complex polypectomy) were excluded	
Notes:	retrospective, age and sex-matched, casecontrol study comparing 132 super obese patients (BMI ≥ 50 kg/m ²) to 132 control patients with normal BMIs (18.5–25 kg/m ²)		
	Author's conclusion: General endoscopic procedures can be safely and effectively performed in super obese patients with moderate sedation. Brief intra-procedure hypoxia more commonly occurs in super obese patients, and higher medication doses are required.		
Outcome Measures/results	<p>Primary procedure duration, total medication doses administered, procedure-related adverse events.</p> <p>Adverse events included intra-procedural events, events within 24 h of the procedure, and events within 30 days post-procedure attributable to the procedure.</p> <p>Secondary</p>	<p>Results: The mean BMI for the obese cohort was 55.6 compared with 22.5 for the controls (P < 0.001).</p> <p>The mean intra-procedure fentanyl and midazolam dose was higher for the obese patients compared with the controls, fentanyl 180 mcg, midazolam 7.7 mg vs fentanyl 148 mcg, midazolam 6.4 mg, respectively (P < 0.001).</p> <p>There was a significantly higher percentage of brief intraprocedure hypoxia (oxygen blood saturation < 90%) for the obese patients compared with the controls, 5% vs 0% (P = 0.02).</p> <p>There was no difference in delayed adverse events with 2% of the cases and 2% of the controls having delayed adverse events (P = 1.0).</p> <p>Procedure completion rates were 100% for both cases and controls.</p>	

Buxbaum, J. et al. Anesthetist-Directed Sedation Favors Success of Advanced Endoscopic Procedures. Am J Gastroenterol. 112. 290-296. 2017			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 4 Study type:	Funding sources: Conflict of Interests: Randomization: Blinding: Dropout rates:	Total no. patients: Patient characteristics: Inclusion criteria: Exclusion criteria:	Interventions: Comparison:
Notes:	<p>The authors are comparing anesthetist-directed sedation vs. gastroenterologist-directed sedation. In fact the sedation regime was different Propofol mono (ADS) vs. Fentanyl/Mida (GDS). To my mind it is more a comparison between the two sedation regimes than comparing ADS vs. GDS.</p> <p>Author's conclusion:</p>		
Outcome Measures/results	Primary Secondary	Results:	

de Paulo, G. A. et al. Sedation in gastrointestinal endoscopy: a prospective study comparing nonanesthesiologist-administered propofol and monitored anesthesia care. Endosc Int Open. 3. E7-e13. 2015			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 2 Study type: Prospective non-randomized	Funding sources: None Conflict of Interests: None	Total no. patients: N =1.000 in each group Patient characteristics:	Interventions: Patients who scheduled their examination in Unit 1 underwent NAAP-sedation

<p>outpatients who underwent gastroscopy or colonoscopy or both</p>	<p>Randomization: none</p> <p>Blinding: none</p> <p>Dropout rates: not reported</p>	<p>10/2009 - 12/2011</p> <p>Inclusion criteria: Consecutive patients with ASA-class I or II who underwent upper and/or lower GI-endoscopy under sedation.</p> <p>Exclusion criteria: Age < 13 years; BMI > 40, prior adverse reactions to sedation; known drug allergies, asthma, recent myocardial infarction; ASA class III or higher.</p>	<p>whereas patients from Unit 2 underwent MAC-sedation.</p> <p>Comparison: Outcome parameters in Unit 1 vs. Unit 2</p>
<p>Notes:</p>	<p>NAAP was provided in one endoscopy unit and MAC in another endoscopy unit of the same hospital.</p> <p>Author's conclusion: In this setting, NAAP was as safe and effective as MAC for healthy patients undergoing GI-endoscopy.</p>		
<p>Outcome Measures/results</p>	<p>Primary Complication rate. However the calculated number of patients needed to detect significant differences was 85.000, whereas the study was finished for time restraints after 2000 patients.</p> <p>Secondary Sedative regimes used by NAAP and MAC.Procedure and sedation legth.</p>	<p>Results: Patients with NAAP received more propofol and fentanyl than by MAC-sedation. However, the were fewer cases of deep sedation by NAAP than by MAC. Hypoxemia rates were similar in boh groups. Agitation was observed more often under MAC-sedation. Patient satisfaction was equal.</p>	

<p>Gürbulak, B. et al. Impact of anxiety on sedative medication dosage in patients undergoing esophagogastroduodenoscopy. Wideochir Inne Tech Maloinwazyjne. 13. 192-198. 2018</p>			
Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 3</p> <p>Study type: case-control study</p>	<p>Funding sources: not mentioned</p> <p>Conflict of Interests: none</p> <p>Randomization: no</p> <p>Blinding: the anxiety scores were not reported to the endoscopist and the anesthesiologist</p> <p>Dropout rates:</p>	<p>Total no. patients: 210 consecutive patients who underwent EGD under sedation</p> <p>Patient characteristics: between January 2016 and June 2016</p> <p>Inclusion criteria: Patients who underwent diagnostic EGD for upper gastrointestinal system complaints under sedation and agreed to have their anxiety measured by a psychiatrist with the Spielberger State-Trait Anxiety Inventory (STAI-S, STAI-T) before the procedure</p> <p>Exclusion criteria: Patients under 18 years old and above 65 years old, patients who did not want sedation, who were sensitive or allergic to drugs used for sedation, who had a previous EGD or other sedative procedure or sedation-related complication history, psychiatric disorder, drug addiction, patients with a history of gastrointestinal system (GIS) surgery or with an American Society of Anesthesiologists (ASA) score of 3 or above were not included in the study.</p>	<p>Interventions: EGD with sedation, assessment of anxiety</p> <p>Comparison: effect of anxiety scores on medication doses in EGD</p>

Notes:	Author's conclusion: The medications used for sedation during EGD may be inadequate or an additional dose of medication may be needed for patients who have higher anxiety scores, younger age, and lower body mass index	
Outcome Measures/results	Primary Secondary	Results: The average STAI-S score was 40.28 and the average STAI-T score was 40.18. There was no relationship between anxiety scores and gender ($p = 0.058$, $p = 0.869$). Statistically significant results were obtained for anxiety scores with additional sedation dosing ($p < 0.05$). Patients who were young, had a low body mass index and had high anxiety scores had significantly higher additional dose requirements.

Hung, A. et al. Risk Factors and Outcomes of Reversal Agent Use in Moderate Sedation During Endoscopy and Colonoscopy. J Clin Gastroenterol. 50. e25-9. 2016			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 4 Study type: case controll	Funding sources: From the Departments of *Gastroenterology; zAnesthesiology; and wDivision of Pharmacy, Beth Israel Deaconess Medical Center (BIDMC), Boston, MA. Conflict of Interests: The authors declare that they have nothing to disclose. Randomization: keine Blinding: keine Dropout rates: Analyse gespeicherter Daten (ITT)	Total no. patients: unter 130000 Endoskopie fanden sich 45 mit Gebrauch von Antidots; diese wurden gematsched mit 90 Endoskopien derselben Art und am selben Tag Patient characteristics: 2008 - 2013 Inclusion criteria: Koloskopie und "Endoskopien" Exclusion criteria: EUS und ERCP	Interventions: keine Comparison: Gebrauch von Antidots zur Sedierung
Notes:	<p>die Studie spricht von adverse events. Tatsächlich wurde aber nur nach dem Gebrauch von Antidoten gesucht. Bei den so gefundenen Patienten wurde erst dann nach adverse events unterschieden. Es wurde nur 45 unter 130000 Endoskopie gefunden. Es handelt sich also um ein sehr seltenes Ereignis; detaillierte Ableitungen aus diesen Daten erscheinen fragwürdig</p> <p>Author's conclusion: Prevalence of reversal agent use during moderate sedation is low and outcomes are generally good. Several clinically relevant risk factors for reversal agent use were found suggesting that certain groups may benefit from closer monitoring.</p>		

Outcome Measures/results	Primary n.a Secondary n.a	Results: Prevalence of reversal agent use was 0.03% [95% confidence interval (CI), 0.02-0.04]. Events triggering reversal use were oxygen desaturation (64.4%), respiration changes (24.4%), hypotension (8.9%), and bradycardia (6.7%). Two patients required escalation of care and the majority of patients were stabilized and discharged home. Compared with the control group, the reversal group was older (61±1.8 vs. 55±1.6, P=0.01), mostly female (82% vs. 50%, P<0.01), and had lower body mass index (24±0.8 vs. 27±0.7, P=0.03) but received similar dosages of sedation. When adjusted for age, race, sex, and body mass index, the odds of reversal agent patients having a higher ASA score than controls was 4.7 (95% CI, 1.7-13.1), and the odds of having a higher Mallampati score than controls was 5.0 (95% CI, 2.1-11.7) with P<0.01
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Jirapinyo, P. et al. Patients With Roux-en-Y Gastric Bypass Require Increased Sedation During Upper Endoscopy. Clin Gastroenterol Hepatol. 13. 1432-6. 2015			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 1 Study type: Case Controll	Funding sources: Supported by Harvard Digestive Diseases Center at Harvard Medical School (DK034854). Conflict of Interests: The authors disclose no conflicts. Randomization: nicht zutreffend Blinding: nicht zutreffend Dropout rates: retrospektive Studie, dropout nicht möglich	Total no. patients: 400 Patient characteristics: retrospektiv 2005 - 2010 Inclusion criteria: Patienten mit Roux-Y-Magenbypass und gematched solche ohne diesen Eingriff als Kontrollen Exclusion criteria: keine	Interventions: Sedierungsbedarf bei ÖGD Comparison: Patienten mit und ohne Magenbypass-OP
Notes:	sauberes Studiendesign, insbesondere wurde gematched für Alter, Geschlecht und BMI Author's conclusion: This study demonstrated that RYGB patients required higher sedation doses during EGD than the non-RYGB patients with similar age, gender, and BMI. In addition, for a subgroup of patients who underwent EGD both before and after RYGB, sedation requirement increased significantly after gastric bypass, despite weight loss. In addition to a history of RYGB, our study also demonstrated that ASA classification and therapeutic endoscopic procedure were independent predictors of higher sedation doses.		
Outcome Measures/results	Primary Sedierungsbedarf Fentanyl und Midazolam Secondary Subgruppenanalyse für die Patienten mit ÖGD vor und nach der Bypass-OP	Results: RYGB patients required higher doses of fentanyl and midazolam during EGD than the non-RYGB patients with similar age, gender, and BMI. The RYGB group took significantly longer than the control to be sedated (P < .001, =Sedierung zur und während der ÖGD)	

Khoi, C. S. et al. Age correlates with hypotension during propofol-based anesthesia for endoscopic retrograde cholangiopancreatography. Acta Anaesthesiol Taiwan. 53. 131-4. 2015			
Evidence level	Methodical Notes	Patient characteristics	Interventions

<p>Evidence level: 3</p> <p>Study type: Case Controll</p>	<p>Funding sources: k.A.</p> <p>Conflict of Interests: All authors have no conflicts of interest to dec</p> <p>Randomization: nicht zutreffend</p> <p>Blinding: nicht zutreffend</p> <p>Dropout rates: nicht zutreffend</p>	<p>Total no. patients: 552</p> <p>Patient characteristics: 2006-2010</p> <p>Inclusion criteria: we retrospectively reviewed the anesthetic records, history charts, and procedure records of the patients who underwent ERCP under propofol-based deep sedation from January 2006 to July 2010 at the Far Eastern Memorial Hospital. All propofol-based deep sedations were conducted by anesthesiologists.</p> <p>Exclusion criteria: es wurde keine Fälle aus diesem Zeitraum ausgeschlossen</p>	<p>Interventions: ERCP</p> <p>Comparison: kein Komparator</p>
<p>Notes:</p>	<p>es handelt sich um die deskriptive, rertospektive Analyse eine Kohorte ohne Komparator.</p> <p>Author's conclusion: Hypotension was the most frequent anesthetic complication during procedure under propofol-based deep sedation, but this method was safe and effective under appropriate monitoring. Age is the strongest predictor of hypotension and therefore propofol-based deep sedation should be conducted with caution in the elderly</p>		
<p>Outcome Measures/results</p>	<p>Primary patients with hypotension, hypertension, and desaturation during anesthesia</p> <p>Secondary</p>	<p>Results: Multivariate logistic regression identified sex and age as significantly associated with hypotension ($p < 0.05$);. However, when age was excluded from analysis, hypertension and anesthetic time were identified as a significant predictor ($p = 0.002$ and $p = 0.03$, respectively), while sex remained a significant independent predictor ($p = 0.038$).</p>	

<p>Kim, S. Y. et al. Impacts of age and sedation on cardiocerebrovascular adverse events after diagnostic GI endoscopy: a nationwide population-based study. Gastrointest Endosc. 92. 591-602.e16. 2020</p>			
Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 4</p> <p>Study type: Case Controll. Es gibt aber eigentlich eine Kontrollgruppe, außer man sieht Sedierung/nicht-Sedierung und die Altersgruppen als "Kontrollen"</p>	<p>Funding sources: This study used the HIRA databases (study no. M20180612227). We thank the Korean HIRA for providing insurance claims data. National Research Foundation of Korea grant funded by the Korea government (MSIT; 2010-0027945) and from the Basic Science Research Program through the National Research Foundation of Korea funded by the Ministry of Education (2017R1D1A1B03035311):</p> <p>Conflict of Interests: keine</p> <p>Randomization: nicht zutreffend</p> <p>Blinding: nicht zutreffend</p> <p>Dropout rates: nicht zutreffend</p>	<p>Total no. patients: 1,943,15</p> <p>Patient characteristics: 1.12015-31.12.2015</p> <p>Inclusion criteria: diagnostische Endoskopie in diesem Zeitraum</p> <p>Exclusion criteria: Cardiovasculäre Ereignisse jenseites von 2 Wochen nach oder innerhalb des Jahres vor dem Auswertungszeitraum und Personen mit Einnahme von Antikoagulationen</p>	<p>Interventions: Sedierung, Alter > 69</p> <p>Comparison: keine Sedierung, Alter <70</p>

Notes:	<p>In der Studie wurde die Häufigkeit von kardiovaskulären Ereignissen nach diagnostischer Endoskopie innerhalb von 14 Tagen anhand von Krankenversicherungsdaten analysiert. Es wurden keine Kontrollen angelegt. Es fand sich ein höheres Risiko, wenn die Patienten eine Sedierung erhielten oder älter waren. Warum eine Sedierung erfolgte, wurde nicht untersucht. Das Kollektiv enthielt nur diagnostische Untersuchungen, keine Vorsorgeuntersuchungen, keine therapeutischen Interventionen. Die Aussagen beziehen sich auf Midazolam; Propofol wurde selten eingesetzt.</p> <p>Author's conclusion: CCD adverse events after diagnostic endoscopy were significantly frequent in individuals with older age (70-99 years) and/or sedation during endoscopy. Stratification by age and sedation shows that the impact of these 2 factors on CCD adverse events differs according to endoscopy type</p>	
Outcome Measures/results	<p>Primary incidence of CCD adverse events after diagnostic GI endoscopy, namely, cardiac and cerebral adverse events, other arterial thromboembolism (ATE), and pulmonary embolism (PE),</p> <p>Secondary impact of age and sedation</p>	<p>Results: Among 1,943,150 subjects, CCD adverse events occurred in approximately 2.23%. On multivariate analysis, older age (70-99 years vs 40-69 years) (OR 1.69; P < .001) and sedation during endoscopy (OR, 1.12; 95% CI, 1.09-1.14; P < .001) were identified as independent risk factors for CCD adverse events.</p>

Kollmann, C. M. et al. Gastrointestinal endoscopy under sedation is associated with pneumonia in older inpatients-results of a retrospective case-control study. United European Gastroenterol J. 6. 382-390. 2018			
Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 3</p> <p>Study type: Case controll</p>	<p>Funding sources: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.</p> <p>Conflict of Interests: keine</p> <p>Randomization: nicht zutreffend</p> <p>Blinding: nicht zutreffend</p> <p>Dropout rates: nicht zutreffend</p>	<p>Total no. patients: 500</p> <p>Patient characteristics: 2005-2015</p> <p>Inclusion criteria: Laboratory parameters had to be available before (d0) gastrointestinal endoscopy under sedation (GIES) as well as three (d3) and/or seven days (d7) after endoscopy. Age- (2 years), gender- and time-matched (10%) inpatients who had neither obtained any invasive procedure nor sedation served as controls in a ratio of 1:1.</p> <p>Exclusion criteria: elevated inflammation parameters (WBC>10,000/ml or<4000/ml, CRP>2 mg/dl), preexisting antibiotic treatment, preexisting pneumonia and diseases or conditions accompanied by increased risk of aspiration</p> <p>Additional exclusion criteria</p>	<p>Interventions: ÖGD oder ÖDG und Koloskopie</p> <p>Comparison: keine Endoskopie und keine andere Sedierung</p>

		for the control group included any type of sedation.	
Notes:	<p>die Studie wurde formal korrekt geplant. Doch zeigt die Auswertung, dass die Kontrollgruppe sich bereits in den untersuchten Parametern, z.B. in BMI und Karnowsky-Index, signifikant unterscheidet.</p> <p>Author's conclusion: Patients of advanced age carry an increased risk of pneumonia and LRI after GIES. Patients are generally more likely to feature inflammation and to receive antibiotic treatment.</p>		
Outcome Measures/results	<p>Primary Anteil von Patienten, die nach 3 Tagen eine Pneumonie entwickelt haben, besondere Auswertung für mindestens 65-Jährigen wird als Unterpunkt der primären Endpunktes aufgeführt</p> <p>Secondary</p>	<p>Results: Kein signifikanter Unterschied in der Gesamtgruppe. Signifikanter Unterschied bei den mindesten 65-Jährigen (Pneumonia (n=4 (2.6%) vs. 0 (0.0%), p=0.041) and LRI (n=12 (7.8%) vs. n=4 (2.5%), p=0.034)</p>	

Kudaravalli, P. et al. Patient Satisfaction and Understanding of Moderate Sedation During Endoscopy. Cureus. 12. e7693. 2020			
Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 5</p> <p>Study type:</p>	<p>Funding sources:</p> <p>Conflict of Interests:</p> <p>Randomization:</p> <p>Blinding:</p> <p>Dropout rates:</p>	<p>Total no. patients:</p> <p>Patient characteristics:</p> <p>Inclusion criteria:</p> <p>Exclusion criteria:</p>	<p>Interventions:</p> <p>Comparison:</p>
Notes:	<p>diese ist nicht auf Deutschland übertragbar</p> <p>Author's conclusion:</p>		
Outcome Measures/results	<p>Primary</p> <p>Secondary</p>	Results:	

Laffin, A. E. et al. Severity and duration of hypoxemia during outpatient endoscopy in obese patients: a retrospective cohort study. Can J Anaesth. 67. 1182-1189. 2020			
Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 2</p> <p>Study type: Case Controll. Eigentlich wird die untersuchte Gesamtgruppe nur in 4 BMI-Klassen unterteilt</p>	<p>Funding sources: Department of Anesthesiology, Perioperative Care, & Pain Medicine at the New York University School of Medicine.</p> <p>Conflict of Interests: keine</p> <p>Randomization: nicht zutreffend</p> <p>Blinding: nicht zutreffend</p> <p>Dropout rates: nicht</p>	<p>Total no. patients: 11595</p> <p>Patient characteristics: 6-2015 bis 6 2016</p> <p>Inclusion criteria: Erwachsene > 17 LJ mit ÖGD oder Koloskopie unter tiefer Sedierung durch Anästhesisten oder qualifizierte Pflegekraft (supervised certified registered nurse anesthetists (CRNA))</p> <p>Exclusion criteria: ASA>2 (bei "aktuell vorliegenden Befunden" auch kardiale Vorerkrankungen erlaubt, 8,3% hatten ASA 3 und einzelne ASA 4) und Schlafapnoe.</p>	<p>Interventions: Aufteilung der gesamten Patientengruppe nach 5 BMI-Klassen: < 25, 25-29.9, 30-34.9, 35-39.9, > 40</p> <p>Comparison: s.o</p>
<p>Lorenz P et al. Leitlinienreport der Deutschen Gesellschaft für Gastroenterologie, Verdauungs- und Darmkrankheiten © 2023. Thieme. All rights reserved.</p>			

	zutreffend		
Notes:	<p>die Studie nennt sich selbst retrospektive Kohortenstudien. Beobachtet wird aber nur das singuläre Ereignis einer Endoskopie.</p> <p>Author's conclusion: The incidence of severe hypoxemia increased nearly six-fold in obese patients and 8.5-fold in class III obese patients when compared with those of normal BMI. Intravenous fentanyl was associated with intraoperative hypoxemia independent of BMI. Patients who represent the highest risk for hypoxia should be stratified to procedure locations with adequate resources for the safest care.</p>		
Outcome Measures/results	<p>Primary hypoxemia (O2-Saet.. <90%, severe hypoxemia (>85%), and prolonged hypoxemia (Y>5 min) as the binary outcome variable in a separate analysis</p> <p>Secondary Fentanyl als unabhängiger Risikofaktor</p>	<p>Results: ein statistisch signifikante Erhöhung der adjustierten OR fand sich ab einem BMI >29 für Hypoxämie, schwere Hypoxämie und langanhaltende Hypoxämie</p> <p>Fentanyl war ein Risikofaktor für Hypoxämie und schwere Hypoxämie ohne Assiziation mit dem BIM, für eine langanhaltende Hypoxämie mit Abhängigkeit vom BMI</p>	

Lee, S. P. et al. Factors impacting patient cooperation during elective gastroscopy. Korean J Intern Med. 32. 819-826. 2017			
Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 5</p> <p>Study type: retrospektive Fallstudie ohne Kontrolle</p>	<p>Funding sources: k.A.</p> <p>Conflict of Interests: keine</p> <p>Randomization: nein</p> <p>Blinding: nein</p> <p>Dropout rates: nein</p>	<p>Total no. patients: 4500</p> <p>Patient characteristics: k.a.</p> <p>Inclusion criteria: konsekutiv vom Autor untersucht</p> <p>Exclusion criteria:</p>	<p>Interventions: keine, nur deskriptiv</p> <p>Comparison:</p>
Notes:	<p>retrospektive Analyse eines Einzeluntersuchers mit seiner subjektiven Bewertung</p> <p>Author's conclusion: Endoscopists must keep in mind that examinee cooperation is more likely to be poor in the young, obese people, women, patients with hiatal hernias, and those who receive procedural sedation.</p>		
Outcome Measures/results	<p>Primary</p> <p>Secondary</p>	<p>Results: Examinee cooperation during the endoscopic procedure was poor in 358 out of 4,422 subjects (8.1%). Of the subjects with poor cooperation, the endoscopic examination was incomplete in 36 subjects (10.1%). Multivariate analysis revealed that young age (< 40 years), female sex, high body mass index (≥ 25), hiatal hernia, and procedural sedation using midazolam were independent risk factors for poor cooperation.</p>	

Lee, S. S. et al. Are Histrionic Personality Traits Associated with Irritability during Conscious Sedation Endoscopy?. Gastroenterol Res Pract. 2015. 702492. 2015

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 5 Study type:	Funding sources: Conflict of Interests: Randomization: Blinding: Dropout rates:	Total no. patients: Patient characteristics: Inclusion criteria: Exclusion criteria:	Interventions: Comparison:
Notes:	Studienaussage: agitierte Persönlichkeiten und/oder solche mit erhöhtem Alkoholkonsum sind während der endoskopie agitiert. Für letzteres wird ein selbst geschaffener, subjektiver Score verwendet. Daher habe ich keine Evidenztabelle angelegt. Author's conclusion:		
Outcome Measures/results	Primary Secondary	Results:	

Lee, S. et al. Efficacy and safety of a patient-positioning device (EZ-FIX) for endoscopic retrograde cholangiopancreatography. World J Gastroenterol. 21. 5995-6000. 2015			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 4 Study type: Case controll	Funding sources: Supported by Korea Healthcare Technology R and D Project, Ministry of Health and Welfare, South Korea (A100054). Conflict of Interests: keine Randomization: ja (nicht beschrieben) Blinding: nein Dropout rates: ITT	Total no. patients: 105 Patient characteristics: April 2013 bis März 2014 Inclusion criteria: konsekutive Patienten zur therapeutischen ERCP Exclusion criteria: Alter unter 18, ASA V; Anamnestisch Komplikationen/unverträglichkeit Sederiung, Propofol, Midazolam, Ei, Sojybohnen. Schwangerschaft	Interventions: Lagerung/Fixierung der Patienten mit EZ-Fix Comparison: Kein Lagerung mit dem Device
Notes:	ein geringere Propofoldosis bei Patienten, die fixiert sind wie ein Beinbruch im Rettungsdienst verwundet nicht. Die weiteren gefundenen Unterschiede waren nicht primärer Endpunkt und subjektiv Author's conclusion: Using EZ-FIX reduced the total dose of propofol and the recovery time, and increased the satisfaction of the endoscopist and nurses.		
Outcome Measures/results	Primary propofol and sedative-related complications, including hypoxia and hypotension. Secondary Secondary outcome measures were recovery time and sedation satisfaction of the endoscopist, nurses, and patients.	Results: no significant difference in the rate of hypoxia mean total dose of propofol lower in the EZ-FIX group than in the non-EZ-FIX group (89.43 ± 49.8 mg vs 112.4 ± 53.8 mg, P = 0.025)	

Mudambi, L. et al. Obstructive Sleep Apnea Is Not Associated with Higher Health Care Use after Colonoscopy under Conscious Sedation. Ann Am Thorac Soc. 13. 419-24. 2016

Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 1</p> <p>Study type: Retrospective case-control study</p>	<p>Funding sources: Not found (available online)</p> <p>Conflict of Interests: Not found (available online)</p> <p>Randomization: None</p> <p>Blinding: None</p> <p>Dropout rates: None</p>	<p>Total no. patients: 6.690 (4316 OSA/ 2374 control group)</p> <p>Patient characteristics: 12 years (1999-2012)</p> <p>Inclusion criteria: Patients who undergone an elective colonoscopy. The control group was defined as patients without any sleep related diagnosis, defined by all ICD-9 codes related to sleep anytime during the study period. The OSA group was defined as patients who met all of the following criteria: OSA-related ICD-9 codes, codes for sleep testing, and at least one follow-up examination in the outpatient sleep clinic in all the years preceding and 3 years after the inception date.</p> <p>Exclusion criteria: All emergent colonoscopies, inpatient colonoscopies, and cases with general anesthesia were excluded.</p>	<p>Interventions:</p> <p>Comparison: OSA vs. control group</p>
Notes:	<p>Author's conclusion: Patients with and without OSA do not differ from in terms of hospital admissions, ICU admissions, and ER visits during the first 30 days after a colonoscopy with sedation. Patients with OSA can undergo moderate sedation during colonoscopy.</p>		
Outcome Measures/results	<p>Primary Terms of hospital admissions, ICU admissions, and ER visits during the first 30 days after a colonoscopy with sedation</p> <p>Secondary Subgroup analysis: Polysomnogram results available</p>	<p>Results: There were no differences in hospitalizations, ICU admissions, or ER visits between the control and study groups at any period during the first 30 days after the procedure. The subgroup analysis shows as well no difference regarding to the outcome measures.</p>	

Nonaka, S. et al. Safety and effectiveness of propofol-based monitored anesthesia care without intubation during endoscopic submucosal dissection for early gastric and esophageal cancers. Dig Endosc. 27. 665-73. 2015

Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 4</p> <p>Study type: Prospective cohort study</p>	<p>Funding sources: none</p> <p>Conflict of Interests: none</p> <p>Randomization: none</p> <p>Blinding: none</p> <p>Dropout rates: not given</p>	<p>Total no. patients: 794 pts under regular sedation and 219 pts. with MAC-sedation</p> <p>Patient characteristics: 2010-2014</p> <p>Inclusion criteria: Patients who underwent ESD - treatment for either early gastric or early esophageal cancer at a single institution</p>	<p>Interventions: Upper Gi-endoscopy with ESD under regular sedation by a nurse supervised by the endoscopist or MAC-sedation without intubation</p> <p>Comparison: Effectiveness regarding the body movements of the patients in both groups</p>

		Exclusion criteria: not mentioned	
Notes:	Author's conclusion: Propofol-based MAC-sedation without intubation provided a safer treatment environment by significantly reduced body movements and was very effective for difficult cases requiring longer procedure times or more powerful sedation.		
Outcome Measures/results	<p>Primary Frequency of significant body movements noted by an independent observer in both groups</p> <p>Secondary Occurrence of hypoxemia</p>	<p>Results: Significant body movements were registered in 66/219 pts. under MAC-sedation whereas in 586/794 cases under regular sedation ($p < 0.0001$).</p> <p>The median minimum O₂-saturation was significantly lower under MAC-sedation than under regular sedation (96 % vs. 98 %, $P < 0.004$).</p>	

NEWCASTLE - OTTAWA Checklist: Cohort: 28 Bewertung(en)

Adams, M. A. et al. Predictors of Use of Monitored Anesthesia Care for Outpatient Gastrointestinal Endoscopy in a Capitated Payment System. Gastroenterology. 153. 1496-1503.e1. 2017			
Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 3</p> <p>Study type: Retrospective cohort study analyzed with multiple logistic regression</p>	<p>Funding sources: Funded by NIH and VA Health Services Career awards.</p> <p>Conflict of Interests: none</p> <p>Randomization: one</p> <p>Blinding: n/a</p> <p>Dropout rates: n/a</p>	<p>Total no. patients: 2.091.590</p> <p>Recruiting Phase: 2000 - 2013</p> <p>Inclusion criteria: Patients who underwent EGD or colonoscopy or both at Veterans administration hospitals (n=133) under MAC-sedation (coding of anesthesia assistance during upper or lower endoscopy)</p> <p>Exclusion criteria: Patients < 18 or > 100 years of age, body weight < 60 or > 700 lbs.</p>	<p>Interventions: Multiple random effects logistic modeling was used to analyze the MAC-use over time as a function of patient-, provider- or facility-level influences.</p> <p>Comparison:</p>
Notes:	<p>Retrospective cohort study from 133 Veterans administration institutions who underwent either EGD or colonoscopy or both. By using multilevel logistic regression the reasons for the use of monitored-anesthesia care (MAC) sedation were analyzed from coding sources.</p> <p>Author's conclusion: We found that even in a capitated system (Veterans administration hospitals), patient factors are only weakly associated with the use of MAC. Facility-level effects are the most prominent factor influencing increasing use of MAC. It will be important to align resources and incentives to promote appropriate allocation of MAC, based on clinically meaningful patient factors.</p>		
Outcome Measures/results	<p>Primary Patient-, provider- or facility-level associated factors that influence the frequency of MAC-use over time in this cohort of pts.</p> <p>Secondary</p>	<p>Results: The adjusted rate of MAC use increased 17 % per year from 2000 - 2013. The most rapid increase started in 2011. The use of MAC was associated with patient-related factors like obesity, sleep apnoea, higher co-morbidity and the use of opioids, although the magnitude of these associations was small. Unmeasured facility-level effects had the greatest impact on the trend of MAC use.</p>	

Aravapalli, A. et al. Increased Anesthesia Usage in a Large-Volume Endoscopy Unit: Patient Acuity Is Not the Main Predictor. South Med J. 108. 547-52. 2015
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Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 4 Study type: Retrospective analysis	Funding sources: None Conflict of Interests: None Randomization: N/a Blinding: N/a Dropout rates: N/a	Total no. patients: 37.803 colonoscopies performed from 2003 - 2012 Recruiting Phase: 2003 - 2012 (10 years) Inclusion criteria: All colonoscopy procedures Exclusion criteria: None	Interventions: MAC-sedation ordered Comparison: Colonoscopies performed without MAC-sedation
Notes:	<p>The frequency of MAC-sedation during colonoscopies in one hospital were registered over a 10 year-period.</p> <p>Author's conclusion: The use of MAC sedation performed in our endoscopy unit increased significantly from 2003 to 2012. Increased MAC use was most significantly associated with the year of the procedure. This suggests there were other non-patient-related factors influencing its use.</p>		
Outcome Measures/results	Primary Frequency of MAC-sedations per year. Secondary Demographic patient data (sex, age, ASA-class, co-morbidity)	Results: The frequency of MAC-sedation increased over time, from 0,4 % in 2003 to 10,0 % in 2012 (the adjusted odd for MAC-sedation increased by 35,8). The greatest predictor of MAC use was the year of the procedure, whereas no clear relation to demographic patient data werde found.	

Ball, A. J. et al. Sedation practice and comfort during colonoscopy: lessons learnt from a national screening programme. Eur J Gastroenterol Hepatol. 27. 741-6. 2015			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: database analysis	Funding sources: not mentioned Conflict of Interests: The authors declare that there is no conflict of interest. Randomization: not relevant, comprehensive database analysis Blinding: Dropout rates:	Total no. patients: 113.316 colonoscopy examinations were performed (99.044 screening and 14.272 surveillance examinations). Recruiting Phase: January 2010 to 31 December 2012 Inclusion criteria: Exclusion criteria: none	Interventions: intravenous sedation and opiate analgesia in screening and surveillance colonoscopies Comparison: Correlations between the proportion of examinations associated with significant discomfort and the amounts of medication used by colonoscopists were assessed using Spearman's ρ . Logistic regression modelling examined the independent predictors of significant discomfort
Notes:	<p>Dataset: The Bowel Cancer Screening System (BCSS) is a national database related to all colonoscopy examinations performed within the English Bowel Cancer Screening Programme (BCSP). An Specialist Screening Practitioner (SSP) attends each examination and rates patient comfort, independent of the colonoscopist, using the urse-rated Modified Gloucester Comfort Scale (MGCS). Studies have shown that the BCSS has a high level of completeness and accuracy.</p> <p>Author's conclusion: Comfort ratings vary widely between colonoscopists and appear to be unrelated to medication practice. Tailoring medication use to achieve comfortable procedures, while minimizing risk and inconvenience, remains an important area for future research.</p>		
Outcome Measures/results	Primary discomfort rated on the five-point Modified Gloucester Comfort Scale: 1, no discomfort; 5, severe discomfort. Scores of 4 and 5 were considered to	Results: In 91% of examinations, there was no significant discomfort reported during examination; however, there was considerable variation between individual colonoscopists (range 76.1–99.2%). Intravenous sedation and opiate analgesia were used during most examinations, but there was wide variation between colonoscopists, with a median (range) usage of 95.1% (4.1–100%) and 97.3% (5.0–100%), respectively. There was no association	

indicate discomfort.	significant	between the amount of sedation and analgesia used and significant discomfort ($p < 0.2$). On multivariate analysis, significant discomfort was found to be more common among female individuals [odds ratio (OR)=2.0], on incomplete examinations (OR=6.7), and among patients with diverticulosis (OR=1.4).
Secondary		

Behrens, A. et al. [Safety of sedation during gastroscopy and colonoscopy in low-risk patients - results of a retrospective subgroup analysis of a registry study including over 170,000 endoscopies]. Z Gastroenterol. 54. 733-9. 2016

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: subgroup analysis of a registry study (database)	Funding sources: Fa. E&L medical systems GmbH, budget resources of the researchers Conflict of Interests: not mentioned Randomization: not relevant, comprehensive registry study Blinding: no Dropout rates: none	Total no. patients: 177944 patients of 39 research centers Recruiting Phase: December 2011 to June 2014 Inclusion criteria: ASA 1 or ASA 2, esophagogastroduodenoscopy or colonoscopy with sedation Exclusion criteria: ASA 3 or higher, emergency endoscopies, therapeutic procedures, no sedation	Interventions: sedation (propofol alone in 64.4% of the sedations, a combination of propofol and midazolam in 22.4%, midazolam mono in 6.6%, midazolam and opiate in 5.1%, other 1.5%) Comparison:
Notes:	Author's conclusion: Sedation can therefore be regarded as extremely safe in this group of patients. Even though this analysis did not include therapeutic colonoscopies (e.g. polypectomy), these data should lower the threshold for patients undergoing preventive check-up examinations and it should therefore be offered as a standard.		
Outcome Measures/results	Primary minor and major complications Secondary	Results: A total of 332 minor complications were documented (0.2%). No major complications or deaths occurred. The following risk factors were identified for the development of sedation-associated complications: Patients in ASA class 2 and sedation with midazolam in combination with an opiate	

Borgaonkar, M. R. et al. Canadian Association of Gastroenterology Indicators of Safety Compromise following Colonoscopy in Clinical Practice. Can J Gastroenterol Hepatol. 2016. 2729871. 2016

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 1 Study type: a retrospective study of all the colonoscopies performed in one of two hospitals in the city of St. John's, NL, between January 1, 2012, and June 30, 2012	Funding sources: not mentioned Conflict of Interests: none Randomization: none Blinding: one Dropout rates: one	Total no. patients: 3235 colonoscopies included Recruiting Phase: between January 1, 2012, and June 30, 2012 Inclusion criteria: all the colonoscopies performed in one of two hospitals in the city of St. John's, NL, between January 1, 2012, and June 30, 2012 both screening and surveillance patients Data were collected from both the physician and nursing procedure reports.	Interventions: colonoscopy Comparison: immediate and delayed adverse effects in relation to medication and procedure

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		Exclusion criteria:	
Notes:	<p>a retrospective study of all the colonoscopies performed in one of two hospitals in the city of St. John's, NL, between January 1, 2012, and June 30, 2012</p> <p>Author's conclusion: The most common adverse events were mild and sedation related. Rates of serious adverse events were in keeping with published reports.</p>		
Outcome Measures/results	<p>Primary adverse effects</p> <p>Secondary</p>	<p>Results: Medication-related includes use of reversal agents 0.1%, hypoxia 9.9%, hypotension 15.4%, and hypertension 0.9%. No patients required CPR or experienced allergic reactions or laryngospasm/bronchospasm. The indicator, "sedation dosages in patients older than 70," showed lower usage of fentanyl and midazolam in elderly patients.</p> <p>Procedure-related immediate includes perforation 0.2%, immediate postpolypectomy bleeding 0.3%, need for hospital admission or transfer to the emergency department 0.1%, and severe persistent abdominal pain proven not to be perforation 0.4%. Instrument impaction was not seen.</p> <p>Procedure-related delayed includes death within 14 days 0.1%, unplanned health care visit within 14 days of the colonoscopy 1.8%, unplanned hospitalization within 14 days of the colonoscopy 0.6%, bleeding within 14 days of colonoscopy 0.2%, infection 0.03%, and metabolic complication 0.03%.</p>	

Dumonceau, J. M. et al. Non-anesthesiologist administration of propofol for gastrointestinal endoscopy: European Society of Gastrointestinal Endoscopy, European Society of Gastroenterology and Endoscopy Nurses and Associates Guideline--Updated June 2015. Endoscopy. 47. 1175-89. 2015			
Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 1</p> <p>Study type: Guideline-could not be censored</p>	<p>Funding sources:</p> <p>Conflict of Interests:</p> <p>Randomization:</p> <p>Blinding:</p> <p>Dropout rates:</p>	<p>Total no. patients:</p> <p>Recruiting Phase:</p> <p>Inclusion criteria:</p> <p>Exclusion criteria:</p>	<p>Interventions:</p> <p>Comparison:</p>
Notes:	<p>Guideline - could not be censored</p> <p>Author's conclusion:</p>		
Outcome Measures/results	<p>Primary</p> <p>Secondary</p>	Results:	

Jin, E. H. et al. How to improve patient satisfaction during midazolam sedation for gastrointestinal endoscopy?. World J Gastroenterol. 23. 1098-1105. 2017			
Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 5</p> <p>Study type:</p>	<p>Funding sources:</p> <p>Conflict of Interests:</p> <p>Randomization:</p> <p>Blinding:</p>	<p>Total no. patients:</p> <p>Recruiting Phase:</p> <p>Inclusion criteria:</p> <p>Exclusion criteria:</p>	<p>Interventions:</p> <p>Comparison:</p>
<p>Lorenz P et al. Leitlinienreport der aktualisierten... Z Gastroenterol 2023; 61: e628-e633 © 2023. Thieme. All rights reserved.</p>			
			65

	Dropout rates:	
Notes:	eine prospektive Kohorte aber OHNE Komparator. Fragebogen offensichtlich am Ende der Aufwachphase beantwortet.	
	Author's conclusion:	
Outcome Measures/results	Primary Secondary	Results:

Lauriola, M. et al. Intolerance of Uncertainty and Anxiety-Related Dispositions Predict Pain During Upper Endoscopy. Front Psychol. 10. 1112. 2019			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 5	Funding sources:	Total no. patients:	Interventions:
Study type:	Conflict of Interests:	Recruiting Phase:	Comparison:
	Randomization:	Inclusion criteria:	
	Blinding:	Exclusion criteria:	
	Dropout rates:		
Notes:	Es handelt sich nicht um eine Kohortenstudie im eigentlichen Sinne mit Vergleiche zweier Kohorten über die Zeit. Verglichen wurde der psychologische Status/Stress vor einer ÖGD mit den selbstberichteten Symptomen/Schmerz nach der ÖGD. Hoher Stress-Level zuvorkorreliert mit negativer Wahrnehmung.		
	Author's conclusion:		
Outcome Measures/results	Primary Secondary	Results:	

Leslie, K. et al. Safety of sedation for gastrointestinal endoscopy in a group of university-affiliated hospitals: a prospective cohort study. Br J Anaesth. 118. 90-99. 2017			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3	Funding sources:	Total no. patients: 2132	Interventions:
Study type: prospektive Kohortenstudie, wobei eine eigentlichen Kontrollkohorte fehlt sondern eine Differenzierung innerhalb der Beobachtungsgruppe erfolgt	Project Grant from the Australian and New Zealand College of Anaesthetists (15/037).	Recruiting Phase: 20 Wochentage und 8 Nicht-Wochentage, konsekutv in eine Zeitfenster zwischen Februar und August 2015	Stratifizierung des Kollektiv anhand bekannter Risikofaktoren (Alter, Gewicht ASA, OSA etc.)
	Conflict of Interests: keine	Inclusion criteria: >17 LJ, elektive und Notfall-Patienten und Sedierung, definiert als Anästhesisten-begleitet, auch wenn kein Medikament gegeben wurde. Alle gastrointestinalen Endoskopie außer Endosonographie mit allen endoakopischen Interventionen	Comparison: nur diegenannte Stratifizierung
	Randomization: keine	Exclusion criteria: Endoskopie in Kombination mit einer Operation (wozu auch die PEG gezählt wurde). Endoskopien ohne Anästhesisten.	
	Blinding: keines		
	Dropout rates: kein Dropout		

<p>Notes:</p>	<p>Es handelt sich um eine detaillierte Analyse des Ist-Zustande der teilnehmenden Kliniken durch eine prospektive Erfassung bekannte Risikofaktoren einer anästhesiologischen Endoskopie-Begleitung. Die lokale Ergebnisse bestätigen die bekannten Risikofaktoren. Die Autoren sehen keine Aussagemöglichkeit zum Vergleich einer Sedierung durch Anästhesisten und Nicht-Anästhesisten.</p> <p>Author's conclusion: patients presenting for gastrointestinal endoscopy under anaesthetist-managed sedation at a group of public hospitals had a high risk profile and a substantial incidence of significant unplanned intraoperative events and 30-day mortality.</p>	
<p>Outcome Measures/results</p>	<p>Primary signifikante ungeplante Ereignisse:</p> <ol style="list-style-type: none"> 1. Significant airway obstruction: requiring unplanned use of airway management device(s) 2. Significant hypoxia: oxygen saturation <90% and not responsive to sustained jaw thrust and/or increased oxygen flow 3. Significant hypotension: systolic blood pressure <90mm Hg and requiring i.v. fluid bolus or vasopressor 4. Significant bradycardia: heart rate <55 beats min⁻¹ and requiring chronotropic agent 5. Abandoned procedure (endoscopy-related reasons such as poor bowel preparation excluded) 6. Unplanned tracheal intubation (for any indication) 7. Advanced life support (cardiopulmonary resuscitation in cardiac arrest and related conditions) 8. Duration of post-procedure admission >2 h for patients who went home on the day of the procedure (both elective and emergency) 9. Unplanned over 	<p>Results: In der multivariaten Analyse signifikant unterschiedliche OR für Alter, BMI, ASA-Status, Charlson-comorbiditi-Score, Art des Eingriff und geplante Intubation.</p>

night hospital admission for planned elective day patients
10. 30-day mortality, including date and cause of death

Secondary

Leslie, K. et al. Survey of anaesthetists' practice of sedation for gastrointestinal endoscopy. Anaesth Intensive Care. 44. 491-7. 2016

Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 4</p> <p>Study type: cohort study</p>	<p>Funding sources: None</p> <p>Conflict of Interests: None</p> <p>Randomization: None</p> <p>Blinding: None</p> <p>Dropout rates: drop out: 60% (1000 questionnaire, results: inclusion of 395 /40%)</p>	<p>Total no. patients: anesthetists: 1000</p> <p>Recruiting Phase: 3 months</p> <p>Inclusion criteria: Australian anesthetists (ANZCA)</p> <p>Exclusion criteria: demographic data only</p>	<p>Interventions: - monkey survey: 24 questions, mailing process</p> <p>Comparison: None</p>
<p>Notes:</p>	<ul style="list-style-type: none"> - homogenous data - data lacks in subgroups - limited response rate (41%) <p>Author's conclusion: These results give an indication of compliance by Australian anaesthetists with the relevant ANZCA guideline.</p>		
<p>Outcome Measures/results</p>	<p>Primary Standard regime for sedation in gastrointestinal endoscopy: EGD, colonoscopy, ERCP (elective/emergency): regarding to</p> <ul style="list-style-type: none"> - monitoring - airway management - drug combinations including MAC, TCI, Bolus - depth of sedation <p>Secondary</p>	<p>Results: Propofol is the drug of choice for endoscopy sedation administered by specialist anaesthetists in Australia, with a maximum depth of sedation in which patients were unresponsive to painful stimulation routinely targeted by the majority of respondents for all procedures except for elective gastroscopy.</p> <p>Oxygen administration and pulse oximetry are universally applied but blood pressure is not routinely measured by all respondents.</p>	

Liou, S. C. et al. Assessment of the Berlin Questionnaire for evaluation of hypoxemia risk in subjects undergoing deep sedation for screening gastrointestinal endoscopy. Ther Clin Risk Manag. 14. 1331-1336. 2018

Evidence level	Methodical Notes	Patient characteristics	Interventions
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Evidence level: 1 Study type: prospektive Kohortenstudie	Funding sources: k.A. Conflict of Interests: keine Randomization: keine Blinding: nein Dropout rates: kein Dropout	Total no. patients: 615 (notwendige Fallzahl wurde kalkuliert) Recruiting Phase: k.A. Inclusion criteria: mindestent 18 LJ, Vorstellung zur kombinierten ÖGD und Koloskopie Exclusion criteria: 1) 18 years and younger 2) allergy to propofol, eggs or soybeans, 3) pregnancy, 4) significant cardiopulmonary diseases such as congestive heart failure, arrhythmia, asthma attack or chronic obstructive pulmonary disease, 5) American Society for Anesthesiology (ASA) class III–V, and 6) refusal or inability to complete the questionnaire.	Interventions: Identifikation einer einer OSA-Risikogruppe mithilfe des BQ Comparison: Gruppe ohne erhöhtes OSA-Risiko im BQ
Notes:	Author's conclusion: Around one-third of Chinese subjects undergoing screening GI endoscopy were at high risk of OSA. Subjects at high risk of OSA undergoing deep sedation were associated with an increased risk of hypoxemia during endoscopic procedures when compared with the low-risk group.		
Outcome Measures/results	Primary Prävalenz von Personen mit erhöhtem OSA-Risiko auf Basis des BQ in eine Screeningpopulation und Evaluations des Hypoxämierisikos Secondary	Results: 35,5% der Studienpopulation hatten eine hohe Risiko für das Vorliegen eines OSA im BQ. 24,8% erlitten eine Entsättigung unter 90% in dieser Gruppe verglichen mit 7,3 % in der Gruppe mit geringerem Risiko im BQ (Relative Risk 3.38 (2.22–5.15))	

McCain, J. D. et al. Creation of a score to predict risk of high conscious sedation requirements in patients undergoing endoscopy. Gastrointest Endosc. 91. 595-605.e3. 2020			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 1 Study type:	Funding sources: Conflict of Interests: Randomization: Blinding: Dropout rates:	Total no. patients: Recruiting Phase: Inclusion criteria: Exclusion criteria:	Interventions: Comparison:
Notes:	keine Sedierung in dieser Studien. Untersucht wird der Einfluss der gegebenen Vorinformationen auf die Erfahrung der Untersuchungssituation von Patienten, die zu einer ersten ÖGD vorgestellt wurden Author's conclusion:		
Outcome Measures/results	Primary Secondary	Results:	

Perbtani, Y. B. et al. Impact of Endotracheal Intubation on Interventional Endoscopy Unit Efficiency Metrics at a Tertiary Academic Medical Center. Am J Gastroenterol. 111. 800-7. 2016			
Evidence level	Methodical Notes	Patient characteristics	Interventions
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Evidence level: 3 Study type: Datenbankanalyse, retrospektiv.	Funding sources: keine Conflict of Interests: keine Randomization: nein Blinding: n. d. Dropout rates: n. d.	Total no. patients: 1421 Recruiting Phase: 2013 Inclusion criteria: n. d. Exclusion criteria: n. d.	Interventions: verschiedene endoskopische Interventionen (ÖGD, ERCP, EUS etc.) Comparison: Intubierte versus nicht-intubierte, sedierte Patienten
Notes:	Prozessdatenanalyse aus einer eigenen Datenbank. Keine Interventionen. Author's conclusion: Intubation beeinflusst Prozessparameter negativ. Indikation zur Intubation sollte mit Bedacht gestellt werden.		
Outcome Measures/results	Primary Prozesszeiten von intubierten versus nicht-intubierte, sedierte Patienten in der Endoskopie Secondary Patientenvariablen anhand von Alter, Geschlecht, ASA, Mallampati, Art der Prozedur, Anästhesist anwesend, CCIS	Results: Kein Gruppenunterschied. Patienten mit ERCP werden häufiger intubiert. Ambulante Patienten werden seltener intubiert als stationäre. Alle Prozessparameter waren bei intubierten Patienten verlängert.	

Pérez-Cuadrado Robles, E. et al. Safety and risk factors for difficult endoscopist-directed ERCP sedation in daily practice: a hospital-based case-control study. Rev Esp Enferm Dig. 108. 240-5. 2016

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 4 Study type: Datenbankanalyse, retrospektiv.	Funding sources: n. d. Conflict of Interests: n. d. Randomization: nein Blinding: nein Dropout rates: n. d.	Total no. patients: 189 Recruiting Phase: 2014 - 2015 Inclusion criteria: Schwierige Sedierung definiert als hohe Dosierungen von Sedativa, Antagonisierung sowie AEs. Exclusion criteria: n. d.	Interventions: n. d. Comparison: Dosierungen von Sedativa, Antagonisierung sowie AEs vs. Kontrollen
Notes:	Literaturstelle lag nur als Abstrakt vor, download nicht möglich. Author's conclusion: Endoskopist-durchgeführte Sedierung ist sicher (unklar woher diese Schlussfolgerung).		
Outcome Measures/results	Primary Dosierungen von Sedativa, Antagonisierung sowie AEs Secondary n. d.	Results: AEs in 1,4% d. F. AE Rate höher bei Propofol + Midazolam als Propofol allein. Risikofaktoren sind: C2-Abusus, Opioid-Abusus, psychiatrische Medikation.	

Predmore, Z. et al. Anesthesia Service Use During Outpatient Gastroenterology Procedures Continued to Increase From 2010 to 2013 and Potentially Discretionary Spending Remained High. Am J Gastroenterol. 112. 297-302. 2017

Evidence level	Methodical Notes	Patient characteristics	Interventions
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Evidence level: 1	Funding sources:	Total no. patients:	Interventions:
Study type:	Conflict of Interests:	Recruiting Phase:	Comparison:
	Randomization:	Inclusion criteria:	
	Blinding:	Exclusion criteria:	
	Dropout rates:		
Notes:	The study shows that anesthesia service in GI procedures increased from 2010 to 2013 in the United states. To my mind there is no relevance for the guideline. Author's conclusion:		
Outcome Measures/results	Primary	Results:	
	Secondary		

Protopapas, A. A. et al. Endoscopic sedation practices of Greek gastroenterologists: a nationwide survey. Ann Gastroenterol. 33. 366-373. 2020

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: Kohortenstudie	Funding sources: n. d. Conflict of Interests: keine Randomization: nein Blinding: n. d. Dropout rates: s o.	Total no. patients: 195 bzw. 258 Gastroenterologen beantworteten den Fragebogen. Recruiting Phase: 2015 und 2018 Inclusion criteria: Alle griechischen Gastroenterologen der hellenischen Fachgesellschaft wurden angeschrieben. Exclusion criteria: n. d.	Interventions: keine Comparison: Sedierungspraxis im Verlauf (2015 und 2018)
Notes:	Fragebogenumfrage bei griechischen Gastroenterologen zur Sedierung bei ERCP und EUS, Fragebogen nicht validiert. Author's conclusion: Trainingsprogramme sollten implementiert werden zur Nutzung von Propofol unter Gewährleistung einer adäquaten Patientensicherheit.		
Outcome Measures/results	Primary n. d. Secondary n. d.	Results: Antwortraten 38,3% bzw. 47,1%. 25,1% bzw. 16,7% nutzten keine Sedierung. In der Regel gibt es keine Zusammenarbeit mit einem Anästhesisten bei der Sedierung. Sedativum der Wahl ist Midazolam (90%), Propofol 30,8% bzw. 27%. Zufriedenheit mit Propofol ist höher, der geringere Nutzen hat medikolegale GRünde sowie inadäquates Training.	

Quinn, L. et al. Sedation for gastroscopy: Is it an adequately understood and informed choice?. Ir J Med Sci. 185. 785-789. 2016

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 4 Study type: Umfrage	Funding sources: n. d. Conflict of Interests: keine Randomization: nein	Total no. patients: 111 von 113 Recruiting Phase: 8 Wochen, Jahr n. d.	Interventions: Sedierung für ÖGD; keine Studienbezogene Intervention Comparison: vorher/nachher Vergleich
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	Blinding: nein Dropout rates: 111 von 113	Inclusion criteria: n. d. Exclusion criteria: n. d.	intraindividuell
Notes:	Fragebogen; konsekutive Patienten, keine Vergleichsgruppe, keine Ein- und Ausschlußkriterien Author's conclusion: Die Entscheidung für oder gegen eine Sedierung basiert offensichtlich nicht auf dem Informationsstand des Patienten. Es bedarf daher besserer Informationen und Aufklärung der Patienten.		
Outcome Measures/results	Primary Qualität der Information über die Sedierung anhand 7 Statements gemäß der BSG. Secondary Patientenzufriedenheit und -verständnis über die Prozedur	Results: Frauen, jüngere und ältere Patienten wünschen sich eher eine Sedierung. Patientenzufriedenheit bei Patienten mit Sedierung höher als bei Patienten mit LA. Es bestehen profunde Unterschiede zum Informationsgehalt über die geplante Prozedur zwischen den Gruppen mit Sedierung und LA.	

Ra, Y. S. et al. Survey of Anxiety in Ordinary Workers and Doctors Regarding Sedative Use during Endoscopic Examination in the Seoul Metropolitan Area. Gut Liver. 10. 786-95. 2016			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: Fragebogen	Funding sources: n d. Conflict of Interests: keine Randomization: nein Blinding: nein Dropout rates: 9 bzw. 6 Teilnehmer	Total no. patients: 1747 Patienten/Arbeiter; 655 Ärzte Recruiting Phase: 2015 Inclusion criteria: n. d. Exclusion criteria: n. d.	Interventions: keine; Umfrage mittels Fragebogen Comparison: Patienten/Arbeiter vs. Ärzte in Bezug auf Angst vor Sedierung
Notes:	Auswahlkriterien für befragte Patienten/Arbeiter bzw. Ärzte unklar. Author's conclusion: Wiederholung der Ergebnisse. Die Ergebnisse sollten zugrundegelegt werden um ein besseres Management der Sedierung zu etablieren.		
Outcome Measures/results	Primary Sedierungsscores Secondary AEs	Results: Patienten/Arbeiten haben größere Angst vor einer Sedierung als Ärzte. Alter < 40 Jahre, weibliches Geschlecht, vorherige AEs, unzureichende Aufklärung begünstigen Angst. Bei Ärzten die AEs erlebt haben ist die Angst vor einer Sedierung größer als bei denjenigen die keine entsprechende Erfahrung haben.	

Sargin, M. et al. Anxiety Levels in Patients Undergoing Sedation for Elective Upper Gastrointestinal Endoscopy and Colonoscopy. Med Arch. 70. 112-5. 2016			
Evidence level	Methodical Notes	Patient characteristics	Interventions

Evidence level: 3	Funding sources: unklar	Total no. patients: 500	Interventions: Messung der Sedierungsqualität anhand des Beck Anxiety Inventory
Study type: Prospektiv	Conflict of Interests: keine	Recruiting Phase: n. d.	Comparison:
	Randomization: nein	Inclusion criteria: Sedierung für ÖDG und Colonoskopie; Alter 18-80 Jahre, ASA I-III	
	Blinding: nein	Exclusion criteria: Demenz, psychiatrische Erkrankung, körperliche Unmöglichkeit zur Teilnahme, Taubheit	
Notes:	Author's conclusion: Genaugenommen keine, weitere Studien angeraten.		
Outcome Measures/results	Primary Angstlevel Secondary Angstlevel im Vergleich zu individuellen und sozialen Faktoren	Results: Das Niveau des Angstlevels ist abhängig von Geschlecht und Comorbiditäten, jedoch nicht vom Alter oder dem Bildungsstatus	

Shingina, A. et al. Identification of factors associated with sedation tolerance in 5000 patients undergoing outpatient colonoscopy: Canadian tertiary center experience. World J Gastrointest Endosc. 8. 770-776. 2016			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: Retrospektiv, Auswertung der Krankenunterlagen, Einzelzentrum.	Funding sources: keine Angaben Conflict of Interests: kein Randomization: nein Blinding: nein Dropout rates: 5064 von 5282	Total no. patients: 5064 von 5282 Recruiting Phase: 2009 - 2010 Inclusion criteria: Alle Patienten, die sich einer ambulante Anästhesie unterzogen. Exclusion criteria: Patienten mit ÖDG am gleichen Tag.	Interventions: Colonoskopie in Sedierung Comparison: kein Vergleichskollektiv
Notes:	Es handelt sich um eine retrospektive Analyse von 5064 ambulanten Patienten, die sich in einem einzelnen Zentrum einer Colonoskopie unterzogen. Author's conclusion: Das vorgelegte Modell weist einen hohen prädiktiven Wert auf. Die Validität der Ergebnisse müssen extern überprüft werden.		
Outcome Measures/results	Primary Sedierungsbedarf Secondary	Results: Jüngeres Alter, Indikation zur Colonoskopie, intraprozedurale Faktoren (Schwierigkeiten, Interventionen, unzureichende Vorbereitung, vorherige Abdominalchirurgie) führten zu einem erhöhten Bedarf von Fentanyl. Jüngeres Alter, weibliches Geschlecht, Blutung, Abdominalbeschwerden, schwierige Prozedur, vorherige Abdominalchirurgie, Opioidabusus führten zu einem erhöhten Bedarf an Midazolam. Hieraus wurde ein Prädiktionsmodell erstellt. Erhöhter Bedarf an Sedierung bei jüngerem Alter, weiblichen Geschlecht, schwieriger Endoskopie, spezifische Indikationen, kardiopulmonale Komplikationen sowie Abusus von Opioiden/Midazolam.	

Theivanayagam, S. et al. ASA Classification Pre-Endoscopic Procedures: A Retrospective Analysis on the Accuracy of Gastroenterologists. South Med J. 110. 79-82. 2017
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Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 4 Study type: Retrospektive Datenanalyse	Funding sources: n. d. Conflict of Interests: n. d. Randomization: nein Blinding: n. d. Dropout rates: n. d.	Total no. patients: n. d. Recruiting Phase: 2012 - 2013 Inclusion criteria: ÖGD Exclusion criteria: n. d.	Interventions: Evaluation der ASA-Scores Comparison: keine
Notes:	Für diese Studie liegt nur das Abstrakt vor, das Orinalpaper konnte nicht aufgefunden werden. Author's conclusion: Die ASA-Klassifikation ist gemäß diesen Studienergebnissen nur von unzureichendem Wert für die Risikoeinschätzung.		
Outcome Measures/results	Primary Korrektheit der prä-diagnostischen ASA-Klassifikation durch verschiedene Untersucher Secondary n. d.	Results: Die Eischätzung des Patientenrisikos anhand der ASA-Klassifikation ist moderat vergleichbar zwischen Gastroenterologen und Anästhesisten, unzureichend zwischen unterschiedlichen Gastroenterologen und in moderater Übereinstimmung mit sich selber (?).	

Thornley, P. et al. Efficiency and patient experience with propofol vs conventional sedation: A prospective study. World J Gastrointest Endosc. 8. 232-8. 2016			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 4 Study type: Prospektive, nicht-randomisierte Vergleichsstudie	Funding sources: intern Conflict of Interests: nein Randomization: nein Blinding: nein Dropout rates: unklar	Total no. patients: 230 Recruiting Phase: 12 Wochen Inclusion criteria: Colonoskopie in Sedierung, > 18 Jahre. Exclusion criteria: Patient nicht in der Lage zu Lesen und nicht der englischen Sprache mächtig. Neurologische und psychiatrische Erkrankungen	Interventions: Colonoskopie in Sedierung. Comparison: Propofol versus Midazolam/Fentanyl.
Notes:	Keine Randomisierung Author's conclusion: Propofolsedierung führt zu verkürzten Prozedurenzeiten, Assistenzärztliche Sedierung verdoppelt diese unabhängig vom Sedierungskonzept.		
Outcome Measures/results	Primary Prozedurenzeiten, gesamte Prozesszeiten. Secondary Prozedurenzeiten mit und ohne Assistenzarzt, Patientensicherheit, Prozeduren-assoziierte Komplikationsraten.	Results: Kürzere Prozedurenzeiten unter Propofol. Bei Durchführung der Sedierung durch Spezialisten kein Gruppenunterschied. 2 AE. Prädiktoren verlängerter Prozedurenzeiten: erhöhter BMI, erhöhte ASA-Klasse, therapeutische Intervention.	

Tsou, M. Y. et al. Patient response prediction with logistic regression in gastrointestinal endoscopy under midazolam-alfentanil sedation performed as well as response surface model. J Chin Med Assoc. 81. 1071-1076. 2018			
Evidence level	Methodical Notes	Patient characteristics	Interventions

Evidence level: 3 Study type: Pharmakologische MOdellentwicklung	Funding sources: Taiwan Ministry of Science and Technology Conflict of Interests: nein Randomization: nein Blinding: nein Dropout rates: nein	Total no. patients: 33 Recruiting Phase: unklar Inclusion criteria: Patienten mit EGD und Colonoskopie, < 65 Jahre, ASA I-III Exclusion criteria: nicht definiert	Interventions: EGD und Colonoskopie unter Sedierung mit Midazolam und Alfentanil Comparison: Logisches Regressionsmodell versus nicht-lineares Response Surface Model
Notes:	Pharmakologische Modellentwicklung Author's conclusion: Beide untersuchten Modelle ermöglichen den sedativen Effekt von Midazolam und Alfentanil während einer Endoskopie in gleicher Weise vorherzusagen.		
Outcome Measures/results	Primary entfällt Secondary entfällt	Results: Beide untersuchten Modelle unterscheiden sich nicht hinsichtlich ihres prädiktiven Wertes.	

Turse, E. P. et al. Impact of moderate versus deep sedation on adenoma detection rate in index average-risk screening colonoscopies. Gastrointest Endosc. 90. 502-505. 2019			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: Retrospektive monozentrische Studie	Funding sources: nein Conflict of Interests: nein Randomization: nein Blinding: unklar Dropout rates: n. d.	Total no. patients: 585 Recruiting Phase: 6 Monate in 2015 (moderate Sedierung) und 6 Monate in 2016 (tiefe Sedierung) Inclusion criteria: Patienten mit Colonoskopie > 50 Jahre Exclusion criteria: Hochrisikopatienten, Darmblutungen, Konstipation, Abdominalschmerzen, Diarrhoe,	Interventions: tiefe bzw. moderate Sedierung Comparison: tiefe versus moderate Sedierung
Notes:	Author's conclusion: Tiefe Sedierung hat keine Vorteil auf die Detektionsraten von Adenomen und Polypen		
Outcome Measures/results	Primary Qualitätsindikatoren (n. d.) Secondary Effekt unterschiedlicher Sedierungstiefen auf die Detektionsraten von Adenome und Polypen	Results: Kein signifikanter Einfluss der Sedierungstiefe auf die Detektionsraten von Adenomen und Polypen	

Vaessen, H. H. et al. Considerable Variability of Procedural Sedation and Analgesia Practices for Gastrointestinal Endoscopic Procedures in Europe. Clin Endosc. 49. 47-55. 2016			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 1 Study type: Umfrage	Funding sources: unklar Conflict of Interests: keine	Total no. patients: 68 Umfragebögen wurden versendet Recruiting Phase: 2012	Interventions: Comparison:

	Randomization: nein Blinding: nein Dropout rates: unklar	Inclusion criteria: Internationale Leitlinien Exclusion criteria:	
Notes:	Author's conclusion: Moderate und tiefe Sedierung wird zunehmend häufiger durchgeführt. Sicherheitsaspekte erlangen zunehmende Bedeutung.		
Outcome Measures/results	Primary Secondary	Results: Große Variationen innerhalb und zwischen Europäischen Ländern in Bezug auf Sicherheit, Anwender, Verantwortlichkeiten,, Aufklärung, Patientenzufriedenheit, Ausbildung.	

van de Ven, S. et al. Propofol sedation without endotracheal intubation is safe for endoscopic submucosal dissection in the esophagus and stomach. United European Gastroenterol J. 7. 405-411. 2019			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: retrospektive Kohortenstudie	Funding sources: nein Conflict of Interests: nein Randomization: nein Blinding: nein Dropout rates: 9 Patienten	Total no. patients: 88 Recruiting Phase: 2013 - 2018 Inclusion criteria: ESD for esophageal and stomach cancer Exclusion criteria: Allgemeinanästhesie und operativer Eingriff	Interventions: ESD unter Analgosedierung Comparison:
Notes:	Author's conclusion: Propofol-basierte Sedierung ist sicher bei ESD Prozeduren		
Outcome Measures/results	Primary Rate intraproceduraler Komplikationen Secondary Rate postproceduraler Komplikationen innerhalb 30 TAgen, Rate an Intubationen	Results: Drei intraprocedurale Komplikationen 15 postproceduraler Komplikationen	

Yurtlu, D. A. et al. Propofol-Based Sedation Versus General Anesthesia for Endoscopic Submucosal Dissection. Medicine (Baltimore). 95. e3680. 2016			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: Retrospective analysis	Funding sources: Not reported. Conflict of Interests: Not reported. Randomization: None. Blinding: None. Dropout rates: Patients were excluded from the analysis.	Total no. patients: 91 Recruiting Phase: Between 2013 and 2015 Inclusion criteria: ASA 1 to 3 patients receiving gastric ESD Exclusion criteria: Not reported.	Interventions: General anesthesia or propofol-based sedation methods at gastric endoscopic submucosal dissection (ESD) procedures. Comparison: General anesthesia versus propofol-based sedation

Notes:	Author's conclusion: general anesthesia administration may prevent an increase in procedure time due to frequent breaks caused by gag reflex, cough, mobilization, and oropharyngeal suctioning needs of the patient, and thus reduce the dissection time. Finally, ensuring the reliability of the airway with endotracheal intubation increases the comfort of the endoscopist, in addition to preventing respiratory problems for the anesthesiologist, creating a safe reliable alternative to sedation methods for gastric ESD procedures.	
Outcome Measures/results	Primary Procedure time, lesion size, dissection speed, anesthesia time, adverse effects such as gag reflex, nausea, vomiting, cough, number of desaturation episodes (SpO2) Secondary Primary and secondary endpoints not clearly stated.	Results: The calculated dissection speed was significantly high in group general anesthesia (G) ($36.02 \pm 20.96 \text{ mm}^2/\text{min}$) compared with the propofol sedation group (S) ($26.04 \pm 17.56 \text{ mm}^2/\text{min}$; $P=0.010$). The incidence of nausea, cough, number of oropharyngeal suctioning, and desaturation episodes were significantly high in group S compared with that in group G (P

Zakeri, N. et al. Risk factors for endoscopic sedation reversal events: a five-year retrospective study. Frontline Gastroenterol. 6. 270-277. 2015			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: retrospektiv	Funding sources: nein Conflict of Interests: keine Randomization: nein Blinding: nein Dropout rates: fehlt	Total no. patients: > 52000 Recruiting Phase: 2007 - 2012 Inclusion criteria: alle Patienten dreier Institutionen Exclusion criteria: fehlen	Interventions: keine Comparison: Patienten ohne Antagonisierung mit Flumazenil oder Naloxon
Notes:	Author's conclusion: In Hochrisikogruppen sollten alternative Sedierungsstrategien verwendet werden. Es braucht weitere Studien.		
Outcome Measures/results	Primary Wiederaufnahme in Klinik. Secondary Mortalität, ASA-Status, Sedierungsmedikation	Results: 0,28% Wiederaufnahmen. ERCP und ASA-Klasse positiv korreliert mit Wiederaufnahme. 10/52000 verstarben innerhalb 30 Tagen.	

Literatursammlung:**AG 2 - Literatur 2013 - 2014***Inhalt: 38 Literaturstellen*

Literaturstelle	Evidenzlevel	Studientyp
Amornyotin, S. 2011	1	Not assessed; see Check list
Amornyotin, Somchai 2013	2	RCT prospective
Arakawa, H. 2013		
Aydogan, H. 2013	2	RCT
Borrat, X. 2013	3	RCT
Cheung, C. W. 2015	1	RCT
Chiang, M. H. 2013	2	RCT
Eberl, S. 2013	5	Presentation of the description of a RT study No results and conclusions
Fanti, L. 2013	2	RCT
Fanti, Lorella 2014	2	RCT
Han, G. 2014	4	randomized trial
Hsieh, Y. H. 2013	4	RCT, randomized, blinded
Hsu, W. H. 2013	3	RCT
Kilgert, B. 2014	4	Prospective, double-blind controlled trial data collection
Lan, C. 2013	3	Prospective RT
Lee, B. S. 2014	1	RCT, double blinded
Lera dos Santos, M. E. 2013	2	RCT single-blind
Li, X. T. 2019	2	Prospective RCT double blind
Mao, Wei 2014	2	Cohort study
Mazanikov, M. 2013	3	randomized trial
Motamed, F. 2012	1	RCT
Nguyen, N. Q. 2013	2	RCT
Nguyen, Nam Q. 2016		
Nishizawa, T. 2014	2	Systematic review
Saif Khan, Mohd 2014	1	Not assessed , see Check list
Sameh, A. Ahmed 2020	5	RCT

Sethi, S. 2014	2	Systematic review
Suh, S. J. 2014		
Tandon, Manish 2014	2	RCT prospective double blind
Terui, T. 2013	3	Prospective RT
Treepasertsuk, S. 2014	4	RCT
Türk, H? 2013	3	randomized prospective study
Wang X, Li Y, Zhao Y, Li H, Yang Z, Xu X, Lian Q, Zeng R 2018	2	single-center, prospective, randomized, double-blinded study
Wang, D. 2013	1	metanalysis of RCT
Worthington, M. T. 2013	2	RCT, two parts open-label initial dose escalation study and flumazenil reversal part
Wu, W. 2014	3	Retrospective randomized study
Xiao, Qian-Song 2018	4	Prospective RT single center
Zeng R, Li Y, Wu Q, Qi L, Li H, Wang X, Lian Q, Yang J 2019	3	randomized, controlled study

OXFORD (2011) Appraisal Sheet: Systematic Reviews: 3 Bewertung(en)

Nishizawa, T. et al. Propofol versus traditional sedative agents for endoscopic submucosal dissection. Dig Endosc. 26. 701-6. 2014			
Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 2</p> <p>Study type: Systematic review</p> <p>Databases: PubMed, the Cochrane library, and the Igaku-ChuoZasshi</p> <p>Search period: 1950 to April 2014</p> <p>Inclusion Criteria: Articles were considered eligible if the studies met the following inclusion criteria: (i) study type: RCT; (ii) population: patients who underwent ESD; (iii) intervention: an active treatment with propofol; (iv) comparator: traditional sedative agents; (v) outcome: safety and efficacy of the sedation</p> <p>Exclusion Criteria: Duplicate publications and reviews were excluded.</p>	<p>Population: NA</p> <p>Intervention: Methodical analysis</p> <p>Comparison: Propofol vs other sedatives</p>	<p>Primary: Correct sedation was defined as the absence of body movements (restlessness) forcing discontinuation of the treatment. Restlessness was used as evaluation target of efficacy. Full awakening at 1 h post-ESD, hypoxia, and hypotension were used as evaluation target of safety</p> <p>Secondary:</p> <p>Results: We identified three randomized trials (298 patients) from the database search. Compared with traditional sedative agents, the pooled OR of restlessness and full awakening at 1 h post-ESD with propofol sedation were 0.41 (95% confidence interval [CI]: 0.21–0.81) and 8.59 (95% CI: 4.29–17.2), respectively, without significant heterogeneity. Compared with traditional sedative agents, the pooled OR of hypoxia and hypotension with propofol sedation were 1.13 (95%</p>	

	<p>CI: 0.58–2.21) and 0.92 (95% CI: 0.25–3.41), respectively, indicating no significant differences between the groups</p> <p>Author's Conclusion: Propofol sedation during ESD is more effective as compared with traditional sedative agent. The risk of complications is similar</p>
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Methodical Notes

Funding Sources: not noted

COI: DURING THE LAST 2 years, author H.S. received scholarship funds for research from Astellas Pharm Inc., Astra-Zeneca K.K., Otsuka Pharmaceutical Co., Ltd, Takeda Pharmaceutical Co., Ltd, and Zeria Pharmaceutical Co., Ltd and received service honoraria from Astellas Pharm Inc., Astra-Zeneca K.K., Eisai Co., Otsuka Pharmaceutical Co., Ltd, Takeda Pharmaceutical Co., Ltd, and Zeria Pharmaceutical Co., Ltd. Author T.K. received scholarship funds

for research from Astellas Pharm Inc., Astra-Zeneca K.K., Otsuka Pharmaceutical Co., Ltd, Takeda Pharmaceutical Top Corporation, Kaigen Pharm Co., Ltd, ASKA Pharmaceutical Co., Ltd, FUJIFILM Corporation, Boston Scientific Japan K.K., Century Medical Inc., and Covidien Japan Inc. The funding source had no role in the design, practice or analysis of this study. There are no other conflicts of interest for this article.

Co., Ltd, Eisai Pharmaceutical Co., Ltd, Zeria Pharmaceutical Co., Ltd, Tanabe Mitsubishi Pharmaceutical Co., Ltd, JIMRO Co., Ltd, Kyorin Pharmaceutical Co. Ltd, and received service honoraria from Astellas Pharm Inc., Eisai Pharmaceutical Co., Ltd, JIMRO Co., Ltd, Tanabe Mitsubishi Pharmaceutical Co. Ltd, Otsuka Pharmaceutical Co., Ltd, Takeda Pharmaceutical Co., Ltd, Miyarisan Pharmaceutical Co. Ltd, and Zeria Pharmaceutical Co., Ltd. Author N.Y. received scholarship funds for research from AstraZeneca K.K., Takeda Pharmaceutical Co., Ltd, Eisai Co.,

Study Quality: high

Heterogeneity: $\chi^2 = 0.44$, $df = 2$, $I^2 = 0.80$, $2 P I = 0\%$

Publication Bias: none reported

Notes:

Sethi, S. et al. Propofol versus traditional sedative agents for advanced endoscopic procedures: a meta-analysis. *Dig Endosc.* 26. 515-24. 2014

Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 2</p> <p>Study type: Systematic review</p> <p>Databases: PubMed, Embase, Web of Science and the Cochrane Central Register of Controlled Trials updated as of January 2013</p> <p>Search period: 1966 through 15 June, 2013</p> <p>Inclusion Criteria: Inclusion and</p>	<p>Population: adult patients aged >18 years who underwent advanced endoscopic procedures</p> <p>Intervention: adult patients aged >18 years who underwent advanced endoscopic procedures</p>	<p>Primary: Outcome measures were procedure duration, recovery time, sedation level, patient cooperation during procedure, incidence of hypotension and hypoxia during procedure and amnesia of the procedure</p> <p>Secondary:</p> <p>Results: Results: Nine prospective randomized trials with</p>	

exclusion criteria
 Only randomized controlled trials (RCT) in adult patients aged >18 years who underwent advanced endoscopic procedures, published as full articles or meeting abstracts in peerreviewed journals, were considered. Selection criteria were:
 (i) studies that examined the efficacy and safety of propofol sedation and traditional sedative agents in advanced endoscopic procedures (i.e ERCP, EUS, deep small bowel enteroscopy); (ii) studies that were prospective and randomized;
 (iii) studies in humans; and (iv) data not duplicated in another manuscript. Inclusion was not otherwise restricted by study size or language. To understand the risk of bias in individual studies, a formal quality assessment of studies was carried out. The methodological quality of the RCT was assessed by two authors independently (SS and MSS) using the scale validated by Jadad et al. 29 and scored from 0 to 5: randomization (0–2 points), blinding (0–2 points), and full accounting of all patients (0–1 point); a higher score indicating better quality

Comparison:

a total of 969 patients (485 propofol, 484 conscious sedation) were included in the meta-analysis. Pooled mean difference in procedure duration between propofol and traditional sedative agents was -2.3 min [95% CI: -6.36 to 1.76, P = 0.27], showing no significant difference in procedure duration between the two groups. Pooled mean difference in recovery time was -30.26 min [95% CI: -46.72 to -13.80, P < 0.01], showing significantly decreased recovery time with propofol. There was also no significant difference between the two groups with regard to hypoxia and hypotension.

Author's Conclusion: Propofol for advanced endoscopic procedures is associated with shorter recovery time, better sedation and amnesia level without an increased risk of cardiopulmonary complications. Overall patient cooperation was also improved with propofol sedation.

Exclusion Criteria:

Methodical Notes

Funding Sources:

COI:

Study Quality:

Heterogeneity:

Publication Bias:

Notes:

Wang, D. et al. Propofol combined with traditional sedative agents versus propofol- alone sedation for gastrointestinal endoscopy: a meta-analysis. Scand J Gastroenterol. 48. 101-10. 2013

Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
Evidence level: 1 Study type: metanalysis of RCT Databases: PubMed, Ovid, MEDLINE and EMBASE, Cochrane Central Register of Controlled Trials	Intervention: metanalysis Comparison: cardiopulmonary complications	Primary: cardiopulmonary complications (hypoxia, hypotension, arrhythmia, and apnea), total dose of propofol used, and amnesia.	

<p>Search period: 1966 to June 2012</p> <p>Inclusion Criteria: search terms endoscopic ultrasonography (EUS), Endoscopic retrograde cholangiopancreatography (ERCP), esophagogastroduodenoscopy (EGD), double-balloon endoscopy (DBE), upper gastrointestinal endoscopy, colonoscopy, sigmoidoscopy, propofol, diprivan, and sedation were used. References, lists of retrieved articles, reviews and meta-analyses were then scanned for additional articles.</p> <p>Exclusion Criteria: no use of propofol as the sedative agent</p>	<p>(hypoxia, hypotension, arrhythmia, and apnea), total dose of propofol used, and amnesia.</p>	<p>Secondary:</p> <p>Results:</p> <p>Author's Conclusion: PTSA sedation during gastrointestinal endoscopy could significantly reduce the total dose of propofol, but without benefits of lower risk of cardiopulmonary complications compared with propofol-alone sedation.</p>
<p>Methodical Notes</p>		
<p>Funding Sources: grants from the National Natural Science Foundation of China (No. 81201885 & No. 81172279).</p> <p>COI: none</p> <p>Study Quality: all RCT</p> <p>Heterogeneity:</p> <p>Publication Bias: Funnel plotting and Egger's testing was performed to assess the publication bias of the studies used. In overall studies, no significant publication bias ($p < 0.05$) was found (data not shown).</p> <p>Notes: metaanalysis of RCT comparing propofol alone sedation to other regimens special focus on complications, reduction of dose of propofol</p>		

OXFORD (2011) Appraisal Sheet: RCT: 29 Bewertung(en)

<p>Amornyotin, S. et al. Clinical efficacy of the combination of propofol and ketamine versus propofol alone for deep sedation for colonoscopy: 2AP1-4. European Journal of Anaesthesiology EJA. 28. . 2011</p>		
<p>Population</p>	<p>Intervention - Comparison</p>	<p>Outcomes/Results</p>
<p>Evidence level: 1</p> <p>Study type: Not assessed; see Check list</p> <p>Number of Patient:</p> <p>Recruitment Phase:</p> <p>Inclusion Criteria:</p> <p>Exclusion Criteria:</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary:</p> <p>Secondary:</p> <p>Results:</p> <p>Author's Conclusion:</p>
<p>Methodical Notes</p>		
<p>Funding Sources:</p> <p>COI:</p> <p>Randomization:</p>		

Blinding:

Dropout Rate/ITT-Analysis:

Notes:

Amornyotin, Somchai. Deep sedation with propofol and pethidine versus moderate sedation with midazolam and fentanyl in colonoscopic procedure. Journal of Gastroenterology and Hepatology Research. 2. 885-890. 2013

Population	Intervention Comparison	Outcomes/Results
Evidence level: 2 Study type: RCT prospective Number of Patient: 1032 pts eligible and randomized 514 (M/F) - 518 (P/P) Recruitment Phase: 2/2006-1/2008 Inclusion Criteria: >18 yrs ASA I-III Exclusion Criteria: Severe cardio-pulmonary instability hepatic encephalopathy ASA IV refusal	Intervention: Colonoscopy diagnostic and therapeutic Sedation M/F vs P/P Comparison: see above	Primary: Successfully performed Colonoscopy Secondary: Patient's tolerance, patient and endoscopists satisfaction, discomfort, pain, complications during and after Results: All endoscopies successfully performed except 33 in M/F group and 11 in P/P group, $p > 0.019$ Patient's tolerance $p > 0.001$, Patient and Endoscopist satisfaction $p > 0.001$ higher in P/P group, also recovery time, and procedural pain score were better for P/P $p > 0.001$ Higher complication rate in P/P $p > 0.001$ but no serious complications in both groups Author's Conclusion: Efficacy of P/P for deep sedation showed distinct advantage over M/F moderate sedation in colonoscopy

Methodical Notes

Funding Sources: Not stated

COI: Not stated

Randomization: Yes

Blinding: Yes

Dropout Rate/ITT-Analysis: None

Notes:

Aydogan, H. et al. PROPOFOL-KETAMINE COMBINATION HAS SHORTER RECOVERY TIMES WITH SIMILAR HEMODYNAMICS COMPARED TO PROPOFOL ALONE IN UPPER GASTROINTESTINAL ENDO- SCOPY IN ADULTS. A RANDOMIZED TRIAL 2013

Population	Intervention Comparison	Outcomes/Results
Evidence level: 2 Study type: RCT Number of Patient: 100 Recruitment Phase:	Intervention: P group received iv %1 propofol until Ramsay Sedation Scale (RSS) increased to 3- 4. Comparison: PK group received iv propofol-ketamine 3:1 mix- ture (%1	Primary: The heart rate, mean arterial blood pressure and peripheral O2 saturation were recorded. Total drug dosage, endoscopy time, spontaneous eye opening and response to verbal command time. Secondary: Patient and doctor satisfaction scores. Results: Demographic data, hemodynamic data and

<p>n.a.</p> <p>Inclusion Criteria: Patients who underwent upper GIE intervention.</p> <p>Exclusion Criteria: (1) presence of liver and/or kidney failure, neuropsychiatric disorders, morbid obesity, (2) history of substance abuse or dependence, (3) history of serious adverse effects related to anesthetics (e.g. allergic reactions), a family history of reactions to the study drugs (4), and pregnancy.</p>	<p>15 ml propofol + 1 ml 50mg/ml keta- mine+ 4 ml SF in a 20-ml syringe which resulted in 0.25 mg.ml-1 ketamine and 0.75 mg.ml-1 propofol) until Ramsay Sedation Scale (RSS) increased to 3- 4.</p>	<p>endoscopy time were found similar in the two groups (p>0.05 for all comparisons). Spontaneous eye opening and response to verbal commands time were shorter in PK group (p=0.03, p=0.01 respectively). Heart rate, mean arterial pressure, peripheral oxygen saturation were similar between groups in all time intervals (p>0.05 for all comparisons). Side effects including respiratory depression, bradycardia, hypotension, nausea, vomiting and secretion increase were found to be similar in both groups (p>0.05 for all comparisons). Patients' and endoscopists' satisfaction scores were also similar in both groups (p>0.05 for all comparisons).</p> <p>Author's Conclusion: Propofol ketamine combination is associated with a shorter mean recovery time than propofol, with similar hemodynamic stability and satisfaction scores, without any important side effects in GIE interventions.</p>
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Methodical Notes

Funding Sources: None stated

COI: None stated

Randomization: Patients were randomized to propofol (P) and propofol-ketamine (PK) group with closed envelope method. 50:50 patients.

Blinding: No

Dropout Rate/ITT-Analysis: None after randomization

Notes:

Borrat, X. et al. Modeling the influence of the A118G polymorphism in the OPRM1 gene and of noxious stimulation on the synergistic relation between propofol and remifentanil: sedation and analgesia in endoscopic procedures. Anesthesiology. 118. 1395-407. 2013

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: RCT</p> <p>Number of Patient: 207</p> <p>Recruitment Phase: n.a.</p> <p>Inclusion Criteria: patients undergoing endoscopic ultrasound, not clearly mentioned as far as indication is concerned</p> <p>Exclusion Criteria: n.a.</p>	<p>Intervention: patient received different concentrations of remi and propofol assessed by nausea response reflex</p> <p>Comparison:</p>	<p>Primary: requirement of propofol and remi as measured by changes in Bispectral index (BIS) for different genetic polymorphisms</p> <p>Secondary: n.a.</p> <p>Results: Eleven were recessive homozygous for A118G (OPRM = 1). A total of 165 patients were either dominant homozygous or heterozygous and considered normal (OPRM = 0). Propofol and remifentanil were synergistic with respect to the BIS ($\alpha = 1.85$). EC50 estimate for propofol was 3.86 μg/ml and for remifentanil 19.6 ng/ml in normal patients and 326 ng/ml in OPRM = 1 patients.</p> <p>Author's Conclusion: Subjects with A118G single nucleotide polymorphism showed no synergy between propofol and remifentanil under sedation</p>

for upper endoscopy using bispectral index as a measure of effect

Methodical Notes

Funding Sources: not mentioned

COI: none

Randomization: analysis of polymorphisms and allocation to 4 groups

Blinding: n.a.

Dropout Rate/ITT-Analysis: 176 of 207 analysed

Notes:

subjective parameters were used like nausea response to endoscopy tube introduction.
groups were different e.g. regarding demographics and gender

Cheung, C. W. et al. Intranasal dexmedetomidine in combination with patient-controlled sedation during upper gastrointestinal endoscopy: a randomised trial. Acta Anaesthesiol Scand. 59. 215-23. 2015

Population

Intervention - Comparison

Outcomes/Results

Evidence level: 1

Study type: RCT

Number of Patient: 50

Recruiting Phase: January 2009 to April 2010

Inclusion Criteria: ASA I to III and age between 18 and 60 years

Exclusion Criteria: Clinical history or eKG evidence of haert block, KHK, asthma, sleep apnoe syndrome, BMI > 35, impaired liver or renal function or hepatic disease , alcohol cunsumption, in excess of 28 units per week, pregnancy, patient refusal, known psychiaqtrric illness, chronis sedative use of or known allergy of dexmedetomidine, propofol and opioids.

Intervention:
25 patients
intranasal
dexdor

Comparison:
25 patients
saline

Primary: total consumption of PCS propofol and alfentanil

Secondary: Weighted areas under the curve of OAA/S scores , AUC w of heart rate and systolic blood pressure were also significantly lower during the procedure with dexmedetomidine. There was no difference in recovery, side effects or satisfaction.

Results: Total consumption of PCS propofol and alfentanil was significantly less in the dexmedetomidine

Author's Conclusion: Intranasal dexmedetomidine with PCS propofol and alfentanil confers deeper perioperative clinical sedation with significantly less use of additional sedatives during upper gastrointestinal endoscopy.

Methodical Notes

Funding Sources:

COI: No

Randomization: omputer-generated random sequence wasused for drug allocation, and this was prepared by a statistician who was unaware of the clinicalnature of the study.

Blinding: double blind

Dropout Rate/ITT-Analysis: 0

Notes:

intranasal dexmedetomidine reduces dosis of propofol/alfentanyl by pcs; level of sedation was deeper

Chiang, M. H. et al. Target-controlled infusion vs. manually controlled infusion of propofol with alfentanil for bidirectional endoscopy: a randomized controlled trial. Endoscopy. 45. 907-14. 2013

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: RCT</p> <p>Number of Patient: 220</p> <p>Recruiting Phase: 2008-2010</p> <p>Inclusion Criteria: Patients were American Society of Anesthesiology (ASA) physical status 1 or 2 and were undergoing bidirectional endoscopy.</p> <p>Exclusion Criteria: Patients with a history of known allergy to propofol or its lipid emulsion, or drug or alcohol abuse were excluded from this prospective randomized controlled trial (RCT).</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary: The primary endpoint was recovery time.</p> <p>Secondary: The secondary endpoints were hemodynamic performance (duration of decreased MAP>20%/30%) and respiratory manifestations (periods of bradypnea and desaturation, and incidence of desaturation). A further secondary endpoint was satisfaction of patients, endoscopists, and nurse anesthetists</p> <p>Results: Compared with the MCI group, the TCI group had a faster recovery time (17.91±7.72 minutes vs. 14.58±8.55 minutes; P=0.002), less moderate hypotension (7.37±15.46% vs. 1.82±5.15 %; P<0.001), and shorter period of bradypnea (13.81±15.92% vs. 9.18±12.00 %; P=0.013). In addition, the TCI group reduced the relative risk of moderate desaturation by 50% compared with the MCI group (30.9% vs. 15.5 %; 95% confidence interval 1.191–3.360; P=0.007).</p> <p>Author's Conclusion: The study demonstrated that TCI of propofol combined with alfentanil was associated with a faster recovery time, and better hemodynamic and respiratory stability than MCI in same-day bidirectional endoscopy</p>
<p>Methodical Notes</p>		
<p>Funding Sources: NA</p> <p>COI: None</p> <p>Randomization: Yes</p> <p>Blinding: Yes</p> <p>Dropout Rate/ITT-Analysis: NA</p> <p>Notes:</p>		

Eberl, S. et al. Safety and effectiveness using dexmedetomidine versus propofol TCI sedation during oesophagus interventions: a randomized trial. BMC Gastroenterol. 13. 176. 2013

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 5</p> <p>Study type: Presentation of the description of a RT study No results and conclusions</p> <p>Number of Patient:</p> <p>Recruitment Phase:</p> <p>Inclusion Criteria:</p> <p>Exclusion Criteria:</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary:</p> <p>Secondary:</p> <p>Results:</p> <p>Author's Conclusion:</p>
Methodical Notes		
<p>Funding Sources:</p> <p>COI:</p> <p>Randomization:</p> <p>Blinding:</p> <p>Dropout Rate/ITT-Analysis:</p> <p>Notes: Study design description but not results of the study itself - so no rating</p>		

Fanti, L. et al. Two dosages of remifentanyl for patient-controlled analgesia vs. meperidine during colonoscopy: a prospective randomized controlled trial. Dig Liver Dis. 45. 310-5. 2013

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: RCT</p> <p>Number of Patient: 90</p> <p>Recruitment Phase: January 2010 to October 2010</p> <p>Inclusion Criteria: Ninety patients undergoing colonoscopy were randomly assigned to three groups.</p> <p>Exclusion Criteria: Enrolment was proposed to consecutive patients with following exclusion criteria: refusal or inability to provide written informed consent, ASA physical</p>	<p>Intervention: Group M received a meperidine bolus (0.7 mg/kg) and sham patient controlled analgesia. Group R1 received remifentanyl 0.5 g/kg and group R2 remifentanyl 0.8 g/kg together with a patient-controlled analgesia pump injecting further boluses (2-min lock-out).</p> <p>Comparison: Technical difficulties of the examination, gastroenterologist's and patient's satisfaction with sedoanalgesia were evaluated after colonoscopy on a 100 mm Visual Analogue Scale. Patient's satisfaction was assessed 24 h later</p>	<p>Primary: Standard monitoring included arterial blood pressure, electrocardiogram (Lead II) and pulse oximetry (M3 monitor, Philips Medical System 3,000 m Road Andover, MA) was performed and the parameters were monitored throughout the study and recorded at 5 min intervals. A face mask was positioned to deliver oxygen at 4 l/min. Level of sedation was evaluated using the Observer's Assessment of Alertness/Sedation (OAA/S) scale [9] at the baseline and every 5 min until the end of colonoscopy. After the procedure, the data recorded included: time to reach the cecum and time from the insertion of the scope to withdrawal from the anus, including the time when the procedure was stopped to take biopsies or to perform polypectomy (total procedural time). Adverse events</p>

status > II, age < 18 years, previous colonic surgery, pregnancy, psychiatric disorders, history of addiction to opiates and/or sedatives, contraindications to any drug employed in the study.

were recorded throughout the study as well as the total amount of drug consumption. Hypotension was defined as a decrease of SAP more than 20% and bradycardia was defined as a decrease of HR more than 20% from baseline level; desaturation was defined as SpO₂ < 90%. Disinhibition was defined as euphoria, impulsivity and socially inappropriate behaviour and amnesia as the inability of the patient to remember procedure 24 h later. Patients were openly asked if they suffered from nausea or headache. After the procedure, patients were transferred to the recovery area and evaluated by an independent observer every 5 min until ready for discharge from the Endoscopy Unit. Recovery was assessed using the Modified Aldrete Scoring System [10]; patients were considered fit for discharge when they achieved an Aldrete score of 18 or more, had stable vital signs, were able to tolerate oral fluids, had no nausea, vomiting or itching and could walk unaided. This was evaluated by a physician not involved in the study. When completely awake, after the colonoscopy, patients were asked to rate the degree of pain and the quality of sedation by a 100 mm VAS (0 = minimum/100 = maximum). The same scale was used to assess independently technical difficulty of examination and satisfaction with sedo-analgesia experienced by the endoscopist. Patients were contacted via telephone 24–72 h after the procedure by an independent observer blinded to the type of sedo-analgesia given, and asked about their satisfaction with level of sedo-analgesia achieved during colonoscopy. A verbal rating scale was used to rate satisfaction, with 0 representing total dissatisfaction and 100 representing complete satisfaction. They were also asked if they would request the same anaesthetic technique for similar procedures in the future.

Secondary: NA

Results: : Group M had more adverse events ($p = 0.044$), required more rescue boluses ($p = 0.0010$), had lower Observer's Assessment of Alertness and Sedation Scale score at the end of the procedure ($p = 0.0016$)

and longer discharge time (p = 0.0001). Groups R1 and R2 did not differ with respect to these variables. Patient's degree of pain and satisfaction with sedo-analgesia, endoscopist's technical difficulty and satisfaction were not different among groups.

Author's Conclusion: Remifentanyl patient controlled analgesia is a safe approach to sedation for colonoscopy.

Methodical Notes

Funding Sources: NA

COI: None

Randomization: Yes

Blinding: Yes

Dropout Rate/ITT-Analysis: NA

Notes:

Fanti, Lorella et al. Target Controlled Infusion (TCI) for Non-Anesthesiologist Propofol Sedation During GI Endoscopy: a Randomized Double Blind Controlled Study. Gastrointestinal Endoscopy. 79. AB332. 2014

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: RCT</p> <p>Number of Patient: 140</p> <p>Recruitment Phase: February 2014 to May 2014</p> <p>Inclusion Criteria: This randomized double-blind controlled trial involved 140 consecutive outpatients scheduled to undergo EGD or colonoscopy</p> <p>Exclusion Criteria: Exclusion criteria were: clinically significant systemic disease (American Society of Anaesthesiologists (ASA) risk class III–IV), morbid obesity (BMI ≥ 30), severe sleep apnoea, predictably difficult airway management, Mallampati score >2, history of allergic reactions to study drugs, chronic use of opioids, psychiatric disorders, pregnancy, age <18</p>	<p>Intervention: Group S (standard midazolam sedation): Intravenous bolus 0.04 mg/kg if aged <70, 0.03 mg/kg if aged ≥70, followed by 1 mg i.v. boluses up to a maximum of 5 mg. Group P (propofol TCI sedation): Target concentration was initially set at 1.2–1.6 !g/ml (side effect concentration), according to patient's body weight and general condition, then titrated with 0.1 !g/ml increments up to a maximum of 2 !g/ml. Thereafter, if any moderate/severe pain or discomfort appeared, normal saline placebo i.v. boluses were administered to maintain blinding of patient and endoscopist.</p> <p>Comparison: Standard group (n = 70), received fentanyl (1 !g/kg) + midazolam (0.03–0.04 mg/kg) or midazolam only; propofol</p>	<p>Primary: We recorded the following endoscopy timing data: time from insertion of endoscope to the reaching of caecum, time from insertion of endoscope to its withdrawal, time to obtain biopsies or to perform polypectomy. Drug administration and complications were also recorded</p> <p>Secondary:</p> <p>Results: Colonoscopy: discharge time was significantly shorter in the propofol than the standard group (1.1 ± 0.3 vs. 5 ± 10.2 min, respectively; P = 0.03). Endoscopist satisfaction was significantly higher (98.3 ± 11.4/100 vs. 87.2 ± 12/100; P = 0.001); patient satisfaction was significantly higher (95 ± 9.3/100 vs. 85.5 ± 14.4/100; P = 0.002) in the propofol compared to the standard group.</p> <p>EGD: discharge time was not significantly different in the propofol and standard groups (1.1 ± 0.7 vs. 3.9 ± 9.2 min, respectively; P = 0.146). Endoscopist satisfaction was significantly higher (92.7 ± 14.3/100 vs. 82.8 ± 21.2/100; P = 0.03); patient satisfaction was significantly higher (93.8 ± 18.2/100 vs. 76.5 ± 25.2/100; P = 0.003). In the propofol group 94.3% of patients vs. 71.4% of patients in standard group asked to receive the same sedation in the future (P = 0.021).</p> <p>Author's Conclusion: Target Controlled Infusion</p>

	group (n = 70), received fentanyl (1 !g/kg) + propofol Target Controlled Infusion (1.2–1.6 !g/ml) or propofol Target Controlled Infusion only
	is a promising method for non-anaesthesiologist-administered propofol sedation

<p>Methodical Notes</p> <p>Funding Sources: NA</p> <p>COI: none</p> <p>Randomization: yes</p> <p>Blinding: yes</p> <p>Dropout Rate/ITT-Analysis: NA</p> <p>Notes:</p>
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Han, G. et al. A randomized study of intranasal vs. intravenous infusion of dexmedetomidine in gastroscopy. Int J Clin Pharmacol Ther. 52. 756-61. 2014

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 4</p> <p>Study type: randomized trial</p> <p>Number of Patient: 60</p> <p>Recruiting Phase: NA</p> <p>Inclusion Criteria: NA</p> <p>Exclusion Criteria: NA</p>	<p>Intervention: Dexmedetomidine (0.5 µg/kg, 1 mL) and normal saline (NS, 1 mL) were given by intranasal route 40 minutes before induction, and then NS (20 mL) and dexmedetomidine (0.5 µg/kg, 20 mL) were given intravenously 10 minutes before induction, respectively, in groups D1 and D2.</p> <p>Comparison: nasal dexmedetomidine vs. intravenous</p>	<p>Primary: Heart rate (HR), mean arterial pressure (MAP), pulse oxygen saturation(SpO₂), and respiratory rate (RR) were monitored. The latent period of falling asleep, the duration of gastroscopy, the time of awakening, and the total dose of propofol consumption were also recorded. Postoperative sedation scale and adverse reactions were observed.</p> <p>Secondary:</p> <p>Results: One patient in group D1 was excluded from the study due to atrioventricular block. The HR and SpO₂ were significantly lower, but RR was significantly higher in group D2 than in group D1(all p < 0.05). The time of awakening was significantly longer and the rates of respiratory depression were significantly higher in group D2 than in group D1 (all p < 0.05) There were no significant differences in other parameters between both groups.</p> <p>Author's Conclusion: Intranasal dexmedetomidine is a new, safe, and effective approach for gastroscopy because it has more stable respiratory and circulatory parameters and less adverse reactions than intravenous dexmedetomidine.</p>

<p>Methodical Notes</p> <p>Funding Sources: NA</p> <p>COI: NA</p> <p>Randomization: yes</p> <p>Blinding: NA</p> <p>Dropout Rate/ITT-Analysis: NA</p> <p>Notes:</p>

Hsieh, Y. H. et al. Meperidine as the single sedative agent during esophagogastroduodenoscopy, a double-blind, randomized, controlled study. J Gastroenterol Hepatol. 28. 1167-73. 2013

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 4</p> <p>Study type: RCT, randomized, blinded</p> <p>Number of Patient: 140</p> <p>Recruiting Phase: June 2011 and March 2012</p> <p>Inclusion Criteria: diagnostic EGD</p> <p>Exclusion Criteria: therapeutic EGD, sedation with other agents, contraindication to Buscopan (hyoscine N-butylbromide), allergy to meperidine, American Society of Anesthesiology risk Class 3 or higher, renal failure, decompensated cirrhosis, age less than 18 years or more than 65 years, pregnancy, or refusal to provide written informed consent.</p>	<p>Intervention: diagnostic EGD</p> <p>Comparison:</p>	<p>Primary: patient comfort during EGD</p> <p>Secondary: patient, endoscopist, and EGD-related variables.</p> <p>Results: Patients in the meperidine group reported less discomfort during esophageal intubation and during the procedure. The endoscopist found patients in the meperidine group had better tolerance during esophageal intubation and during the procedure more self-limited dizziness in meperidine group.</p> <p>Author's Conclusion: After receiving meperidine injection, patients had better tolerance and less discomfort during diagnostic EGD.</p>

Methodical Notes

Funding Sources: This study was supported by research funds from Buddhist Dalin Tzu Chi General Hospital.

COI: none

Randomization: yes

Blinding: yes

Dropout Rate/ITT-Analysis: not mentioned

Notes:

RCT of meperidine vs. placebo for EGD
 small cohort, high interindividual tolerance of EGD without sedation
 subjective parameters

Hsu, W. H. et al. Low effect-site concentration of propofol target-controlled infusion reduces the risk of hypotension during endoscopy in a Taiwanese population. J Dig Dis. 14. 147-52. 2013

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: RCT</p> <p>Number of Patient: 121 patients.</p> <p>Recruiting Phase: April to December 2009</p> <p>Inclusion Criteria: undergoing GI endoscopy for GI problems</p>	<p>Intervention: Targeted controlled infusion of propofol using an infusion pump. The dose and infusion rate are regulated by computer.</p> <p>Comparison:</p>	<p>Primary: complications cardiovascular and airway events</p> <p>Secondary: Patients' satisfaction with sedation</p> <p>Results: complication rate/cardiovascular or airway events no severe complication occurred during the study Few patients had involuntary movement</p>

Exclusion Criteria: refusal to participate or inability to provide informed consent, age under 18 years, pregnant and lactating women, ASA class IV, allergic to propofol or benzodiazepine and a requirement for general anesthesia.

during the endoscopy: 2.4% (1/41) and 3.8% (3/80) in respective groups (P = 1.00). airway events were of oxygen desaturation. 9.8% (4/41) in the low Ce group and 13.8% (11/80) in the high Ce group (P = 0.772) cardiovascular events, patients in the low Ce group had a lower frequency of hypotension (12.2% in the low Ce group vs 31.3% in the high Ce group, P = 0.026).

Author's Conclusion: A low Ce of propofol TCI (1.5–2.5 µg/mL) achieved adequate anesthesia, reduced the risk of hypotension, and attained a high satisfaction rate in a Taiwanese population undergoing diagnostic painless endoscopy.

Methodical Notes

Funding Sources: supported by a grant from Kaohsiung Medical University Hospital (KMUH96-7R30, KMUH97-7R31) and Excellence for Cancer Research Center grant (DOH100-TD-C-111-002) Department of Health, Executive Yuan, Taiwan, China.

COI: NONE

Randomization: 121 patients. Patients were randomly assigned to the low and high Ce groups in a ratio of 1: 2.

Blinding: all staff but anaesthesiologists

Dropout Rate/ITT-Analysis:

Notes:

restricted to Asian population
 All patients received medication to induce conscious sedation, including a bolus of midazolam (0.04 mg/kg) and fentanyl (0.5 µg/kg).
 no routine application in Western countries.

Lan, C. et al. Comparison of nitrous oxide to no sedation and deep sedation for diagnostic upper gastrointestinal endoscopy. J Gastrointest Surg. 17. 1066-72. 2013

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: Prospective RT</p> <p>Number of Patient: 450; 150 /group</p> <p>Recruitment Phase: 10/2011-12/2011</p> <p>Inclusion Criteria: 18-60 yrs Upper GI symptoms Willing to participate, written consent</p>	<p>Intervention: Diagnostic upper GI endoscopy 3 groups : N2O vs no sedation vs propofol/midazolam/remifentaniil</p> <p>Comparison: see above</p>	<p>Primary: Satisfaction of endoscopist and patient Diagnostic accuracy Complications</p> <p>Secondary: Not stated</p> <p>Results: P/M/R group higher level of sedation to N2O p>0.05 but increased recovery time/hospital stay p>0.05, but best patients tolerance and lowest pain score p>0.05 Satisfaction rates patints and examiners highest for P/M/R group P> 0.000 and p>0.05, also complication rate and pain score compared to N2O and no sedation group</p> <p>Author's Conclusion: Multiple factorsshould be considered before selecting sedation with N2O as sedative for upper GI endoscopy, including pt's economic status, potential risk of cardiopulmonary distress and sensitivity to potential adverse effects ofN2O administration.</p>

<p>Exclusion Criteria: History of former abdominal surgery Pregnancy, lactation Mental disorders Severe concomitant disease Intended for therapeutic endoscopy</p>		
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Methodical Notes

Funding Sources: Not stated

COI: Not stated

Randomization: Yes

Blinding: Unclear

Dropout Rate/ITT-Analysis: 7 patients retracted from N2O and no sedation group
149-150-144

Notes:

Uncommon procedure in the Western world, also the cocktail for deep sedation (propofol, midazolam, remifentanyl)
N2O and deep sedation performed by an anaesthesiologist

Lee, B. S. et al. Midazolam with meperidine and dexmedetomidine vs. midazolam with meperidine for sedation during ERCP: prospective, randomized, double-blinded trial. Endoscopy. 46. 291-8. 2014

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT, double blinded</p> <p>Number of Patient: 110</p> <p>Recruiting Phase:</p> <p>Inclusion Criteria: patients undergoing ERCP. ASA I– III, 20 – 80 years, and were scheduled to undergo diagnostic or therapeutic ERCP.</p> <p>Exclusion Criteria: no informed consent ASA physical classes IV and V pregnant or breast-feeding women body mass index ≥ 36; alcohol dependency; sedative or narcotic analgesic drug abuse; chronic illicit drug use; history of intolerance to benzodiazepines or opioids; baseline oxyhemoglobin saturation (SaO₂) 180 mmHg; respiratory rate >25 or 120 or</p>	<p>Intervention: ERCP</p> <p>Comparison:</p>	<p>Primary: The sedation level (Ramsay Sedation Scale [RSS])</p> <p>Secondary: procedure and discharge times, pain and patient satisfaction, BIS scores and adverse events.</p> <p>Results: Adequate sedation (RSS≥ 3) was maintained during ERCP in 75.5% and 36.8% of the MMD and midazolam–meperidine group RSS scores were significantly higher in the MMD group Intraoperative bispectral index scores were significantly lower in the MMD group Lower additional and total doses of midazolam were required in the MMD group. MMD group showed lower pain scores and higher satisfaction scores Desaturation occurred more frequently in the midazolam–meperidine group</p> <p>Author's Conclusion: addition of dexmedetomidine to the midazolam - meperidine regimen provided better sedative efficacy and a superior safety profile during</p>

ERCP compared with a midazolam - meperidine regimen.

Methodical Notes

Funding Sources: none

COI: none

Randomization: 1:1

Blinding: blinded clinicians

Dropout Rate/ITT-Analysis: n.a.

Notes:

Lera dos Santos, M. E. et al. Deep sedation during gastrointestinal endoscopy: propofol-fentanyl and midazolam-fentanyl regimens. World J Gastroenterol. 19. 3439-46. 2013

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: RCT single-blind</p> <p>Number of Patient: 200</p> <p>Recruiting Phase: 1/2007-10/2010</p> <p>Inclusion Criteria: >18 yrs. ASA I-III</p> <p>Exclusion Criteria: Pregnancy Allergy Psychotic disorder or psychoactive medication Chronic kidney disease; Child C Cirrhosis Heavy consumption of alcohol</p>	<p>Intervention: Diagnostic upper GI endoscopy</p> <p>Comparison: Propofol/Fentanyl vs Midazolam/Fentanyl Sedation performed by Endoscopist or Nurse</p>	<p>Primary: Time to induction and discharge of sedation Deep sedation events OAA/S vs BIS</p> <p>Secondary: Mean time to recovery</p> <p>Results: Deep sedation more frequent in P/F group OAA/S score $p > 0.014$; BIS $p > 0.039$ Time to induction of sedation, recovery ($p > 0.001$) and discharge were shorter in P/F group More O2 supplementation in P/F $p > 0.025$ No complications</p> <p>Author's Conclusion: Deep sation more often with P/F than M/F, but faster recovery Safe application by endoscopist Presence of anaesthesiologist not necessary</p>

Methodical Notes

Funding Sources: Not mentioned

COI: Not mentioned

Randomization: 200 pts 100 vs 100
62 pts excluded

Blinding: Yes

Dropout Rate/ITT-Analysis: no

Notes:

Fentanyl as a combination drug to propofol or midazolam is rarely used in Germany

Li, X. T. et al. Combination of propofol and dezocine to improve safety and efficacy of anesthesia for gastroscopy and colonoscopy in adults: A randomized, double-blind, controlled trial. World J Clin

Cases. 7. 3237-3246. 2019

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: Prospective RCT double blind</p> <p>Number of Patient: 516 pts recruited; 116 excluded 400 pts divided in 4 Groups, 100 subjects each group</p> <p>Recruitment Phase: 13.8. 2018 - 30.3. 2019</p> <p>Inclusion Criteria: ASA I-II 18-85 yrs gastroscopy, colonoscopy</p> <p>Exclusion Criteria: BMI>30 Pregnancy Severe cardiopulmonary, liver and kidney disease sleep apnea</p>	<p>Intervention: Gastroscopy or colonoscopy</p> <p>Comparison: Propofol combined with 1 Dezocine; 2 Sufentanil; 3 Fentanyl; 4 Saline (Propofol alone)</p>	<p>Primary: Quality; Safety; Overall dose of Propofol; Awakening time and intraoperative indexes Pain score</p> <p>Secondary: Adverse effects</p> <p>Results: Dosage of propofol, awakening time, BIS, Steward score and postoperative pain score in dezocine group lower than in all other groups p<0.01 Mean arterial pressure, pulse oxygen saturation more stable p<0.01 Rates of hypopnoe, usage of vasoactive drugs , uncontrolled body movements lower in dezocine group p<0.01</p> <p>Author's Conclusion: Combination of Propofol/Dezocine can decrease propofol dosage reduce the risk for the development of inhibitory effects on the respiratory and cardiovascular System, increase analgesic effect and improve awaking quality</p>

Methodical Notes

Funding Sources: Not indicated

COI: None

Randomization: Yes

Blinding: Double blinded

Dropout Rate/ITT-Analysis: None

Notes:

Single Center study, 4 Groups with 100 Patients

Mazanikov, M. et al. A randomized comparison of target-controlled propofol infusion and patient-controlled sedation during ERCP. Endoscopy. 45. 915-9. 2013

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: randomized trial</p> <p>Number of Patient: 82</p> <p>Recruitment Phase: 2010</p> <p>Inclusion Criteria: scheduled for elective ERCP</p> <p>Exclusion Criteria: Exclusion</p>	<p>Intervention: In the TCI group, the procedure was started after reaching the initial targeted effect-site concentration (Ce) of 2 µg/mL using the Schnider pharmacokinetic model [12]. The initial Ce was chosen on the basis of a previous study [7] and our pilot experiments. In order to avoid deep sedation, Ce was adjusted by the anesthesiologist (M.M.) in increments of 0.5 µg/mL. In</p>	<p>Primary: The primary endpoint of the study was the consumption of propofol (mg) during ERCP procedures.</p> <p>Secondary:</p> <p>Results: All procedures were performed without interruptions or major sedation-related complications. The mean (±SD) consumption of propofol</p>

<p>criteria were allergy to propofol, alfentanil or lidocaine, American Society of Anesthesiologists (ASA) class >3, chronic alcoholism and/or substance abuse, inability to co-operate or patient refusal.</p>	<p>the PCS group a 1-mL single dose of propofol was delivered to the patient every time he or she pressed a self-administration button. Lockout time was adjusted to zero and background infusion was not used. Patients were instructed to take 3–4 doses before the beginning of ERCP and additional boluses every time they needed to be more deeply sedated. If patient lost co-operation and the ability to administer propofol, PCS was converted to the anesthesiologist-managed sedation.</p> <p>Comparison: target controlled vs patient controlled propofol</p>	<p>was 306 ± 124mg in the TCI group and 224 ± 101 mg in the PCS group (P=0.002). Patients in the PCS group recovered faster (P=0.035). The mean (±SD) consumption of alfentanil was 0.5 ± 0.4mg in both groups. The combination of propofol and alfentanil was associated with an increased risk of sedation-related adverse events (P=0.031).</p> <p>Author's Conclusion: No benefits of TCI over PCS could be demonstrated in this study. We recommend considering PCS as a feasible option for propofol administration during ERCP because of its ease of use, high success rate, reduced consumption of propofol, and faster recovery.</p>
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Methodical Notes

Funding Sources: NA

COI: None

Randomization: yes

Blinding: no

Dropout Rate/ITT-Analysis: NA

Notes:

Motamed, F. et al. Midazolam-ketamine combination for moderate sedation in upper GI endoscopy. J Pediatr Gastroenterol Nutr. 54. 422-6. 2012

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 150</p> <p>Recruitment Phase:</p> <p>Inclusion Criteria: upper gastrointestinal endoscopy in outpatient paediatric patiente</p> <p>Exclusion Criteria: eneral anesthesia administration; emergency endoscopies and interventional procedures; children with a history of allergies to benzodiazepines, ketamine, fentanyl, or to their components; cardiovascular, respiratory, metabolic, or neurologic impairments, malignancies, or renal diseases; children with previous complications with IV sedation; children with ASA grade</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary: sedation level, distress level during separation of parents and iv line placement recovery time</p> <p>Secondary: dose of midazolam, complications</p> <p>Results: deeper sedation level for midazolam and ketamine more comfort and shorter recovery time for this regimen, less stressful iv line placement and separation from parents</p> <p>Author's Conclusion: synergistic sedation with oral ketamine and IV midazolam for</p>

(American Society of Anesthesiologists' Physical Status Classification) >II

UGIE in children is a suitable and safe sedation more vomiting for ketamine due to the oral route

Methodical Notes

Funding Sources: none

COI: none

Randomization: yes

Blinding: yes

Dropout Rate/ITT-Analysis: n.a.

Notes:

RCT, blinded, paediatric patients

Nguyen, N. Q. et al. Patient-controlled analgesia with inhaled methoxyflurane versus conventional endoscopist-provided sedation for colonoscopy: a randomized multicenter trial. Gastrointest Endosc. 78. 892-901. 2013

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: RCT</p> <p>Number of Patient: 251</p> <p>Recruiting Phase: NA</p> <p>Inclusion Criteria: The inclusion criteria were age 18 to 75 years, ability to give informed consent, and ability to understand adequately the use of the Pentrox inhaler.</p> <p>Exclusion Criteria: Exclusion criteria were as follows: (1) a history of significant alcohol (O40 g/day for men, 20 g/day for women) or narcotic use; (2) previous history of significant liver, cardiac, or respiratory illnesses (ie, ischemic heart disease, chronic obstructive pulmonary disease, chronic liver disease); (3) weight ! 45 kg; (4) smoking history of more than 20 pack/years; (5) previous history of GI surgery (likely to increase difficulty of colonoscopy); (6) renal impairment; (7) diabetes mellitus with known diabetic nephropathy; (8) previous possible allergy to the medication by the patient or a relative; (9)</p>	<p>Intervention: the subjects were randomized to receive either Pentrox or conventional IV sedation (midazolam and fentanyl) in a 1:1 ratio fashion.</p> <p>Comparison: methoxyflurane vs. midazolam fentanyl</p>	<p>Primary: Primary endpoints were as follows: (1) pain and anxiety scores during colonoscopy, (2) time of discharge (defined as the time the caring nurses and physician deemed it to be "medically safe" for the patients to leave the Endoscopy Unit; any delay because of transport need or other unrelated medical issue was excluded), and (3) the proportion of patients who were willing to undergo the procedure again with the given analgesic/sedative modality. Timing from the end of the procedure to the time the patient was awake, time to oral intake, and time to be ready for discharge were also documented prospectively</p> <p>Secondary: Secondary endpoints were (1) time to cecal intubation, (2) rate of completing colonoscopy, (3) polyp detection rate, (4) total colonoscopy procedural time, (5) rate of adverse events, (6) use of rescue medication before completion of procedure, and (7) patient's recollection of the procedure</p> <p>Results: Precolonoscopy VAS pain and STAI-Y scores were comparable between the 2 groups. There were no differences between groups in (1) pain VAS or STAI Y-1 anxiety scores during or immediately after colonoscopy,</p>

hypersensitivity to fluorinated agents; (10) previous head injury; (11) difficulty in following instructions (including language barrier); (12) concurrent use of any potential nephrotoxic drugs (eg, aminoglycosides) or tetracyclines; and (13) personal or a family history of malignant hyperthermia.

(2) procedural success rate (Pentrox: 121/125 vs M&F: 124/126), (3) hypotension during colonoscopy (7/125 vs 8/126), (4) tachycardia (5/125 vs 3/126), (5) cecal arrival time (8.1 vs 8.1 minutes), or (6) polyp detection rate (30/125 vs 43/126). Additional intravenous sedation was required in 10 patients (8%) who received Pentrox. Patients receiving Pentrox alone had no desaturation (oxygen saturation [SaO₂] < 90%) events (0/115 vs 5/126; P > .03), awoke quicker (3.0 vs 19.1 minutes; P < .001) and were ready for discharge earlier (37.1 vs 66.2 minutes; P < .001) than those receiving intravenous M&F

Author's Conclusion: : Patient-controlled analgesia with inhaled Pentrox is feasible and as effective as conventional sedation for colonoscopy with shorter recovery time, is not associated with respiratory depression, and does not influence the procedural success and polyp detection

Methodical Notes

Funding Sources: NA

COI: no

Randomization: yes

Blinding: yes

Dropout Rate/ITT-Analysis: none

Notes:

Saif Khan, Mohd. Comparison of dexmedetomidine, midazolam, and propofol as an optimal sedative for upper gastrointestinal endoscopy: A randomized controlled trial. J Dig Endosc. 5. 51-7. 2014

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: Not assessed , see Check list</p> <p>Number of Patient:</p> <p>Recruitment Phase:</p> <p>Inclusion Criteria:</p> <p>Exclusion Criteria:</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary:</p> <p>Secondary:</p> <p>Results:</p> <p>Author's Conclusion:</p>

Methodical Notes

Funding Sources:

COI:

Randomization:

Blinding:

Dropout Rate/ITT-Analysis:

Notes:

Sameh, A. Ahmed et al. Randomised Study Comparing the use of Propofol Versus Dexmedetomidine as a Sedative Agent for Patients Presenting for Lower Gastrointestinal Endoscopy. *Current Drug Therapy*. 15. 61-66. 2020

Population	Intervention - Comparison	Outcomes/Results
Evidence level: 5 Study type: RCT Number of Patient: 100 Recruitment Phase: NA Inclusion Criteria: NA Exclusion Criteria: NA	Intervention: group P, in which patients received propofol in a loading dose of 1.5 mg/kg and maintenance dose of 0.5 mg/kg/hr, and group D, in which patients received dexmedetomidine at a loading dose of 1ug/kg and maintenance dose of 0.5 ug/kg/hr. Comparison:	Primary: NA Secondary: NA Results: The basic patients' characteristics, time to recovery, and time of discharge were comparable between the two groups. Moreover, the endoscopist did not significantly report more convenient procedure with one group over the other. Also, there was no significant difference in hemodynamic parameters or in the incidence of complications between the two studied groups. However the use of dexmedetomidine decreased the incidence of hypoxemia. Author's Conclusion: The use of dexmedetomidine seems to have a similar effect to the use of propofol as a sedative agent for lower GIT endoscopy with the positive effect of dexmedetomidine in decreasing the incidence of perioperative hypoxemia.

Methodical Notes

Funding Sources: NA

COI: NA

Randomization: NA

Blinding: NA

Dropout Rate/ITT-Analysis: NA

Notes:

Tandon, Manish et al. Addition of sub-anaesthetic dose of ketamine reduces gag reflex during propofol based sedation for upper gastrointestinal endoscopy: A prospective randomised double-blind study. *Indian journal of anaesthesia*. 58. 436-441. 2014

Population	Intervention - Comparison	Outcomes/Results
Evidence level: 2 Study type: RCT prospective double blind Number of Patient: 270 enrolled 282 assessed for eligibility 12 declined participation 135 vs 135 Recruitment Phase: 5/2012-	Intervention: Diagnostic or interventional (variceal banding) upper GI endoscopy Comparison: 135 propofol alone vs 135 propofol/ketamine	Primary: Incidence of gag reflex Secondary: quality of sedation Recovery profile Results: Fewer pts in Propofol/Ketamine group had gag reflex p>0.005 Incidence of hypotension p>0.06, number of required airway manoeuvres p>0.0014, mean tim to recovery p>0.028 and propofol dose administered p>0.004 were

1/2013		less in P/K group
Inclusion Criteria: ASA I-II including pts with well compensated liver cirrhosis		Author's Conclusion: Ketamine in sub-anesthetic dose decreases gag reflex during upper GI endoscopy
Exclusion Criteria: Significant cardiovascularor respiratory disease Epilepsy Allergy		

Methodical Notes

Funding Sources: Not mentioned

COI: Not mentioned

Randomization: Yes

Blinding: Yes

Dropout Rate/ITT-Analysis: 5 in propofol group and 3 in Propofol/ ketamine group(food in stomach but for primary endpoint included)

Outcome date incomplete 1 in Propofol group 134 vs 135

Notes:

Terui, T. et al. Administration of additional analgesics can decrease the incidence of paradoxical reactions in patients under benzodiazepine-induced sedation during endoscopic transpapillary procedures: prospective randomized controlled trial. Dig Endosc. 25. 53-9. 2013

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: Prospective RT</p> <p>Number of Patient: 160 80 vs 80</p> <p>Recruiting Phase: 2/2013 End of recruiting phase not reported</p> <p>Inclusion Criteria: Pts for diagnostic and therapeutic ERCP</p> <p>Exclusion Criteria: >18 yrs major cardiovascular/respiratory disease renal impairment hydromorphone for cancer related pain</p>	<p>Intervention: midazolam vs midazolam/pentazocine Effect (paradoxical incidence) measured by transcutaneous arterialcarbo dioxide tension (PtcCO2) as indicator of safety</p> <p>Comparison: see above</p>	<p>Primary: PTcCO2 values during ERCP Sedation level measured by OAA/S scale</p> <p>Secondary: Total Midazolam dose Sedation time</p> <p>Results: Paradoxical reactions (PR) higher $p>0.0108$ in midazolam (group 1) as in Mid/Pent (Group 2) Midazolam dosage to achieve deep sedation higher in Group 1 $p>0.0054$ Predictive factors for PR : Procedure time and total midazolam dose Significantly higher PtcCO2 level in Group 2 during first 15 min $p=0.029$</p> <p>Author's Conclusion: Given Pentazocine effects significant decrease of PR incidence under midazolam induced sedation during ERCP Careful monitoring for hypoventilation for the first 15 min</p>

Methodical Notes

Funding Sources: Not mentioned

COI: None

Randomization: Yes

Data collection, randomization and procedure follow up made by an independent physician

Blinding: Endoscopists Nurses Patients were blinded to PR assessments

Dropout Rate/ITT-Analysis: no

Notes:

Methodological quality o.k

but question and results not very interesting, because of the administered analgetics pentazocine, which is not available any more in Germany since 10 yrs at least

Treprasertsuk, S. et al. The safety of propofol infusion compared to midazolam and meperidine intravenous bolus for patients undergoing double balloon enteroscopy. J Med Assoc Thai. 97. 483-9. 2014

Population	Intervention - Comparison	Outcomes/Results
Evidence level: 4 Study type: RCT Number of Patient: 48 Recruitment Phase: NA Inclusion Criteria: NA Exclusion Criteria: NA	Intervention: In group 1, 28 patients were enrolled for intravenous midazolam/meperidine, In group 2, 28 patients were enrolled for propofol infusion, Comparison: Midazolam/Meperidine vs. Propofol	Primary: NA Secondary: NA Results: For the safety profile, 25.9% of the midazolam/meperidine group and 33.3% of the propofol group developed hypotension and/or desaturation (p = 0.45). The patients' satisfaction of group 1 and group 2 were 86.7 +/- 6.5% and 86.3 +/- 8.1%, respectively, and presented no significant difference (p = 0.89). Author's Conclusion: Propofol infusion is safe and shows no difference in outcome from the midazolam and meperidine sedation for the DBE procedure.

Methodical Notes

Funding Sources: NA

COI: NA

Randomization: NA

Blinding: NA

Dropout Rate/ITT-Analysis: 8 of 48

Notes:

Türk, H? et al. Sedation-analgesia in elective colonoscopy: propofol-fentanyl versus propofol-alfentanil. Braz J Anesthesiol. 63. 352-7. 2013

Population	Intervention - Comparison	Outcomes/Results
Evidence level: 3 Study type: randomized prospective study Number of Patient: 80 Recruitment Phase: NA	Intervention: 1 µg.kg-1 fentanyl and 1 mg.kg-1 propofol in Group PF and 10 µg.kg-1 alfentanil and 1 mg.kg-1 propofol in Group PA.	Primary: We established colonoscopy time as the time from induction to the end of the colonoscopy screening. The recovery time was the time from induction until the RSS scores progressed to value 2. We recorded total propofol doses and complications. After the procedure, patients with scores of 9 or greater, according to the Aldrete Score (Table 2), were discharged. After recovery, patients orally scored satisfaction

<p>Inclusion Criteria: ASA I-II patients between 18 and 65 years scheduled for elective colonoscopy screening.</p> <p>Exclusion Criteria: pregnancy, gastrointestinal hemorrhage, known or predicted airway difficulty, alcohol or drug addiction, neuropsychiatric disease, severe heart or respiratory insufficiency, and sedative drug allergy.</p>	<p>Comparison: Fentanyl vs. Alfentanil</p>	<p>on a scale of 1 to 10 (1: not satisfied, 10: very satisfied). Colonoscopist satisfaction was scored with 10 cm visual analog scale. We recorded colonoscopist and patient satisfaction scores. We recorded anesthesia and endoscopy-related complications that appeared during or after procedure, such as allergic reactions, bradycardia, tachycardia, hypotension, hypertension, respiratory depression, desaturation, perforation, bleeding, nausea and vomiting. Desaturation was defined as the decrease of oxygen saturation to below 85%.</p> <p>Secondary: NA</p> <p>Results: MAP at the 15th minute in Group PA was significantly higher than in Group PF (p = 0.037). Group PA's beginning mean heart rate was higher than the mean heart rate at subsequent readings (p = 0.012, p = 0.002). The mean total propofol dose of Group PA was significantly higher than the total dose of Group PF (p = 0.028). The mean recovery time of Group PA was significantly longer than that of Group PF (p = 0.032).</p> <p>Author's Conclusion: Fentanyl provides better operative conditions and reduces the need for additional propofol doses. These advantages cause a shorter recovery time. Therefore, propofol-fentanyl is superior to the propofol-alfentanil for sedation-analgesia in colonoscopy</p>
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<p>Methodical Notes</p>
<p>Funding Sources:</p> <p>COI: NA</p> <p>Randomization: yes</p> <p>Blinding: unclear</p> <p>Dropout Rate/ITT-Analysis: NA</p> <p>Notes:</p>

<p>Wang X, Li Y, Zhao Y, Li H, Yang Z, Xu X, Lian Q, Zeng R. Premedication of atropine benefits sedated screening gastrointestinal endoscopy: a randomized, controlled, double-blinded clinical trial. International journal of clinical and experimental medicine. 11(2). 1270-1277 . 2018</p>		
<p>Population</p>	<p>Intervention Comparison</p>	<p>Outcomes/Results</p>
<p>Evidence level: 2</p> <p>Study type: single-center, prospective, randomized, double-blinded study</p> <p>Number of Patient: 120, 60 per group</p> <p>Recruitment Phase: October 2016 and December 2016</p> <p>Inclusion Criteria: ASA classification of I-II; Scheduled for elective gastrointestinal endoscopy (esophagogastroduodenoscopy followed by colonoscopy); aged 18 to 65 years; (4) BMI between 18 and 26 kg/m².</p>	<p>Intervention: routine endoscopy followed by colonoscopy - different mode of sedation, addition of atropin</p> <p>Comparison:</p>	<p>Primary: stability of hemodynamics characterized as fluctuations of mean arterial pressure (MAP)</p> <p>Secondary: degree of satisfaction of endoscopists and patients total consumption of propofol adverse events such as bucking/hiccupping, body movement, and xerostomia.</p> <p>Results: Patients in the atropine group have more stable hemodynamics, characterized by less fluctuation MAP The colonoscopic insertion time in the atropine group was shorter than placebo</p>

Exclusion Criteria: Allergy to propofol, Sinus tachycardia and other arrhythmia; Heart, liver or kidney dysfunction; Scheduled for gastrointestinal endoscopic treatment; Glaucoma or prostatic hypertrophy; Abdominal surgery; Hyperthyroidism, diabetes, endocrine disease.

group (3.58 ± 1.13 vs 4.64 ± 1.24, P < 0.001).

satisfaction scores in the atropine group were higher than placebo group for the endoscopists

consumptions of propofol were less in the atropine group

more patients in the atropine group suffered from xerostomia

Author's Conclusion: Premedication with atropine could improve hemodynamic stability and endoscopist satisfaction, and reduce the time taken to insert the colonoscope under sedation with propofol and low dose sufentanil in screening gastrointestinal endoscopy.

Methodical Notes

Funding Sources: Medical and Health Technology Projects (No. 2012RCA044,), and the International Exchange Program (No. 2014116) of Health and Family Planning Commission of Zhejiang Province, China, and the Wenzhou Science and Technology Project (No. Y20160403, ; 2016Y0504, ; Y20170138,), Zhejiang Province, China

COI: none

Randomization: computer software 1:1

Blinding: yes, investigators blinded to addition of atropin or placebo

Dropout Rate/ITT-Analysis: 15 of 120

Notes:

single-center, prospective, randomized, controlled, double-blinded study
 combination therapy of propofol and sufentanil for standard endoscopic procedures
 addition of atropin

Worthington, M. T. et al. A phase Ib, dose-finding study of multiple doses of remimazolam (CNS 7056) in volunteers undergoing colonoscopy. *Anesth Analg.* 117. 1093-100. 2013

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: RCT, two parts open-label initial dose escalation study and flumazenil reversal part</p> <p>Number of Patient: 45 + 6 (flumazenil reversal)</p> <p>Recruitment Phase: April and September 2009.</p> <p>Inclusion Criteria: Men and women volunteers aged 18 to 75 years inclusive were eligible to enter the study if they had an ASA physical status of I, a weight range of 60 to 120 kg inclusive, and a body mass index of 18 to <30 kg/m².</p>	<p>Intervention: colonoscopy, dose escalation of Remimazolam</p> <p>Comparison: different doses of benzo</p>	<p>Primary: composite end point (1) sufficient sedation as judged by MOAA/S ≤4 for 3 consecutive measurements (2) completion of the procedure (3) no requirement for rescue sedative medication; and (4) no manual or mechanical ventilation.</p> <p>flumazenil reversal part: readiness for discharge</p> <p>Secondary: n.a.</p> <p>Results: Successful sedation in >70% After the procedure, subjects rapidly recovered to fully alert, with a median of <10 minutes overall. Failures were due to the inability to sedate or adverse events, with 1 subject failing due to hypotension (arterial blood pressure 80/40) and low Spo₂ (<90%). There were no serious adverse events reported, and no events that were unexpected with the combination of a benzodiazepine and fentanyl. The study also showed that sedation was rapidly reversible (1.0 minutes flumazenil vs 10.5 minutes placebo) without re-sedation.</p> <p>Author's Conclusion: Remimazolam has the attributes of a sedative drug, with success rates comparable with recent</p>

<p>Exclusion Criteria: suspected or diag-nosed pathology of the gastrointestinal tract that would add to the risk of endoscopy or could require acute treatment. sensitivity to benzodiazepines, flumazenil, opiates, naloxone, or a contraindication to receiving these medications. thyromental distance ≤ 4 cm or Mallampati scores of 3 or 4</p>		<p>studies of other drugs. Remimazolam provided adequate sedation in 33 of 44 subjects undergoing colonoscopy, and its sedative effects were easily reversed with flumazenil</p>
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Methodical Notes

Funding Sources: not mentioned

COI: none

Randomization: patients were randommized to different doses of benzo not blinded reversal part: double blind

Blinding: in the second part flumazenil vs. placebo for reversal of benzo

Dropout Rate/ITT-Analysis: 51 patients, 6 drop puts

Notes:

This study was not powered statistically. combination therapy of opioid and benzo for colonoscopy

Xiao, Qian-Song et al. Comparison of etomidate-remifentanil and propofol-remifentanil sedation in overweight or obese patients prior to diagnostic upper gastrointestinal endoscopy2018

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 4</p> <p>Study type: Prospective RT single center</p> <p>Number of Patient: 300; 150 vs 150 163 excluded prior to randomzation</p> <p>Recruitung Phase: 3/2013-7/2013</p> <p>Inclusion Criteria: Overweight or obese pts BMI >25 18-80 yrs ASA I-III Upper GI endoscopy</p> <p>Exclusion Criteria: Blood pressue >180/110 mm Hg Cardiac pulmonary,hepatic or nephritic disease Cardiac rhythm disorders</p>	<p>Intervention: Upper GI endoscopy</p> <p>Comparison: Etomidate/Remifentanil vs Propofol/Remifentanil</p>	<p>Primary: Hemodynamic responses</p> <p>Secondary: Recovery and discharge times Diagnostic accuracy Pat/Examiner satisfaction Adverse events</p> <p>Results: Eto/Remifent caused less decreased levels of systolc/diastolic blood pressure($p>0.01$),SPO2 ($p>0.01$), heart rate($p>0.05$) Cardiopulmonry adverse events higher in Propofol group ($p>0.01$)-Nausea/Vomiting,Myoclonus higher in Eto group($p>0.01$) Onset time earlier in Eto group (($p>0.01$) Pat/Examiner satisfaction better in Propofol group ($p>0.05$)</p> <p>Author's Conclusion: Etomidate/Remifentanil seems appropriate for obese patients</p>

Methodical Notes

Funding Sources: Supported by National Natural SCience Foundation of China
ChongqingNatural Science Foundation

COI: None

Randomization: Yes

Blinding: Yes

Dropout Rate/ITT-Analysis: None

Notes:

Use of additional Fentanyl is rarely performed in Germany

Zeng R, Li Y, Wu Q, Qi L, Li H, Wang X, Lian Q, Yang J . Premedication of butorphanol benefits gastrointestinal endoscopy screening under sedation: a randomized, controlled, double-blinded clinical trial. International journal of clinical and experimental medicine. 12(1). 283?290. 2019

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: randomized, controlled study</p> <p>Number of Patient: 200, 4 groups</p> <p>Recruiting Phase: January 2018 and May 2018</p> <p>Inclusion Criteria: ASA classification of I-II; scheduled for elective gastrointestinal endoscopy (esophagogastroduodenoscopy followed by colonoscopy; aged 18 to 65 years; body BMI between 18 and 26 kg /m2</p> <p>Exclusion Criteria: allergies to propofol, eggs, beans, or latex sinus tachycardia or other arrhythmia Patients with heart, liver or kidney dysfunction scheduled for gastrointestinal endoscopic treatment history of glaucoma or prostatic hypertrophy history of abdominal surgery; history of hyperthyroidism, diabetes, or other endocrine disease</p>	<p>Intervention: routine egd and colonoscopy - different sedation regimen</p> <p>Comparison:</p>	<p>Primary: total consumption of propofol hemodynamic stability characterized by fluctuations of MAP</p> <p>Secondary: satisfaction scores of the endoscopists and patients adverse events such as bucking/hiccups body movement, injection pain scores and recovery time</p> <p>Results: stable hemodynamics in all groups consumption of propofol was higher in the placebo group than in group 3 (236.2 ± 40.9 mg vs 213.6 ± 41.6 mg, P = 0.007) recovery time of group 2 was shorter injection pain score of placebo group was higher than the other groups satisfaction scores by endoscopists were higher in group 3 than in the other three groups (P < 0.01)</p> <p>Author's Conclusion: Premedication with butorphanol has many benefits decrease of total consumption of propofol, relieve the propofol injection pain, increase patient and endoscopist satisfaction, and it has less effect on respiration compared with 0.05 µg/kg sufentanil. recommendation of premedication of 10 µg/kg butorphanol for patients undergoing gastrointestinal endoscopy screening under sedation with propofol.</p>

Methodical Notes

Funding Sources: grants from the Medical and Health Technology Projects (No. 2012RCA044, Ruifeng Zeng), the International Ex-change Program (No. 2014-116, Ruifeng Zeng) of the Health and Family Planning Commission of Zhejiang Province, China, and the Wenzhou City Public Welfare Science and Technology Project (No. Y20170138, Ruifeng Zeng; No. Y20160504, Xiaocou Wang), Zhejiang Province, China.

COI: none

Randomization: 4 groups

Blinding: yes

Dropout Rate/ITT-Analysis: n.a.

Notes:

randomized study, however mixed sedation for routine procedures

difficult end points duration of endoscopy procedure, satisfaction scores of the endoscopist and patients...

NEWCASTLE - OTTAWA Checklist: Cohort: 3 Bewertung(en)

Kilgert, B. et al. Prospective long-term assessment of sedation-related adverse events and patient satisfaction for upper endoscopy and colonoscopy. Digestion. 90. 42-8. 2014

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 4 Study type: Prospective, double-blind controlled trial data collection	Funding sources: Not reported. Conflict of Interests: None. Randomization: None. Blinding: None. Dropout rates: Not reported.	Total no. patients: 307 Recruiting Phase: During June 2012 till April 2013. Inclusion criteria: >18 years, sufficient linguistic and cognitive qualifications, literacy and patient's agreement to the study. Exclusion criteria: <18 years, illiteracy, limited language skills, dementia or other diseases limiting cognitive qualifications, hearing loss or deficiency, absent or refused patient's agreement and emergency examinations.	Interventions: Different sedation protocols for varying endoscopic procedures. Comparison: Different sedation protocols for varying endoscopic procedures.
Notes:	Severe methodological flaws. Allocation to sedation protocols not reported. Authors' conclusions cannot be drawn from results. Author's conclusion: Propofol in monosedation should preferably be used for patient sedation in screening and surveillance endoscopies.		
Outcome Measures/results	Primary Patient satisfaction, fear and pain. Secondary Safety.	Results: Different types of sedation were assessed: propofol in monosedation (6.5%), combination of propofol + meperidine (41.0%), combination of midazolam + meperidine (48.5%) and other combinations (3.9%). Patient satisfaction was significantly reduced regarding fear and pain during the endoscopic procedure ($p = 0.001$ and $p = 0.0001$, respectively). All patients receiving propofol monosedation indicated significantly less pain in comparison to other sedation groups ($p < 0.0001$). Moreover, sedation with midazolam + meperidine increased the fear during the procedure significantly in comparison to monosedation with propofol ($p = 0.082$). Propofol/meperidine in combination and midazolam/meperidine increased the probability for cardiovascular events in comparison to monosedation with propofol ($p = 0.005$; $p = 0.039$).	

Mao, Wei et al. The safety of combined sedation with propofol plus fentanyl for endoscopy screening and endoscopic variceal ligation in cirrhotic patients. Journal of Digestive Diseases. 15. 124-130. 2014

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 2	Funding sources: NA	Total no. patients: 409	Interventions: sedation with fentanyl plus propofol

<p>Study type: Cohort study</p>	<p>Conflict of Interests: NA</p> <p>Randomization: no</p> <p>Blinding: no</p> <p>Dropout rates: NA</p>	<p>Recruiting Phase: October 2010 to June 2012</p> <p>Inclusion criteria: patients with liver cirrhosis were enrolled</p> <p>Exclusion criteria: Exclusion criteria were: (i) patients aged over 65 years; (ii) patients with liver cancer such as hepatocellular carcinoma; (iii) those with total portal vein thrombosis; (iv) those who were pretreated with portosystemic shunt or transjugular intrahepatic portosystemic shunt; (v) an American Society of Anesthesiologists (ASA) classification of IV or V; (vi) difficult intubation; (vii) those had undergone emergency procedures (such as active variceal bleeding); (viii) those with chronic pulmonary disease; and (ix) those with severe systematic diseases including renal insufficiency and hypotension, etc. Patients with minimal hepatic encephalopathy were also excluded after confirmed by number connection test-A (NCT-A), a digit symbol substitution test and West Haven Criteria</p>	<p>in the patients with cirrhosis during endoscopy</p> <p>Comparison: Sedation vs. no sedation</p>
<p>Notes:</p>	<p>Author's conclusion: A combined sedation with propofol plus fentanyl is safe for EVL as well as for SEGD in cirrhotic patients. Sedation might make it easier for endoscopists to perform procedures and might be more acceptable for cirrhotic patients.</p>		
<p>Outcome Measures/results</p>	<p>Primary The primary outcomes were to compare the incidence of minimal hepatic encephalopathy or complications of sedation including hypoxia, hypotension, bradycardia and tachycardia in the sedated groups, namely, the sedated SEGD group, the sedated EVL group and the sedated control group.</p> <p>Secondary The secondary outcomes were to assess the satisfaction of the patients as well as the</p>	<p>Results: The incidences of complications during the endoscopic procedures were not significantly different among the sedated groups (20.5% in the sedated SEGD group, 22.6% in the sedated EVL group and 19.0% in the sedated control group). No minimal hepatic encephalopathy was induced in the sedated groups. More patients in the sedated EVL group were satisfactory with the procedure compared with the conscious EVL group, as evaluated by both endoscopists and the cirrhotic patients.</p>	

patients' cooperation between the sedated EVL group and the conscious EVL group.

Wu, W. et al. Dexmedetomidine versus midazolam for sedation in upper gastrointestinal endoscopy. J Int Med Res. 42. 516-22. 2014

Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 3</p> <p>Study type: Retrospective randomized study</p>	<p>Funding sources: n/a</p> <p>Conflict of Interests: none declared</p> <p>Randomization: yes</p> <p>Blinding: unclear</p> <p>Dropout rates: 0</p>	<p>Total no. patients: 60</p> <p>Recruiting Phase: 1/2012 - 12/2012</p> <p>Inclusion criteria: patients with ASA physical status I-II who were scheduled to undergo elective uppergastrointestinal endoscopy</p> <p>Exclusion criteria: inability or unwillingness to participate or to give consent; ASAstatus III; coexisting cardiac anomalies; aged <20 years or >60 years; allergy to study drugs (midazolam, dexmedetomidine or opioids);history of chronic alcoholism, sedative or narcotic analgesic drug abuse; advanced or decompensated liver or renal disease; uncooperative; and any serious illness.</p>	<p>Interventions: patients were assigned to undergo conscious sedation with either dexmedetomidine ormidazolam and were taken into the operating room without any premedication. Patients in the dexmedetomidine group received 0.3mg/kg dexmedetomidine bolus injection and 1mg/kg fentanylcitrate intravenous infusion 10min before endoscopy, followed by 0.2–0.3mg/kg per h dexmedetomidine continuous infusion until anappropriate level of sedation was achieved. Patients in the midazolam group received 0.05mg/kg midazolam bolus injection and 1mg/kg fentanyl citrate intravenous infusion 10 min before endoscopy, followed by 0.01mg/kg midazolam at intervals of approximately 2–5min until a satisfactory level of sedation was achieved.</p> <p>Comparison: dexmedetomidine vs. midazolam sedation</p>
Notes:	<p>Author's conclusion: Dexmedetomidine has a good safety profile and is an effective sedative for use in upper gastrointestinal endoscopy</p>		
Outcome Measures/results	<p>Primary Aldrete score ≥ 9 in the recovery room</p> <p>Secondary Complications occurring during and after endoscopy, including apnoea, SpO₂<85%, decreased blood pressure (<80% of basal value), HR<50 beats/min, cough or abnormal bodymovements were noted. Patients' overall satisfaction was assessed via questionnaire immediately</p>	<p>Results: Patients in the midazolam group(n=30) experienced a significant decrease in MAP during sedation compared with pre-sedation values. Patients in the dexmedetomidine group (n=30) had significantly higher SpO₂ and RSS scores during sedation than those in the midazolam group. Overall satisfaction was higher in the dexmedetomidine group than the midazolam group. Therewerenoclinicallysignificantcomplicationsineithergroup.</p>	

following discharge from the procedure room

Literatursammlung:**AG 2 - Literatur 2015 - 2020****Inhalt:** 184 Literaturstellen

Literaturstelle	Evidenzlevel	Studientyp
Ahmed, S. A. 2017	2	
Akhondzadeh, R. 2016	1	randomized double blind trial
Al Moussawi, H. 2017	1	RCT
Andrade, C. M. 2016	3	Cohort study
Banno, S. 2018	3	Respective data base analysis
Bashiri, M. 2018	2	RCT, blinded
Baykal Tatal, Z. 2016	4	RCT.
Behrens, A. 2016	3	subgroup analysis of a registry study (database)
Bolat, E. 2016	3	case control
Borkett, K. M. 2015	2	RCT
Borrat, X. 2015	3	RCT
Cai, G. 2017	2	RCT single blind
Carvalho, P. H. 2016	3	Cohort
Chang, Y. T. 2015	2	Randomized controlled trial, single center
Chen, L. 2019	2	Metaanalysis
Chen, M. 2020	1	RCT
Chen, S. H. 2020	3	RCT
Cheung, C. W. 2015	1	RCT
Ching, H. L. 2018	1	Cohort study
Conigliaro, R. 2017	1	Position paper of the Italian Soc. of Digestive Endoscopy, no systematic review. Not censored.
Conway, A. 2016	1	systematic review (Cochrane)
Delgado, A. A. A. 2019	1	prospective randomized double blind study
Deng, C. 2017	1	prospective randomized double blinded trial
Dinc, B. 2016	1	RCT

Do?anay, G. 2017	3	RCT
Dossa, F. 2020	2	Systematic review and meta-analysis
Dumonceau, J. M. 2015	1	Guideline-could not be censored
Eberl, S. 2015	5	Study not already performed just presentation of a design
Eberl, S. 2016	1	RCT
El Shahawy, M. S. 2019	2	RCT
Fanti, L. 2015	1	RCT
Fassoulaki, A. 2015	1	Double blinded randomized Study
Ferreira, A. O. 2016	1	RCT
Ferreira, A. O. 2015	2	31-item survey
Finkelmeier, F. 2015	3	retrospective cohort study
Finn, R. T., 3rd 2017	2	Retrospective analysis
Fontanilla, R. B. 2015	5	Only a protocol for a systematic review!
Forster, C. 2018	2	RCT
García Guzzo, M. E. 2020	4	retrospective case study
Garcia, C. J. 2016	3	retrospective cohort analysis, ERC in elderly patients
Gedeon, M. 2019	1	RCT in a community hospital endoscopy suite
Gemma, M. 2016	3	RCT
Goudra, B. 2017	2	retrospective analysis of 5 years' Data from a tertiary center in the USA comparing propofol-sedated patients vs. patients with another type of sedation in GI with regard to adverse events
Goyal, R. 2016	3	RCT
Green, S. M. 2017	3	Systematic review
Gu, Z. 2019	1	Prospective randomized blinded study
Guacho, J. A. L. 2020	2	Metaanalysis
Han, S. J. 2017	2	Randomised, prospective controlled study
Han, S. J. 2019	1	RCT
Hayashi, T. 2017	1	RCT
Haytural, C. 2015	2	RCT
Heo, J. 2016	1	RCT
Heron, V. 2020	3	Retrospective, single-centre study
Hong, M. J. 2015	3	RCT

Hung, A. 2016	4	case controll
Inatomi, O. 2018	2	retrospective case control study
Ishibashi, C. 2016	4	retrospective cohort analysis of patients after ESD receiving dexdor
Izanloo, A. 2015	3	RCT
Jin, E. H. 2017	4	Prospective design, cohort study
Jo, H. B. 2018	4	retrospective cohort
Jokelainen, J. 2020	1	Prospective randomized double Blind study
Jokelainen, J. 2018	3	Prospective validation study; comparison of 4 different methods to evaluate the depth of sedation in pts during ERCP
Jokelainen, J. 2017	3	observational study
Joshi, D. 2015	3	retrospective cohort study ERCP with conscious sedation vs. propofol
Julián Gómez, L. 2018	2	RCT double blinded
Jung, J. H. 2020	1	RCT
K?l?c, E. 2016	3	RCT double blind
Kais, S. S. 2016	1	Case control
Kashiwagi, K. 2016	1	RCT
Kawano, S. 2015		
Kayaalt?, S. 2018	2	RCT
Khan, K. J. 2019	1	Rct
Khoi, C. S. 2015	3	Case Controll
Kikuchi, H. 2018	4	observational study
Kim, D. B. 2021	2	Randomized study.
Kim, E. H. 2018	2	RCT
Kim, E. J. 2017	2	RCT
Kim, J. E. 2016	1	RCT
Kim, J. E. 2015	2	RCT double -blinded
Kim, J. H. 2020	4	retropsective analysis of prospective collected data
Kim, M. G. 2017	1	
Kim, N. 2015	3	RCT
Kim, S. I. 2015	1	case control
Kinugasa, H. 2018	1	Double blinded ranomized single cener trial
Klare, P. 2016	1	RCT
Ko, C. H. 2017	1	RCT
Kollmann, C. M. 2018	3	Case controll

Kotwal MR, Rinchen CZ 2016	5	
Lee, H. S. 2021	3	Cohort
Lee, J. M. 2019	1	RCT
Lee, J. M. 2018	1	RCT, single center, blinded
Lee, S. P. 2018	3	RCT
Lee, S. P. 2015	2	RCT
Li, Q. 2016	1	Randomized Contolled blinded stuy
Lim, S. 2019	4	systematischer Review von RCTs
Lin, O. S. 2017	4	retrospective analysis of prospectively collected data
Lin, O. S. 2017	3	Case serie
Lin, Y. J. 2020	2	Randomized, prospective Study
Liou, J. Y. 2016	1	Model development
Liou, J. Y. 2016	1	Response Surface Model Fit
Liu, J. 2020	1	RCT
Lovett, P. 2017	3	cohort
Lu, Y. 2015	2	Metaanalysis
Lu, Z. 2018	1	RCT
Lucendo, A. J. 2015	3	Cohort study; Survey among Spanish endoscopits.
Maestro Antolín, S. 2018	4	Retrospective analysis
Majidinejad, S. 2015	3	RCT
McVay, T. 2017	2	Retrospective cohort study
Mizrahi, M. 2016	4	retrospective cohort study
Mudambi, L. 2016	1	Retrospective case-control study
Narayanan, S. 2015	2	Prospective RCT Pilot study
Nilsson, A. 2015	3	RCT
Nishikawa, H. 2017	1	
Nishizawa, T. 2017	2	Metaanalysis
Nishizawa, T. 2015	1	Metaanalysis
Nonaka, M. 2015	3	cohort
Nonaka, S. 2015	4	Prospective cohort study
Nonaka, T. 2016	4	restrospective cohort study
Nusrat, S. 2018	1	RCT
Obara, K. 2015	1	Guideline from the Japanese Soc: of GI-endoscopy; not censored

Ogawa, T. 2020	2	single-center, retrospective observational study
Okeke, F. C. 2016	3	Retrospective cohort
Ominami, M. 2018	1	RCT single-blind
Oshima, H. 2017	2	prospectice observational study wirh a histiroc control population
Padmanabhan, A. 2017	2	RCT
Pambianco, D. J. 2016	2	RCT
Park, C. H. 2016	3	Retrospective analysis
Park, C. H. 2018	1	RCT
Park, C. H. 2015	2	RT
Patel, V. A. 2017	2	restrospective cohort
Prathanvanich, P. 2015	3	Prospectice consecutive cohort study in moribly obese patients
Rex, D. K. 2018	1	RCT
Riphaus, A. 2016	1	Guideline: no analysis necessary
Riphaus, A. 2017	1	RCT
Robertson, A. R. 2017	2	retrospective cohort study
Sachar, H. 2018	2	Randomized double-blind trial
Sasala, L. 2020	4	Case Control study
Sato, M. 2019	3	Data collection,
Schaible, A. 2016	2	Single-center, double-blinded, randomized controlled trial
Schumann, R. 2016	4	no
Seo, S. I. 2016	4	prospective interventional study
Shen, X. C. 2015	2	RCT
Shin, S. 2015	1	rct
Smischney, N. J. 2019	2	register/Cohort Study
Spagnuolo, R. 2020	2	prospective intervention trial, consecutive patients, matched by demographics and allocated to 4 groups
Sue-Chue-Lam, C. 2020	3	Review proposal
Sun, G. Q. 2017	4	Randomized study.
Teoh, A. Y. B. 2018	1	RCT
Tian, L. 2020	2	Randomized, double-blinded, and controlled study
Tsai, H. C. 2015	1	Metaanalysis
Tuncali, B. 2015	2	Prospective RCT double-blinded

Turse, E. P. 2019	3	Retrospektive monozentrische Studie
Twardowski, M. A. 2019	5	retrospective case control study
Urahama, R. 2018	2	Cohort study
Uzman, S. 2016	1	prospective randomized double blind
Vaessen, H. 2016	3	30 months Retrospective Study and Analysis
Vargo, J. J. 2017	2	cohort study
Vu?i?evi?, V. 2016	1	RCT
Wadhwa, V. 2017	2	Metaanalysis
Wahab, E. A. 2019	2	Comparative study
Walter, S. 2020	3	Prospektiv
Wang, C. X. 2016	3	RCT
Wang, F. 2020	5	Only Protocol ! Efficacy and safety of remimazolam in procedural sedation and analgesiaA protocol for systematic review and meta analysis
Wang, J. F. 2016	2	RCT
Watanabe, K. 2018	3	RCT
Wu, Y. 2015	1	RCT
Xiaoqian, Z. 2017	4	Prospective cohort study
Xu, B. B. 2016	4	Cross sectional survey
Yamamoto, H. 2015	3	Randomised controlled trial
Yamasaki, Y. 2017	1	RCT
Ye, L. 2017	2	systematic review
Yin, N. 2017	1	
Yin, S. 2019	2	RCT
Yoo, Y. C. 2015	1	retrospective Study comparing two sedation protocols during ESD
Yoon, S. W. 2018	1	systematic review and meta -analysis
Yoshio, T. 2019	3	single arm prospective, cohort study comparison to historic control
Yurtlu, D. A. 2016	3	Retrospective analysis
Zhang, F. 2016	2	meta analysis
Zhang, J. 2016	1	RCT
Zhang, K. 2020	2	Metaanalysis
Zhang, R. 2018	2	systematic review
Zhang, W. 2018	1	metaanalysis
Zhou, X. 2016	2	RCT
Zhu, X. 2020	1	double blinded randomised study

Chen, L. et al. Safety and efficacy of combined use of propofol and etomidate for sedation during gastroscopy: Systematic review and meta-analysis. *Medicine (Baltimore)*. 98. e15712. 2019

Evidence level/Study Types		P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 2</p> <p>Study type: Metaanalysis</p> <p>Databases: PubMed, Embase, Medline (via Ovid SP), Cochrane library databases, CINAHL (via EBSCO), China Biology Medicine disc (CBMdisc), China National Knowledge infrastructure (CNKI), Wanfang, VIP databases</p> <p>Search period: up to 18 August 2018</p> <p>Inclusion Criteria:</p> <ol style="list-style-type: none"> 1. population: patients in whom gastroscopy was indicated; 2. intervention: etomidate plus propofol or propofol plus etomidate; 3. comparison: etomidate or propofol alone; 4. outcome: recovery time, mean arterial pressure (MAP), hypotension, bradycardia, heart rate (HR), pulse oxygen saturation (SPO2), apnea or hypoxemia, myoclonus, nausea and vomiting, body movements, and injection 	<p>Population: gastroscopy patients</p> <p>Intervention: Gastroscopy</p> <p>Comparison: safety of propofol and etomidate</p>	<p>Primary: Primary outcomes: recovery time</p> <p>Secondary: circulation, respiration, AE</p> <p>Results: Fifteen studies with 2973 participants were included in the analysis. Compared to propofol alone, the combined use of propofol and etomidate possibly increased recovery time (SMD=0.14, 95% CI=0.04–0.24; P=.005), and the risk for myoclonus (OR=3.07, 95% CI=1.73–5.44; P<.001) injection pain and nausea vomiting. Furthermore compared to propofol alone the combination of propofol and etomidate produced an apparent beneficial effect on mean arterial pressure (MAP) after anesthesia (SMD=1.32, 95% CI=0.38–2.26; P=.006), SPO2 after anesthesia (SMD=0.99, 95% CI=0.43–1.55; P<.001) apnea or hypoxemia (OR=0.08–0.33; P injection pain and body movement. Further compared to etomidate alone the combination of propofol reduced risk for myoclonus body movement nausea vomiting.</p> <p>Author's Conclusion: The combination of propofol and etomidate might increase recovery time vs that associated with propofol, but it had fewer side effects on circulation and respiration in patients undergoing gastroscopy. The combined use of propofol and etomidate can improve and produce an apparent beneficial effect on the adverse effects of propofol or etomidate alone, and it was safer and more effective than propofol or etomidate alone.</p>		

pain;
5. design: RCTs.

Exclusion Criteria:

1. reviews, nonclinical studies and case observations;
2. non-RCTs;
3. reduplicated studies;
4. studies in which control groups received etomidate or propofol alone or treatment groups did not receive etomidate plus propofol or propofol plus etomidate;
5. studies in which control groups received the intervention that treatment groups did not receive;
6. improper outcome measures;
7. meta-analysis, case reports, editorials, and meeting abstracts

Methodical Notes

Funding Sources: This project was supported by the scientific research and technological development projects of Hechi, Guangxi Province of China (Heke B1824–4).

COI: none

Study Quality: high

Heterogeneity: no

Publication Bias: unclear

Notes:

Conigliaro, R. et al. Italian Society of Digestive Endoscopy (SIED) position paper on the non-anaesthesiologist administration of propofol for gastrointestinal endoscopy. Dig Liver Dis. 49. 1185-1190. 2017

Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
Evidence level: 1 Study type: Position paper of the Italian Soc. of Digestive Endoscopy, no systematic review. Not	Intervention: Comparison:	Primary: Secondary:	

censored. Databases:		Results:	
Search period:		Author's Conclusion:	
Inclusion Criteria:			
Exclusion Criteria:			

Methodical Notes
Funding Sources:
COI:
Study Quality:
Heterogeneity:
Publication Bias:
Notes:

Conway, A. et al. Midazolam for sedation before procedures. Cochrane Database Syst Rev. 2016. Cd009491. 2016				
Evidence Types	level/Study	P - I - C	Outcomes/Results	Literature References
Evidence level: 1		Intervention:	Primary:	
Study type: systematic review (Cochrane)		Comparison:	Secondary:	
Databases: Cochrane Central Register of Controlled Trials (CENTRAL to January 2016), MEDLINE in Ovid (1966 to January 2016) and Ovid EMBASE (1980 to January 2016).			Results: 30 trials (2319 participants) of midazolam for gastrointestinal endoscopy (16 trials), bronchoscopy (3), diagnostic imaging(5), cardioversion (1), minor plastic surgery (1), lumbar puncture (1), suturing (2) and Kirschner wire removal (1). Comparisons were:intravenous diazepam (14), placebo (5) etomidate (1) fentanyl (1), flunitrazepam (1) and propofol (1); oral chloral hydrate (4), diazepam(2), diazepam and clonidine (1); ketamine (1) and placebo (3); and intranasal placebo (2). There was a high risk of bias due to inadequate reporting about randomization (75% of trials). Effect estimates were imprecise due to small sample sizes. None of the trials reported on allergic or anaphylactoid reactions.	
Search period: 1966 to January 2016			Author's Conclusion: no high-quality evidence to determine if midazolam, when administered as the sole sedative agent prior to a procedure, produces more or less effective sedation than placebo or other medications. low-quality evidence that intravenous midazolam reduced anxiety when compared with placebo. inconsistent evidence that oral midazolam decreased anxiety during procedures compared with placebo. Intranasal midazolam did not reduce the risk of incomplete procedures, although anxiolysis and sedation were observed. There is moderate-quality evidence suggesting that oral midazolam produces less effective sedation than chloral hydrate for completion of procedures for children undergoing non-invasive diagnostic procedures.	
Inclusion Criteria: Randomized controlled trials in which midazolam, administered to participants of any age, by any route, at any dose or any time before any procedure (apart from dental procedures), was compared with placebo or other medications including sedatives and analgesics.				
Exclusion Criteria:				

Methodical Notes

Funding Sources:

COI: none

Study Quality: evidence being of low quality.

many trials did not explain how participants were randomized to either midazolam or to a different treatment, and that the results did not give us a very clearly defined answer.

Heterogeneity: heterogenous studies

Publication Bias:

Notes:

Cochrane analysis

Dossa, F. et al. Propofol versus midazolam with or without short-acting opioids for sedation in colonoscopy: a systematic review and meta-analysis of safety, satisfaction, and efficiency outcomes. *Gastrointest Endosc.* 91. 1015-1026.e7. 2020

Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 2</p> <p>Study type: Systematic review and meta-analysis</p> <p>Databases: Medline, Embase, and the Cochrane library</p> <p>Search period: to July 30, 2018</p> <p>Inclusion Criteria: RCTs comparing propofol (\pm short-acting opioids) and midazolam (\pm short-acting opioids) for elective colonoscopy.</p> <p>Exclusion Criteria: Studies reporting the results of emergency or upper/advanced endoscopic procedures and those that combined propofol or midazolam with longer-acting opioids (ie, meperidine), used uncommon formulations of either study drug (eg, fospropofol), compared alternative sedative combinations, or evaluated special populations (patients with cirrhosis, sleep apnea, obesity, patients \geq80 years of age, pregnant women, children). We also excluded conference abstracts, non-English language studies, and studies that did not</p>	<p>Population: Nine studies of 1427 patients.</p> <p>Intervention: Colonoscopies performed with propofol versus midazolam (\pm short-acting opioids).</p> <p>Comparison: Propofol versus midazolam (\pm short-acting opioids).</p>	<p>Primary: Cardiopulmonary safety.</p> <p>Secondary: Satisfaction and efficiency measures.</p> <p>Results: There were no significant differences in cardiorespiratory outcomes (hypotension, hypoxia, bradycardia) between sedative groups. Patient satisfaction was high in both groups, with most patients reporting willingness to undergo a future colonoscopy with the same sedative regimen. In the meta-analysis, patients sedated with propofol had greater satisfaction than those sedated with midazolam (\pm short-acting opioids) (SMD, .54; 95% confidence interval [CI], .30-.79); however, there was considerable heterogeneity. Procedure time was similar between groups (SMD, .15; 95% CI, .04-.27), but recovery time was shorter in the propofol group (SMD, .41; 95% CI, .08-.74).</p> <p>Author's Conclusion: Both propofol and midazolam (\pm short-acting opioids) result in high patient satisfaction and appear to be safe for use in colonoscopy. The marginal benefits to propofol are small improvements in satisfaction and recovery time.</p>	<p>Bastaki M. Douzinas E.E. Fotis T.G. et al. A randomized double-blind trial of anesthesia provided for colonoscopy by university-degreed anesthesia nurses in Greece: safety and efficacy. <i>Gastroenterol Nurs.</i> 2013; 36: 223-230</p> <p>Eberl S. Polderman J. Preckel B. et al. Is "really conscious" sedation with solely an opioid an alternative to every day used sedation regimes for colonoscopies in a teaching hospital? Midazolam/fentanyl, propofol/alfentanil, or alfentanil only for colonoscopy: a randomized trial. <i>Techn Coloproctol.</i> 2014; 18: 745-752</p> <p>Fanti L. Gemma M. Agostoni M. et al. Target Controlled Infusion for non-anaesthesiologist propofol sedation during gastrointestinal</p>

report at least 1 of outcomes of interest.

endoscopy: the first double blind randomized controlled trial. Dig Liver Dis. 2015; 47: 566-571

Kostash M.A.
Johnston R.
Bailey R.
et al.

Sedation for colonoscopy: a double-blind comparison of diazepam/meperidine, midazolam/fentanyl and propofol/fentanyl combinations. Can J Gastroenterol Hepatol. 1994; 8: 27-31

Tanner J.W.
Lichtenstein G.R.
et al.

A randomized, controlled, double-blind trial of patient-controlled sedation with propofol/remifentanyl versus midazolam/fentanyl for colonoscopy. Anesth Analg. 2008; 106: 434-439

Ng J.-M.
Kong C.-F.
Nyam D.

Patient-controlled sedation with propofol for colonoscopy. Gastrointest Endosc. 2001; 54: 8-13

Padmanabhan A.
Frangopoulos C.
Shaffer L.E.

Patient satisfaction with propofol for outpatient colonoscopy: a prospective, randomized, double-blind study. Dis Colon Rectum. 2017; 60: 1102-1108

Schroeder C.
Kaoutzanis C.
Tocco-Bradley R.
et al.

Patients prefer propofol to midazolam plus fentanyl for sedation for colonoscopy. Dis Colon Rectum. 2016; 59: 62-69

Ulmer B.J.
Hansen J.J.
Overley C.A.
et al.

Propofol versus midazolam/fentanyl for outpatient colonoscopy: administration by nurses supervised by endoscopists. Clin Gastroenterol Hepatol. 2003; 1: 425-432

Methodical Notes

Funding Sources: Research support for this study was provided by the Canadian Institutes of Health Research (CIHR) Foundation Grant (grant no. 148470) and with the support of Cancer Care Ontario through funding provided by the Government of Ontario.

COI: One author received speaker honorarium from Pendopharm.

Study Quality: N/A

Heterogeneity: Statistical heterogeneity was assessed using the I2 statistic. Authors were unable to perform subgroup analyses or meta-regression to explore sources of heterogeneity because of the small number of studies. Where single studies appeared to contribute excessively to heterogeneity, authors performed sensitivity analyses using the leave-one-out method to test the robustness of our findings after exclusion of these studies.

Publication Bias: One study by Spie et al GIE Endoscopy 2002 not included.

Notes:

Exclusion of some studies not clear. Included studies with other endpoints than the primary endpoint of the meta-analysis.

Fontanilla, R. B. et al. Effectiveness of remifentanyl and propofol infusion for procedural sedation in patients undergoing gastrointestinal endoscopic procedures: a systematic review protocol. JBI Database System Rev Implement Rep. 13. 114-26. 2015

Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
Evidence level: 5 Study type: Only a protocol for a systematic review! Databases: Search period: Inclusion Criteria: Exclusion Criteria:	Intervention: Comparison:	Primary: Secondary: Results: Author's Conclusion:	

Methodical Notes

Funding Sources:

COI:

Study Quality:

Heterogeneity:

Publication Bias:

Notes:

ONLY a Protocol!

Green, S. M. et al. Pulmonary aspiration during procedural sedation: a comprehensive systematic review. Br J Anaesth. 118. 344-354. 2017

Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 3</p> <p>Study type: Systematic review</p> <p>Databases: PubMed, Web of Science, and the Cochrane Library</p> <p>Search period: January 1985 to May 10, 2016,</p> <p>Inclusion Criteria: NA</p> <p>Exclusion Criteria: NA</p>	<p>Population: NA</p> <p>Intervention: procedural sedation</p> <p>Comparison: aspiration vs no aspiration</p>	<p>Primary: aspiration</p> <p>Secondary: NA</p> <p>Results: Of 1249 records identified by our search, we found 35 articles describing one or more occurrences of pulmonary aspiration during procedural sedation. Of the 292 occurrences during gastrointestinal endoscopy, there were eight deaths. Of the 34 unique occurrences for procedures other than endoscopy, there was a single death in a moribund patient, full recovery in 31, and unknown recovery status in two. We found no occurrences of aspiration in non-fasted patients receiving procedures other than endoscopy.</p> <p>Author's Conclusion: This first systematic review of pulmonary aspiration during procedural sedation identified few occurrences outside of gastrointestinal endoscopy, with full recovery typical. Although diligent caution remains warranted, our data indicate that aspiration during procedural sedation appears rare, idiosyncratic, and typically benign.</p>	

Methodical Notes

Funding Sources: NA

COI: NA

Study Quality:

Heterogeneity:

Publication Bias:

Notes:

Guacho, J. A. L. et al. Propofol vs midazolam sedation for elective endoscopy in patients with cirrhosis: A systematic review and meta-analysis of randomized controlled trials. World J Gastrointest Endosc. 12. 241-255. 2020

Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 2</p> <p>Study type: Metaanalysis</p> <p>Databases: MEDLINE (Pubmed); EMBASE; Cochrane Central Register of Randomized Controlled Clinical Trials/CENTRAL; and Latin-American and Caribbean Health Sciences Literature LILACS electronic databases from their date of inception to November 2019 with no language restriction. A gray literature search was also performed.</p>	<p>Population: patients with cirrhosis more than 18 years of age</p> <p>Intervention: elective endoscopy</p> <p>Comparison: Propofol vs midazolam sedation</p>	<p>Primary: The outcomes studied were procedure time, recovery time, discharge time, and adverse events (bradycardia, hypotension, and hypoxemia).</p> <p>Secondary: NA</p> <p>Results: The search yielded 3,576 records. Out of these, 8 RCTs with a total of 596 patients (302 in the propofol group and 294 in the midazolam group) were included for the final analysis. Procedure time was</p>	

Search period: date of inception to November 2019 with no language restriction

Inclusion Criteria: RCTs comparing propofol and midazolam for sedation during elective gastrointestinal endoscopy in patients with cirrhosis more than 18 years of age were included

Exclusion Criteria: Studies were excluded if they included patients without cirrhosis, patients with upper gastrointestinal bleeding, decompensated liver disease, neurological or psychiatric diseases; patients who used illicit drugs that could alter their central nervous system; patients that used drugs such as benzodiazepines, anti-depressants, antiepileptics, and patients with ASA class IV-V. Case series and studies that did not provide enough data for outcome analysis or full text were also excluded.

similar between midazolam and propofol groups (MD: 0.25, 95%CI: -0.64 to 1.13, P = 0.59). Recovery time (MD: -8.19, 95% CI: -10.59 to -5.79, P < 0.00001). and discharge time were significantly less in the propofol group (MD: -12.98, 95%CI: -18.46 to -7.50, P < 0.00001). Adverse events were similar in both groups (RD: 0.02, 95%CI: 0-0.04, P = 0.58). Moreover, no significant difference was found for bradycardia (RD: 0.03, 95%CI: -0.01 to 0.07, P = 0.16), hypotension (RD: 0.03, 95%CI: -0.01 to 0.07, P = 0.17), and hypoxemia (RD: 0.00, 95%CI: -0.04 to 0.04, P = 0.93). Five studies had low risk of bias, twodemonstrated some concerns, and one presented high risk. The quality of the evidence was very low for procedure time, recovery time, and adverse events; while low for discharge time.

Author's Conclusion: This systematic review and meta-analysis based on RCTs show that propofol has shorter recovery and patient discharge time as compared to midazolam with a similar rate of adverse events. These results suggest that propofol should be the preferred agent for sedation in patients with cirrhosis.

Methodical Notes

Funding Sources: NA

COI: NA

Study Quality: NA

Heterogeneity: NA

Publication Bias:

Notes:

Lim, S. et al. Moderate versus deep sedation in adults undergoing colonoscopy: systematic review and meta-analysis. Curr Med Res Opin. 35. 879-885. 2019

Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 4</p> <p>Study type: systematischer Review von RCTs</p> <p>Databases: Die Abfrage in Medline, Embase, Central und Google scholar erbrachte 172 Studien, zu denen 2 handausgehählt ergänzt wurden.</p>	<p>Population: 919 Patiente aus 3 Studien (davon 520 aus einer der 3 Studien)</p> <p>Intervention: tiefe Sedierung</p>	<p>Primary: patient satisfaction, physician satisfaction, incidence of recall and incidence of desaturation</p> <p>Secondary: Recovery time</p> <p>Results: incidence of desaturation was higher in the deep group than in the moderate group (RR=0.18; 95% CI:</p>	<p>Allen M, 2015 Can J Anaesth. VanNatta ME, 2006 Am J Gastroenterol. Paspatis GA, 2001, Colorectal Dis.</p>

<p>Am Ende des Auswahlprozesses blieben 3 Studien übrig</p> <p>Search period: bis Mai 2018</p> <p>Inclusion Criteria: (1) RCT; (2) studies that compared deep sedation with moderate sedation, regardless of administration route or agent administered; and (3) studies performed on patients who underwent colonoscopy under sedation. Kommentar: "Colonoscopy" war nicht teil der Suchstrategie</p> <p>Exclusion Criteria: Review articles, case reports, case series, letters to the editor, commentaries, proceedings, laboratory science studies and any other nonrelevant studies were excluded.</p>	<p>Comparison: moderate Sedierung</p>	<p>0.01 to 0.99; NNTB=56.7; 95% CI: 31.6 to 273.1)</p> <p>Author's Conclusion: moderate sedation showed comparable safety and effectiveness to deep sedation with respect to patient satisfaction, physician satisfaction, incidence of recall and recovery time; the incidence of desaturation was higher in deep sedation than in moderate sedation. However, additional larger-scale studies of better quality may be needed to confirm these results.</p>
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Methodical Notes

Funding Sources: kein funding

COI: kein Konflikt

Study Quality: wie bereits ausgeführt, ist der Auswahlprozess der Studien unzureichend transparent und die Studien untereinander bei unterschiedlichen Fragestellungen (z.B. Patientenzufriedenheit vs. Adenomdetektionsrate) eingeschränkt vergleichbar.

Heterogeneity: s.o.

Publication Bias: unklar, da nicht bekannt, welche Rolle die "handausgewählten" Studien haben.

Notes:

der in die Auswertung eingegangenen Studienpool erscheint für die Fragestellung nicht geeignet.

Lu, Y. et al. Systematic review and meta-analysis of patient-controlled sedation versus intravenous sedation for colonoscopy. Int J Clin Exp Med. 8. 19793-803. 2015

Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 2</p> <p>Study type: Metaanalysis</p> <p>Databases: Medline via Pubmed, Embase, and Cochrane Controlled Register Databases</p> <p>Search period: to 1 April, 2015</p> <p>Inclusion Criteria: 1) clinical studies designed as prospective,</p>	<p>Population: colonoscopy patients</p> <p>Intervention: colonoscopy</p> <p>Comparison: patient-controlled sedation versus intravenous sedation</p>	<p>Primary: The outcomes of interest included time for cecal intubation, rate of complete colonoscopy, dose of sedative drugs used, pain scores, recovery time, complications.</p> <p>Secondary: NA</p> <p>Results: In all, 12 trials were finally selected (1091 patients, with 545 in the PCS group, and 546 in the IVS group). The total propofol used, time for cecal intubation, rate of complete colonoscopy and pain score had no statistical difference between the two groups. However, PCS showed a reduction in the recovery time, incidence of oxygen desaturation and hypotension. The rates</p>	<p>[1] Jover R, Herraiz M, Alarcon O, Brullet E, Bujanda L, Bustamante M, Campo R, Carreño R, Castells A, Cubiella J, García-Iglesias P, Hervás AJ, Menchén P, Ono A, Panadés A, Parra-Blanco A, Pellisé M, Ponce M, Quintero E, Reñé JM, Sánchez del Río A, Seoane A, Serradesanferm A, Soriano Izquierdo A, Vázquez Sequeiros E; Spanish Society of Gastroenterology; Spanish Society of Gastrointestinal</p>

randomized, and controlled trials; 2) trials comparing PCS with IVS performed by medical staff, regardless of performed by anesthetist, endoscopist, or nurse.

Exclusion Criteria:

The exclusion criteria were: a) case series or single-arm trials; b) non-randomized trials; c) conference abstract with which data could not be extracted; d) review or systematic review; e) repeated data (chose the one with better quality and more patients).

of other complications and patients' willingness to repeat the same sedation had no statistical difference between the two groups.

Author's Conclusion: PCS is as feasible and effective as traditional IVS for colonoscopy, and there is a tendency that PCS shows its superiority in recovery time, incidence for oxygen saturation and hypotension.

Endoscopy Working Group. Clinical practice guidelines: quality of colonoscopy in colorectal cancer screening. *Endoscopy* 2012; 44: 444-451.

[2] Williams CB. Comfort and quality in colonoscopy. *Gastrointest Endosc* 1994; 40: 769-770.

[3] Iber FL, Sutberry M, Gupta R, Kruss D. Evaluation of complications during and after conscious sedation for endoscopy using pulse oximetry. *Gastrointest Endosc* 1993; 39: 620-625.

[4] Heuss LT, Drewe J, Schnieper P, Tapparelli CB, Pflimlin E, Beglinger C. Patient-controlled versus nurse-administered sedation with propofol during colonoscopy. A prospective randomized trial. *AM J Gastroenterol* 2004; 99: 511-518.

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P, Bauerfeind P, Fried M. Safer colonoscopy with patient-controlled analgesia and sedation with propofol and alfentanil. *Gastrointest Endosc* 2001; 54: 1-7.

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[13] Mandel JE, Lichtenstein GR, Metz DC, Ginsberg GG, Kochman ML. A prospective, randomized, comparative trial evaluating respiratory depression during patient-controlled versus anesthesiologist-administered propofol-remifentanyl sedation for elective colonoscopy. *Gastrointest Endosc* 2010; 72: 112-117.

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[15] Bright E, Roseveare C, Dagleish D, Kimble J, Elliott J, Shepherd H. Patient-controlled sedation for colonoscopy: a randomized trial comparing patient-controlled administration of propofol and alfentanil with physician-adminis[1] Jover R, Herraiz M, Alarcon O, Brullet E, Bujanda L, Bustamante M, Campo R, Carreño R, Castells A, Cubiella J, García-Iglesias P, Hervás AJ, Menchén P, Ono A, Panadés A, Parra-Blanco A, Pellisé M, Ponce M, Quintero E, Reñé JM, Sánchez del Río A, Seoane A, Serradesanferm A, Soriano Izquierdo A, Vázquez Sequeiros E; Spanish Society of Gastroenterology; Spanish Society of Gastrointestinal Endoscopy Working Group. Clinical practice guidelines: quality of colonoscopy in colorectal cancer screening. *Endoscopy* 2012; 44: 444-451.

[2] Williams CB. Comfort and quality in colonoscopy. *Gastrointest Endosc* 1994; 40: 769-770.

[3] Iber FL, Sutberry M, Gupta R, Kruss D. Evaluation of complications during and after conscious sedation for endoscopy using pulse oximetry. *Gastrointest Endosc* 1993; 39: 620-625.

[4] Heuss LT, Drewe J, Schnieper P, Tapparelli CB, Pflimlin E, Beglinger C. Patient-controlled versus nurse-administered sedation with propofol during colonoscopy. A prospective randomized trial. *AM J Gastroenterol* 2004; 99: 511-518.

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40: 418-421.

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of patient-controlled sedation required during colonoscopy?

A prospective randomized controlled trial.

Endoscopy 2004; 36: 197-201.

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study. *Gastrointest Endosc* 2011; 73: 260-266.

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Methodical Notes

Funding Sources: NA

COI: none

Study Quality: ok

Heterogeneity: yes

Publication Bias: yes

Notes:

Nishizawa, T. et al. Dexmedetomidine vs propofol for gastrointestinal endoscopy: A meta-analysis. *United European Gastroenterol J.* 5. 1037-1045. 2017

Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 2</p> <p>Study type: Metaanalysis</p> <p>Databases: pubmed, chochrane,lgaku-chuo-zasshi,</p> <p>Search period: 1950 - 2016</p> <p>Inclusion Criteria: RCT GI Endoscopy,active treatment with DEX, Comparator Propofol, outcome safety and efficacy of sedation</p> <p>Exclusion Criteria: duplicated published Trials</p>	<p>Population: 6 RCTs</p> <p>Intervention: see above</p> <p>Comparison: see above</p>	<p>Primary: seeabove</p> <p>Secondary: see above</p> <p>Results: 6 trials patient's satisfaction decreased in DEx group,no significant differences with respect to pat movement and gagging</p> <p>Author's Conclusion: Propofol sedation better for GI Endoscopy</p>	
Methodical Notes			
<p>Funding Sources: none</p> <p>COI: none</p> <p>Study Quality:</p> <p>Heterogeneity: no</p> <p>Publication Bias:</p> <p>Notes:</p>			

Nishizawa, T. et al. Dexmedetomidine versus midazolam for gastrointestinal endoscopy: a meta-analysis. Dig Endosc. 27. 8-15. 2015			
Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 1</p> <p>Study type: Metaanalysis</p> <p>Databases: electronic databases PubMed, the Cochrane library, and the lgaku-chuo-zasshi database of Japan</p> <p>Search period: from 1950 to August 2014</p> <p>Inclusion Criteria: (i) study type: RCT; (ii) population: patients undergoing gastrointestinal endoscopy;</p> <p>Exclusion Criteria: Duplicate publications, reviews, and</p>	<p>Population: 160 Reports, 9RCT</p> <p>Intervention: active treatment with dexmedetomidine; (iv) comparator: traditional sedative agents;</p> <p>Comparison:</p>	<p>Primary: safety and efficacy of sedation.</p> <p>Secondary:</p> <p>Results: Compared to that of midazolam, the pooled OR for restlessness of dexmedetomidine was 0.078 (95% confidence interval [CI]: 0.013–0.453, P < 0.0001), and there was no significant heterogeneity among the trial results. Dexmedetomidine significantly increased Ramsay sedation score compared with midazolam (WMD: 0.401, 95% CI: 0.110–0.692, P = 0.0069), without significant heterogeneity. Compared with midazolam, the pooled OR for hypoxia, hypotension, and bradycardia with dexmedetomidine sedation were 0.454 (95% CI: 0.098–2.11),</p>	

abstracts conferences from	<p>1.370 (95% CI: 0.516–3.637), and 2.575 (95% CI: 0.978–6.785), respectively, with no significant differences detected between the groups.</p> <p>Author's Conclusion: This meta-analysis shows that dexmedetomidine is a safe and effective sedative agent for gastrointestinal endoscopy, especially endoscopic retrograde cholangiopancreatography and endoscopic submucosal dissection.</p>	
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Methodical Notes

Funding Sources: none

COI: none

Study Quality:

Heterogeneity: no significant

Publication Bias: no

Notes:

Riphaus, A. et al. Update S3-guideline: "sedation for gastrointestinal endoscopy" 2014 (AWMF-register-no. 021/014). Z Gastroenterol. 54. 58-95. 2016

Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 1</p> <p>Study type: Guideline: no analysis necessary</p> <p>Databases:</p> <p>Search period:</p> <p>Inclusion Criteria:</p> <p>Exclusion Criteria:</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary:</p> <p>Secondary:</p> <p>Results:</p> <p>Author's Conclusion:</p>	

Methodical Notes

Funding Sources:

COI:

Study Quality:

Heterogeneity:

Publication Bias:

Notes:

Guideline: not censored

Sue-Chue-Lam, C. et al. Non-pharmacological interventions to improve the patient experience of colonoscopy under moderate or no sedation: a systematic review protocol. BMJ Open. 10. e038621. 2020

Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 3</p> <p>Study type: Review proposal</p> <p>Databases: MEDLINE, Embase, CINAHL, PSYCINFO, Scopus and the Cochrane Central Register of Controlled Trials</p> <p>Search period: up to 2020</p> <p>Inclusion Criteria: Peer-reviewed publications in English of randomised controlled trials will be eligible for inclusion. Studies, including adults >18 years old evaluating the effectiveness of any non-pharmacological intervention (given within 1 week of the date of colonoscopy) compared with placebo or usual care for improving the patient experience of colonoscopy (measured within 24 hours of discharge from the endoscopy suite) under moderate or no sedation will be included.</p> <p>Exclusion Criteria: Peer-reviewed publications in English of randomised controlled trials will be eligible for inclusion. Studies, including adults >18 years old evaluating the effectiveness of any non-pharmacological intervention (given within 1 week of the date of colonoscopy) compared with placebo</p>	<p>Population: NA</p> <p>Intervention: colonoscopy</p> <p>Comparison: non-pharmacological intervention vs. no or moderate sedation</p>	<p>Primary: studies reporting any quantitative measure of patient experience, including satisfaction, anxiety, pain or discomfort as an outcome, will be included</p> <p>Secondary: Secondary outcomes will include willingness to repeat the procedure, adenoma detection rate, polyp detection rate, caecal intubation rate, caecal intubation time, total colonoscopy time, endoscopist satisfaction, cost in dollars and the occurrence of any adverse events (eg, bleeding and perforation).</p> <p>Results: NA</p> <p>Author's Conclusion: NA</p>	<p>NA</p>

or usual care for improving the patient experience of colonoscopy (measured within 24 hours of discharge from the endoscopy suite) under moderate or no sedation will be included.

Methodical Notes

Funding Sources: This work was supported by the Canadian Institutes of Health Research (CIHR) grant number FDN – 148470

COI: none

Study Quality: NA

Heterogeneity: NA

Publication Bias: NA

Notes:

Tsai, H. C. et al. Propofol versus midazolam for upper gastrointestinal endoscopy in cirrhotic patients: a meta-analysis of randomized controlled trials. PLoS One. 10. e0117585. 2015

Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 1</p> <p>Study type: Metaanalysis</p> <p>Databases: We performed the meta-analysis, using a random-effect model, the Review Manager, Version 5.2, statistical software package (Cochrane Collaboration, Oxford, UK) according to the PRISMA guidelines.</p> <p>Search period: NA</p> <p>Inclusion Criteria: NA</p> <p>Exclusion Criteria: NA</p>	<p>Population: cirrhotic patients</p> <p>Intervention: gastrointestinal endoscopy</p> <p>Comparison: propofol vs. midazolam</p>	<p>Primary: NA</p> <p>Secondary: NA</p> <p>Results: Five studies between 2003 and 2012, including 433 patients, were included. Propofol provided a shorter time to sedation (weight mean difference: -2.76 min, 95% confidence interval: -3.00 to -2.51) and a shorter recovery time (weight mean difference -6.17 min, 95% confidence interval: -6.81 to -5.54) than midazolam did. No intergroup difference in the incidence of hypotension, bradycardia, or hypoxemia was observed. Midazolam was associated with the deterioration of psychometric scores for a longer period than propofol.</p> <p>Author's Conclusion: This meta-analysis suggests that Propofol sedation for endoscopy provides more rapid sedation and recovery than midazolam does. The risk of sedation-related side effects for propofol does not differ significantly from that of midazolam. The efficacy of propofol in cirrhotic patients undergoing endoscopy is superior to those of midazolam.</p>	<p>NA</p>

Methodical Notes

Funding Sources: NA

COI: NA

Study Quality: NA

Heterogeneity: NA

Publication Bias: NA

Notes:

Wadhwa, V. et al. Similar Risk of Cardiopulmonary Adverse Events Between Propofol and Traditional Anesthesia for Gastrointestinal Endoscopy: A Systematic Review and Meta-analysis. Clin Gastroenterol Hepatol. 15. 194-206. 2017

Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 2</p> <p>Study type: Metaanalysis</p> <p>Databases: Medline, EMBASE, and the Cochrane controlled trials registry</p> <p>Search period: Medline (Ovid) from 1966 to September 2014, EMBASE from 1980 to September 2014, and the Cochrane controlled registry from 1980 to September 2014.</p> <p>Inclusion Criteria: All randomized studies that enrolled adult patients (age, >18 y) undergoing gastrointestinal endoscopy in which propofol was used were eligible for inclusion if they used other agents as a control. In addition, documentation of complications in actual numbers for</p>	<p>Population: A total of 2518 patients were included in these studies, of whom 1324 received propofol and 1194 received midazolam, meperidine, pethidine, remifentanyl, and/or fentanyl either alone or in combination.</p> <p>Intervention: Gastrointestinal endoscopy</p> <p>Comparison: Propofol vs. traditional sedatives</p>	<p>Primary: The primary outcomes measured were cardiopulmonary complications such as hypoxia, if oxygen saturation decreased to less than 90%; hypotension, if systolic blood pressure decreased to less than 90 mm Hg; arrhythmias, including bradycardia, supraventricular and ventricular arrhythmias, and ectopy. Apnea initially was included in the protocol but a decision was made to omit it because the qualitative synthesis showed only 1 study that had assessed this complication properly.³</p> <p>Secondary: A subgroup analysis also was performed to assess studies in which sedation was directed by gastroenterologists and was compared with nongastroenterologists.</p> <p>Results: Of the 2117 citations identified, 27 original studies qualified for this meta-analysis and included 2518 patients. Of these, 1324 received propofol, and 1194 received midazolam, meperidine, pethidine, remifentanyl, and/or fentanyl. Most of the included studies were randomized trials of moderate quality and nonsignificant heterogeneity (Cochran Q, 26.07; P [.13). Compared with traditional sedative agents, the pooled odds ratio with the use of propofol for developing hypoxia for all the procedures combined was 0.82 (95% confidence interval [CI], 0.63–1.07), and for developing hypotension was 0.92 (95% CI, 0.64–1.32). In the nonadvanced endoscopic procedure group, those who received propofol were 39% less likely to develop complications than those receiving traditional sedative agents (odds ratio, 0.61; 95% CI, 0.38–0.99). There was no difference in the complication rate for the advanced endoscopic procedure group</p>	<ol style="list-style-type: none">1. Vargo JJ, DeLegge MH, Feld AD, et al. Multisociety sedation curriculum for gastrointestinal endoscopy. <i>Gastrointest Endosc</i> 2012;76:e1–e25.2. Igea F, Casellas JA, Gonzalez-Huix F, et al. Sedation for gastrointestinal endoscopy. Clinical practice guidelines of the Sociedad Espanola de Endoscopia Digestiva. <i>Rev Esp Enferm Dig</i> 2014;106:195–211.3. Vargo JJ, Zuccaro G Jr, Dumot JA, et al. Gastroenterologist-administered propofol versus meperidine and midazolam for advanced upper endoscopy: a prospective, randomized trial. <i>Gastroenterology</i> 2002;123:8–16.4. Vargo JJ. Propofol: a gastroenterologist's perspective. <i>Gastrointest Endosc Clin N Am</i> 2004;14:313–323.5. Coté GA, Hovis RM, Ansstas MA, et al. Incidence of sedation-related complications with propofol use during advanced endoscopic procedures. <i>Clin Gastroenterol Hepatol</i> 2010; 8:137–142.6. Nayar DS, Guthrie WG, Goodman A, et al. Comparison of propofol deep sedation versus moderate sedation during endoscopy. <i>Dig Dis Sci</i> 2010;55:2537–2544.7. Nishizawa T, Suzuki H, Matsuzaki J, et al. Propofol versus traditional sedative agents for

both the groups, rather than percentages, was a prerequisite for inclusion in the meta-analysis. This was essential to allow us to calculate proportions. The bibliography of the selected articles was searched for additional citations, which then were assessed in exactly the same mode. All studies selected for this meta-analysis were assessed for quality and heterogeneity.

Exclusion

Criteria: All studies that used propofol and another agent concurrently in the same arm were excluded because we proposed to estimate complications attributable only to propofol. The studies whose data were duplicated in more than 1 article were excluded to prevent doubling of patients. Studies also were excluded if they did not provide actual frequencies of the complications but instead provided percentages of

(odds ratio, 0.86; 95% CI, 0.56–1.34). A subgroup analysis did not show any difference in adverse events when propofol was administered by gastroenterologists or nongastroenterologists.

Author's Conclusion: Propofol sedation has a similar risk of cardiopulmonary adverse events compared with traditional agents for gastrointestinal endoscopic procedures. Propofol use in simple endoscopic procedures was associated with a decreased number of complications. When used for gastrointestinal endoscopic procedures of a complex nature and longer duration, propofol was not associated with increased rates of hypoxemia, hypotension, or arrhythmias. Administration of propofol by gastroenterologists does not appear to increase the complication rates.

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complications or
a
percentage
decrease in
complications.

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Methodical Notes

Funding Sources: NA

COI: none

Study Quality: good

Heterogeneity: no

Publication Bias: no

Notes:

Wang, F. et al. Efficacy and safety of remimazolam in procedural sedation and analgesia: A protocol for systematic review and meta analysis. Medicine (Baltimore). 99. e20765. 2020

Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 5</p> <p>Study type: Only Protocol ! Efficacy and safety of remimazolam in procedural sedation and analgesiaA protocol for systematic review and meta analysis</p> <p>Databases:</p> <p>Search period:</p> <p>Inclusion Criteria:</p> <p>Exclusion Criteria:</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary:</p> <p>Secondary:</p> <p>Results:</p> <p>Author's Conclusion:</p>	

Methodical Notes

Funding Sources:

COI:

Study Quality:

Heterogeneity:

Publication Bias:

Notes:

Ye, L. et al. The Comparison of Etomidate and Propofol Anesthesia in Patients Undergoing Gastrointestinal Endoscopy: A Systematic Review and Meta-Analysis. Surg Laparosc Endosc Percutan Tech. 27. 1-7. 2017

Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 2</p> <p>Study type: systematic review</p> <p>Databases: Pub med Embase Web of science, EBSCO, Chocrane library database</p> <p>Search period: 2010-2017</p> <p>Inclusion Criteria: RCT assessing the effect of ethomidat ond Propofol based anethesia of pats undergoing GI Endoscopy</p> <p>Exclusion Criteria: no RCT</p>	<p>Intervention: anaesthesia during GI Endoscopy</p> <p>Comparison: ethoimidat vs. propofol</p>	<p>Primary: Anesthesia Duration, recivery time</p> <p>Secondary:</p> <p>Results: simliar in many measure, different and better for ethomidat in : less apnea, hypoxemia,, injection pain, more myoclonus in ethomidat studies than in propfol studies</p> <p>Author's Conclusion: relevant Parameters not different</p>	

Methodical Notes

Funding Sources: none

COI: non

Study Quality: good

Heterogeneity: no

Publication Bias: no

Notes:

Yoon, S. W. et al. Comparison of propofol monotherapy and propofol combination therapy for sedation during gastrointestinal endoscopy: A systematic review and meta-analysis. Dig Endosc. 30. 580-591. 2018

Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 1</p> <p>Study type: systematic review and mata -analysis</p> <p>Databases: Medline, Embase,Central database</p> <p>Search period: na</p> <p>Inclusion Criteria: RCT, Studies comparin Trials with combined Porofol sedation and propfol monotherapy in Gi endoscopy</p> <p>Exclusion Criteria:</p>	<p>Population: 45 Studies assessed, 22 Studie eligible, 2250 patients</p> <p>Intervention: seadtion in GI endoscopy</p> <p>Comparison: Propofol momnotherapy vs. Propofol combination therapy</p>	<p>Primary: respiratory complications, Hypotension, arrhythmia, recovery time, procedure Duration, patients satisfaction,</p> <p>Secondary:</p> <p>Results: no statistical differences in measures; only Propofoldos was higher in the Monotherapy Group</p> <p>Author's Conclusion: Endoscopists who are aprehesnive about Propofol overdose could adopt combination therapy</p>	

Methodical Notes

Funding Sources: none

COI: none

Study Quality: ok

Heterogeneity: none

Publication Bias: None after trim and foll analysis

Notes:

Zhang, F. et al. Dexmedetomidine versus midazolam for sedation during endoscopy: A meta-analysis. Exp Ther Med. 11. 2519-2524. 2016

Evidence Types	level/Study	P - I - C	Outcomes/Results	Literature References
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Evidence level: 2

Study type: meta analysis

Databases: PubMed (www.ncbi.nlm.nih.gov/pubmed), Cochrane Library (www.cochranelibrary.com/), Ovid (ovidsp.ovid.com/autologin.cgi) and ClinicalTrials (https://clinicaltrials.gov/) databases. In addition, Chinese databases were searched, including CQVIP (http://en.cqvip.com/), WanFang Data (www.wanfangdata.com/) and Chinese Biomedical Literature databases (www.sinomed.ac.cn)

Search period: up to 11/2014

Inclusion Criteria:

i) Randomized controlled trials (RCTs); ii) the study focused on the sedation effects of dexmedetomidine and midazolam; and iii) the study involved patients with an American Society of Anesthesiologists (ASA) (12) grade I to III, and who presented for outpatient endoscopy procedures under conscious sedation.

Exclusion Criteria: Exclusion criteria were as follows: i) Case reports, letters, reviews, editorial articles, meta-analyses and retrospective studies; ii) duplicates of

Population:

patients undergoing endoscopy, patients with an American Society of Anesthesiologists (ASA) grade I to III, no children

Intervention:

outpatient endoscopy procedures under conscious sedation

Comparison:

dexmedetomidine vs. midazolam

Primary:

The primary outcome of interest were changes in vital signs, including the continuous peripheral oxygen saturation (SpO₂), heart rate, respiration rate, mean arterial pressure (MAP) of the patients, Ramsay sedation scale (RSS) and Alertness/Sedation scale (OOA/S).

Secondary:

Secondary outcomes included numeric rating scale pain scores, post-procedure satisfaction questionnaire and adverse events.

Results:

dexmedetomidine demonstrated a significantly lower rate of respiratory depression and adverse events compared with those presented upon midazolam administration. A significant difference was also observed in the sedation potency of the sedatives.

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previous published articles; and iii) studies which included children.

Conclusion: The current controlled data suggest that dexmedetomidine may be an alternative to midazolam in the sedation for endoscopy.

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Methodical Notes

Funding Sources: National Special grant projects of China (grant no. 201002005).

COI: none declared

Study Quality: First, two of the included trials were published in Chinese (21,22), and these studies were of relatively poor quality due to unclear concealment of research details. In addition, it was difficult to draw a definitive conclusion regarding whether dexmedetomidine was a better sedative compared with midazolam since no uniform criteria exist to assess the effects of sedatives. Furthermore, a greater number of well-designed trials are required to confirm the aforementioned results.

Heterogeneity: high

Publication Bias: high

Notes:

the review included chinese studies that are not accessible to non-chinese speaking readers

Zhang, K. et al. Safety and efficacy of propofol alone or in combination with other agents for sedation of patients undergoing colonoscopy: an updated meta-analysis. *Eur Rev Med Pharmacol*

Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 2</p> <p>Study type: Metaanalysis</p> <p>Databases: PubMed, Embase, Scopus, Google Scholar, and Web of Science CENTRAL (Cochrane Central Register of Controlled Trials) databases</p> <p>Search period: published before the 30th of November 2019</p> <p>Inclusion Criteria: search terms: ("propofol" OR "Propofol-fentanyl" AND "sedation" or "Traditional Sedative Agent" AND ("colonoscopy" OR "gastrointestinal surgery"). We also searched the references of the selected studies for additional possibly relevant publications</p> <p>Exclusion Criteria: NA</p>	<p>Population: colonoscopy patients</p> <p>Intervention: colonoscopy</p> <p>Comparison: Propofol vs. propofol plus adjuvants</p>	<p>Primary: Our measured outcomes included recovery time, procedure duration, time-to-discharge, sedation scores, and hypotension, apnea occurrence, and cecal intubation rates</p> <p>Secondary: NA</p> <p>Results: We included 22 eligible trials in our analysis, with a total of 2575 participants. We found strong associations between propofol use and short recovery (SMD MD, -1.15 [-1.55, -0.75], p<0.00001), procedure duration (SMD -0.28 [-0.55, -0.02], p<0.05), discharge times (SMD= - 0.71 [-1.06, - 0.36], p<0.0001), and sedation scores (SMD 1.29 [0.36, 2.22], p<0.05). Propofol in combination with traditional agents led to a significant decrease in discharge time compared with the discharge times of traditional sedatives alone (SMD=-0.69 [-1.07, -0.31], p<0.0004). The effects of propofol on cecal intubation rates, and occurrences of hypotension and apnea were similar to those of TAs.</p> <p>Author's Conclusion: Our results suggest that propofol can be used as a safe alternative to TAs, and can significantly shorten procedure duration, recovery and discharge times, and improve sedation depth.</p>	

Methodical Notes

Funding Sources: none reported

COI: none

Study Quality: NA

Heterogeneity: yes

Publication Bias: minor

Notes:

Zhang, R. et al. The Comparison of Midazolam and Propofol in Gastrointestinal Endoscopy: A Systematic Review and Meta-analysis. Surg Laparosc Endosc Percutan Tech. 28. 153-158. 2018

Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 2</p> <p>Study type: systematic review</p> <p>Databases: Pub med, Embase, Web of science, EBSCO, Cochrane library databases</p> <p>Search period: na</p> <p>Inclusion Criteria: assessing the effect of Midazolam vs propofol</p> <p>Exclusion Criteria: no RCT</p>	<p>Population: 552 patients</p> <p>Intervention: Sedation with Midazolam or Propofol during GI Endoscopy</p> <p>Comparison: Midazolam, vs. Propofol</p>	<p>Primary: endoscopist satisfaction score patients satisfaction score procedure time hypoxämia bradycardia hypotension</p> <p>Secondary:</p> <p>Results: better endoscopist staisfaction score similar patient's satifaction score similar rate of bradycardia and hypoxämia, similar procedure times more hypotensions in patients wirh propofol</p> <p>Author's Conclusion: Incidence of Hypotension is higher with propofol, but endoscopist satisfaction rate higher</p>	

Methodical Notes

Funding Sources: no

COI: no

Study Quality: good

Heterogeneity: analysed

Publication Bias: no

Notes:

Zhang, W. et al. Effect and safety of propofol for sedation during colonoscopy: A meta-analysis. J Clin Anesth. 51. 10-18. 2018

Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 1</p> <p>Study type: metaanalysis</p> <p>Databases: PUB med , Embase , Web of science</p> <p>Search period: March 2028 and backwards</p>	<p>Population: 625 papers , eligible 19 , all RCT; 2512 Patients</p> <p>Intervention: Colonoscopy in SEdation with Propofol or in Combination with propofol</p> <p>Comparison:</p>	<p>Primary: recovery time, procedure time, Tim to sedation, Ambulation, Complication rate, satifaction score, pain score, discharge time</p> <p>Secondary:</p> <p>Results: Propofol had better effects in: recovery time, discharge time, satisfaction score, time to sedation and time to ambulation</p>	

<p>Inclusion Criteria: RCT, case Control study, cohort Study; Colonoscopy,</p> <p>Exclusion Criteria:</p>	<p>comparable effects : Procedure time, pain score, Apnoe rate, amnesia rate, decreased heart rate, devreased blood pressureand complication rate</p> <p>Author's Conclusion: The present study demonstrated that, propofol for sedation during colonoscopy can result in a faster recovery and discharge, a shorter time to sedation and ambulation, as well as improved patient satisfaction, but it did not increase the rate of complications. There is a need for more well-performed, large-scale trials to verify our findings.</p>	
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Methodical Notes		
<p>Funding Sources: none</p> <p>COI: none</p> <p>Study Quality: 625 - 19</p> <p>Heterogeneity: in some outcomes (recovery time, discharge time, pain score), there were substantial heterogeneity among the included studies. in some of the included studies, double-blind was not performed, which may result in the performance and detection bias.</p> <p>Publication Bias:</p> <p>Notes:</p>		

OXFORD (2011) Appraisal Sheet: RCT: 96 Bewertung(en)

<p>Ahmed, S. A. et al. Randomized Controlled Study Comparing Use of Propofol Plus Fentanyl versus Midazolam Plus Fentanyl as Sedation in Diagnostic Endoscopy in Patients with Advanced Liver Disease. Int J Hepatol. 2017. 8462756. 2017</p>		
Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type:</p> <p>Number of Patient:</p> <p>Recruiting Phase:</p> <p>Inclusion Criteria:</p> <p>Exclusion Criteria:</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary:</p> <p>Secondary:</p> <p>Results:</p> <p>Author's Conclusion:</p>
Methodical Notes		
<p>Funding Sources:</p> <p>COI:</p>		

Randomization:

Blinding:

Dropout Rate/ITT-Analysis:

Notes:

Akhondzadeh, R. et al. A comparison between the effects of propofol-fentanyl with propofol-ketamine for sedation in patients undergoing endoscopic retrograde cholangiopancreatography outside the operating room. Biomed J. 39. 145-9. 2016

Population	Intervention Comparison	Outcomes/Results
Evidence level: 1 Study type: randomized double blind trial Number of Patient: 98 Recruitment Phase: 12 month Inclusion Criteria: indication for and possibility of an ERCP Exclusion Criteria: no ERCP possible	Intervention: IV sedation during ERCP Comparison: Propofol ketamine vs. propofol fentanyl	Primary: hemodynamic measures and sedation criteria Secondary: Results: lower amount of Pain and Apnoe in the PK Group, similar criteria of sedation and hemodynamics Author's Conclusion: PK better for ERCP because of less pain and less apnoe

Methodical Notes

Funding Sources: none

COI: none

Randomization: odd and numbers

Blinding: blinded

Dropout Rate/ITT-Analysis: none

Notes:

Al Moussawi, H. et al. The effect of premedication with peppermint oil capsules (Colpermin) prior to colonoscopy: A double blind randomized placebo-controlled trial. Arab J Gastroenterol. 18. 220-223. 2017

Population	Intervention - Comparison	Outcomes/Results
Evidence level: 1 Study type: RCT Number of Patient: 80 Recruitment Phase: 1/15 bis 1/16 Inclusion Criteria: colonoscopy	Intervention: Pfefferminzöl/ Colpermin 374 mg double blind vs. placebo/ B12 (4 h bevor endoskopie) Comparison: 2 vergleichbare Gruppen hinsichtlich alter, Geschlecht, Raucherstatus, Untersuchungsgrund, Anzahl stattgehabte früherer Koloskopien ,infolge der Koloskopie festgestellter Diagnosen	Primary: Zökumintubationszeit (7,8 vs. 7,5 min) Secondary: colonic spastic score, endoscopist satisfaction, patients PAIN SCORE; demand for sedation, Bereitschaft zur Wiederholung der Koloskopie Results: no differences in results of both groups primary or secondary aims

preparation with full dosis (no split dosis moviprep)	Author's Conclusion: Pfefferminzöl ohne Einfluß auf Pat.Komfort, Zökumintubatintubationszeit, Untersucherzufriedenheit
Exclusion Criteria: schwangerschaft, stillzeit, kardiopulm. Komorbiditäten, Glaukom, Substanzkonsum	

Methodical Notes

Funding Sources:

COI: no

Randomization: 1:1 , 2 arms

Blinding: double

Dropout Rate/ITT-Analysis: 2 patients (verschmutzung, complianceproblem)

Notes:

Pfefferminzöl ohne Einfluß auf Pat-Komfort, Zökumintubationszeit, Untersucherzufriedenheit

Bashiri, M. et al. Evaluation of pain and patient satisfaction by music therapy in patients with endoscopy/colonoscopy. Turk J Gastroenterol. 29. 574-579. 2018

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: RCT, blinded</p> <p>Number of Patient: 154</p> <p>Recruiting Phase: June and October 2017</p> <p>Inclusion Criteria: Patients who were 18-70 years old, American Anesthe-siologist Association (ASA) status I-III, and scheduled for endoscopy/colonoscopy</p> <p>Exclusion Criteria: endoscopic ultrasound or endoscopic ret-rograde colangiopancreaticography and having difficulty in communication were excluded from the study.</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary: effect of music treatment on drug consumption, anxiety, and pain was investigated no clear definition</p> <p>Secondary:</p> <p>Results: Music therapy added to deep sedation administered by anesthesiologists provided decreased anxiety score and propofol consumption. Patient satisfaction was increased, and patients reported a desire for the same protocol for recurrent procedures.</p> <p>Author's Conclusion: Music and other non-pharmacological treatment methods must be remembered to increase patient comfort during enco/colonoscopies and other painful procedures.</p>

Methodical Notes

Funding Sources: none

COI: none

Randomization: yes

Blinding: yes

Dropout Rate/ITT-Analysis: not mentioned

Notes:

RCT, influence of music on sedation, pain, anxiety

Baykal Tatal, Z. et al. Propofol-ketamine combination: a choice with less complications and better hemodynamic stability compared to propofol? On a prospective study in a group of colonoscopy patients. Ir J Med Sci. 185. 699-704. 2016

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 4</p> <p>Study type: RCT.</p> <p>Number of Patient: 95 patients were included.</p> <p>Recruiting Phase: 01.05.2013 and 01.01.2014</p> <p>Inclusion Criteria: Colonoscopy.</p> <p>Exclusion Criteria: Preoperative American Society of Anesthesiologists (ASA) physical status classification 3–4, <18 or >70 years old, previous coronary heart disease, hypertension, arterial aneurysm, epilepsy, intracranial mass of benign or malign nature, respiratory–hepatic or renal impairment, and propofol or ketamine allergy history.</p>	<p>Intervention: Patients were block randomized to either sedation with propofol (GroupP) or propofol-ketamine (GroupPK) for colonoscopy.</p> <p>Comparison: Propofol or propofol-ketamine.</p>	<p>Primary: Duration for reaching desired Ramsay Sedation Score (RSS ≥ 4).</p> <p>Secondary: Postoperative recovery duration according to Modified Aldrete Scores (MAS ≥ 9), rates of cardiovascular (hypertension, hypotension, bradycardia), respiratory depression, laryngospasm, visual side effects, nausea/vomiting complications.</p> <p>Results: GroupPK patients needed shorter duration for achieving RSS ≥ 4 (3.3 ± 4.2 vs 2.4 ± 1.6 min, p: 0.038).</p> <p>GroupPK patients had longer recovery duration (MAS ≥ 9, 1 vs 5 min, p: 0.005).</p> <p>Author's Conclusion: Propofol-ketamine combination is an advantageous choice compared to propofol alone in colonoscopy patients in means of achieving desired sedation level in a shorter period of time with lower dose requirements. Propofol-ketamine also provides a better hemodynamic stability, less nausea and vomiting, and respiratory complication rates. Yet it seems that this choice might be related with longer recovery duration.</p>

Methodical Notes

Funding Sources: Not reported.

COI: Not reported.

Randomization: Block wise.

Blinding: Correct.

Dropout Rate/ITT-Analysis: Not done.

Notes:

Borkett, K. M. et al. A Phase IIa, randomized, double-blind study of remimazolam (CNS 7056) versus midazolam for sedation in upper gastrointestinal endoscopy. Anesth Analg. 120. 771-80. 2015

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: RCT</p> <p>Number of Patient: 100</p> <p>Recruiting</p>	<p>Intervention: On the morning of their scheduled gastroscopy, eligible patients were randomly assigned to 1 of the 4 treatment groups:</p>	<p>Primary: a composite end point that consisted of the following: (1) sufficient sedation as judged by MOAA/S ≤4 for 3 consecutive measurements; (2) completion of the endoscopy procedure (i.e., the procedure was not abandoned early for any reason); (3) no requirement for rescue sedative medication; and (4) no manual or mechanical ventilation.</p> <p>Secondary: Pain on injection was assessed using a visual analog scale of 0 to 100 mm, where 0 is no pain and 100 mm is the</p>

<p>Phase: NA</p> <p>Inclusion Criteria: Male and female patients aged 18 to 65 years inclusive were eligible to enter the study if they were scheduled to undergo a diagnostic upper GI endoscopy. In addition, they had to have an ASA physical status score of I or II, with a weight range of 60 to 120 kg inclusive, and a body mass index (BMI) of 18 to 29 kg/m².</p> <p>Exclusion Criteria: Male and female patients aged 18 to 65 years inclusive were eligible to enter the study if they were scheduled to undergo a diagnostic upper GI endoscopy. In addition, they had to have an ASA physical status score of I or II, with a weight range of 60 to 120 kg inclusive, and a body mass index (BMI) of 18 to 29 kg/m².</p>	<p>a single dose of remimazolam 0.10, 0.15, or 0.20 mg/kg; or midazolam 0.075 mg/kg.</p> <p>Comparison: Different doses of remimazolam vs. midazolam</p>	<p>worst imaginable. This assessment was made 1 and 15 minutes after the start of administration of study drug, or if the patient was still sedated, every 5 minutes thereafter until the patient was able to complete the scale.</p> <p>In addition, safety was assessed by the monitoring of adverse events and clinical laboratory testing. Particular attention was paid to vital signs (heart rate, arterial blood pressure, respiratory rate), and events associated with decreased oxygen saturation with continuous pulse oximetry throughout the treatment period.</p> <p>Results: A single dose of remimazolam resulted in a successful procedure in 32%, 56%, and 64% of patients in the low (0.10), middle (0.15), and high (0.20 mg/kg) dose groups compared with 44% of patients in the midazolam (0.075 mg/kg) dose group. The onset of sedation was 1.5 to 2.5 minutes in the remimazolam dose groups compared with 5 minutes for midazolam. Because this was a single administration study, sedation could be maintained for as long as necessary to complete the procedure, using rescue midazolam or propofol. Recovery from sedation was rapid for all treatment groups but was influenced by the choice of rescue medication. There were no obvious differences in the safety profiles of remimazolam and midazolam.</p> <p>Author's Conclusion: This exploratory dose-finding study showed that a single administration of remimazolam (0.10–0.20 mg/kg) was capable of inducing rapid sedation with a quick recovery profile in patients undergoing a diagnostic upper gastrointestinal endoscopy. The safety profile was favorable and appeared to be similar to that of midazolam, warranting further development of this short-acting compound.</p>
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Methodical Notes

Funding Sources: Funding: This study was funded by PAION UK Ltd

COI: Name: Keith M. Borkett, BSc.

Contribution: This author helped design the study, conduct the study, analyze the data, and write the manuscript.

Attestation: Keith M. Borkett has seen the original study data, reviewed the analysis of the data, approved the final manuscript, and is the author responsible for archiving the study files.

Conflicts of Interest: Keith M. Borkett worked for PAION UK Ltd.

Name: Dennis S. Riff, MD.

Contribution: This author helped conduct the study.

Attestation: Dennis S. Riff has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

Conflicts of Interest: Dennis S. Riff acted in an advisory capacity to PAION as part of an expert panel.

Name: Howard I. Schwartz, MD.

Contribution: This author helped conduct the study.

Attestation: Howard I. Schwartz has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

Conflicts of Interest: The author has no conflicts of interest to declare.

Name: Peter J. Winkle, MD.

Contribution: This author helped conduct the study.

Attestation: Peter J. Winkle has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

Conflicts of Interest: The author has no conflicts of interest to declare.

Name: Daniel J. Pambianco, MD.

Contribution: This author helped conduct the study.

Attestation: Daniel J. Pambianco has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

Conflicts of Interest: This author has no conflicts of interest to declare.

Name: James P. Lees, BSc.

Contribution: This author helped design the study, conduct the study, and analyze the data.

Attestation: James P. Lees has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

Conflicts of Interest: James P. Lees worked for PAION UK Ltd.

Name: Karin Wilhelm-Ogunbiyi, MD.

Contribution: This author helped design the study, conduct the study, and analyze the data.

Attestation: Karin Wilhelm-Ogunbiyi has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

Conflicts of Interest: Karin Wilhelm-Ogunbiyi worked for PAION GmbH.

Randomization: yes

Blinding: yes

Dropout Rate/ITT-Analysis: NA

Notes:

Borrat, X. et al. Sedation-analgesia with propofol and remifentanyl: concentrations required to avoid gag reflex in upper gastrointestinal endoscopy. Anesth Analg. 121. 90-6. 2015

Population	Intervention Comparison	Outcomes/Results
Evidence level: 3 Study type: RCT Number of Patient: 124	Intervention: Upper Gastrointestinal Endoscopy Comparison: Patients were randomized to 4 groups of fixed target effect site concentrations: remifentanyl 1ng ml-1, 2ng	Primary: The main outcome measure was the presence or absence of a gag response to insertion of an endoscope probe. Gag response was determined by the same endoscopist for all patients. Secondary: NA Results: One hundred twenty-four patients were analyzed. To achieve between a 50% and 90% probability of no gag response,

<p>Recruiting Phase: NA</p> <p>Inclusion Criteria: NA</p> <p>Exclusion Criteria: NA</p>	<p>ml-1, propofol 2 ug or 3ug ml-1</p>	<p>propofol TCIs were between 2.40 and 4.23 µg•mL (that could be achieved with a bolus of 1 mg•kg) when remifentanil TCI was fixed at 1 ng•mL, and target propofol TCIs were between 2.15 and 2.88 µg•mL (that could be achieved with a bolus of 0.75 mg•kg) when remifentanil TCI was fixed at 2 ng•mL. Remifentanil ranges were 1.00 to 4.79 ng•mL and 0.72 to 3.19 ng•mL when propofol was fixed at 2 and 3 µg•mL, respectively.</p> <p>Author's Conclusion: We identified a set of propofol and remifentanil TCIs that blocked the gag response to endoscope insertion in patients undergoing endoscopy. Propofol bolus doses and remifentanil infusion rates designed to achieve similar effect-site concentrations can be used to prevent gag response when TCI is not available.</p>
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Methodical Notes

Funding Sources: NA

COI: DISCLOSURES

Name: Xavier Borrat, MD.

Contribution: This author helped design the study, conduct the study, analyze the data, and write the manuscript.

Attestation: Xavier Borrat has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

Name: José Fernando Valencia, PhD.

Contribution: This author helped design the study, analyze the data, and write the manuscript.

Attestation: José Fernando Valencia has seen the original study data, reviewed the analysis of the data, approved the final manuscript, and is the author responsible for archiving the study files.

Name: Rudys Magrans, MSc.

Contribution: This author helped analyze the data and write the manuscript.

Attestation: Rudys Magrans has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

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Contribution: This author helped conduct the study and write the manuscript.

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Contribution: This author helped conduct the study and write the manuscript.

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Attestation: Oriol Sendino has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

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Attestation: Matilde Nunez has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

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Attestation: Mathieu Jospin has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

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Attestation: Erik Weber Jensen has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

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Contribution: This author helped design the study, analyze the data, and write the manuscript.

Attestation: Inaki Troconiz has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

Randomization: yes

Blinding: no

Dropout Rate/ITT-Analysis:

Notes:

Cai, G. et al. Clinical application of a novel endoscopic mask: A randomized controlled trial in aged patients undergoing painless gastroscopy. Int J Med Sci. 14. 167-172. 2017

Population	Intervention Comparison	- Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: RCT single blind</p> <p>Number of Patient: 141 eligible 7 lost to follow up Analysed 69 in nasal catheter group and 65 in endoscopic mask group</p> <p>Recruitment Phase: Not specific Date of registration 8.9 2013</p> <p>Inclusion Criteria: 65-80 yrs Body mass index <25 ASA I-II No serious cardiopulmonary or kidney diseases</p> <p>Exclusion Criteria: severe coronary heart disease Esophageal stenosis Aortic aneurysm Asthmatic breathing difficulties Pneumonia Acute pharyngitis and tonsillitis Allergies</p>	<p>Intervention: Diagnostic gastroscopy</p> <p>Comparison: Nasal catheter vs Endoscopic mask</p>	<p>Primary: Minimum pulse oxygen saturation Incidence of adverse events Recovery time Propofol dosage</p> <p>Secondary: Not specified</p> <p>Results: Minimum pulse oxygen Saturation higher in endoscopic mask group p=0.0075 Incidence of pulse oxygen saturation >90 % did not significantly differ Use of endoscopic mask without differences in time to examination, recovery time and propofol dosage</p> <p>Author's Conclusion: Use of endoscopic mask increased minimum pulse oxygen saturation in the aged patients without severe events and increasing time to examination Recommendation of its routine use in gastroscopy in the aged patients</p>

Methodical Notes

Funding Sources: Not stated

COI: None

Randomization: Yes

Blinding: Single blind

Dropout Rate/ITT-Analysis: 7/141 patients

Notes:

Relative low number in only ASA I-II patients

Chang, Y. T. et al. Sedation for gastrointestinal endoscopy with the application of target-controlled infusion. Turk J Gastroenterol. 26. 417-22. 2015

Population

Intervention - Comparison

Outcomes/Results

Evidence level: 2

Study type: Randomized controlled trial, single center

Number of Patient: n =100, n= 50 for each group

Recruitment Phase: not mentioned

Inclusion Criteria: Outpatients who underwent both, upper and lower Gi-endoscopy in a single procedure.

Exclusion Criteria: ASA class > III; known allergic reactions against the used drugs; chronic use of sedative or anagesic drugs; sleep apnoea; BMI > 42 in men or BMI> 35 in women; any seizure disorder.

Intervention: Sedation with alfentanil and propofol via bolus titration as needed or by means of a TCI-pump (orchestra, Fresenius-Kabi, Germany)). All pts. of both groups received additionally a fixed dose of midazolam (2-2,5 mg) before administration of propofol/alfentanil.

Comparison: Sedation with TCI-pump vs. standard bolus sedation.

Primary: Not expressively stated in the manuscript!

An anesthesia quality score (featuring no. of interruptions of the procedure due to sedation problems, respiratory and hemodynamic stability as well as the recovery time) was assessed.

Procedure and recovery times as well as any side effects were recorded.

No sample size calculation was given.

Secondary: Not expressively mentioned in the manuscript.

Results: A significantly ($p < 0.05$) lower anesthesia quality score in the TCI-group (12,2) than in the control group (12,7). In the TCI-group the propofol dose was higher than in the control group, however, the alfentanil dose was lower in the TCI-group than in the controls.No significant side effects occurred in both groups.

Author's Conclusion: Sedation with TCI provided safe and effective sedation with a better sedation quality in endoscopic GI-procedures. They believe that TCI can be used to provide routine sedation for patients receiving GI-endoscopy.

Methodical Notes

Funding Sources: None

COI: None

Randomization: Computer-generated block randomization.

Blinding: No blinding.

Dropout Rate/ITT-Analysis: Not given

Notes:

Chen, M. et al. The propofol-sparing effect of intravenous lidocaine in elderly patients undergoing colonoscopy: a randomized, double-blinded, controlled study. BMC Anesthesiol. 20. 132. 2020

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 92</p> <p>Recruiting Phase: March 11, 2019, and the first case enrolled was on March 12, 2019. The last patient completed on September 25, 2019,</p> <p>Inclusion Criteria: aged ≥ 65, ASA I-II, undergoing colonoscopy under sedation were initially included</p> <p>Exclusion Criteria: severe cardiovascular and pulmonary diseases such as hypertension and respiratory insufficiency; mental disorders, such as schizophrenia and psychosis on long-term psychotropic drugs; history of having previous colectomy; hyperalgesia or refractory cancer pain; and intravenous anesthesia contraindication.</p>	<p>Intervention: Ninety-two patients undergoing colonoscopy were randomly enrolled into lidocaine+propofol (L + P) group or normal saline+propofol (NS + P) groups. Subjects received intravenous bolus of 1.5 mg/kg lidocaine followed by 4 mg kg⁻¹ h⁻¹ lidocaine continuous infusion in L + P group or equivalent volumes of normal saline for boluses and infusion in NS + P group.</p> <p>Comparison: The recorded primary endpoints included: the total amount of propofol administered during entire procedure, the supplemental amount of propofol after induction, and the frequencies of boluses of supplemental propofol. Results: A</p>	<p>Primary: A total of 79 patients were included in the final analysis. Compared with NS + P group, the total amounts of propofol (induction plus supplemental) were no significant differences in L + P group; however, the required supplemental propofol was less (69.9 ± 39.2 vs. 51.5 ± 38.6 mg) ($P = 0.039$);</p> <p>Secondary: the average frequencies of boluses of supplemental propofol given after induction were lower (2.1 ± 1.1 vs. 1.4 ± 0.9) ($P = 0.003$); the calculated “unit propofol” infusion rate was lower (0.18 ± 0.05 vs. 0.14 ± 0.04 mg kg⁻¹ min⁻¹) ($P = 0.002$)</p> <p>Results: The addition of intravenous lidocaine to propofol-based sedation resulted in a remarked reduction of supplemental propofol in the elderly during colonoscopy</p> <p>Author's Conclusion: In summary, the addition of intravenous lidocaine to propofol sedation during colonoscopy led significant reduction in both of the supplemented propofol and the frequency of supplemental boluses of propofol without compromises of hemodynamic and respiratory profiles.</p>

Methodical Notes

Funding Sources: The research was funded by Zhejiang provincial public welfare technology application research foundation of China (2018ZD033, 2020KY186). The foundation provided the cost of printing files and technical consultation.

COI: no

Randomization: sequential numbers from 1 to 92 for patient enrollments placed inside based on a computer-generated randomized order, double blinded

Blinding: Another anesthesiologist who observed and recorded L + P group and NS + P group according to the random assignment generated by an anesthesiologist through computer data intraoperatively and postoperatively was also blinded to the medication patient had received

Dropout Rate/ITT-Analysis: 13 patients (2 not enrolled for the study poor venous access , then in both groups 5 vs. 6 patients excluded for prolonged endoscopic procedure time)

Notes: in der Interventionsgruppe waren weniger Propofolboli notwendig, auch eine geringere Propofolgesamt-dosis, dies aber nicht signifikant. Die Patienten der Gruppen waren 71 bzw. 70 Jahre alt. Durchführung sicher, Methodik o.,k.

Chen, S. H. et al. Remimazolam tosilate in upper gastrointestinal endoscopy: A multicenter, randomized, non-inferiority, phase III trial. J Gastroenterol Hepatol. . . 2020

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: RCT</p> <p>Number of Patient: 384</p> <p>Recruiting Phase: September 2017 and November 2017</p> <p>Inclusion Criteria: Male and female subjects, aged 18 to 60 years, scheduled to undergo upper GI endoscopy were eligible to enter the study. Patients had to have an American Society of Anesthesiologists (ASA) physical status of I or II, and a body mass index (BMI) of 18 to < 30 kg/m². Meanwhile, patients were enrolled if the upper GI endoscopy was expected to take no more than 30 min.</p> <p>Exclusion Criteria: Patients were excluded if they had a suspected or diagnosed pathology of the GI tract that would require complicated or therapeutic endoscopy. Patients in whom the management of airways were judged to be difficult (Mallampati score of 3), and required trachea cannula were also excluded. In addition, patients were excluded if they had anemia, thrombocytopenia, abnormal liver function and abnormal renal function, or had a sitting systolic blood pressures of ≤ 90 mmHg, or had hypertension that was not satisfactorily controlled using antihypertensive drugs, as well as pregnant or lactating patients at screening. Patients with a history of drug abuse and/or alcoholism within 2 years before screening, a known sensitivity to benzodiazepines, opioids, propofol, lidocaine, or a contraindication to receiving these medications were also excluded. Patients participating any clinical trials of other drugs within 3 months before study initiation were excluded.</p>	<p>Intervention: upper gastrointestinal endoscopy</p> <p>Comparison: remimazolam vs. propofol</p>	<p>Primary: The primary efficacy endpoint was the success rate of sedation (the proportion of patients achieving the success of the procedure), which defined as (i) completion of the whole endoscopy procedure; (ii) no requirement for an alternative and/or rescue sedative; (iii) administered up to a maximum of five supplemental doses within 15 min after the initial dose.</p> <p>Secondary: Secondary efficacy endpoints included the following: (i) time to adequate sedation, defined as the time from the initial dose to obtain adequate sedation (the first of MOAA/S scores ≤ 3); (ii) time to fully alert, defined as the time from discontinuation of sedative medication to fully alert (the first of three consecutive MOAA/S score of 5); (iii) the incidence of hypotension (defined as a 20% or greater drop in systolic blood pressure [SBP] from pre-sedation value, or SBP ≤ 80 mmHg during the procedure) from drug administration to fully alert; (iv) the incidence of treatment-related hypotension (defined as hypotension that occurs during sedation, which requires medication at least once); (v) the incidence of respiratory depression (defined as respiratory rate < 8 breaths per minute and/or oxygen saturation < 90%) from drug administration to fully alert. All secondary efficacy endpoints were analyzed in the subjects with successful sedation.</p> <p>Results: The success rate of sedation in the RT group was non-inferior to that in the propofol group (97.34% vs 100.00%; difference in rate 2.66%, 95% CI 4.96 to 0.36, meeting criteria for non-inferiority). Patients in the RT group had longer time to adequate sedation (P < 0.0001) but shorter time to fully alert (P < 0.0001) than that in the propofol group. The incidences of hypotension (13.04% vs 42.86%, P < 0.0001), treatment-related hypotension (0.54% vs 5.82%, P < 0.0001), and respiratory depression (1.09% vs 6.88%, P = 0.0064) were significantly lower in the RT group. AEs were reported in 74 (39.15%) patients in the RT group and 114 (60.32%) patients in the propofol group, with significant difference (P < 0.0001).</p> <p>Author's Conclusion: This trial established non-</p>

inferior sedation success rate of RT compared with propofol. RT allows faster recovery from sedation compared with propofol. The safety profile is favorable and appears to be superior to propofol, indicating that it was feasible and well tolerated for patients.

Methodical Notes

Funding Sources: none reported

COI: none

Randomization: yes

Blinding: partially

Dropout Rate/ITT-Analysis:

Notes:

Cheung, C. W. et al. Intranasal dexmedetomidine in combination with patient-controlled sedation during upper gastrointestinal endoscopy: a randomised trial. Acta Anaesthesiol Scand. 59. 215-23. 2015

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 50</p> <p>Recruiting Phase: January 2009 to April 2010</p> <p>Inclusion Criteria: ASA I to III and age between 18 and 60 years</p> <p>Exclusion Criteria: Clinical history or eKG evidence of haert block, KHK, asthma, sleep apnoe syndrome, BMI > 35, impaired liver or renal function or hepatic disease , alcohol cunsumption, in excess of 28 units per week, pregnancy, patient refusal, known psychiaqtrric illness, chronis sedative use of or known allergy of dexmedetomidine, propofol and opiods.</p>	<p>Intervention: 25 patients intranasal dexdor</p> <p>Comparison: 25 patients saline</p>	<p>Primary: total consumption of PCS propofol and alfentanil</p> <p>Secondary: Weighted areas under the curve of OAA/S scores , AUC w of heart rate and systolic blood pressure were also significantly lower during the procedure with dexmedetomidine. There was no difference in recovery, side effects or satisfaction.</p> <p>Results: Total consumption of PCS propofol and alfentanil was significantly less in the dexmedetomidine</p> <p>Author's Conclusion: Intranasal dexmedetomidine with PCS propofol and alfentanil confers deeper perioperative clinical sedation with significantly less use of additional sedatives during upper gastrointestinal endoscopy.</p>

Methodical Notes

Funding Sources:

COI: No

Randomization: omputer-generated random sequence wasused for drug allocation, and this was prepared bya statistician who was unaware of the clinicalnature of the study.

Blinding: double blind

Dropout Rate/ITT-Analysis: 0

Notes:

intranasal dexmedetomidine reduces dosis of propofol/alfentanyl by pcs; level of sedation was deeper

Delgado, A. A. A. et al. Propofol vs traditional sedatives for sedation in endoscopy: A systematic review and meta-analysis. World J Gastrointest Endosc. 11. 573-588. 2019

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: prospective randomized double blind study</p> <p>Number of Patient: 140</p> <p>Recruiting Phase: 12 month</p> <p>Inclusion Criteria: diagnostic colonoscopy, 18-60 years ,</p> <p>Exclusion Criteria: chronic use of benzodizepines, neurolepti, anticonvulants hypersensitivities ti drugs used in the study, BMI > 35 kg/ m2, psychiatric patients, inadaequate preparation conditions</p>	<p>Intervention: iv Sedation</p> <p>Comparison: Midazolam as preanaesthetic followed by Propofol and fentanyl vs</p>	<p>Primary: reaction to the colonoscope intruduction cardiovascular cahnges mean dose of Propofol for induction Aldrete-Kroulik Scal bevor demission</p> <p>Secondary:</p> <p>Results: Reducing doses of prop ofol better satisfaction of patients with preanaesthetic midazolam</p> <p>Author's Conclusion: Better preanaesthetic midazolam</p>
Methodical Notes		
<p>Funding Sources: none</p> <p>COI: none</p> <p>Randomization: blinded randomisation</p> <p>Blinding: yes third Physican</p> <p>Dropout Rate/ITT-Analysis: none</p> <p>Notes:</p>		

Deng, C. et al. Comparison of nalbuphine and sufentanil for colonoscopy: A randomized controlled trial. PLoS One. 12. e0188901. 2017

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: prospective randomized double blinded trial</p> <p>Number of Patient: 240</p> <p>Recruiting Phase: 3 month</p> <p>Inclusion Criteria: age, BMI < 30 kgm2; ASA I_II,duration of colonoscopy < 30 min,</p> <p>Exclusion Criteria: abnormal recovery of anaesthesia, heart rate < 60 / min; RR > 180 mmHg, airway inflmmation, inability to communicate, Allegrty to Propofol or oiods</p>	<p>Intervention: Sedated Colonoscopy</p> <p>Comparison: Nalbuphine, sufentanil in combintion with propofol</p>	<p>Primary: Baseine vortal signs, BIS, Pain Scale, Pain relief , tozal Propofol dose</p> <p>Secondary:</p> <p>Results: No differences in analgesia. Differences: mor Nausea in N more respiratory Depression in S</p> <p>Author's Conclusion: Nal, reasonable alter´native to sufenty mainly in patients with respiratory problems</p>
Methodical Notes		

Funding Sources: none

COI: none

Randomization: double blind randomized sealed allocation envelope

Blinding: yes

Dropout Rate/ITT-Analysis: 230 randomized analysed 231

Notes:

Dinc, B. et al. The efficacy of intravenous hyoscine-N-butylbromide during colonoscopy: a prospective, randomized, double-blind, placebo-controlled study. Acta Gastroenterol Belg. 79. 179-85. 2016

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 121</p> <p>Recruitment Phase: December 2014 and February 2015</p> <p>Inclusion Criteria: ASA score of 1-2 and aged between 18 and 80 years that were referred to the surgical endoscopy unit for elective colonoscopy</p> <p>Exclusion Criteria: Patients aged < 18 and > 80 years, those with an ASA score of ≥ 3, those who had undergone abdominal surgery or colonic polypectomy, those with known allergy to HBB, and those with glaucoma, chronic renal failure, arrhythmia, myasthenia, pregnancy, obstructive uropathy, or autonomic dysfunction were excluded with inadequate bowel preparation and those in whom cecum intubation could not be performed were also excluded</p>	<p>Intervention: The patients received either 1 ml of HBB (20 mg) or 1 ml of 0.9% NaCl (saline) intravenously, administered for no longer than 30 s by an anesthesia nurse at the endoscopy room. Before the procedure, 1 mg/kg of propofol or 0.05 mg/kg of midazolam for sedation and 1 μg/kg of fentanyl for analgesia were administered intravenously. No additional sedation or analgesia was performed</p> <p>Comparison: Before the procedure, the study and placebo groups received 20 mg intravenous hyoscine-N-butylbromide and intravenous saline solution of the same amount, respectively.</p>	<p>Primary: cecal intubation time and total procedure time,</p> <p>Secondary: evaluate patient and endoscopist satisfaction.</p> <p>Results: Of 198 patients referred for elective colonoscopy, 121 were included (study group = 60, placebo group = 61). No differences were observed between the study and placebo groups in terms of demographic data, pre-procedure characteristics, and colonoscopic characteristics including the cecal intubation time, total procedure time, bowel preparation, sedation doses, hemodynamic findings, endoscopist satisfaction, patient comfort, and polyp detection rate. The only difference was an increase in the heart rate by 32% in the study group</p> <p>Author's Conclusion: Hyoscine-N-butylbromide did not reduce the time to reach the cecum and the total colonoscopy time, and patient and endoscopist satisfaction and polyp detection rate did not change. Furthermore, it was concluded that hyoscine-N-butylbromide can increase the risk of drug-related complications</p>

Methodical Notes

Funding Sources: From the administration of the medication to the end of the colonoscopy, the pulse oximeter alarm was put on silent mode and turned to a direction where it could not be seen by the endoscopy team. In this way, the tachycardia effect that can be seen with HBB was masked

COI: none

Randomization: stratified, The randomization list was accessible only to the anesthesia nurse

Blinding: The endoscopist, independent observer, patient, endoscopy nurse, and room staff were totally blinded to the medication

Dropout Rate/ITT-Analysis: 17 patients that met ≥ 1 exclusion criteria and 32 patients with inadequate bowel preparation (BBPS score of 0) were excluded 12 were excluded because of failed cecal intubation due to obstruction or patient intolerance and 16 were excluded because of requirement for additional sedation or analgesia. In total, 121 patients (60 in the study and 61 in the placebo group) were analyzed

Notes:

die o.g. Zusatzmedikation hatte keinen Einfluß auf die Zökumintubationsrate, ADR oder Patientenkomfort, auch war die Zeit zum Erreichen des Zökums in der Interventionsgruppe nicht kürzer als in der Placebogruppe . Allerdings war die HF erwartungsgemäß höher in der Interventionsgruppe als in der Placebogruppe. Frage erhöhtes kardiovaskuläres Risiko durch Zusatzmedikation ...

Do?anay, G. et al. Effects of alfentanil or fentanyl added to propofol for sedation in colonoscopy on cognitive functions: Randomized controlled trial. Turk J Gastroenterol. 28. 453-459. 2017

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: RCT</p> <p>Number of Patient: 150</p> <p>Recruiting Phase: not mentioned</p> <p>Inclusion Criteria: ASA 1-3, elective colonoscopy</p> <p>Exclusion Criteria: Mini-Mental Test (MMT) scores of <26, Amsterdam Preoperative Anxiety Information Scale (APAIS) scores of >10, advanced systemic disease orientation and cooperation disorders, history of neuropsychiatric disease, chronic alcohol dependency, morbid obesity, history of undergoing anesthesia in the last 7 days, and known allergy to the study drugs.</p>	<p>Intervention: randomization to different sedative regimens, routine colonoscopy</p> <p>Comparison:</p>	<p>Primary: no clear definition of primary and secondary endpoint</p> <p>Bispectral index values and vital signs Trieiger dot test (TDT) and Digit Symbol Sub-stitution Test (DSST) as psychomotoric tests of cognitive function at baseline and after procedure</p> <p>Secondary:</p> <p>Results: Bispectral index values were lower in propofol ($p<0.001$). DSST scores were higher in Group Alfentanil. TDT scores were higher in Group Propofol ($p<0.005$). Apnea incidence ($p=0.009$) and Observer's Assessment of Alertness/Sedation Scale scores ($p=0.002$) were also higher in Group Propofol. Patient satisfaction and endoscopist satisfaction were similar among all patients.</p> <p>Author's Conclusion: Compared with propofol-alfentanil and propofol-fentanyl, propofol alone is associated with an increased incidence of apnea, drug consumption, and reported pain. Propofol-alfentanil has a less negative effect on cognitive functions than propofol alone or propofol-fentanyl.</p>

Methodical Notes

Funding Sources: none

COI: none

Randomization: RCT to 3 groups

Blinding: not clearly mentioned only for psychomotoric tests

Dropout Rate/ITT-Analysis: 3 of 153

Notes:

RCT, blinding unclear, no clear definition of primary secondary endpoint

Eberl, S. et al. A randomised controlled trial: can acupuncture reduce drug requirement during analgesedation with propofol and alfentanil for colonoscopy? A study protocol. BMC Complement Altern Med. 15. 406. 2015

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 5</p> <p>Study type: Study not already performed just presentation of a design</p> <p>Number of Patient:</p> <p>Recruitment Phase:</p> <p>Inclusion Criteria:</p> <p>Exclusion Criteria:</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary:</p> <p>Secondary:</p> <p>Results:</p> <p>Author's Conclusion:</p>

Methodical Notes

Funding Sources:

COI:

Randomization:

Blinding:

Dropout Rate/ITT-Analysis:

Notes:

Eberl, S. et al. Satisfaction and safety using dexmedetomidine or propofol sedation during endoscopic oesophageal procedures: A randomised controlled trial. Eur J Anaesthesiol. 33. 631-7. 2016

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 63</p> <p>Recruitment Phase: between July 2012 and August 2013</p> <p>Inclusion Criteria: Inclusion criteria were age at least 18 years, American Society of Anesthesiologists' physical status 1 to 3, and provision of informed consent.</p> <p>Exclusion Criteria: Exclusion criteria were known allergic reaction to planned medication, SBP less than 80mmHg, heart rate (HR) less than 50 bpm, ejection fraction less than 30%,</p>	<p>Intervention: elective endoscopic oesophageal procedure</p> <p>Comparison: propofol vs. dexmedetomidine</p>	<p>Primary: We focused on the PSSI subscores for global satisfaction, procedural recall and sedation side-effects, and within the CSSI to the corresponding issues among gastroenterologists: global satisfaction and recovery.</p> <p>Secondary: Secondary outcomes were safety related, assessed by BP, HR and SpO2 during and after the procedure, and respiratory rate and noninvasive cardiac output during the procedure. Bradycardia during and after the procedure was defined as HR 20% lower than baseline.</p>

estimated glomerular filtration rate less than 15 ml min⁻¹ or impaired liver function (Child–Pugh Class A, B or C).

Results: Satisfaction of patients [median (IQR); group D, 5.0 (3.75 to 5.75) vs. group P, 6.25 (5.3 to 6.5)] and satisfaction of gastroenterologists [group D, 5.0 (4.4 to 5.8) vs. group P, 6.0 (5.4 to 6.0)] were lower in group D (both P<0.001). More patients in group D would not recommend this form of sedation to one of their friends (group D, 15 of 32 vs. group P, 1 of 31; P<0.001). Total 30 min after the procedure, heart rate [group D, 60bpm (52 to 69) vs. group P, 70bpm (60 to 81), P¼0.031] and SBP group D, 112mmHg (92 to 132) vs. group P, 120mmHg (108 to 132); P¼0.013] were significantly lower after dexmedetomidine sedation. There were no other differences in safety between groups.

Author's Conclusion: Compared with propofol, sedation with dexmedetomidine resulted in less satisfaction, and caused prolonged haemodynamic depression after endoscopic oesophageal procedures.

Methodical Notes

Funding Sources: none

COI: none

Randomization: yes

Blinding: yes

Dropout Rate/ITT-Analysis:

Notes:

El Shahawy, M. S. et al. The Influence of Adding Diphenhydramine Before Initiation of Moderate Sedation with Midazolam and Pethidine for Improving Quality of Colonoscopy. J Natl Med Assoc. 111. 648-655. 2019

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: RCT</p> <p>Number of Patient: 100</p> <p>Recruitment Phase: between May 2018 and March 2019</p> <p>Inclusion Criteria: between</p>	<p>Intervention: adding diphenhydramine before initiation of moderate sedation with midazolam and pethidine</p> <p>Comparison:</p>	<p>Primary: amount of pethidine and midazolam used, Quality of sedation pain scores</p> <p>Secondary: endoscopist satisfaction, patient satisfaction and tolerance without increasing the number of adverse events.</p> <p>Results: The mean dose of pethidine was significantly higher in placebo</p>

May 2018 and March 2019 for patients undergoing screening, surveillance, diagnostic colonoscopy. Patients aged 18 to 75 years

Exclusion Criteria: severe cardio-respiratory instabilities oxygen saturation less than 85%; blood pressure less than 80 or greater than 180 systolic or greater than 110 diastolic), ASA physical status of class III, IV or V, pregnancy, allergy to diphenhydramine, Pethidine, or midazolam, history of colon resection, chronic narcotic usage alcoholic usage, past experience with sedation problems, colonoscopic interventions, no consent

no significant differences between the two groups regarding midazolam Procedure time in placebo group was significantly longer than in diphenhydramine group, procedural pain in placebo group was significantly greater than diphenhydramine group recovery times were similar

Author's Conclusion: better sedation with diphenhydramine in colonoscopy (midazolam, pethidin)

Methodical Notes

Funding Sources:

COI:

Randomization: not clear

Blinding: double- blind

Dropout Rate/ITT-Analysis: 50 were excluded due to either meeting the exclusion criteria or declined to participate. From patients 100 none excluded

Notes:

RCT, combination therapy for routine colonoscopy

Fanti, L. et al. Target Controlled Infusion for non-anaesthesiologist propofol sedation during gastrointestinal endoscopy: The first double blind randomized controlled trial. Dig Liver Dis. 47. 566-71. 2015

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 140</p> <p>Recruitment Phase: from February 2014 to May 2014</p> <p>Inclusion Criteria: This randomized double-blind controlled trial involved 140 consecutive outpatients scheduled to undergo EGD or colonoscopy</p> <p>Exclusion Criteria:</p>	<p>Intervention: EGD or colonoscopy</p> <p>Comparison: standard moderate sedation vs. non-anaesthesiologist-administered propofol sedation</p>	<p>Primary: Discharge time, endoscopist satisfaction and patient satisfaction were recorded</p> <p>Secondary: NA</p> <p>Results: Colonoscopy: discharge time was significantly shorter in the propofol than the standard group (1.1 ± 0.3 vs. 5 ± 10.2 min, respectively; P = 0.03). Endoscopist satisfaction was significantly higher (98.3 ± 11.4/100 vs. 87.2 ± 12/100; P = 0.001); patient satisfaction was significantly higher (95 ± 9.3/100 vs. 85.5 ± 14.4/100; P = 0.002) in the propofol compared to the standard group. EGD: discharge time was not significantly different in the propofol and standard groups (1.1 ± 0.7 vs. 3.9 ± 9.2 min, respectively; P = 0.146). Endoscopist satisfaction was significantly higher (92.7 ± 14.3/100 vs. 82.8 ± 21.2/100; P = 0.03); patient satisfaction was significantly higher (93.8 ± 18.2/100 vs. 76.5 ± 25.2/100; P = 0.003). In the propofol group 94.3% of patients vs.</p>

Exclusion criteria were: clinically significant systemic disease (American Society of Anaesthesiologists (ASA) risk class III–IV), morbid obesity (BMI ≥ 30), severe sleep apnoea, predictably difficult airway management, Mallampati score >2, history of allergic reactions to study drugs, chronic use of opioids, psychiatric disorders, pregnancy, age <18.

71.4% of patients in standard group asked to receive the same sedation in the future (P = 0.021).

Author's Conclusion: Target Controlled Infusion is a promising method for non-anaesthesiologist-administered propofol sedation.

Methodical Notes

Funding Sources: NA

COI: none

Randomization: yes

Blinding: yes

Dropout Rate/ITT-Analysis:

Notes:

Fassoulaki, A. et al. Deep sedation for endoscopic cholangiopancreatography with or without pre or intraprocedural opioids: A double-blind randomised controlled trial. Eur J Anaesthesiol. 32. 602-8. 2015

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: Double blinded randomized Study</p> <p>Number of Patient: 57</p> <p>Recruiting Phase: 30</p> <p>Inclusion Criteria: ASA 1-3, 45 -75 years old, elective ercp</p> <p>Exclusion Criteria: chronic pain, sedation medication abuse , allergy</p>	<p>Intervention: Sedation during ERCp</p> <p>Comparison: lplacebo vs remifentanyl vs. fentanyl nasal</p>	<p>Primary: total propofol requirement</p> <p>Secondary: recovery, postinterventoal pain cognitive function</p> <p>Results: statistical significant difference only in the postinterventional pain, other measures not different. less pai in the fentanyl group the best</p> <p>Author's Conclusion: propofol requirement not different, but no pai ifentanyl group</p>

Methodical Notes

Funding Sources: none

COI: noine

Randomization: computer randomisation

Blinding: double

Dropout Rate/ITT-Analysis: 6

Notes:

Ferreira, A. O. et al. Non-anesthesiologist administration of propofol sedation for colonoscopy is safe in low risk patients: results of a noninferiority randomized controlled trial. Endoscopy. 48. 747-53. 2016

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 277</p> <p>Recruiting Phase: 1/2014 and 2/2015</p> <p>Inclusion Criteria: patients 18-80 years . ASA I and II , elective colonoscopy</p> <p>Exclusion Criteria: ASA > II, pregnancy, patients with intravenous drug use, predicted difficult airway and ventilation, as defined</p>	<p>Intervention: sedation non-anaesthesiologist administered / NAAP</p> <p>Comparison: comparing NAAP (group A) with anaesthesiologist administered sedation group (group B)</p>	<p>Primary: incidence of adverse events, minor an de sentinel.</p> <p>to evaluate sedation safety, colonoscopy quality and patient satisfaction with NAAP.</p> <p>Secondary: propofol dose, patient satisfaction, pain, colonoscopy quality indicators, and procedure and recovera times.</p> <p>Results: there were no differences in mean propofol dose, withdral time, painless colonoscopy, satisfaction, and amnesia. There were no sentinel adverse events. There were no differences in cecal intubation and adenom dwetection rate.</p> <p>Author's Conclusion: NAAP is equivalent to anaesthesiologist-administered sedation in the rate of adverse events in a lowe risk population</p>

Methodical Notes

Funding Sources:

COI: none

Randomization: www.randomization .com

Blinding: single blinded , only patients were kept blinjd

Dropout Rate/ITT-Analysis: none attendance n-5, respiratory infection n-3 at the time of procedure

Notes:

Forster, C. et al. Intravenous infusion of lidocaine significantly reduces propofol dose for colonoscopy: a randomised placebo-controlled study. Br J Anaesth. 121. 1059-1064. 2018

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: RCT</p> <p>Number of Patient: 42</p> <p>Recruiting Phase: not clear</p> <p>Inclusion Criteria: ASA 1-2 patients undergoing colonoscopy</p>	<p>Intervention: colonoscopy sedation with propofol ketamine plus lidocaine or placebo</p> <p>Comparison: sedation with propofol ketamine plus lidocaine or placebo</p>	<p>Primary: propofol requirements</p> <p>Secondary: number of oxygen desaturation episodes, endoscopists' working conditions, discharge time to the recovery room, post-colonoscopy pain, fatigue.</p> <p>Results: significant reduction in propofol requirements for lidocaine Doses of ketamine were similar Number of episodes of oxygen desaturation, endoscopists' comfort, and times for discharge to</p>

<p>Exclusion age<18and>70yr,renal failure,liver insufficiency,epilepsy, major cardiac arrhythmia, and allergy to lidocaine</p>	<p>Criteria:</p>	<p>the recovery room weres imilar in both groups. Post-colonoscopy pain (P<0.01) and fatigue (P¼0.03) were significantly lower in the lidocaine group.</p> <p>Author's Conclusion: Intravenous infusion of lidocaine resulted in a 50% reduction in propofol dose requirements during colo-noscopy. Immediate post-colonoscopy pain and fatigue were also improved by lidocaine.</p>
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Methodical Notes

Funding Sources: none

COI: none

Randomization: yes, two groups using sealed envelopes.

Blinding: yes, double blind

Dropout Rate/ITT-Analysis: 2 of 42

Notes:

RCT, blinded
propofol sparring with lidocaine

Gedeon, M. et al. Use of noninvasive positive pressure ventilation in patients with severe obesity undergoing esophagogastroduodenoscopy: a randomized controlled trial. Surg Obes Relat Dis. 15. 1589-1594. 2019

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT in a community hospital endoscopy suite</p> <p>Number of Patient: 56 (A total of 208 patients were screened between April 2017 to April 2018 and 56 patients completed the procedure (28patients per study arm)</p> <p>Recruiting Phase: Participants were identified from 3 physician practices from April 2017 to April 2018.</p> <p>Inclusion Criteria: EGD Obesity (body mass index of 40 to 60)</p> <p>Exclusion Criteria: The exclusion criteria were as follows: pregnancy, BMI >60 or <40, active substance abuse (alcohol, benzodiazepines,</p>	<p>Intervention: EGD</p> <p>Comparison: treatment (NIPPV) and control (nasal cannula, NIPPV for rescue) groups.</p>	<p>Primary: Primary endpoints were oxygen desaturation events !94% and oxygen desaturation events ,90% requiring intervention.</p> <p>Secondary: A secondary endpoint was the use of NIPPVas a rescue maneuver.</p> <p>Results: A statistically significant difference was noted between the groups for desaturation events !94% (14.3% of treatment and 57.1% of control groups, P 5.002). There was also a statistically significant difference in the risk of a desaturation event ,90% requiring intervention (3.5% of treatment and 28.6% of control groups, P 5.025). All patients in the control group who developed desaturation events requiring intervention were rescued with NIPPV.</p> <p>Author's Conclusion: This study demonstrated the successful use of NIPPV as an adjunct to decrease the incidence of desaturation events in patients with severe obesity undergoing EGD. It also suggests that NIPPV can be used as a rescue maneuver.</p>

and illicit drugs), previous weight loss or gastric surgery, current tobacco use, lung disease (chronic obstructive pulmonary disease, asthma), history of upper respiratory tract infection within 2 weeks of the procedure, baseline oxygen saturation <94%, and patients undergoing combined EGD and colonoscopy

Methodical Notes

Funding Sources: not mentioned

COI: The authors have no commercial associations that might be a conflict of interest in relation to this study.

Randomization: yes

Blinding: none

Dropout Rate/ITT-Analysis: 152 patients (of 208) did not complete the procedure

Notes:
RCT in a community hospital endoscopy suite

Gemma, M. et al. Swallowing Impairment During Propofol Target-Controlled Infusion. Anesth Analg. 122. 48-54. 2016

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: RCT</p> <p>Number of Patient: 80</p> <p>Recruiting Phase: Between May 2012 and May 2013</p> <p>Inclusion Criteria: elective gastrointestinal endoscopy under propofol TCI sedation</p> <p>Exclusion Criteria: Exclusion criteria were as follows: clinical evidence or history of swallowing disorders, age <18 years, pregnancy, emergent procedure, indwelling feeding</p>	<p>Intervention: gastrointestinal endoscopy</p> <p>Comparison: Evaluations were obtained within each patient at 3 target effect-site propofol concentrations of 2, 3, and 4 µg/mL (Marsh model)</p>	<p>Primary: Fiberoptic endoscopic evaluation of swallowing (FEES)</p> <p>Secondary: NA</p> <p>Results: At 2 µg/mL TCI, the OAAS score was 2 in 21 (26.25%) patients and 1 in 59 (73.75%). The OAAS score was 1 in all patients at 3 and 4 µg/mL TCI target. At 3 µg/mL TCI target, 19 (24.36%) patients had a DSS = 3 and 18 patients (23.08%) had a PAS = 7–8 (severe swallowing impairment). DSS was associated with increasing age (5-year odds ratio [OR] 1.53 [1.22–1.93]; P < 0.001), body mass index (BMI; OR 1.24 [1.08–1.42]; P = 0.002), and TCI target (OR 15.80 [7.76–32.20]; P < 0.001). In an alternative model incorporating OAAS instead of TCI target, DSS was associated with increasing age (5-year OR 1.13 [1.02–1.24]; P = 0.014) and BMI (OR 1.08 [1.02–1.15]; P = 0.006) and decreasing OAAS (OR 0.05 [0.006–0.36]; P = 0.003). PAS was associated with increasing age (5-year OR 1.09 [1.04–1.15]; P < 0.001), BMI (OR 1.23 [1.07–1.41]; P = 0.003), and TCI target (OR 15.23 [7.45–31.16]; P < 0.001). In an alternative model incorporating OAAS instead of TCI target, PAS was associated with increasing age (5-year OR 1.14 [1.04–1.26]; P = 0.007) and BMI (OR 1.09 [1.02–1.15]; P = 0.006) and decreasing OAAS (OR 0.05 [0.006–0.41]; P = 0.005).</p> <p>Author's Conclusion: Aspiration due to swallowing impairment may occur during deep sedation produced by propofol at commonly used TCI targets. TCI targets are</p>

tube, respiratory disease with Spo2 <95% or with a need for supplemental oxygen, neurological disease, psychiatric disease, use of antidepressant drugs, insulin-dependent diabetes mellitus, ASA physical status ≥IV, previous tracheostomy, otolaryngology surgery or radiotherapy, and previous surgery for mouth, pharyngeal, or esophageal cancer. Patients were also excluded if major glottis abnormalities (e.g., bilateral vocal cord palsy, benign or malignant laryngeal neoplasms protruding in the glottis plane) were found during the study.

predictors of swallowing impairment; increased age and high BMI are concomitant risk factors.

Methodical Notes

Funding Sources: none

COI: none

Randomization: no

Blinding: no

Dropout Rate/ITT-Analysis:

Notes:

Goyal, R. et al. A randomized, controlled trial to compare the efficacy and safety profile of a dexmedetomidine-ketamine combination with a propofol-fentanyl combination for ERCP. Gastrointest Endosc. 83. 928-33. 2016

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: RCT</p> <p>Number of Patient: 83</p> <p>Recruitment Phase: NA</p> <p>Inclusion Criteria: The patients included in the study</p>	<p>Intervention: ERCP</p> <p>Comparison: dexmedetomidine ketamine vs. propofol fentanyl</p>	<p>Primary: The primary outcome of the study was the SpO2</p> <p>Secondary: NA</p> <p>Results: The mean values of the hemodynamic and respiratory parameters were in clinically acceptable range, but there were more episodes of hypotension (19%), bradycardia (4.7%) and fall in oxygen saturation (SpO2 <80% in 11.9% and SpO2 <90% for >10 s in 42.8%) in the</p>

were those scheduled for elective ERCP aged between 18 to 75 years and ASA I-III

Exclusion Criteria:
(excluding those diagnosed as hypertension, coronary heart disease and central nervous system abnormality). Patients with a known allergy to the study drugs, pregnancy, and anticipated difficult airway were excluded from the study

group PF. The procedure could be completed in all the patients but was interrupted in 6 patients in the group PF because of desaturation (5) or sudden patient movement (one). The recovery time was higher in the group DK than in the group PF.

Author's Conclusion: The sedation-related adverse effects were significantly lesser but the recovery time was longer with dexmedetomidine and ketamine.

Methodical Notes

Funding Sources: none

COI: none

Randomization: yes

Blinding: partially

Dropout Rate/ITT-Analysis:

Notes:

Gu, Z. et al. Doxapram alleviates low SpO₂ induced by the combination of propofol and fentanyl during painless gastrointestinal endoscopy. BMC Anesthesiol. 19. 216. 2019

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: Prospective randomized blinded study</p> <p>Number of Patient: 110</p> <p>Recruiting Phase: 6 month</p> <p>Inclusion Criteria: All patients over 18 years of age scheduled for a diagnostic gastrointestinal endoscopy</p> <p>Exclusion Criteria: medical history such as medication of diazepam, neuroleptics, and anticonvulsants that interfere with heart rate; anaphylaxis to drugs used in the study; cardiovascular diseases such as hypertension, arrhythmia, abnormal electrocardiogram (ECG); abnormal liver and/or kidney functions; lung disease, such as chronic obstructive pulmonary disease (COPD); abdominal laparotomy; body mass index</p>	<p>Intervention: GIU Endoscopy in sadation</p> <p>Comparison: combination of propofol and fentanyl compared with additional saline or doxapram .</p>	<p>Primary: propofol consumption and examination Duration low SpO₂ oxygenation with a face mask treated with jaw Liftingassisted respiration compared MAP and HR</p> <p>Secondary:</p> <p>Results: There were no statistical differences in propofol consumption and examination duration between the two groups. Twenty-six patients in group S experienced low SpO₂ versus 10 in group D (P = 0.001). Nineteen patients in group S underwent oxygenation with a face mask in contrast to 8 in group D (P = 0.015). Eighteen patients in group S were treated with jaw lifting compared to 5 in group D (P = 0.002). Four patients in group S underwent assisted respiration compared to 2 in group D (without statistical difference). The average oxygen saturation in group S was significantly lower than that in group D at 1, 2 and 3 min after propofol injection (P < 0.001, P = 0.001 and P = 0.020, respectively). There were no</p>

above 30 kg·m⁻²; age over 75 years or below 18 years; clinical suspicion of intestinal subocclusion or stenosis; colorectal tumors; psychiatric patients; and requirement for complex therapeutic procedures during diagnostic colonoscopy.

statistical differences in oxygen saturation at other time points. There were no statistical differences in MAP and HR (except for the time point of 1 min after the induction) between the two groups.

Author's Conclusion: Low dose of doxapram can effectively alleviate low SpO₂ in painless gastrointestinal endoscopy with intravenous propofol, without affecting propofol consumption, examination duration, MAP, or HR.

Methodical Notes

Funding Sources: none

COI: non

Randomization: computed

Blinding: yes double

Dropout Rate/ITT-Analysis: none

Notes:

Han, S. J. et al. Efficacy of midazolam- versus propofol-based sedations by non-anesthesiologists during therapeutic endoscopic retrograde cholangiopancreatography in patients aged over 80 years. Dig Endosc. 29. 369-376. 2017

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: Randomised, prospective controlled study</p> <p>Number of Patient: 109</p> <p>Recruitment Phase: 2,5 years</p> <p>Inclusion Criteria: - Patients aged 80 years or older - ASA I-IV - naive papilla</p> <p>Exclusion Criteria: - uncontrolled coagulopathy - allergy to the study drugs - sedative or alcohol abuse - history of a sedation-associated complication</p>	<p>Intervention: Midazolam vs. propofol-based sedation plus fentanyl</p> <p>Comparison: safety and efficacy</p>	<p>Primary: Safety: cardiopulmonary components: - hypoxia - increased oxygen supply - bradycardia - tachycardia - hypotension</p> <p>Efficacy: - satisfaction with sedation (patient, endoscopist, nurse) - pain (10 points VAS)</p> <p>Secondary: - recovery time - ERCP-related complications - procedure outcome</p> <p>Results: No significant difference regarding safety and efficacy, recovering time, ERCP related complications, procedure outcome.</p> <p>Author's Conclusion: Midazolam and propofol based sedation are safe and effective in patients aged 80yrs and older in therapeutic ERCP. Based on the availability of an antidote and the tendency for sedation safety, midazolambased sedation may be preferred in patients over 80 years of age undergoing non-anesthesiologist-induced sedation.</p>

- inability to provide informed consent

Methodical Notes

Funding Sources: Soonchunhyang University Research Fund

COI: None

Randomization: computer based

Blinding: Blinding of the nurse and endoscopist only partly present, 100% to the patient

Dropout Rate/ITT-Analysis: 9 drop outs /109 enrolled pts.

Notes:

Good methodological quality of this study

Limitations: number of patients too small for capturing rare complications, single center study, asian population, low sedation depth, mean low body weight, delayed complications e.g. falls were not recorded

Han, S. J. et al. Etomidate Sedation for Advanced Endoscopic Procedures. Dig Dis Sci. 64. 144-151. 2019

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 186</p> <p>Recruiting Phase: August 2016 to January 2017</p> <p>Inclusion Criteria: patients undergoing advanced endoscopy (ERCP, ESD...)</p> <p>Exclusion Criteria: ASA class IV–V, hypersensitivity to drug or milk fat, history of complications of sedation, obstructive sleep apnea–hypopnea syndrome (OSAHS), history of adre-nal insufficiency, and refusal to participate.</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary: efficacy measured on a 10-point visual analog scale (VAS) and safety</p> <p>Secondary:</p> <p>Results: BES did not show noninferiority in terms of overall patient satisfaction Among endoscopists and nurses, BES showed noninferiority to BPS Incidence of cardiopulmonary adverse events was lower in the BES group (27.7 versus 14.1 %, p = 0.023). Hypoxia occurred in 5.3 and 1.1 % of patients in the BPS and BES group (p = 0.211). BES had lower risk of overall cardiopulmonary adverse events (odds ratio 0.401, p = 0.018).</p> <p>Author's Conclusion: BES was not noninferior to BPS in terms of patient satisfaction. However, BES showed better safety outcomes in terms of cardiopulmonary adverse events</p>

Methodical Notes

Funding Sources: Soonchunhyang University Research Fund

COI: none

Randomization: yes

Blinding: yes

Dropout Rate/ITT-Analysis: 8 of 200

Notes:

RCT, blinded

Hayashi, T. et al. Lidocaine spray alone is similar to spray plus viscous solution for pharyngeal observation during transoral endoscopy: a clinical randomized trial. *Endosc Int Open*. 5. E47-e53. 2017

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 327</p> <p>Recruiting Phase: January and March 2015</p> <p>Inclusion Criteria: Upper GI endoscopy</p> <p>Exclusion Criteria: surgical or endoscopic mucosal resection for pharyngeal cancer his-tory of allergy of lidocaine, difficulty participating in the test because of psychosis or psychotic symptoms</p>	<p>Intervention: endoscopy with or without dual treatment of lidocain</p> <p>Comparison:</p>	<p>Primary: pharyngeal observable sites (non-inferiority test)</p> <p>Secondary: pain by visual analogue scale, observation time, and the number of gag reflexes</p> <p>Results: no differences in pain, observation time, or number of gag reflexes no differences between the two groups for the number of pharyngeal observation sites and the number of gag reflexes. number of gag reflexes was higher in the spray group compared to the combination group</p> <p>Author's Conclusion: Lidocaine spray for pharyngeal anesthesia was not in-ferior to lidocaine spray and viscous solution in terms of pharyngeal observation. lidocaine viscous solution was unnecessary for pharyngeal observation</p>

Methodical Notes

Funding Sources: none

COI: none

Randomization: yes

Blinding: yes

Dropout Rate/ITT-Analysis: n.a.

Notes:
RCT

Haytural, C. et al. Comparison of Propofol, Propofol-Remifentanil, and Propofol-Fentanyl Administrations with Each Other Used for the Sedation of Patients to Undergo ERCP. *Biomed Res Int*. 2015. 465465. 2015

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: RCT</p> <p>Number of Patient: 90</p> <p>Recruiting Phase: na</p> <p>Inclusion Criteria: ASA I -III, elective ERCP, 18- 70 years old,</p> <p>Exclusion Criteria: prgnant, > 70 years old, epileptic, allergy to medicine used in the trial, use or</p>	<p>Intervention: ERCP</p> <p>Comparison: Proofol vs. Propofol + Remifentanil versus propofol plus fentanil</p>	<p>Primary: SSpO2 lower 95, hypocapnia,apnea,nausea,vomiting, hypotension,hypertension,bradycardia, , comfortlevel by the gastroenterologosist</p> <p>Secondary:</p> <p>Results: Significant differenes in propofol doses and in post interventional pain. Most in Propofol mono group, most dose in propofol monogroup most pain in propofol mono, best gastroenterologist satisfactory in combination groups</p> <p>Author's Conclusion: Combination of propofol with a</p>

abuse of opioids, sedatives, analgesics, having had a condition requiring emergency intervention, having undergone surgery between the last 72 hours,

opioid provides a effective and reliable sedation, reduced dose of propofol increased practitioner satisfaction, decreased pain level and provides haemodynamic stability

Methodical Notes

Funding Sources: none

COI: none

Randomization: randomly divided no other comment

Blinding: none

Dropout Rate/ITT-Analysis: lost of two in propofol mono

Notes:

Heo, J. et al. Effects of bispectral index monitoring as an adjunct to nurse-administered propofol combined sedation during colonoscopy: a randomized clinical trial. Korean J Intern Med. 31. 260-6. 2016

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 280</p> <p>Recruiting Phase: February 2012 and August 2013.</p> <p>Inclusion Criteria: routine colonoscopy</p> <p>Exclusion Criteria: age < 18 years, critical illness, pregnancy, long-term use of benzodiazepines or opiates, history of allergy to eggs, past history of abdominal surgery, and other contraindications for endoscopy such as uncooperativeness, or signs of peritonitis.</p>	<p>Intervention: routine colonoscopy, 4 groups 2 experienced 2 unexperienced endoscopists subgroup of monitoring: BIS vs. standard</p> <p>Comparison:</p>	<p>Primary: Total dose of propofol and midazolam</p> <p>Secondary: procedure time, patient pain level during the colonoscopy, satisfaction level of patients and endoscopists, and adverse events were compared between the BIS group and the MOAA/S group.</p> <p>Results: mean BIS value throughout the procedure was 74.3 ± 6.7 for all 141 patients in the BIS group. The mean total propofol dose administered in the BIS group was higher than that in the MOAA/S group, independently of the endoscopists' experience level</p> <p>total dose of propofol administered was not significantly different between the inexperienced endoscopist group and the expert endoscopist group, both with and without the use of BIS</p> <p>Author's Conclusion: BIS monitoring was not effective for titrating the dose of propofol during colonoscopy, irrespective of colonoscopist experience.</p>

Methodical Notes

Funding Sources: Biomedical Research Institute, Kyung-pook National University Hospital (2012)

COI: no

Randomization: yes

Blinding: staff performing post-procedural tests

Dropout Rate/ITT-Analysis: 20 of 300, 280 patients finally in study

Notes:

RCT, evaluation of bispectral index monitoring as tool for sedation titration during colonoscopy

Hong, M. J. et al. Randomized comparison of recovery time after use of remifentanyl alone versus midazolam and meperidine for colonoscopy anesthesia. Dig Endosc. 27. 113-20. 2015

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: RCT</p> <p>Number of Patient: 54</p> <p>Recruitment Phase: NA</p> <p>Inclusion Criteria: Patients of the American Society of Anesthesiologists physical status 1–2, undergoing elective colonoscopy under MAC, were recruited after provision of written informed consent and were randomly assigned to receive one of two regimens</p> <p>Exclusion Criteria: Exclusion criteria were as follows: refusal or inability to provide written consent, age <19 years, pregnancy, previous history of large bowel surgery, a psychiatric disorder, an addiction to opiates/sedatives, a previous history of adverse events to any drug used in the present study, and performance of any additional diagnostic procedure after completion of colonoscopy.</p>	<p>Intervention: Colonoscopy</p> <p>Comparison: remifentanyl alone versus midazolam and meperidine</p>	<p>Primary: Times to achieve Aldrete score = 10 (Table 1) were determined for intergroup comparisons of patient recovery time as the primary outcome.</p> <p>Secondary: Extents of distress/satisfaction (100-mmVAS) of patients and endoscopist were determined.</p> <p>Results: Group-R showed a significantly shorter recovery time than group-MM (median [25–75%], 0 [0–10] vs 30 [15–30] min, $P < 0.001$). Group-R showed significantly higher bispectral-index values during colonoscopy (92 [85–96] vs 84 [80–87], $P = 0.001$); a higher incidence of recall of explanations given during and after colonoscopy (100 vs 48% and 96 vs 52%, both $P < 0.001$); and a lower distress score (visual analog scale 30/100 vs 37/100 mm, $P = 0.002$), than did group-MM. Neither extent of pain, incidence of hemodynamic instability nor incidence of respiratory depression differed between the groups.</p> <p>Author's Conclusion: Remifentanyl for colonoscopy afforded faster recovery compared to midazolam-meperidine combination. It also provided greater patient–endoscopist communication and satisfaction with comparable patient analgesia and cardiorespiratory profile during colonoscopy.</p>

Methodical Notes

Funding Sources: none

COI: none

Randomization: yes

Blinding: partially

Dropout Rate/ITT-Analysis:

Notes:

Izanloo, A. et al. Efficacy of Conversational Hypnosis and Propofol in Reducing Adverse Effects of Endoscopy. Anesth Pain Med. 5. e27695. 2015

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: RCT</p> <p>Number of Patient: 186</p> <p>Recruitment Phase: October to January 2013</p> <p>Inclusion Criteria: middle school education, 18-85 age, lacking any history of psychological problem, and submitting a consent form for participating in the study</p> <p>Exclusion Criteria: opioids or benzo use</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary: reduction anxiety</p> <p>Secondary: endoscopy related complications, nausea, vomiting</p> <p>Results: reduction of anxiety after endoscopy no significant result for reduction of complications such as vomiting, nausea</p> <p>Author's Conclusion: reduce anxiety, lower number of complications although no statistical difference</p>

Methodical Notes

Funding Sources: education and research department of Razavi hospital

COI: none

Randomization: yes

Blinding: not possible

Dropout Rate/ITT-Analysis: 46 patients in control group!

Notes:

simple randomization, blinding not possible for hypnosis

Jokelainen, J. et al. Doxapram as an additive to propofol sedation for endoscopic retrograde cholangiopancreatography: a placebo-controlled, randomized, double-blinded study. Surg Endosc. 34. 5477-5483. 2020

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: Prospective randomized double blind study</p> <p>Number of Patient: 56</p> <p>Recruitment Phase: 2 month</p> <p>Inclusion Criteria: patients scheduled for an ERCP</p> <p>Exclusion Criteria: criteria were age > 75, epilepsy, coronary artery</p>	<p>Intervention: ERCP in sedation</p> <p>Comparison: doxapram as an initial 1 mg/kg bolus and an infusion of 1 mg/kg/h (group DOX) or placebo (group P) during propofol sedation for ERCP</p>	<p>Primary: Main outcome measures were apneic episodes and hypoxemia defined as SpO2 < 90%.</p> <p>Secondary: SpO2, blood pressure, heart rate, rate of breathing and end-tidal CO2, BiS and mOAAS, during the procedure blood pressure, heart rate, rate of breathing, pain intensity, Gilham score, and Aldrete score during recovery, patient and endoscopist satisfaction</p> <p>Results: There were no statistically significant differences in apneic episodes (p = 0.18) or hypoxemia (p = 0.53) between the groups. There was a statistically significant rise in etCO2</p>

disease (stable or unstable angina pectoris), chronic obstructive pulmonary disease, acute alcohol withdrawal syndrome, allergy to propofol, or doxapram.

levels in both groups, but the rise was smaller in group P. There was a statistically significant rise in Bispectral Index ($p = 0.002$) but not modified Observer's Assessment of Agitation/Sedation ($p = 0.21$) in group P. There were no statistically significant differences in any other measured parameters.

Author's Conclusion: Conclusions Doxapram was not effective in reducing respiratory depression caused by deep propofol sedation during ERCP. Further studies are warranted using different sedation protocols and dosing regimens

Methodical Notes

Funding Sources: none

COI: none

Randomization: computer-generated table of random numbers

Blinding: double

Dropout Rate/ITT-Analysis: 56, eligible 83 , after randomisation no loss of patients

Notes:

Julián Gómez, L. et al. A clinical trial comparing propofol versus propofol plus midazolam in diagnostic endoscopy of patients with a low anesthetic risk. Rev Esp Enferm Dig. 110. 691-698. 2018

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: RCT double blinded</p> <p>Number of Patient: 83 Pats in total; 42 Pats Propofol/Placebo - 41 Pats Propofol/Midazolam</p> <p>Recruiting Phase: 2 months ; exact recruiting phase not specified</p> <p>Inclusion Criteria: 18-80 yrs. ASA I-II</p> <p>Exclusion Criteria: Pregnancy Alcohol and drug abuse Relevant cardiopulmonary disease, severe sleep apnea syndrome Sedativa administered 24 h before</p>	<p>Intervention: Diagnostic gastroscopy</p> <p>Comparison: P/P vs M/P</p>	<p>Primary: Safety: frequency of complications Efficiency : Time of the procedure, induction and recovery time Quality of endoscopy</p> <p>Secondary: Not specified</p> <p>Results: Lower dose of Propofol in the M/P group $p < 0.01$ No significant differences in adverse effects, overall time of exploration, quality of endoscopic exploration, patient's satisfaction</p> <p>Author's Conclusion: Use of M/P does not effect the exploration time and a lower dose of propofol can be used and it is safe as administering propofol as monotherapy</p>

Methodical Notes

Funding Sources: Not stated

COI: None

Randomization: Yes

Blinding: Yes

Dropout Rate/ITT-Analysis: None

Notes:

Methodically o.k., but very small numbers

Jung, J. H. et al. Neurologic Safety of Etomidate-Based Sedation during Upper Endoscopy in Patients with Liver Cirrhosis Compared with Propofol: A Double-Blind, Randomized Controlled Trial. J Clin Med. 9. . 2020

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 126</p> <p>Recruiting Phase: December 2017 to December 2019</p> <p>Inclusion Criteria: all patients aged 18–80 years with chronic liver disease who had evidence of LC by clinical, laboratory, and/or pathologic criteria (Child–Pugh class A, B, or C) and were undergoing diagnostic or therapeutic upper gastrointestinal (GI) endoscopy</p> <p>Exclusion Criteria: a) clinically detectable hepatic encephalopathy, psychiatric illness, mental impairment, or active neurological impairment; (b) recent administration of neuro-active drugs that might interfere with etomidate or propofol metabolism; (c) a history of prior adverse events with sedative agents; (d) known allergy to egg products, tofu, soy beans, propofol, or etomidate; (e) known adrenocortical insufficiency, long-term steroid therapy, or porphyria; (f) renal impairment with serum creatinine >2 mg/dL; (g) breast-feeding or pregnant; (h) willingness to have endoscopy without sedation; and (i) refusal to participate in the study or provide informed consent.</p>	<p>Intervention: EGD with propofol or etomidat</p> <p>Comparison: EGD with propofol or etomidat</p>	<p>Primary: number connection test (NCT)</p> <p>Secondary: factors for the safety of sedatives during endoscopy</p> <p>Results: NCT times were significantly lower in the etomidate group than in the propofol group severe or very severe degree of encephalopathy was higher in the propofol group but was not significantly different. Pharmacological properties and the overall incidence of respiratory and cardiovascular events did not differ significantly between the groups.</p> <p>Author's Conclusion: Etomidate-based sedation exacerbates neither subclinical nor overt hepatic encephalopathy. It guarantees efficacies similar to those of propofol regarding rapid sedation, fast recovery, and early discharge, with no increased risk of adverse respiratory or cardiovascular events in patients with LC</p>

Methodical Notes

Funding Sources: SK Chemical Research Fund of The Korean Society of Gastroenterology (2018)

COI: none

Randomization: yes, computer-generated random numbers

Blinding: yes

Dropout Rate/ITT-Analysis: none

Notes:

RCT, different sedation in patients with Liver cirrhosis propofol vs. etomidat

K?I?c, E. et al. Alfentanil versus ketamine combined with propofol for sedation during upper gastrointestinal system endoscopy in morbidly obese patients. Saudi Med J. 37. 1191-1195. 2016

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: RCT double blind</p> <p>Number of Patient: 52pts; 26pts in each group A/P vs K/P</p> <p>Recruitment Phase: 1/2014-1/2015 (?)</p> <p>Inclusion Criteria: BMI 45-60 kg/m² ASA I-III</p> <p>Exclusion Criteria: Severe hepatorenal, neuromuscular, pulmonary or neuropsychiatric disorder</p>	<p>Intervention: Upper GI-endoscopy</p> <p>Comparison: Alfentanil/Propofol vs Ketamine/Propofol</p>	<p>Primary: Safety Total amount of propofol Time to onset of sedation and duration of sedation Patient/Physician satisfaction</p> <p>Secondary: not specified</p> <p>Results: Time to onset of sedation, duration of sedation shorter and total amount of propofol significantly lower in A/P group Satisfaction scores and adverse effects without significance</p> <p>Author's Conclusion: A/P and K/P sedation are both safe options for morbidly obese patients Total Propofol consumption higher in combination with Ketamine</p>

Methodical Notes

Funding Sources: Not stated

COI: Not stated

Randomization: Yes

Blinding: Yes, but open questions concerning details

Dropout Rate/ITT-Analysis: none

Notes:

Not evident, who administered sedation and how the person was blinded
no details about Upper GI endoscopy

Kashiwagi, K. et al. Prospective, randomized, placebo-controlled trial evaluating the efficacy and safety of propofol sedation by anesthesiologists and gastroenterologist-led teams using computer-assisted personalized sedation during upper and lower gastrointestinal endoscopy. Dig Endosc. 28. 657-64. 2016

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 272</p> <p>Recruitment Phase: Oktober 2013-März 2014</p> <p>Inclusion Criteria: > 20 Jahre, ASA I-II, geplante ÖGD oder Colo</p> <p>Exclusion Criteria: Allergie</p>	<p>Intervention: Propofol Sedierung über SEDASYS-System oder Infusion mit Sojabohnenöl (Intralipid fluid solution Fresenius)</p> <p>Comparison: safety and efficacy of propofol sedation vs. no sedation</p>	<p>Primary: ability to maintain moderate sedation (MOAA/S scores of 2-4 bei > 50% von allen Messungen)</p> <p>Secondary: patient and clinical satisfaction</p> <p>Results: proportion of subjects maintained in moderate sedation was significantly higher than in the no sedation group</p> <p>Author's Conclusion: Moderate</p>

Propofol/Soja, Alkohol-Drogenabusus, Sättigung < 90% bei Raumluft, Schwangerschaft/Stillen, BMI > 35

sedation can be achieved an maintained with propofol, improving both patient and physicians satisfaction

Methodical Notes

Funding Sources: Fa. Ethicon

COI: no

Randomization: yes

Blinding: yes

Dropout Rate/ITT-Analysis: 11 patients

Notes:

Kayaalt?, S. et al. Safety of applying midazolam-ketamine-propofol sedation combination under the supervision of endoscopy nurse with patient-controlled analgesia pump in colonoscopy. World J Clin Cases. 6. 1146-1154. 2018

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: RCT</p> <p>Number of Patient: 60</p> <p>Recruiting Phase: NA</p> <p>Inclusion Criteria: the American Statistical Association (ASA) I - II 60 patients who underwent elective colonoscopy between 18 and 75 years of age.</p> <p>Exclusion Criteria: ASA III-IV-V patients who had uncontrolled chronic disease (uncontrolled diabetes mellitus and hypertension), severe respiratory and cardiopulmonary insufficiency or liver and kidney failure who did not accept the method were not included in the study. Patients with a history of long-term analgesic, opioid, and sedative use, with hypersensitivity to soybean oil or eggs, and drugs used in our study, with pregnancy or suspected pregnancy or lactating, and with the use of antipsychotic or antidepressant drugs were also excluded in the study.</p>	<p>Intervention: colonoscopy</p> <p>Comparison: anaesthetist vs. nurse supervision of sedation</p>	<p>Primary: patient satisfaction, which is one of our primary goals.</p> <p>Secondary: NA</p> <p>Results: Total propofol consumption in the SSEN group was significantly higher (P < 0.05) than that in the SSA group. When the groups were compared in terms of VAS score, recovery time, patient satisfaction, recall of the procedure, re-preference for the same method in case of re-endoscopy, and side effects, there were no significant differences (P > 0.05) between the two groups. No long-term required intervention side effects were observed in either group.</p> <p>Author's Conclusion: Colonoscopy sedation in ASA I - II patients can be safely performed by an endoscopy nurse using PCA pump with the incidence of side effects and patient satisfaction levels similar to sedation under anaesthetist supervision.</p>

Methodical Notes

Funding Sources: none

COI: none

Randomization: yes

Blinding: no

Dropout Rate/ITT-Analysis:

Notes:

Khan, K. J. et al. The Benefit of Fentanyl in Effective Sedation and Quality of Upper Endoscopy: A Double-Blinded Randomized Trial of Fentanyl Added to Midazolam Versus Midazolam Alone for Sedation. J Can Assoc Gastroenterol. 2. 86-90. 2019

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: Rct</p> <p>Number of Patient: 137</p> <p>Recruitment Phase: March-Dezember 2012</p> <p>Inclusion Criteria: Alter 18-65, ambulante Routine-ÖGD</p> <p>Exclusion Criteria: geistige Beeinträchtigung, SS, Gewicht <55kg, Notfall-Untersuchung, Allergie auf Fentanyl/Midazolam, Betäubungsmittelabusus, therapeutische Untersuchung, kardiorespiratorische Begeleiterkrankungen, Schlaf-Apnoe, Leberzirrhose, Niereninsuffizienz</p>	<p>Intervention: 100 mcg Fentanyl i.v.</p> <p>Comparison: placebo i.v.</p>	<p>Primary: satisfaction with sedation</p> <p>Secondary: adverse effects of fentanyl, effect on procedure</p> <p>Results: endoscopist and nurse rated sedation significantly better in fentanyl group, no difference in patient satisfaction. Significantly shorter procedure time 8,5 vs. 11.1 min</p> <p>Author's Conclusion: adding fentanyl leads to a improved sedation for endoscopist and nurse, but did not affect the patient experience of sedation. Significant shorter procedure time with fentanyl.</p>

Methodical Notes

Funding Sources: no

COI: no

Randomization: ja

Blinding: no

Dropout Rate/ITT-Analysis: 2 patients

Notes:

nahezu ausschließlich ASA I Patienten!

Kim, D. B. et al. Propofol compared with bolus and titrated midazolam for sedation in outpatient colonoscopy: a prospective randomized double-blind study. Gastrointest Endosc. 93. 201-208. 2021

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: Randomized</p>	<p>Intervention: Sedation for outpatient colonoscopy</p>	<p>Primary: Total procedure time, induction time, recovery time, and discharge time among the 3 groups.</p> <p>Secondary: Patient satisfaction and the incidence of adverse events.</p>

<p>study.</p> <p>Number of Patient: 267</p> <p>Recruiting Phase: Unknown. Only Abstract accessible.</p> <p>Inclusion Criteria: Unknown. Only Abstract accessible.</p> <p>Exclusion Criteria: Unknown. Only Abstract accessible.</p>	<p>Comparison: Propofol group, bolus midazolam group, and titrated midazolam group.</p>	<p>Results: Patients in the propofol group had a shorter total procedure time (39.5 vs 59.4 vs 58.1 minutes; P < .001), induction time (4.6 vs 6.3 vs 7.6 minutes; P < .001), recovery time (11.5 vs 29.5 vs 29.2 minutes; P < .001), and discharge time (20.6 vs 34.9 vs 34.7 minutes; P < .001) than patients in the bolus midazolam group and titrated midazolam group. Patients in the propofol group reported higher degrees of satisfaction than patients in the bolus or titrated midazolam plus meperidine groups (9.9 vs 9.6 vs 9.6 [P = .007] and 4.9 vs 4.7 vs 4.8 [P = .008], respectively). Adverse events were not significantly different between groups.</p> <p>Author's Conclusion: Propofol was superior to bolus or titrated midazolam in terms of endoscopy unit efficiency and patient satisfaction during outpatient colonoscopy.</p>
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Methodical Notes

Funding Sources: Unknown. Only Abstract accessible.

COI: Unknown. Only Abstract accessible.

Randomization: Unknown. Only Abstract accessible.

Blinding: Unknown. Only Abstract accessible.

Dropout Rate/ITT-Analysis: Unknown. Only Abstract accessible.

Notes:

Only abstract accessible.

Kim, E. H. et al. Effect of the midazolam added with propofol-based sedation in esophagogastroduodenoscopy: A randomized trial. J Gastroenterol Hepatol. 33. 894-899. 2018

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: RCT</p> <p>Number of Patient: 120</p> <p>Recruiting Phase: January 2013-Februar 2015</p> <p>Inclusion Criteria: patients scheduled for diagnostic EGD</p> <p>Exclusion Criteria: age < 20 yrs, did not want sedation, allergy to study drugs, operation history of esophagus, stomach or duodenum, obstructive sleep apnoe syndrom, drug history of narcotics or sleeping pills for more than 6 months, pregnant or breast feeding, ASA > III, history of complications in previous sedations</p>	<p>Intervention: 2 mg Midazolam or no midazolam, propofol based sedation</p> <p>Comparison: so.</p>	<p>Primary: level of satisfaction of the patients between the two groups</p> <p>Secondary: level of satisfaction of endoscopists and nurses, administered dosage of sedative, number of required booster injection of propofol, incidence of adverse events</p> <p>Results: no difference in procedure and recovery time, administered dose of propofol significantly lower in the Midazolam group (0,3 +0,3 vs. 0,8 + 0,2 mg/kg). Sedation related adverse events did not differ.</p> <p>Author's Conclusion: Adding midazolam to propofol did not reduced the safety and efficacy, and sedation using propofol alone could be suitable for sedation during diagnostic EGD.</p>

Methodical Notes

Funding Sources: no

COI: no

Randomization: yes

Blinding: no

Dropout Rate/ITT-Analysis: no

Notes:

Kim, E. J. et al. Safety and efficacy of glycopyrrolate as a premedication for endoscopic submucosal dissection: a randomized, double-blind, placebo-controlled study. Endoscopy. 49. 949-956. 2017

Population	Intervention Comparison	Outcomes/Results
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Evidence level: 2

Study type: RCT

Number of Patient: 196

Recruiting Phase:
between December 2014
and February 2016

Inclusion Criteria:
Patients older than 18
years and younger than
75 years of age were
eligible for
inclusion

Exclusion Criteria:
Patients who had
previously participated in
a similar
study; patients with a
history of paralytic ileus,
heart disease
(including arrhythmia,
coronary heart disease, or
congestive
heart failure), glaucoma,
or obstructive urinary
disorders; and
patients with less than
90% baseline oxygen
saturation on finger
pulse oximetry were
excluded

Intervention:
endoscopic
submucosal
dissection (ESD)

Comparison:
glycopyrrolate vs.
placebo

Primary: The primary endpoint of this study was the incidence of secretion-induced hypoxemia during the procedure, which was reported as a number agreed between the endoscopist and the trained anesthesia nurse who performed oropharyngeal suction during the procedure.

Secondary: the ease of performing the procedure; the amount of secretion; cough during the procedure; and other adverse events, including cardiac, respiratory, and urinary problems

Results: Glycopyrrolate and placebo were received by 96 and 100 patients, respectively. ESD was successfully performed in all patients without any serious adverse events related to sedation or ESD. The median visual analog scale for procedure ease was higher in the glycopyrrolate group at 8 (interquartile range [IQR] 7 – 9) vs. 7 (IQR 6 – 8.25); $P < 0.001$. The proportions of patients with secretion-induced hypoxemia (4.4% vs. 14.3%; $P = 0.03$) and cough (16.7% vs. 35.7%; $P = 0.005$) were lower in the glycopyrrolate group.

Author's Conclusion: The use of glycopyrrolate as a premedication for ESD significantly improved the ease of performing the procedure and reduced the incidence of secretion-induced hypoxemia and cough during ESD. Glycopyrrolate may be a promising premedication to ensure safe and stable ESD procedures

Methodical Notes

Funding Sources: not reported

COI: none

Randomization: yes

Blinding: yes

Dropout Rate/ITT-Analysis:

Notes:

Kim, J. E. et al. Efficacy of Intravenous Lidocaine During Endoscopic Submucosal Dissection for Gastric Neoplasm: A Randomized, Double-Blind, Controlled Study. Medicine (Baltimore). 95. e3593. 2016

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 66</p> <p>Recruiting Phase: September November 2015</p> <p>Inclusion Criteria: 20-80 years, gastric cancer ESD</p> <p>Exclusion Criteria: hypersensitivity to lidocaine, chronic pain, chronic abuse of opioid or nonsteroidal anti-inflammatory drug, atrio-ventricular block, liver or renal dysfunction, multiple gastric lesions, or gastrointestinal pain.</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary: requirement of fentanyl</p> <p>Secondary: pain after ESD</p> <p>Results: Fentanyl requirement during ESD reduced by 24% in the lidocaine group (P<0.001). The lidocaine group reached sedation faster [P<0.001], and incidence of patient movement during ESD decreased in the lidocaine group. Numerical rating scale for epigastric pain was significantly lower at 6 hours after ESD [2 (0–6) vs. 3 (0–8), median (range); P=0.023] and incidence of throat pain was significantly lower in the lidocaine group.</p> <p>Author's Conclusion: Administration of intravenous lidocaine reduced fentanyl requirement and decreased patient movement during ESD. It alleviated epigastric and throat pain after ESD.</p>

Methodical Notes

Funding Sources: none

COI: none

Randomization: yes

Blinding: yes

Dropout Rate/ITT-Analysis: 5 of 66

Notes:

RCT addition of i.v. lidocaine vs. placebo for ESD (propofol and fentanyl)

Kim, J. E. et al. Beneficial effect of intravenous magnesium during endoscopic submucosal dissection for gastric neoplasm. Surg Endosc. 29. 3795-802. 2015

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: RCT double-blinded</p> <p>Number of Patient: 2x 30</p>	<p>Intervention: ESD with prior intravenous Mg or Placebo</p> <p>Comparison: Mg vs Placebo (Saline infusion)</p>	<p>Primary: Total amount of fentanyl during ESD</p> <p>Secondary: Hemodynamic data</p> <p>Results: Total dose of Fentanyl was reduced by 24% in the Mg group p=0.002</p>

<p>Recruitment Phase: 10/2014 -2/2015</p> <p>Inclusion Criteria: 40-80 yrs. Early gastric neoplasm (carcinoma or adenoma) ESD</p> <p>Exclusion Criteria: Neuromuscular disease Liver or renal dysfunction Chronic abuse of NSAID or opioids Multiple gastric lesions , ulcers pain</p>	<p>No significant difference in total dose of Propofol Mg attenuated elevation of mean blood pressure at the time of epinephrine injection (p=0.0389) and 5 min after ESD (p=0.0004) Less patients of the Mg group required additional analgesics in the recovery room (p=0.043); intensity of abdominal pain was lower in the Mg group (p=0.034)</p> <p>Author's Conclusion: Single intravenous dose of Mg (50 mg/kg) before sedation reduced analgesic requirements without adverse effects and contributed to stable hemodynamics</p>
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<p>Methodical Notes</p> <p>Funding Sources: None</p> <p>COI: None</p> <p>Randomization: Yes</p> <p>Blinding: Double blind</p> <p>Dropout Rate/ITT-Analysis: Eligible 62; Randomized 60/62 3 drop out's; Analyzed : 28 (Mg) and 29 (Placebo)</p> <p>Notes: Very small numbers and a very good and simple design</p>

<p>Kim, M. G. et al. Etomidate versus propofol sedation for complex upper endoscopic procedures: a prospective double-blinded randomized controlled trial. Gastrointest Endosc. 86. 452-461. 2017</p>		
Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type:</p> <p>Number of Patient:</p> <p>Recruitment Phase:</p> <p>Inclusion Criteria:</p> <p>Exclusion Criteria:</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary:</p> <p>Secondary:</p> <p>Results:</p> <p>Author's Conclusion:</p>
<p>Methodical Notes</p> <p>Funding Sources:</p> <p>COI:</p> <p>Randomization:</p> <p>Blinding:</p> <p>Dropout Rate/ITT-Analysis:</p>		

Notes:

RCT, blinded eto vs. propofol EUS

Kim, N. et al. Comparison of the efficacy and safety of sedation between dexmedetomidine-remifentanil and propofol-remifentanil during endoscopic submucosal dissection. World J Gastroenterol. 21. 3671-8. 2015

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: RCT</p> <p>Number of Patient: 59</p> <p>Recruiting Phase: from September 2012 to January 2013.</p> <p>Inclusion Criteria: patients aged > 20 years belonging to American Society of Anesthesiologists classification 1 to 3 and scheduled for ESD</p> <p>Exclusion Criteria: Patients with end-organ diseases (i.e., heart failure, respiratory failure, hepatic failure, or renal failure), known drug allergies, or a history of drug abuse were excluded.</p>	<p>Intervention: endoscopic submucosal dissection</p> <p>Comparison: dexmedetomidine-remifentanil vs. propofol-remifentanil</p>	<p>Primary: The ease of advancing the scope into the throat, gastric motility grading, and satisfaction of the endoscopist and patient were assessed.</p> <p>Secondary: Hemodynamic variables and hypoxemic events were compared to evaluate patient safety.</p> <p>Results: Demographic data were comparable between the groups. The hemodynamic variables and pulse oximetry values were stable during the procedure in both groups despite a lower heart rate in the DR group. No oxygen desaturation events occurred in either group. Although advancing the scope into the throat was easier in the PR group ("very easy" 24.1% vs 56.7%, P = 0.010), gastric motility was moresuppressed in the DR group ("no + mild" 96.6% vs 73.3%, P = 0.013). The endoscopists felt that the procedure was more favorable in the DR group ("very good + good" 100% vs 86.7%, P = 0.042), whereas patient satisfaction scores were comparable between the groups. En bloc resection was performed 100% of the time in both groups, and the complete resection rate was 94.4% in the DR group and 100% in the PR group (P = 0.477).</p> <p>Author's Conclusion: The efficacy and safety of dexmedetomidine and remifentanil were comparable to propofol and remifentanil during ESD. However, the endoscopists favored dexmedetomidine perhaps due to lower gastric motility.</p>

Methodical Notes**Funding Sources:** NA**COI:** NA**Randomization:** yes**Blinding:** no**Dropout Rate/ITT-Analysis:****Notes:**

Kinugasa, H. et al. Dexmedetomidine for conscious sedation with colorectal endoscopic submucosal dissection: a prospective double-blind randomized controlled study. Clin Transl Gastroenterol. 9. 167. 2018

Population	Intervention Comparison	Outcomes/Results
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<p>Evidence level: 1</p> <p>Study type: Double blinded ranomized single cener trial</p> <p>Number of Patient: 80</p> <p>Recruitung Phase: 12 month</p> <p>Inclusion Criteria: age 18 -95 years; requiring colorectal esd, written informed consent</p> <p>Exclusion Criteria: DEX allergy, liver disorder,renal failure,severe heart or lung disease</p>	<p>Intervention: sedated colorectal esd</p> <p>Comparison: pethidine plus placebo vs. pethidine plus DEX</p>	<p>Primary: patient's satisfaction</p> <p>Secondary: endoscopist's satisfaction, pain level fro the patient and endoscopist's view, ro resection, en bloc resection adverse evants</p> <p>Results: all analysed factors were better for DEX</p> <p>Author's Conclusion: Dex is useful for patiet and endoscopsit</p>
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<p>Methodical Notes</p> <p>Funding Sources: none</p> <p>COI: none</p> <p>Randomization: no clear details with respect to randomisation</p> <p>Blinding: double</p> <p>Dropout Rate/ITT-Analysis: 4</p> <p>Notes:</p>

<p>Klare, P. et al. Magnetic endoscope imaging for routine colonoscopy: impact on propofol dosage and patient safety - a randomized trial. Endoscopy. 48. 916-22. 2016</p>		
<p>Population</p>	<p>Intervention - Comparison</p>	<p>Outcomes/Results</p>
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 334</p> <p>Recruitung Phase:</p> <p>Inclusion Criteria: Outpatients and inpatients aged >18 years who were scheduled for colonoscopy</p> <p>Exclusion Criteria: emergency examinations; ASA risk classes IV and V ; pregnancy; and pre-existing hypotension (systolic blood pressure<90mmHg), bradycardia (heart rate <50/minute), or hypoxemia(SaO2<90%) before the start of the endoscopy. Patients preferringto have deep sedation and those who wanted to undergo colo-noscopy without sedation were also excluded from the study.</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary: total dosage of propofol</p> <p>Secondary: adverse events, adenoma detection, procedure time</p> <p>Results: no severe adverse events median propofol dosage was significantly lower in the MEIarm Patient satisfaction scores were higher in the MEI arm no significant differences in patients'coopera-tion, cecal intubation time, and adenoma detec-tion were observed between the study arms</p> <p>Author's Conclusion: The use of MEI may be useful in redu-cing propofol dosage for colonoscopy and improv-ing patient satisfaction.</p>
<p>Methodical Notes</p>		

Funding Sources: Olympus Germany providing Evis Exera III CF-HQ190 colonoscopes and processors as well as the MEI function units to the study site for the duration of the study.

COI: none

Randomization: yes, computer-generated list was used for randomization.

Blinding: no, neither patients nor endoscopists participating in the trial were blinded to the allocation of the study arm.

Dropout Rate/ITT-Analysis:

Notes:
RCT

Ko, C. H. et al. Effect of music on level of anxiety in patients undergoing colonoscopy without sedation. J Chin Med Assoc. 80. 154-160. 2017

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 138</p> <p>Recruitment Phase: 6 years</p> <p>Inclusion Criteria: Colonoscopy without sedation</p> <p>Exclusion Criteria: myocardial infarction, pulmonary embolism, cerebral vascular infarction, unstable and severe cardiac disease, or severe gastroenteritis disease,</p>	<p>Intervention: Colonoscopy without sedation</p> <p>Comparison: with or without Music during colonoscopy</p>	<p>Primary: Anxiety score</p> <p>Secondary:</p> <p>Results: A trend test for mild anxiety was performed on the patients in the three groups, and a significant trend was noted (p ¼ 0.017 for all patients; p ¼ 0.014 for analysis by sex). Multivariate analysis for mild anxiety on the patients in each group was also performed in this study, and music by Kevin Kern was found to have the lowest odds ratio (Odds ratio ¼ 0.34, p ¼ 0.045).</p> <p>Author's Conclusion: Listening to music, especially music by Kevin Kern, reduced the level of anxiety in patients undergoing colonoscopy examination without sedation.</p>

Methodical Notes

Funding Sources: none

COI: non

Randomization: table

Blinding: non

Dropout Rate/ITT-Analysis: none

Notes:

Kotwal MR, Rinchen CZ . Stress reduction by listening Indian classical music during gastroscopy. Journal of Gastroenterology and Hepatology. 31. 282?283. 2016

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 5</p> <p>Study type:</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary:</p> <p>Secondary:</p>

Number of Patient:		Results:
Recruitment Phase:		Author's Conclusion:
Inclusion Criteria:		
Exclusion Criteria:		

Methodical Notes

Funding Sources:

COI:

Randomization:

Blinding:

Dropout Rate/ITT-Analysis:

Notes:

Diese Arbeit stammt von 1998 und nicht von 2016; ich habe sie deswegen nicht bewertet. Es gibt zu diesem Thema aber durchaus Literatur aus den letzten Jahren

Lee, J. M. et al. Using Etomidate and Midazolam for Screening Colonoscopies Results in More Stable Hemodynamic Responses in Patients of All Ages. Gut Liver. 13. 649-657. 2019

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 200</p> <p>Recruitment Phase: August 2017-November 2017</p> <p>Inclusion Criteria: pat. scheduled for screening colonoscopy and/or gastroscopy</p> <p>Exclusion Criteria: age < 20 yrs., no sedation, hypersensitivity to study drugs, adrenocortical insufficiency, chronic corticoid therapy, porphyria, pregnant or breast-feeding, history of adverse events with prior sedation, unable to provide informed consent. RR < 90 mmHg, SpO2 < 90 with room air</p>	<p>Intervention: etomidate 0,1mg/kg bolus injection followed by titration of etomidate</p> <p>Comparison: Propofol 0,05 mg/kg bolus injection, followed by titration of propofol</p>	<p>Primary: cardiopulmonary adverse events (tachcardia, bradycardia, hypertension, transient hypotension, respiratory depression, oxygen desaturation, arrhythmia)</p> <p>Secondary: Vital sign fluctuations: oxygen desaturation and transient hypotension, adverse events disturbing the procedure. Induction time, total procedure time, awake time, satisfaction scores of the patients and endoscopists</p> <p>Results: adverse cardiopulmonary events more common in the propofol group 65 vs. 51 %. Significant more experienced fluctuations in the vital signs in the propofol group (46% vs. 29%). Similar sedation related outcomes.</p> <p>Author's Conclusion: Midazolam/etomidate for screening colonoscopies results in more stable hemodynamic responses than midazolam/propofol</p>

Methodical Notes

Funding Sources: none

COI: none

Randomization: yes

Blinding: yes

Dropout Rate/ITT-Analysis: no

Notes:

Lee, J. M. et al. Efficacy and safety of etomidate-midazolam for screening colonoscopy in the elderly: A prospective double-blinded randomized controlled study. *Medicine (Baltimore)*. 97. e10635. 2018

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT, single center, blinded</p> <p>Number of Patient: 124</p> <p>Recruiting Phase: November 2017 to January 2018</p> <p>Inclusion Criteria: over 65 years old with ASA scores from I to III screening colonoscopy and/or gastroscopy</p> <p>Exclusion Criteria: suspected history of adverse events with previous sedation; known hypersensitivity to egg products, soybeans, etomidate, and propofol; known adrenocortical insufficiency, or porphyria or received chronic corticoid therapy were pregnant or breastfeeding; desired to undergo endoscopy without sedation; and could not provide informed consent.</p>	<p>Intervention: colonoscopy different sedation</p> <p>Comparison:</p>	<p>Primary: incidence of cardiopulmonary adverse events</p> <p>Secondary: vital sign fluctuation (VSF), adverse events disturbing the procedure, and sedation-related outcomes.</p> <p>Results: incidence of cardiopulmonary adverse events was higher in the propofol group (72.6%) than in the etomidate group (54.8%) (P=.040). VSF was detected in 17 (27.4%) and 31 (50.0%) patients in the etomidate and propofol group (P=.010). incidence rate of adverse events disturbing the procedure was significantly higher in the etomidate group (25.8%) than in the propofol group (8.1%) (P=.008). incidence rate of myoclonus was significantly higher in the etomidate group (16.1%) than in the propofol group (1.6%) (P=.004).</p> <p>Author's Conclusion: etomidate-midazolam in patients with high ASA score or vulnerable to risk factors; propofol-midazolam may be used as a guideline in patients with low ASA score</p>

Methodical Notes

Funding Sources: National Research Foundation of Korea (NRF) grant funded by the Korea government (MSIT) (No. 2017R1C1B5076677) and by Korea University.

COI: none

Randomization: in 2 groups

Blinding: yes

Dropout Rate/ITT-Analysis: n.a.

Notes:

RCT, single center, blinded
efficacy and safety of eto vs. propofol

Lee, S. P. et al. Efficacy and safety of flumazenil injection for the reversal of midazolam sedation after elective outpatient endoscopy. *J Dig Dis*. 19. 93-101. 2018

Population	Intervention - Comparison	Outcomes/Results
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<p>Evidence level: 3</p> <p>Study type: RCT</p> <p>Number of Patient: 409</p> <p>Recruiting Phase: July 2016 to February 2017</p> <p>Inclusion Criteria: elective outpatient endoscopy</p> <p>Exclusion Criteria: aged <20 or >90 years, pregnancy, heavy alcohol consumption or had a history of benzodiazepine dependence or allergy, ASA III or more, or who refused to sign the consent form.</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary: safety and efficacy of flumazenil injections after elective endoscopy</p> <p>Secondary: patients' sensation of pain and satisfaction, their memory of the procedure, mental status and subjective experience of uncomfortable symptoms</p> <p>Results: The length of stay in recovery was significantly shorter in group I than in group II. No significant differences were found in the number of patients with pain (VAS\geq1), adverse events and discomfort between the two groups. Additionally, no differences in the patients' memory of the procedure, satisfaction with sedation, willingness to repeat the endoscopy and mental status</p> <p>Author's Conclusion: time in the recovery room after flumazenil administration was significantly shortened, and the use of the drug did not increase the risk of adverse events or discomfort.</p>
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Methodical Notes

Funding Sources: Bukwang Pharmaceutical Company (Seoul, Korea), the manufacturer of Flunil.

COI: not stated

Randomization: yes

Blinding: no

Dropout Rate/ITT-Analysis: 41 of 450

Notes:

RCT, no blinding for flumazenil or nothing

Lee, S. P. et al. Comparison of dexmedetomidine with on-demand midazolam versus midazolam alone for procedural sedation during endoscopic submucosal dissection of gastric tumor. J Dig Dis. 16. 377-84. 2015

Population	Intervention Comparison	Outcomes/Results
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<p>Evidence level: 2</p> <p>Study type: RCT</p> <p>Number of Patient: 80</p> <p>Recruiting Phase: 36 month</p> <p>Inclusion Criteria: ESD gastric</p> <p>Exclusion Criteria: non ESD possible</p>	<p>Intervention: Ix'v sedation during gastric ESD</p> <p>Comparison: Mida Vs Mida plus DEX on demand</p>	<p>Primary: sedation score, number of reactions interfering with the procedure, sedation related adverse events</p> <p>Secondary:</p> <p>Results: no differences with respect to safety, better sedation effect for Mida plus dex</p> <p>Author's Conclusion: gastric esd better with mida plus dex</p>
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Methodical Notes

Funding Sources: none

COI: none

Randomization: random

Blinding: no

Dropout Rate/ITT-Analysis: no

Notes:

Li, Q. et al. Determination of the appropriate propofol infusion rate for outpatient upper gastrointestinal endoscopy-a randomized prospective study. BMC Gastroenterol. 16. 49. 2016

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: Randomized Controlled blinded study</p> <p>Number of Patient: 300</p> <p>Recruiting Phase: 3 month</p> <p>Inclusion Criteria: upper GI Endoscopy; ASA 1-3; 18-65 years old</p> <p>Exclusion Criteria: pregnancy, sleep apnoea, allergy, sedative drug abuse</p>	<p>Intervention: Sedation during upper GI Endoscopy</p> <p>Comparison: three dose variants of propofol</p>	<p>Primary: Adverse effects and satisfaction of endoscopist and patient</p> <p>Secondary:</p> <p>Results: 1000 ml /h is the best dose the less of hypotension and oxygen desaturation, the less of motor activity and nausea the best of patients satisfaction and endoscopist satisfaction</p> <p>Author's Conclusion: 1000 ml /h the best suitable Infusionrate</p>
Methodical Notes		
<p>Funding Sources: funded by hospital college</p> <p>COI: non</p> <p>Randomization: table randomisation</p> <p>Blinding: endoscopist and anesthsist</p> <p>Dropout Rate/ITT-Analysis: 10</p> <p>Notes:</p>		

Lin, Y. J. et al. Target-controlled propofol infusion with or without bispectral index monitoring of sedation during advanced gastrointestinal endoscopy. J Gastroenterol Hepatol. 35. 1189-1195. 2020

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: Randomized, prospective Study</p> <p>Number of Patient: 200, 100 BIS-open group, 100 BIS blind group</p> <p>Recruiting Phase:</p> <p>Inclusion Criteria: patients undergoing advanced endoscopy</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary: Total amount of propofol required to maintain anesthesia</p> <p>Secondary: Sedation induced adverse events, recovery, and quality of sedation (endoscopist and patient satisfaction)</p> <p>Results: Propofol mean infusion rate were higher in patients without BIS</p> <p>Author's Conclusion:</p>

Exclusion Criteria:

Methodical Notes

Funding Sources:

COI: none

Randomization:

Blinding:

Dropout Rate/ITT-Analysis:

Notes:

Treatment not blinded for endoscopist

Liou, J. Y. et al. A Response Surface Model Exploration of Dosing Strategies in Gastrointestinal Endoscopies Using Midazolam and Opioids. Medicine (Baltimore). 95. e3520. 2016

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: Model development</p> <p>Number of Patient: 33</p> <p>Recruiting Phase: NA</p> <p>Inclusion Criteria: Patients between 18 and 65 years old, American Society of Anesthesiologists (ASA) Physical status I II who underwent EGD (esophagogastroduodenoscopy) and colonoscopy as a single-stage procedure, were chart-reviewed.</p> <p>Exclusion Criteria: Those with documented verbal communication impairment, cerebrovascular diseases, incomplete records, or a history of sedative, opioid, or chronic alcohol use were excluded.</p>	<p>Intervention: EGD (esophagogastroduodenoscopy) and colonoscopy</p> <p>Comparison: none</p>	<p>Primary: NA</p> <p>Secondary: NA</p> <p>Results: The average age of the patient population is 49.3 years. Mean BMI is 21.92.3 kg/m2. About 56.7% were females and none received prior abdominal surgery. The cecal intubation rate was 100%. Only 1 patient (3%) developed temporary hypoxemia, which was promptly managed with simple measures. The RSMs for each phase showed significant synergy between midazolam and alfentanil. The balanced midazolam and alfentanil combination provided adequate anesthesia and most rapid return of consciousness.</p> <p>Author's Conclusion: Simulation of regimens with different characteristics gives insights on dosing strategies. A balanced midazolam–alfentanil regimen is adequate in providing good anesthetic depth and most rapid return of consciousness. We believe with the aid of our RSM, clinicians</p>

can perform sedation with more flexibility and precision.

Methodical Notes

Funding Sources: none

COI: none

Randomization: none

Blinding: none

Dropout Rate/ITT-Analysis:

Notes:

Liu, J. et al. Efficacy and safety of intravenous lidocaine in propofol-based sedation for ERCP procedures: a prospective, randomized, double-blinded, controlled trial. *Gastrointest Endosc.* 92. 293-300. 2020

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 48</p> <p>Recruiting Phase: July 1, 2019 and November 31 2019</p> <p>Inclusion Criteria: Inpatients aged 18 to 80 years ERCP</p> <p>Exclusion Criteria: ASA class IV or V, pre-existing hypoxemia, hypotension, bradycardia (heart rate [HR] <50beats/min), uncontrolled hypertension (SBP>170 mmHg, diastolic blood pressure>100 mm Hg), severe renal or liver failure, pregnancy or lactation, allergy to lidocaine,atrioventricular block, epilepsy, and inability to give informed consent.</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary: total propofol dose requirements</p> <p>Secondary: dverse eventsand satisfaction, change in vital parameters, sedation-related time, and postprocedure evaluations.</p> <p>Results: propofol requirements were reduced by 33.8% in the lidocaine group Involuntary movement was less common in the lidocaine group In the lidocaine group, postprocedure pain and fatigue, as measured by the visual analog scale, were significantly reduced The incidence of oxygen desaturation, hypotension, and bradycardia tended to be lower in the lidocaine group</p> <p>Author's Conclusion: intravenous lidocaine can significantly decrease propofol requirements during ERCP, with higher sedation quality and endoscopist satisfaction.</p>

Methodical Notes

Funding Sources: Key Research andDevelopment Program of Shandong Province, China, Shandong, China(2018CXGC1209 to Y.-Q.L.) and by the Taishan Scholars Program ofShandong, Shandong, China and National Clinical Research Center forDigestive Diseases supporting technology project of China (2015BAI13B07).

COI: none

Randomization: yes 1:1

Blinding: yes

Dropout Rate/ITT-Analysis: 4 of 52

Notes:

RCT, effect of i.v. lidocain in ERCP, sedation with propofol and premedication

Lu, Z. et al. Efficacy of a Dexmedetomidine-Remifentanil Combination Compared with a Midazolam-Remifentanil Combination for Conscious Sedation During Therapeutic Endoscopic Retrograde Cholangio-Pancreatography: A Prospective, Randomized, Single-Blinded Preliminary Trial. Dig Dis Sci. 63. 1633-1640. 2018

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 198</p> <p>Recruiting Phase: 3 months</p> <p>Inclusion Criteria: ERCP</p> <p>Exclusion Criteria: ASA physical classes IV and V, refusal to anticipate, comorbid uncontrolled inter-nal problems, pregnant or breast-feeding women, history of long-term sedative or narcotic analgesic drug or alcohol abuse, baseline peripheral oxygen saturation (SaO₂) < 90%, age > 85 years and severe hypertensio</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary: Hemodynamic and respiratory changes, Ramsay Sedation Scale, Visual Analogue Scale, endoscopist and patient satisfaction were assessed. Furthermore, adverse events as well as recovery time and discharge time</p> <p>Secondary:</p> <p>Results: Patient satisfaction scores were significantly higher in the DR group compared with MR group. desaturation was statistically higher, and the operation time was longer in the MR group. Nausea during catheterization of oropharynx was found to be more pronounced in the DR group.</p> <p>Author's Conclusion: dexmedetomidine-remifentanil protocol provided a parallel sedative efficacy and improved respiratory sparing effects. higher patient satisfaction scores potentially offer a more reproducible ERCP quality. Adding dexme-detomidine to remifentanil can be used safely as a conscious sedation method during ERCP.</p>

Methodical Notes

Funding Sources: none

COI: none

Randomization: yes 1:1

Blinding: yes

Dropout Rate/ITT-Analysis: 4 of 198

Notes:

RCT

Majidinejad, S. et al. Ketamine administration makes patients and physicians satisfied during gastro-enteric endoscopies. J Res Med Sci. 20. 860-4. 2015

Population	Intervention - Comparison	Outcomes/Results
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<p>Evidence level: 3</p> <p>Study type: RCT</p> <p>Number of Patient: 86</p> <p>Recruiting Phase: 2014-2015</p> <p>Inclusion Criteria: Age between 18 and 65 years, absence of hypersensitivity or any contraindication for ketamine, absence of mental or physical retardation, and no history of hypertension, seizure, hyperthyroidism, immune deficiency, or increased intraocular pressure</p> <p>Exclusion Criteria: emergency, hypersensitivity</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary: patients and physicians' satisfaction of sedation</p> <p>Secondary:</p> <p>Results: pain and discomfort scores higher for placebo patients and physicians more satisfied with ketamine sedation than placebo</p> <p>Author's Conclusion: ketamine sedation useful for EGD</p>
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<p>Methodical Notes</p> <p>Funding Sources: grant of Isfahan University of Medical Sciences</p> <p>COI: none</p> <p>Randomization: computer randomizing system meaning that every participant had a number categorized into case or control group by the computer</p> <p>Blinding: yes</p> <p>Dropout Rate/ITT-Analysis: not stated</p> <p>Notes: evaluation of ketamine orally vs. placebo for endoscopy</p>
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<p>Narayanan, S. et al. Alternative sedation for the higher risk endoscopy: a randomized controlled trial of ketamine use in endoscopic retrograde cholangiopancreatography. Scand J Gastroenterol. 50. 1293-303. 2015</p>		
Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: Prospective RCT Pilot study</p> <p>Number of Patient: 59 eligible, 41 randomized, 2 excluded in the study M/K group, 2 excluded in the control M/P group from analysis 19 vs 18</p> <p>Recruiting Phase: 22-week period Exact data not specified</p> <p>Inclusion Criteria: ERCP patients from the list ASA I-III</p> <p>Exclusion Criteria: Severe cardiopulmonary disease Obstructive sleep apnea Pregnancy Confusion or dementia Age <18 yrs</p>	<p>Intervention: ERCP</p> <p>Comparison: Midazolam/Ketamine vs Midazolam/Pethidine</p>	<p>Primary: Adequate sedation during endoscopy Incidence of side effects-emergency reactions</p> <p>Secondary: Satisfaction of patients and endoscopists but not clearly specified</p> <p>Results: For all criteria M/K was as effective as M/P</p> <p>Author's Conclusion: Sedation for endoscopy with M/K was as effective as conventional sedation as acceptable to patients. Ketamine may have potential as an agent for sedation in higher risk patients</p>

Methodical Notes

Funding Sources: Boston Scientific, Ferring Pharmaceuticals
Datascop Patient Monitoring

COI: None

Randomization: Yes

Blinding: Double blinded, but not endoscopist

Dropout Rate/ITT-Analysis: 2 in each group

Notes:

Very small numbers 18 vs 19 pts limit the conclusions drawn

Nilsson, A. et al. Sedation during endoscopic retrograde cholangiopancreatography: a randomized controlled study of patient-controlled propofol sedation and that given by a nurse anesthetist. Scand J Gastroenterol. 50. 1285-92. 2015

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: RCT</p> <p>Number of Patient: 281</p> <p>Recruiting Phase: between January 2011 and May 2012</p> <p>Inclusion Criteria: 281 patients for 301 ERCP procedures were included in the study</p> <p>Exclusion Criteria: Exclusion criteria were an allergy to the drugs being used; pregnancy; the use of Spy-Glass equipment; American Society of Anesthesiologists (ASA) class IV or more; or a history of confusion, dementia, or other communication problems.</p>	<p>Intervention: ERCP</p> <p>Comparison: propofol PCA vs. propofol ACS vs. midazolam</p>	<p>Primary: In the three groups, oxygen saturation (SpO₂), an electrocardiogram, and heart rate (HR) were continuously monitored during the procedure and recorded every 5 min.</p> <p>Secondary: To evaluate safety further and to record any adverse events, all interventions made by the nurse anesthetist in the two intervention groups were recorded</p> <p>Results: PCS and ACS increased the ease of the procedure and reduced the number of sedation failures compared to midazolam sedation (ACS n = 0; PCS n = 4; midazolam n = 20). The ACS group had more deeply sedated patients (OAA/S level 2), desaturation and obstructed airways than the PCS and midazolam groups. Time to full recovery (Aldrete score \pm 9) was shortest following PCS. PCS resulted in the least fatigue and pain after the procedure. Patients' preference for PCS and ACS was the same.</p> <p>Author's Conclusion: PCS with propofol is superior to midazolam and comparable to ACS. PCS resulted in a rapid recovery, fewer respiratory events, and was almost as effective as ACS in ensuring a successful examination.</p>

Methodical Notes

Funding Sources: NA

COI: non

Randomization: yes

Blinding: no

Dropout Rate/ITT-Analysis:

Notes:

Nishikawa, H. et al. Effect of dexmedetomidine in the prophylactic endoscopic injection sclerotherapy for oesophageal varices: a study protocol for prospective interventional study. *BMJ Open Gastroenterol.* 4. e000149. 2017

Population	Intervention - Comparison	Outcomes/Results
Evidence level: 1 Study type: Number of Patient: Recruiting Phase: Inclusion Criteria: Exclusion Criteria:	Intervention: Comparison:	Primary: Secondary: Results: Author's Conclusion:
Methodical Notes		
Funding Sources: COI: Randomization: Blinding: Dropout Rate/ITT-Analysis: Notes:		

Nusrat, S. et al. Use of diphenhydramine as an adjunctive sedative for colonoscopy in patients on chronic opioid therapy: a randomized controlled trial. *Gastrointest Endosc.* 88. 695-702. 2018

Population	Intervention - Comparison	Outcomes/Results
Evidence level: 1 Study type: RCT Number of Patient: 119 Recruiting Phase: Juli 2014- November 2016 Inclusion Criteria: history of chronic opioid use, colonoscopy, sedation Exclusion Criteria: inability to execute informed consent, allergy to study drugs, pregnancy, history of colon resection, severe cardiopulmonary disease, other endoscopic procedure scheduled on the same day	Intervention: 10 ml (50 mg) diphenhydramine i.v. Comparison: placebo 10 ml 0,9% sodium chlorid i.v.	Primary: mean dose of fentanyl and midazolam difference in qualitative analysis of sedation Secondary: induction time, procedure duration and recovery time Results: mean dose of fentanyl and midazolam not different mean sedation score significant different in favor of diphenhydramine no difference in induction time, procedure duration and recovery time. More hypotensive episodes in placebo group Author's Conclusion: In patients on chronic opioid therapy, administration of diphenhydramine does not allow for lower doses of procedural sedatives but improves quality of sedation without increasing the number of adverse events.
Methodical Notes		

Funding Sources: none

COI: none

Randomization: yes

Blinding: yes

Dropout Rate/ITT-Analysis: 1 patient

Notes:

Ominami, M. et al. Comparison of propofol with midazolam in endoscopic submucosal dissection for esophageal squamous cell carcinoma: a randomized controlled trial. J Gastroenterol. 53. 397-406. 2018

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT single-blind</p> <p>Number of Patient: 132</p> <p>Recruiting Phase: 4/2014 -10/2015</p> <p>Inclusion Criteria: SCC > 20yrs written consent</p> <p>Exclusion Criteria: Pregnancy; Propofol allergy; Mental incompetency; severe liver disorder; renal failure severe heart and lung disease ;patients considered to be inappropriate for inclusion</p>	<p>Intervention: ESD</p> <p>Comparison: Propofol vs midazolam</p>	<p>Primary: Incidence of discontinuation of ESD</p> <p>Secondary: Risk factorsfor poor respanse to sedation Satisfaction scores edoscopist patient Adverse events En Boc resection</p> <p>Results: Propofol 0%/66 Midazolam 37,9% 25/66 p<0,01 for discontinuation of ESD</p> <p>Risk factors for poor response to sedation : younger age, total area of the lesions, use of midazolam</p> <p>Author's Conclusion: Propofol is a more efficient sedative for modified neuroleptanalgesia in ESD for E-SCC</p>

Methodical Notes

Funding Sources: No

COI: 3 authors received consultation fees from pharma industry

Randomization: RCT

Blinding: Single Blind

Dropout Rate/ITT-Analysis: 45 pts excluded before randomization
No drop out during study

Notes:

Very clear designed study

Important for performance of ESD

Padmanabhan, A. et al. Patient Satisfaction With Propofol for Outpatient Colonoscopy: A Prospective, Randomized, Double-Blind Study. Dis Colon Rectum. 60. 1102-1108. 2017

Population	Intervention	Outcomes/Results
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Comparison

<p>Evidence level: 2</p> <p>Study type: RCT</p> <p>Number of Patient: 600</p> <p>Recruitment Phase: NA</p> <p>Inclusion Criteria: Patients scheduled for an outpatient colonoscopy by the principal investigator (PI) at our health system's ambulatory surgery center were invited to participate in the study.</p> <p>Exclusion Criteria: Patients who were not eligible to have their colonoscopies done at the ambulatory surgery center were excluded from the study, as were patients with high-risk cardiac or pulmonary disease, those aged <18 years, and those from vulnerable populations (eg, cognitive impairment, pregnancy, prisoners).</p>	<p>Intervention: Anesthesia personnel administered either fentanyl/midazolam (n = 300) or propofol (n = 300) for sedation during outpatient colonoscopy. A single, highly experienced endoscopist performed all colonoscopies.</p> <p>Comparison: propofol vs. midazolam/fentanyl</p>	<p>Primary: The primary outcomes measured were patient satisfaction (5-point Likert scale) and procedure complications.</p> <p>Secondary: A subinvestigator blinded to the randomization called patients 24 to 72 hours after discharge to obtain data on postprocedure problems and status of resumption of normal activities.</p> <p>Results: Fewer patients who received propofol remembered being awake during the procedure (2% vs 17% for fentanyl, $p < 0.0001$) and were more likely to rate the amount of anesthesia received as being "just right" (98.7% vs 91.3% for fentanyl, $p = 0.0002$) and state that they were "very satisfied" with their anesthesia (86.3% vs 74% for fentanyl, $p = 0.0005$). Twenty-six percent of fentanyl procedures were rated "difficult" compared with 4.3% for propofol ($p < 0.0001$), and complications were fewer in the propofol group (2.7% vs 11.7%, $p < 0.0001$).</p> <p>Author's Conclusion: Patients prefer propofol over a combination of fentanyl/midazolam as their anesthetic for outpatient colonoscopies. From a patient and provider perspective, propofol appears to be superior to fentanyl/midazolam for outpatient colonoscopy.</p>
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Methodical Notes

Funding Sources: none

COI: none

Randomization: yes

Blinding: partially

Dropout Rate/ITT-Analysis: NA

Notes:

Pambianco, D. J. et al. A phase IIb study comparing the safety and efficacy of remimazolam and midazolam in patients undergoing colonoscopy. *Gastrointest Endosc.* 83. 984-92. 2016

Population Intervention - Outcomes/Results

Comparison

<p>Evidence level: 2</p> <p>Study type: RCT</p> <p>Number of Patient: 162</p> <p>Recruitment Phase: NA</p> <p>Inclusion Criteria: Male and female patients aged 18 to 70 years scheduled to undergo a routine diagnostic or therapeutic colonoscopy were eligible. Patients had to have an American Society of Anaesthesiologists Physical Status Classification System (ASA) Score of I, II, or III, a weight range of 55 to 130 kg inclusive, and a body mass index (BMI) of 18 to 33 kg/m².</p> <p>Exclusion Criteria: Patients were excluded if the colonoscopy was expected to take longer than 30 minutes and if they had a suspected or diagnosed pathology of the lower GI tract that would require advanced therapeutic endoscopy. Patients with ASA scores of III were excluded if they had a history of sleep apnea or if they were obese (BMI >33 kg/m²). Patients in whom the management of airways was judged to be difficult also were excluded (eg, thyromental distance <4 cm or Mallampati score of 4)</p>	<p>Intervention: routine colonoscopy.</p> <p>Comparison: remimazolam vs. midazolam</p>	<p>Primary: The primary efficacy endpoint was to assess the success of the procedure, which was defined as (1) MOAA/S \geq 4 on 3 consecutive measurements taken every minute, (2) completion of the procedure, (3) no requirement for an alternative and/or rescue sedative, and (4) no manual or mechanical ventilation.</p> <p>Secondary: Secondary endpoints included time to fully alert (first of 3 consecutive MOAA/S of 5), recall of the procedure, cognition by the Hopkin's Verbal Learning Test (HVLT-R), and time to ready for discharge as assessed by the Aldrete Score \geq 16 as well as adverse events. Pain on injection was assessed by the patient immediately after administration of the study drug, or as soon as possible thereafter, by using a verbal rating scale of 0 to 10, where 0 represents no pain, and 10 the worst possible pain.</p> <p>Results: This study showed that a single dose of remimazolam or midazolam, followed by top-up doses to maintain suitable sedation, provided adequate sedation with a high success rate (>92%) for the remimazolam groups, compared with 75% for the midazolam group (PZ.007). There was no requirement for mechanical ventilation in any group, and procedure failures were all due to use of rescue sedative.</p> <p>Author's Conclusion: The high success rates and good safety profile of remimazolam observed in this study warrants further investigation and confirmation in phase III trials.</p>
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Methodical Notes

Funding Sources: This work was funded by PAION, UK Ltd. K. Borkett and K. Wilhelm-Ogunbiyi are employees of PAION and D. Pambianco is a consultant for PAION.

COI: yes

Randomization: yes

Blinding: Yes

Dropout Rate/ITT-Analysis: NA

Notes:

Park, C. H. et al. Efficacy and safety of etomidate-based sedation compared with propofol-based sedation during ERCP in low-risk patients: a double-blind, randomized, noninferiority trial. Gastrointest Endosc. 87. 174-184. 2018

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 127</p> <p>Recruitment Phase: July 2015 and March 2016</p> <p>Inclusion Criteria: ERCP scheduled, ASA 1-2</p> <p>Exclusion Criteria: history of adverse events with prior sedation; (2) known hypersensitivity to egg products, soy beans, etomidate, propofol, or its emulsifier; (3) known adrenocortical insufficiency, chronic corticoid therapy, or porphyria; (4) severe renal failure (serum creatinine level >2 mg/dL); (5) pregnant or breast-feeding; (6) desire to have endoscopy without sedation; and (7) inability to provide informed consent.</p>	<p>Intervention:</p> <p>Comparison: different sedation</p>	<p>Primary: overall respiratory events</p> <p>Secondary: cardiovascular events</p> <p>Results: overall respiratory events: etomidate non-inferior overall incidence of cardiovascular events tended to be higher in the etomidate group (67.2% vs 50.8%, P=0.060). tachycardia (heart rate >100 beats/min) was more common in the etomidate group than in the propofol group (64.1% vs 34.9%, P=0.001). Transient hypotension tended to be less common in the etomidate group (6.3 vs 15.9%, P=0.084)</p> <p>Author's Conclusion: Etomidate-based sedation during ERCP was non-inferior to propofol-based sedation in terms of the overall incidence of respiratory events in patients with ASA physical status I-II.</p>

Methodical Notes

Funding Sources: none

COI: none

Randomization: yes 1:1

Blinding: yes

Dropout Rate/ITT-Analysis:

Notes:

RCT comparin etomidat vs. propofol for ERCP induction with midazolam in both groups

Park, C. H. et al. Assessing the stability and safety of procedure during endoscopic submucosal dissection according to sedation methods: a randomized trial. PloS one. 10. e0120529. 2015

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: RT</p> <p>Number of Patient: 154</p>	<p>Intervention: ESD Stomach</p> <p>Comparison: 2</p>	<p>Primary: Level of satisfaction of the endoscopist</p> <p>Secondary: Level of patient's satisfaction and pain scores events interfering with the procedure Unintended deep sedation</p>

<p>Recruitment Phase: 3-12 / 2013</p> <p>Inclusion Criteria: Early gastric cancer/adenoma ASA I-III 20-80 yrs</p> <p>Exclusion Criteria: Previous gastric resection Pregnancy, breastfeeding Allergies Prior sedation for another procedure Neurologic or psychotic disorder</p>	<p>different modalities</p> <p>sedation</p>	<p>Outcomes of ESD</p> <p>Results: Level of satisfaction higher in ContrPropofol Group $p > 0.001$ Unintended deep sedation higher in Mid/Prop Group $p > 0.018$ as well as spontaneous movements $p > 0.024$ and physical restraint $p > 0.006$ Level of pts satisfaction higher in Mid/Prop Group $p > 0.027$ No other differences, also not ESD outcomes</p> <p>Author's Conclusion: Continuous propofol/remifentanyl infusion by anaest. provides more stable state of sedation, increasing endoscopists satisfaction level</p>
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Methodical Notes

Funding Sources: Korean College of Helicobacter and Upper Gastrointestinal research
JC Park received therefore funding

COI: No

Randomization: 1:1 ratio patients remained blinded

Blinding: Patients
Inevitably not endoscopists

Dropout Rate/ITT-Analysis: No

Notes:

Rex, D. K. et al. A phase III study evaluating the efficacy and safety of remimazolam (CNS 7056) compared with placebo and midazolam in patients undergoing colonoscopy. Gastrointest Endosc. 88. 427-437.e6. 2018

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 461</p> <p>Recruitment Phase: NA</p> <p>Inclusion Criteria: Inclusion criteria Male and female patients, aged 18, scheduled to undergo a diagnostic or therapeutic colonoscopy (therapeutic procedures may include hemostasis, resection, ablation, decompression, foreign body extraction, for example) American Society of Anesthesiologists Physical Status Classification System risk class 1-3</p>	<p>Intervention: Colonoscopy</p> <p>Comparison: remimazolam vs. placebo vs. midazolam</p>	<p>Primary: Success of procedure as measured by completion of colonoscopy and no requirement for an alternative sedative and, in the case of remimazolam and placebo, no requirement for more than 5 top-ups of study medication within any 15-minute period. In the case of midazolam, no requirement for more than 3 doses in any 12-minute window</p> <p>Secondary: Time to start of procedure after administration of the first dose of medication Time to peak sedation after administration of the first dose of medication Times to readiness for discharge after the end of the procedure Times to fully alert (first of 3 MOAA/S scores of 5 after end of the procedure) Recall of the procedure by the Brice questionnaire¹⁵ when fully alert and on day 4 Changes to the patient's cognitive function by the Hopkins Verbal Learning Test-Revised administered before study medication and after patient was fully alert Safety of multiple doses of remimazolam after a standard dose of fentanyl Ready to discharge 30, 60, and 90 minutes after injection of the initial dose</p>

Body mass index 40 kg/m²

For female patients with child-bearing potential, negative result of pregnancy test (serum or urine) as well as use of birth control during the study

period (from the time of consent until all specified observations were completed)

Patient voluntarily signs and dates an informed consent form that is approved by an institutional review board before patient participates in any

study procedure

Patient is willing and able to comply with study requirements and return for a follow-up visit on day 4 (±1 days) after the colonoscopy

Exclusion Criteria:

Exclusion criteria

Patients with a known sensitivity to benzodiazepines, flumazenil, opioids, naloxone, or a medical condition such that these agents are contraindicated

Chronic use of benzodiazepines for any indication (eg, insomnia, anxiety, spasticity)

Chronic use of opioids for any indication

Female patients with a positive serum human chorionic gonadotropin pregnancy test at screening or baseline

Lactating female patients

Patients with positive drugs of abuse screen or a positive serum ethanol at baseline

Patient with a history of drug or ethanol abuse within the past 2 years

Patients in receipt of any investigational drug within 30 days or less than 7 half-lives (whichever is longer) before screening or are scheduled to receive 1 during the study period

Participation in any

Assessment of re-sedation using a visual analogue scale for drowsiness

Requirement for flumazenil during the procedure

Patient's self-evaluation of back-to-normal after the procedure

Pain on injection at application of the study medication

Population pharmacokinetics in patients aged <65 years and patients aged 65-74 years

Results: There were 461 randomized patients in 12 U.S. sites. The primary endpoint was met for remimazolam, placebo, and midazolam in 91.3%, 1.7%, and 25.2% of patients, respectively (P < .0001 for remimazolam vs placebo). Patients administered remimazolam received less fentanyl, had faster recovery of neuropsychiatric function, were ready for discharge earlier, and felt back to normal sooner than patients with both placebo and midazolam. Hypotension was less frequent with remimazolam, and hypoxia occurred in 1% of patients with remimazolam or midazolam. There were no treatment-emergent serious adverse events.

Author's Conclusion: Remimazolam can be administered safely under the supervision of endoscopists for outpatient colonoscopy, and it allows faster recovery of neuropsychiatric function compared with placebo (midazolam rescue) and midazolam.

previous clinical trial with remimazolam. Patients with an inability to communicate well in English with the investigator or deemed unsuitable according to the investigator (in each case providing a reason)

Methodical Notes

Funding Sources: PAION UK Limited participated in the study design, funded the study, performed the statistical analyses, prepared data tables and figures, and reviewed the manuscript for content and accuracy.

COI: B. Cash and D. Bernstein are consultants and advisors for PAION. D. Quirk is a Senior Medical Director at Pfizer. All other authors disclosed no financial relationships relevant to this publication.

Randomization: yes

Blinding: yes

Dropout Rate/ITT-Analysis: NA

Notes:

Riphaus, A. et al. Clinical value of the Integrated Pulmonary Index(®) during sedation for interventional upper GI-endoscopy: A randomized, prospective tri-center study. Dig Liver Dis. 49. 45-49. 2017

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 183; at the End Intention to treat Analysis 170</p> <p>Recruiting Phase: short</p> <p>Inclusion Criteria: sedation during endoscopy</p> <p>Exclusion Criteria: No Endoscopy possible</p>	<p>Intervention: sedation with Standard Monitoring with and without Capnography</p> <p>Comparison: Decrease in Oxygen saturation</p>	<p>Primary: decrease in Oxygen saturation</p> <p>Secondary: rate of hypoxis Apnoe rate Need for increased oxygen applicatiuon any Need for Ventilation Hypotension bradycardia otherv procedures</p> <p>Results: no significant differences in drop og Oxygen saturation</p> <p>Author's Conclusion: No advantige of IPI during Deep sedation</p>

Methodical Notes

Funding Sources:

COI: none

Randomization: ok

Blinding: ni

Dropout Rate/ITT-Analysis: 188 -> 170 (9%)

Notes:

Sachar, H. et al. Continued midazolam versus diphenhydramine in difficult-to-sedate patients: a randomized double-blind trial. Gastrointest Endosc. 87. 1297-1303. 2018

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: Randomized double-blind trial</p> <p>Number of Patient: 200</p> <p>Recruiting Phase: Between February 2013 and June 2015.</p> <p>Inclusion Criteria: Patients undergoing elective colonoscopy with moderate sedation were eligible.</p> <p>Exclusion Criteria: Patients were excluded if they had a documented allergy or adverse reaction to prior use of diphenhydramine, closed angle glaucoma, were unable or unwilling to provide informed consent, or were pregnant.</p>	<p>Intervention: Moderate sedation for elective colonoscopy. Patients were randomly assigned to receive intravenous diphenhydramine 25 mg versus midazolam 1.5 mg.</p> <p>Comparison: Patients not adequately sedated with midazolam 5 mg and fentanyl 100 mcg were randomly assigned to diphenhydramine 25 mg versus continued midazolam 1.5 mg.</p>	<p>Primary: Adequate sedation. Adequate sedation, assessed 3 minutes after the last dose of study medication was given and before initiation of the colonoscopy. Adequacy of sedation was assessed 3 minutes after each study medication dose. If MOAA/S was 4 to 5, study medication was repeated, to a maximum of 3 doses.</p> <p>Secondary: Safety endpoints were (1) oxygen desaturation (<90% for ≥1 minute), (2) hypotension (systolic blood pressure <90 mm Hg), or (3) use of a reversal agent. Other endpoints included (1) time from first dose of study drug to discharge from recovery room; (2) need for additional sedation drugs after study drugs were administered (before or during colonoscopy); (3) post-procedural assessment of adequate procedural sedation by endoscopist; (4) post-procedural assessment of adequate procedural sedation by patient; and 5) patient willingness to repeat colonoscopy assessed 24 hours after the procedure. Endoscopists' and patients' assessment of adequate sedation were performed by asking if they felt adequate sedation was achieved (adequate vs inadequate).</p> <p>Results: Adequate sedation was achieved less often with diphenhydramine than midazolam: 27% versus 65%, difference = -38%; 95% CI, -50% to -24%; p<0.0001. After study medications were completed, more patients required additional medication for sedation or analgesia with diphenhydramine versus midazolam (84% vs 68%, p=0.008), whereas the time to discharge from the recovery unit was similar (134 vs 129 minutes).</p> <p>Author's Conclusion: Endoscopists performing moderate sedation should continue midazolam rather than switching to diphenhydramine in patients who do not achieve adequate sedation with usual doses of midazolam and an opioid.</p>

Methodical Notes

Funding Sources: Grant Support: NIH T32 DK007017, P30 DK34989.

COI: None.

Randomization: The randomization schedule was computer-generated by an individual uninvolved in the conduct of the study. The assignments were concealed using opaque coverings that were removed only at the time of randomization.

Blinding: A separate individual, who was uninvolved in patient care or assessment, determined the randomization assignment, obtained the study medication (clear, colorless solutions in identical 5 mL syringes) in a separate room, and then administered the study medication.

Dropout Rate/ITT-Analysis: ITT done.

Notes:

Schaible, A. et al. Acupuncture to improve tolerance of diagnostic esophagogastroduodenoscopy in patients without systemic sedation: results of a single-center, double-blinded, randomized controlled trial (DRKS00000164). *Trials*. 17. 350. 2016

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: Single-center, double-blinded, randomized controlled trial</p> <p>Number of Patient: 354</p> <p>Recruiting Phase: From February 2010 to July 2012.</p> <p>Inclusion Criteria: All patients aged 18 years or older scheduled for elective, diagnostic esophagogastroduodenoscopy who refused systemic sedation.</p> <p>Exclusion Criteria: The exclusion criteria were refusal to participate, ASA score V, participation in another trial that could interfere with the primary endpoint, impaired mental state, expected lack of compliance, need for systemic sedation, emergency procedures, pregnancy, and known allergy to lidocaine anesthetic spray or acupuncture needle material.</p>	<p>Intervention: Real or placebo acupuncture before and during esophagogastroduodenoscopy.</p> <p>Comparison: Real or placebo acupuncture before and during esophagogastroduodenoscopy.</p>	<p>Primary: Rate of successful esophagogastroduodenoscopies.</p> <p>Secondary: Willingness to repeat the procedure, defined as readiness of the patient to repeat the examination under the same conditions; heart rate (beats per minute); blood pressure (mmHg), and oxygen saturation (percent) assessed before esophagogastroduodenoscopy, after passage of the larynx, and after removal of the endoscope; the duration of the examination (min) from insertion to removal of the endoscope; and all peri-interventional complications.</p> <p>Results: Endoscopy could successfully be performed in 130 patients (73.5 %) in the real acupuncture group and 129 patients (72.9 %) in the placebo group. Willingness to repeat the procedure under the same conditions was 86.9 % in the real acupuncture group and 87.6 % in the placebo acupuncture group.</p> <p>Author's Conclusion: Patients planned for elective esophagogastroduodenoscopy without sedation do not benefit from acupuncture of the Sinarteria respondens (Rs) 24 Chengjiang middle line, Pericard (Pc) 6 Neiguan bilateral, or Dickdarm (IC) 4 Hegu bilateral, according to traditional Chinese medicine meridian theory.</p>

Methodical Notes

Funding Sources: Not reported.

COI: None.

Randomization: Block randomization in a 1:1 allocation ratio. The random allocation sequence was generated by the Institute of Medical Biometry and Informatics with SAS version 9.1 (PROC PLAN). Treatment group allocation

was performed using sealed and consecutively numbered opaque envelopes produced by the Institute of Medical Biometry and Informatics.

Blinding: Yes.

Dropout Rate/ITT-Analysis: ITT done.

Notes:

Seo, S. I. et al. Safety of Target-Controlled Propofol Infusion by Gastroenterologists in Patients Undergoing Endoscopic Resection. Dig Dis Sci. 61. 3199-3206. 2016

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 4</p> <p>Study type: prospective interventional study</p> <p>Number of Patient: 431</p> <p>Recruiting Phase: 11/2011-8/2014 (33 months)</p> <p>Inclusion Criteria: - patients undergoing therapeutic endoscopy (ESD and EMR) - ASA I-III</p> <p>Exclusion Criteria: - pregnancy - refusal of sedation endoscopy - ASA >III - hypersensitivity to propofol, egg, soybean, or sulfites; or previous adverse reaction during previous sedation</p>	<p>Intervention: MCI (manual controlled infusion) and TCI (target controlled infusion) propofol infusion for sedation</p> <p>Comparison: Adverse event rates in MCI and TCI groups and assessed independent risk factors for adverse events</p>	<p>Primary: Sedation-related adverse event rate</p> <p>Secondary: Risk factors for minor and major event</p> <p>Results: Total adverse event rate: 5.8 % (25/431) There was no difference in adverse event rate between the MCI and TCI groups [5.5 % (15/27) vs. 6.3 % (10/160), P = 0.759]. ESD group: All adverse events happened in the upper ESD group (16/175), no event in the lower ESD group (0/3). EMR group: No difference between upper and lower endoscopy regarding adverse events. Parameters: Age, sex, BMI, ASA physical status, propofol infusion method, total infusion dose, and infusion dose per minute, were not different between the event-free and event groups</p> <p>Author's Conclusion: Target-controlled propofol infusion by a well-trained gastroenterologist can provide safe sedation in patients undergoing ESD combined with careful respiratory monitoring.</p>

Methodical Notes

Funding Sources: This research was supported by Hallym University Research Fund 2014 (HURF-2014-58).

COI: None

Randomization: None

Blinding: None

Dropout Rate/ITT-Analysis: None

Notes:

No correct randomization.

Shen, X. C. et al. Etomidate-remifentanil is more suitable for monitored anesthesia care during gastroscopy in older patients than propofol-remifentanil. Med Sci Monit. 21. 1-8. 2015

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 2</p>	<p>Intervention:</p>	<p>Primary: adverse events, hemodynamics</p>

<p>Study type: RCT</p> <p>Number of Patient: 720</p> <p>Recruitment Phase: July 2012 and December 2012</p> <p>Inclusion Criteria: unmedicated ASA I-III patients (age 60–80 years) scheduled to undergo diagnostic gastroscopy at Daping Hospital.</p> <p>Exclusion Criteria: cardiac, pulmonary, hepatic or nephritic disease, metabolic dis-ease, electrolyte disturbance, blood pressure >180/110 mmHg, allergy to emulsion or opioid, second-degree atrioventricular block or complete left bundle branch block, and acute airway inflammation in the past 2 weeks.</p>	<p>Comparison:</p>	<p>Secondary: onset of sedation, quality, satisfaction with sedation</p> <p>Results: Systolic pressure and diastolic pressure decreased significantly after the procedure in the propofol group (P<0.001). The average heart rate was significantly lower in the propofol group (P<0.05). No periods of desaturation (SpO2 <95%) were observed in either group. The onset time was earlier in the etomidate group (P=0.00). All adverse events, with the exception of myoclonus, were greater in the propofol group, and physician and patient satisfaction in both groups was similar.</p> <p>Author's Conclusion: Etomidate-remifentanil administration for sedation and analgesia during gastroscopy resulted in more stable hemodynamic responses and less adverse events in older patients.</p>
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Methodical Notes

Funding Sources: National Natural Science Foundation of China (No.81171526) and Chongqing Natural Science Foundation (No. CSTC 2011 jjA10061)

COI: none

Randomization: yes

Blinding: no

Dropout Rate/ITT-Analysis: 5 of 720

Notes:

RCT, but combination therapy for simple diagnostic EGD
no blinding

Shin, S. et al. Conventional versus Analgesia-Oriented Combination Sedation on Recovery Profiles and Satisfaction after ERCP: A Randomized Trial. PLoS One. 10. e0138422. 2015

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: rct</p> <p>Number of Patient: 232</p> <p>Recruitment Phase: 6 month</p> <p>Inclusion Criteria: indication for ercp</p> <p>Exclusion Criteria:</p>	<p>Intervention: ercp with sedation</p> <p>Comparison: meperidine(initial Bolus) plus Propofol with balanced fentanyl</p>	<p>Primary: recovery time pat. and endoscopist satisfaction</p> <p>Secondary:</p> <p>Results: non inferiority with respect to Recovery ans pat and Endosc Satisfaction</p> <p>Author's Conclusion: better propofol with fentanyl because no differences in recovery time</p>

Methodical Notes

Funding Sources: none

COI: none

Randomization: Computer based

Blinding: for outcome measure

Dropout Rate/ITT-Analysis: 30

Notes:

Spagnuolo, R. et al. Effects of listening to music in digestive endoscopy: A prospective intervention study led by nursing. J Adv Nurs. 76. 2993-3002. 2020

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: prospective intervention trial, consecutive patients, matched by demographics and allocated to 4 groups</p> <p>Number of Patient: 311</p> <p>Recruiting Phase: March 2019–June 2019</p> <p>Inclusion Criteria: consecutive outpatients un-undergoing diagnostic digestive endoscopic examinations</p> <p>Exclusion Criteria: younger 18 years cognitive disorders, unable to write and read in Italian, who underwent operative endoscopic procedures, EUS or endoscopic retrograde colangiopancreatography</p>	<p>Intervention: routine endoscopy with or without music anxiety score before and after endoscopy</p> <p>Comparison:</p>	<p>Primary: anxiety score pain</p> <p>Secondary: willingness for re-endoscopy</p> <p>Results: Before and at the end of the procedure, patients who listened to music had a lower level of anxiety than those who did not listen lower pain intensity during procedure for music</p> <p>Author's Conclusion: music in digestive endoscopy reduce pain and anxiety in conscious sedation, thus could be used to reduce anxiety in support to conscious sedation leading to lower usage of deep sedation and consequently reduction of costs and adverse events</p>

Methodical Notes

Funding Sources: no

COI: no

Randomization: no, matched patients allocation to 4 groups

Blinding: no

Dropout Rate/ITT-Analysis:

Notes:

RCT, influence of music, groups not completely equal

Sun, G. Q. et al. Application of remifentanyl for conscious sedation and analgesia in short-term ERCP and EST surgery. Medicine (Baltimore). 96. e6567. 2017

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 4</p> <p>Study type: Randomized study.</p>	<p>Intervention: Patients who underwent ERCP and EST were randomly divided into two groups: research group and control group. Patients in the research group were intravenously injected with remifentanyl (80–2/3* age) for 1 to 2 minutes, combined with the</p>	<p>Primary: Not reported.</p> <p>Secondary: Not reported.</p> <p>Results: In research group, the circulatory and respiratory depression of patients was</p>

<p>Number of Patient: 58 or 68: Different numbers given.</p> <p>Recruiting Phase: From September 2016 to December 2016</p> <p>Inclusion Criteria: Not reported.</p> <p>Exclusion Criteria: Not reported.</p>	<p>intravenous injection of propofol (20–30 mg) during the course of treatment. Sedative drugs were not given in patients in the control group.</p> <p>Comparison: See above.</p>	<p>mild, only one patient needed to be treated, and there was no arrhythmia requiring treatment. Five patients had respiratory depression (blood oxygen saturation decreased to <90%), which was immediately corrected.</p> <p>Author's Conclusion: The use of remifentanyl for conscious sedation and analgesia can be broadly applied in short-term ERCP.</p>
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Methodical Notes

Funding Sources: Not reported.

COI: Not reported.

Randomization: Not reported.

Blinding: None.

Dropout Rate/ITT-Analysis: Not reported.

Notes:

Severe methodological flaws: No description of study details.

Teoh, A. Y. B. et al. Electroacupuncture-reduced sedative and analgesic requirements for diagnostic EUS: a prospective, randomized, double-blinded, sham-controlled study. Gastrointest Endosc. 87. 476-485. 2018

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 128</p> <p>Recruiting Phase: March 2014 and July 2016</p> <p>Inclusion Criteria:</p> <p>Exclusion Criteria:</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary: dosage of propofol</p> <p>Secondary: pain scores, anxiety, satisfaction scores, procedure time, adverse events</p> <p>Results: patients received EA had significantly fewer PCA requirements. The median number of demands for PCA (2 [1 – 5] vs 16.5 [8.5 – 33.8], P<0.001), the number of successful demands (2 [1 – 4] vs 9 [5.3 – 13], P<0.001), the total dose of propofol (0.15 [0.08 – 0.34] vs 0.77 [0.38 – 1.09], P<0.001) and alfentanil (0.38 [0.20 – 0.86] vs 1.92 [0.94 – 2.72], P<0.001) were all significantly less. Patients that received EA also had significantly less procedural pain scores and anxiety scores (P<0.001), higher satisfaction scores (P<0.001), and they are more willing to repeat the procedure (P<0.001). Both being in the SA group and the procedural time were significant</p> <p>Author's Conclusion: EA reduced sedative and analgesic demands, improved patient experience, and was associated with low risk of adverse events during diagnostic EUS.</p>

Methodical Notes

Funding Sources: Health and Medical Research Fund, Hong Kong.

COI: none

Randomization: yes, electroacupuncture vs. sham acupuncture

Blinding: yes

Dropout Rate/ITT-Analysis:

Notes:

RCT, double blind

Tian, L. et al. A randomized controlled trial for measuring effects on cognitive functions of adding ketamine to propofol during sedation for colonoscopy. Medicine (Baltimore). 99. e21859. 2020

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: Randomized, double-blinded, and controlled study</p> <p>Number of Patient: 200</p> <p>Recruitment Phase: Not reported.</p> <p>Inclusion Criteria: Patients aged above 18 years, who were of physical status I-II according to the American Society of Anesthesiologists (ASA), and were scheduled for elective colonoscopy procedure.</p> <p>Exclusion Criteria: Patient refusal, Mini-Mental Test (MMT) scores of <26, advanced cardiopulmonary or psychiatric disease, alcohol or drug addiction, morbid obesity (body mass index >30 kg/m), history of undergoing anesthesia in the last 7 days, and known allergy to the drugs studied.</p>	<p>Intervention: Sedation.</p> <p>Comparison: Allocation to ketamine/propofol admixture group (Group KP, n= 100), and propofol group (Group P, n= 100). Patients in Group KP received 0.25 mg/kg of ketamine and 0.5 mg/kg of propofol. Patients in Group P received 0.5 mg/kg propofol.</p>	<p>Primary: Cognitive impairment: Difference in accuracy on CogState tests between the discharge and baseline assessments between the 2 experimental groups.</p> <p>Secondary: Operating conditions, complications, recovery times, and satisfaction with care</p> <p>Results: one-card learning accuracy and One-back memory was only impaired in Group KP patients (P=.006, P=.040) after the endoscopy but left intact in Group P patients. Group KP patients showed more severe impairment in one-card learning accuracy compared with Group P patients (P=.044). Group KP patients have better 5 minutes MAP (P=.005) and were also less likely to suffer from complications such as respiratory depression (P=.023) and hypotension (P=.015). OAA/S scores, BIS, MAP, complications, recovery times, and endoscopist and patient satisfaction were similar between the 2 groups.</p> <p>Author's Conclusion: Although adding ketamine to propofol for sedation in colonoscopy provided fewer complications such as respiratory depression and hypotension, it also causes more impairment in cognitive functions.</p>

Methodical Notes

Funding Sources: Hansoh Foundation of Lianyungang (QN1706).

COI: None.

Randomization: By using random numbers generated by computer placed in sealed envelopes.

Blinding: Blinding was provided by an anesthesiologist who did not participate in anesthesia application. He had access to the randomization list when the patient was admitted to the colonoscopy suite and met criteria for study inclusion. He prepared appropriate anesthesia-inducing drugs for each group.

Dropout Rate/ITT-Analysis: Ninety five patients in Group KP and 92 patients in Group P had completed the CogStates tests and were included in the data analysis.

Notes:

Tuncali, B. et al. Addition of low-dose ketamine to midazolam-fentanyl-propofol-based sedation for colonoscopy: a randomized, double-blind, controlled trial. J Clin Anesth. 27. 301-6. 2015

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: Prospective RCT double-blinded</p> <p>Number of Patient: 97/100 eligible pts 3 excluded</p> <p>Recruitment Phase: Unclear Ethical approval 12/2011</p> <p>Inclusion Criteria: Pts for outpatient colonoscopy ASA I-II 18-75 yrs.</p> <p>Exclusion Criteria: Pregnancy History of sedation or anaesthesia in the last 7 days Psychiatric or emotional disorder Previous adverse reactions to opioids or sedatives used in this study</p>	<p>Intervention: Colonoscopy pts Sedation with Mid/Fent/Propofol alone (Group C) vs same combination plus Ketamine (Group K)</p> <p>Comparison: see above</p>	<p>Primary: Effectiveness Safety Recovery Propofol consumption Patient's and endoscopists' satisfaction</p> <p>Secondary: not specified</p> <p>Results: Decrease in hemodynamic status higher in Group C $p < 0.05$ Less disruptive movements in Group K $p < 0.05$ Induction time more rapid in Group K $p < 0.01$ Total amount of Propofol lower in Group K $p < 0.01$ No difference in the satisfactory level of Pat/Endoscopist at the end of procedure</p> <p>Author's Conclusion: Addition of low-dose Ketamine to Mid/Fent/Prop sedation in outpatient colonoscopy resulted in more rapid and better quality of sedation, less propofol consumption, more stable hemodynamic status, less adverse effects with similar recovery times</p>

Methodical Notes

Funding Sources: not stated

COI: not stated

Randomization: yes

Blinding: yes

Dropout Rate/ITT-Analysis: none

Notes:

Time of Study period not stated
Unusual combination of 3+1 drugs
Relative low number of pts in the 2 groups

Uzman, S. et al. A comparison of propofol and midazolam/meperidine sedation in upper gastrointestinal endoscopy. Wideochir Inne Tech Maloinwazyjne. 11. 178-185. 2016

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: prospective randomized double blind</p> <p>Number of Patient: 100</p> <p>Recruiting Phase: 5 month</p> <p>Inclusion Criteria: upper GI Endoscopy</p> <p>Exclusion Criteria: Allergy to study drugs ,egg, Soybean oil, age <18, pregnancy oder breast feeding, Risk of difficult intubation, , Mallampati III-IV, OAS, ASA >3, history of complication during previous Sedations</p>	<p>Intervention: Sedation during upper GI Endoscopy</p> <p>Comparison: Sedation with Propofol versus Meperidine/ midazolam</p>	<p>Primary: Cardiopulmonary side effects, procedure related times, patients and endoscopist satisfaction</p> <p>Secondary:</p> <p>Results: No difference with respect to cost, endoscopy time, demographic and clinical characteristics Differences in: awake and discharge time Shorter in propofol Group Hypotension more less in Midazolam Group Satisfaction better in Patients and Endoscopist group</p> <p>Author's Conclusion: Propofol may be preferred with a shorter awake and hospital discharge time and better patients and endoscopist satisfaction</p>

Methodical Notes

Funding Sources: none

COI: none

Randomization: computer

Blinding: yes

Dropout Rate/ITT-Analysis: 125 -> 100

Notes:

Vu?i?evi?, V. et al. Manual versus target-controlled infusion of balanced propofol during diagnostic colonoscopy – A prospective randomized controlled trial. Srp Arh Celok Lek. 144. 514-20. 2016

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 90</p> <p>Recruiting Phase: not documented</p> <p>Inclusion Criteria: diagnostic colonoscopy, ASA I,II, 18-65 Jahre, 50-120kg,</p> <p>Exclusion Criteria: allergy to medication, ASA >2, sleep apnea, history of stridor, pregnant, Mallampati III,IV, history of bowel-surgery</p>	<p>Intervention: MT vs. TCI</p> <p>Comparison: hypoxemia, cardiovascular parameters, endoscopist's comfort</p>	<p>Primary: patient's safety, endoscopist's comfort</p> <p>Secondary:</p> <p>Results: MT lower mean RR 10th minute, end of colonoscopy MT: higher oxygen saturation 5th minute, 15th minute MT: lower heart rate beginning of the procedure endoscopist's comfort (questionnaire): 88,9% MT, 95,6% TCI Adverse event: No difference</p> <p>Author's Conclusion: Both combinations are suitable for deep sedation (diagnostic colonoscopy, ASA I,II)</p>

Methodical Notes

Funding Sources: Not documented

COI: Not documented

Randomization: yes

Blinding: no

Dropout Rate/ITT-Analysis: drop out: 0

Notes:

the study quality is good, but the sedation regime of the intervention unusual (mida/fenta/propofol for diagnostic colonoscopy)

Wang, C. X. et al. Randomized controlled study of the safety and efficacy of nitrous oxide-sedated endoscopic ultrasound-guided fine needle aspiration for digestive tract diseases. World J Gastroenterol. 22. 10242-10248. 2016

Population

Intervention - Comparison

Outcomes/Results

Evidence level: 3

Study type: RCT

Number of Patient: 42

Recruitment Phase: March 1 2015 to May 31 2016

Inclusion Criteria: The inclusion criteria for the study were patients who required EUS-FNA and agreed to sedation with nitrous oxide.

Exclusion Criteria: Patients were excluded if they exhibited any of the following contraindications to nitrous oxide sedation or EUS: (1) intending to get pregnant or in the first trimester of pregnancy; (2) coma; (3) within 1 wk of gas cerebral angiography; (4) diving diseases or a recent history of diving activities; (5) middle ear diseases; (6) pneumothorax, pulmonary cystic fibrosis, or chronic debilitating weakness due to other respiratory disorders; (7) intestinal obstruction; (8) history of gastrointestinal surgery; (9) history of sinus or nasal-septum surgery; (10) need for endoscopic treatment; (11) American Society of Anesthesiology (ASA) grade > 3; and (12) blood oxygen saturation

Intervention: endoscopic ultrasound-guided fine needle aspiration

Comparison: nitrous oxide vs. oxygen

Primary: Patients were monitored closely and the following negative events were recorded: oxygen desaturation (oxygen saturation < 95%, but ≥ 90%), hypoxia (oxygen saturation < 90%, but ≥ 85%), severe hypoxemia (oxygen saturation < 85%), hypotension (systolic blood pressure < 90 mmHg), bradycardia (heart rate < 50 bpm), and tachycardia (heart rate > 120 bpm). Patients and endoscopists completed questionnaires regarding their degree of satisfaction with the examination process, and scored them on a visual analog scale (VAS) scale. The following questions were included: (1) evaluation of the operation by the endoscopist: (smooth, ordinary, not smooth); (2) patient discomfort during the operation process (slight, moderate, severe); (3) patient tolerance with the examination process (good, medium, and low); and (4) willingness to receive the same examination again if needed (yes, no).

Secondary: NA

Results: There was no significant difference in heart rate, blood oxygen saturation, blood pressure, ECG

<p>< 95% and systolic blood pressure < 90 mmHg as displayed on the monitor.</p>		<p>changes, or complication rate between the two groups of patients (P > 0.05). However, patient and physician satisfaction were both significantly higher in the nitrous oxide compared with the control group (P < 0.05).</p> <p>Author's Conclusion: Nitrous oxide-sedation is a safe and effective option for patients undergoing endoscopic ultrasound-guided fine needle aspiration.</p>
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Methodical Notes

Funding Sources: NA

COI: NA

Randomization: yes

Blinding: partially

Dropout Rate/ITT-Analysis:

Notes:

Wang, J. F. et al. Target-Controlled Infusion of Propofol in Training Anesthesiology Residents in Colonoscopy Sedation: A Prospective Randomized Crossover Trial. *Med Sci Monit.* 22. 206-10. 2016

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: RCT</p> <p>Number of Patient: 18 training residents</p> <p>Recruitment Phase: NA</p> <p>Inclusion Criteria: NA</p> <p>Exclusion Criteria: NA</p>	<p>Intervention: colonoscopy</p> <p>Comparison: TCI vs. MCI</p>	<p>Primary: sedation quality of TCI and MCI techniques by comparing satisfaction of endoscopist and patients based on the visual analogue scale (VAS).</p> <p>Secondary: Heart rate (HR), mean blood pressure (MAP), SpO2, and recovery time were also compared as the secondary outcomes</p> <p>Results: The demographic data were similarly distributed among the TCI and MCI patients. Endoscopist's satisfaction score in the TCI group was significantly higher than in the MCI group, 81.3±7.2 versus 74.2±9.5 (P=0.003), but the patients' satisfaction score was similar between the 2 groups. More stable hemodynamic status was obtained in the TCI group, manifested as higher lowest MAP and lower highest MAP than in the MCI group. Lowest SpO2 in the TCI group was significantly higher than in the MCI group. Patients in the TCI group recovered earlier than in the MCI group.</p> <p>Author's Conclusion: TCI is a more effective and safer technique for anesthesiology residents in sedation for colonoscopy</p>

Methodical Notes

Funding Sources: NA

COI: none

Randomization: yes

Blinding: no

Dropout Rate/ITT-Analysis:

Notes:

Watanabe, K. et al. Propofol is a more effective and safer sedative agent than midazolam in endoscopic injection sclerotherapy for esophageal varices in patients with liver cirrhosis: a randomized controlled trial. Fukushima J Med Sci. 64. 133-141. 2018

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: RCT</p> <p>Number of Patient: 23</p> <p>Recruiting Phase: NA</p> <p>Inclusion Criteria: 1) patients with liver cirrhosis who were scheduled for treatment with prophylactic EIS for EVs ; 2) patients without a history of treatment or bleeding of EVs ; 3) patients between 20 and 80 years of age ; 4) patients with a performance status of 0 ; and 5) patients who provided consent to receive EIS and participate in this study.</p> <p>Exclusion Criteria: 1) patients with liver cirrhosis who were scheduled for treatment with prophylactic EIS for EVs ; 2) patients without</p>	<p>Intervention: endoscopic injection sclerotherapy</p> <p>Comparison: propofol vs. midazolam</p>	<p>Primary: The primary endpoint was exacerbation of MHE after EIS, which was defined as deterioration of the NCT.</p> <p>Secondary: The secondary endpoints were postoperative awareness, technical success rate, frequency of body movement, patient and operator satisfaction, cardiorespiratory dynamics during EIS, and adverse events.</p> <p>Results: Exacerbations of MHE at 2 hours after EIS compared with those before EIS were not significantly different between the two groups. In both groups, the deterioration of NCT scores before and 2 hours after EIS was observed (Propofol group : 60.0 vs. 70.0 s, P = 0.026 ; Midazolam group : 42.5 vs. 67.0 s, P = 0.002). There were no significant differences in awareness, technical success rate, or patient satisfaction. However, the frequency of body movement in the Propofol group was significantly lower than that in the Midazolam group (1 vs. 4, P = 0.045), and operator satisfaction in the Propofol group was significantly higher than that in the Midazolam group (P = 0.016). No adverse events were observed.</p> <p>Author's Conclusion: Propofol-based sedation exacerbated MHE after EIS similarly to midazolam-based sedation in patients with liver cirrhosis. However, propofol-based sedation provided stable sedation with a lower frequency of body movements and high operator satisfaction.</p>

a history of treatment or bleeding of EVs ; 3) patients between 20 and 80 years of age ; 4) patients with a performance status of 0 ; and 5) patients who provided consent to receive EIS and participate in this study.

Methodical Notes

Funding Sources: none

COI: none

Randomization: yes

Blinding: no

Dropout Rate/ITT-Analysis: NA

Notes:

Wu, Y. et al. A comparison of propofol vs. dexmedetomidine for sedation, haemodynamic control and satisfaction, during esophagogastroduodenoscopy under conscious sedation. J Clin Pharm Ther. 40. 419-25. 2015

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 70</p> <p>Recruiting Phase: 6 Months</p> <p>Inclusion Criteria: elective EGD, 18-65 years old, ASA I or II,</p> <p>Exclusion Criteria: ASA III, prior gastrectomy, comorbid conditions (cardiovascular , diabetes, hepatic or renal deficiency, chronic alcoholism, narcotic drug abuse, any allergies of components of used drugs, pregnancy</p>	<p>Intervention: Sedation Upper GI Endoscopy</p> <p>Comparison: propofol vs. dexmedetomidine,</p>	<p>Primary: not differentiated between primary and secondary; Vital signs, sedation level, adverse event, patient's and endoscopist's satisfaction score, recovery time</p> <p>Secondary:</p> <p>Results: all mentioned results statistically significant: MAP in the propofol group decreased during the procedure and was also lower than in D Group. Heart rate decreased in D group</p> <p>Author's Conclusion: Both medications provide relatively satisfactory level of sedation without notable adverse effects.</p>

Methodical Notes

Funding Sources: none

COI: non

Randomization: computer generated

Blinding: yes

Dropout Rate/ITT-Analysis: 2 in D 1 in P

Notes:

Yamamoto, H. et al. Clinical impact of gastroenterologist-administered propofol during esophagogastroduodenoscopy: a randomized comparison at a single medical clinic. Gastric Cancer. 18. 326-31. 2015

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: Randomised controlled trial</p> <p>Number of Patient: 106, 54 underwent sedation with propofol, whereas 52 had sedation with midazolam</p> <p>Recruiting Phase: 10/2012 until 5/2013</p> <p>Inclusion Criteria: All patients with suspected gastric cancer who underwent diagnostic upper GI-endoscopy (EGD).</p> <p>Exclusion Criteria: Age < 20 years, Age > 69 years, ASA-class > 2, body weight > 100 kg, pregnant patients, allergy to soybean or eggs, those with former cerebral infarction or psychiatric disorders.</p>	<p>Intervention: Patients who underwent diagnostic EGD under either propofol bolus sedation by registered nurses under supervision of the endoscopist (NAPS) vs. sedation with midazolam by the same team.</p> <p>Comparison: Sedation level and tolerability as well as recovery times were assessed in both groups. They assumed that 50 % of the midazolam group will have full recovery after 30 minutes and tried to detect a 30 % difference by propofol sedation.</p>	<p>Primary: The sample size was calculated from the expected frequency of recovery within 30 minutes.</p> <p>Secondary: Patient tolerability of the procedure and assessment of the sedation level.</p> <p>Results: No severe complications occurred, oxygen desaturation was found in only 1 pts. No significant differences were detected regarding sedation level and patient tolerability. Full recovery time was significant shorter in the propofol group (4,7 Min) than in the midazolam group (24 min, p< 0.01).</p> <p>Author's Conclusion: Regarding post-procedure management of patients propofol use might not necessitate a recovery room and excessive assessment tasks because of rapid recovery time without any prolonged reaction, which causes patient compliance.</p>

Methodical Notes

Funding Sources: none

COI: none

Randomization: Yes

Blinding: none

Dropout Rate/ITT-Analysis: From 117 pts. invited to participate in the study 9 refused to participate and 2 pts. were canceled.

Notes:

Yamasaki, Y. et al. Pethidine hydrochloride is a better sedation method for pharyngeal observation by transoral endoscopy compared with no sedation and midazolam. Dig Endosc. 29. 39-48. 2017

Population	Intervention Comparison	Outcomes/Results
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<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 120 : No sedation 41; Midazolam 40; Pethidine hydr.39</p> <p>Recruitment Phase: 3/2015-5/2015</p> <p>Inclusion Criteria: Esophageal squamous cell carcinoma (SSC) before/under treatment or history of SSC</p> <p>Exclusion Criteria: Pharyngeal cancer (PC) diagnosed before Bleeding tendency Severe organ failure</p>	<p>Intervention: Magnifying upper endoscopy; narrow imaging; 10,2 mm endoscope 7 sites in 5 pharyngeal regions</p> <p>Comparison: Mucolytic agent Lidocaine Sodium bicarbonate all pts before examination</p>	<p>Primary: Total score of 5 pharyngeal regions</p> <p>Secondary: Proportion of the perfect score using a 7-point scale,discomfort score,adverse events</p> <p>Results: Mean total score for No sedation (5,7),midazolam(5,5),pethidine(6,8) p>0.0001 Perfect score 53%, 35%, 89% p>0.0001 Pethidine group had best results Discomfort score better for pethidine p>0.0004 to no sedation and midazolam p>0.0001 to no sedation Adverse events higher in midazolam group p>0.0001 No differences in local diagnostic results (PC)</p> <p>Author's Conclusion: Pethidine hydrochl.was found to be the best and safes method for pharyngeal observation in esophageal cancer patients</p>
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Methodical Notes

Funding Sources: Not mentioned

COI: none

Randomization: Yes

Blinding: Yes

Dropout Rate/ITT-Analysis: none

Notes:

Intersting Study , because using opioids it is possible toobtain pat's cooperation while reducing the gag reflex and discomfort

Yin, N. et al. Effect of propofol combined with opioids on cough reflex suppression in gastroscopy: study protocol for a double-blind randomized controlled trial. BMJ Open. 7. e014881. 2017

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type:</p> <p>Number of Patient:</p> <p>Recruitment Phase:</p> <p>Inclusion Criteria:</p> <p>Exclusion Criteria:</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary:</p> <p>Secondary:</p> <p>Results:</p> <p>Author's Conclusion:</p>

Methodical Notes

Funding Sources:

COI:

Randomization:

Blinding:

Dropout Rate/ITT-Analysis:

Notes:

Yin, S. et al. Efficacy and Tolerability of Sufentanil, Dexmedetomidine, or Ketamine Added to Propofol-based Sedation for Gastrointestinal Endoscopy in Elderly Patients: A Prospective, Randomized, Controlled Trial. Clin Ther. 41. 1864-1877.e0. 2019

Population	Intervention - Comparison	Outcomes/Results
Evidence level: 2 Study type: RCT Number of Patient: 120 Recruiting Phase: ? Inclusion Criteria: ? elderly patients undergoing GI endoscopy Exclusion Criteria:	Intervention: Comparison:	Primary: Mean arterial pressure, heart rate, pulse oximetry, pressure of endtidal carbon dioxide, respiratory rate, and Ramsay sedation scale score were recorded. Induction time, procedure time, recovery time, propofol dose, and adverse events Secondary: Results: AUC of HR was lowest in the propofol + dexmedetomidine group (all, $P < 0.05$), and the AUC of pulse oximetry was significantly higher in the propofol + dexmedetomidine and propofol + ketamine groups compared to the other 2 groups (both, $P < 0.05$). The propofol + dexmedetomidine group had the highest prevalences of hypotension and bradycardia, and the control group experienced the largest number of hypoxia episodes (all, $P < 0.05$). The control group consumed the highest dose of propofol, while the propofol + ketamine group needed the lowest dose (all, $P < 0.05$). Author's Conclusion: combination of propofol + ketamine 0.4 mg/kg maintained hemodynamic and respiratory stability, as evidenced by less hypotension, bradycardia, and hypoxia events, in elderly patients undergoing gastrointestinal endoscopy.

Methodical Notes

Funding Sources: unclear

COI: unclear

Randomization: yes

Blinding: unclear

Dropout Rate/ITT-Analysis: unclear

Notes:

RCT, no full text available....
different regimes of sedation in elderly patients

Zhang, J. et al. Sedation and use of analgesics in endoscopic retrograde cholangiopancreatography: a double-blind comparison study of meperidine/midazolam, remifentanil/ midazolam, and remifentanil alone. Int J Clin Pharmacol Ther. 54. 872-879. 2016

Population	Intervention - Comparison	Outcomes/Results
Evidence level: 1 Study type: RCT Number of Patient: 99 Recruiting Phase: 12 month	Intervention: ERCP in sedation Comparison: Mida/remifentanil RM, Remifentanil R mono, Midazolam/ meperidine C	Primary: Operator satisfaction scores, side effect, operative Duration, anesthesia duration Secondary: Results: blood pressurew significantly increased un Group R and C RM varied in heartv rate

<p>Inclusion Criteria: Patients with the indication of ERCP</p> <p>Exclusion Criteria: Abus of sedation drugs allergy</p>	<p>hypoxämia most often disgnosed in RM Nausea and pain was highest in C Amnesia most boften C and rm OPERATOR SATISFACTION INCREASED IN r</p> <p>Author's Conclusion: REMIFENTANIL INFUSION ALONE AND REMI PLUS MIDA PROVED SATISFACTORY ANALGESIA CONTINOUUS REMIFENTANIL INFUSION RESULTED IN INCREASED OPERATOR SATISFACTION</p>
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<p>Methodical Notes</p> <p>Funding Sources: NONE</p> <p>COI: NON</p> <p>Randomization: rRANDOM TABLES</p> <p>Blinding: YES DOUBLE</p> <p>Dropout Rate/ITT-Analysis: NONE</p> <p>Notes:</p>

<p>Zhou, X. et al. Etomidate plus propofol versus propofol alone for sedation during gastroscopy: a randomized prospective clinical trial. Surg Endosc. 30. 5108-5116. 2016</p>		
<p>Population</p>	<p>Intervention - Comparison</p>	<p>Outcomes/Results</p>
<p>Evidence level: 2</p> <p>Study type: RCT</p> <p>Number of Patient: 400</p> <p>Recruitung Phase: August to September 2014</p> <p>Inclusion Criteria: EGD in sedation ASA I to III grade, ages from 19 to 60, and weighed from 46 to 78 kg.</p> <p>Exclusion Criteria: hypersensitivity to propofol or fatmilk, refuse to participate in the study, serious heart, lung,liver and kidney dysfunction, obstructive sleep apnea–hy-popnea syndrome (OSAHS), defined as severe snoring andrepeated apnea disease history or body mass indexC28 kg/m2, alcohol abuse, use of psychiatric drugs.</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary: efficacy and safety of propofol vs. propofol and etomidate in EGD</p> <p>Secondary:</p> <p>Results: The EP group had a lower incidence of systolic hypotension (13.0 vs. 32.5 %;P\0.0001), bradycardia(8.5 vs. 16.5 %;P=0.0226), mild hypoxemia (6.5 vs.18.0 %;P=0.0007), and severe hypoxemia (2.5 vs.10.0 %;P=0.0031) compared to the P group. Also, the satisfaction of anesthetist and gastroscopist with EP was higher than that of P group (P\0.0001;P=0.018,respectively)</p> <p>Author's Conclusion: Etomidate plus propofol had few effects on respiration and circulation in patients undergoing gastroscopy and was more safe and effective than propofol alone.</p>
<p>Methodical Notes</p> <p>Funding Sources: none</p> <p>COI: none</p> <p>Randomization: yes 1:1, random, digital</p>		

Blinding: single blinded

Dropout Rate/ITT-Analysis: n.a.

Notes:

RCT, comparison of propofol alone vs. propofol and etomidate

Zhu, X. et al. Comparison of ED95 of Butorphanol and Sufentanyl for gastrointestinal endoscopy sedation: a randomized controlled trial. BMC Anesthesiol. 20. 101. 2020

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: double blinded randomised study</p> <p>Number of Patient: 200</p> <p>Recruiting Phase: 3 month</p> <p>Inclusion Criteria: diagnostic upper GI endoscopy or colonoscopy</p> <p>Exclusion Criteria: not fitted for upper GI Endoscopy or colonoscopy or refusing participation on the trial</p>	<p>Intervention: Sedation with Butorphanol or sufentanyl in combination with propofol</p> <p>Comparison: butorphol vs. Sufentanyl</p>	<p>Primary: respiratory depression; Circulation Inhibition; failed sedation ; propofoldoaseg ; Fatigue severity score; postoperative handgrip strength, Recovery time</p> <p>Secondary:</p> <p>Results: differences only in: Recovery time Shorter in Butorphanol; better handgrig strength, lower fatigeu score</p> <p>Author's Conclusion: Butorphanol 'more effective than sufentanyl</p>
Methodical Notes		
<p>Funding Sources: none</p> <p>COI: none</p> <p>Randomization: randomly division</p> <p>Blinding: yes</p> <p>Dropout Rate/ITT-Analysis: none</p> <p>Notes: first ED95 caculation second RCT double blind</p>		

OXFORD (2011) Appraisal Sheet: Diagnostic Studies: 8 Bewertung(en)

Banno, S. et al. Risk Factor for Vital Signs Fluctuation during Colonoscopy under Conscious Sedation Consisting of Midazolam and Meperidine. Dig Dis. 36. 113-117. 2018

Evidence level/Study Types	Population	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: Respective data base analysis</p>	<p>Number of patients / samples: n=755</p> <p>Reference standard: Sedation with Midazolam, meperidine or combination of both</p>	<p>Results: Vital sign fluctuation (VSF) was observed in 17%; hypotension and oxygen desaturation was observed in 13 and 5%, respectively.</p> <p>Multivariate analysis revealed age (OR 1.05 [95% CI 1.04-1.07]), female gender (OR 1.78 [95% CI 1.19-2.70]), and use of midazolam (OR 5.06 [95% CI 3.18-8.08]) as independent risk factors for VSF.</p>

	Validation: Blinding: no Inclusion of clinical information: Consecutive patients undergoing endoscopy Dealing with ambiguous clinical findings:	Author conclusions:
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Methodical Notes
Funding Sources: not given
COI: none
Notes:

Jin, E. H. et al. How to improve patient satisfaction during midazolam sedation for gastrointestinal endoscopy?. World J Gastroenterol. 23. 1098-1105. 2017		
Evidence level/Study Types	Population	Outcomes/Results
Evidence level: 4 Study type: Prospective design, cohort study	Number of patients / samples: 456 Reference standard: yes Validation: no Blinding: no Inclusion of clinical information: Dealing with ambiguous clinical findings:	Results: > 80% of all patients were satisfied with sedation using midazolam Author conclusions: Midazolam is safe and effective. Satisfaction depends on several factors including age < 50 yrs. and procedure duration.
Methodical Notes		
Funding Sources: no		
COI: no		
Notes:		

Jokelainen, J. et al. How patient-controlled sedation is adopted in clinical practice of sedation for endoscopic retrograde cholangiopancreatography? A prospective study of 1196 cases(). Scand J Gastroenterol. 52. 166-172. 2017		
Evidence level/Study Types	Population	Outcomes/Results
Evidence level: 3 Study type:	Number of patients / samples: 956	Results: successful use of PCS was achieved with 526 patients (77% of attempts). PCS was more likely chosen for younger patients

observational study	Reference standard: no Validation: no Blinding: no Inclusion of clinical information: yes Dealing with ambiguous clinical findings:	risk of failure of PCS was increased, if systolic arterial pressure was <90 mmHg, dosage of PCS >17 ml, duration of procedure exceeded 23 min. risk of failure was lower in patients with primary sclerosing cholangitis (PSC) and if sedation was deeper RASS PCS was associated with less respiratory and cardiovascular depression than other methods. Author conclusions: PCS is readily implemented in clinical practice, is suitable for younger and low-risk patients and is associated with less cardiorespiratory adverse effects.
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Methodical Notes

Funding Sources: none

COI: none

Notes: prospective observational study, single center experience

Lin, O. S. et al. The First US Clinical Experience With Computer-Assisted Propofol Sedation: A Retrospective Observational Comparative Study on Efficacy, Safety, Efficiency, and Endoscopist and Patient Satisfaction. Anesth Analg. 125. 804-811. 2017

Evidence level/Study Types	Population	Outcomes/Results
Evidence level: 4 Study type: retrospective analysis of prospectively collected data	Number of patients / samples: 244 Reference standard: yes Validation: no Blinding: no Inclusion of clinical information: Dealing with ambiguous clinical findings:	Results: CAPS was utilized to sedate 244 patients. Similar procedural success rate as compared to midazolam fentanyl. Procedure times were similar between CAPS and MF. Author conclusions: In low-risk patients, CAPS appears to be effective and efficient. CAPS is associated with higher satisfaction than MF for colonoscopies and upper endoscopies.

Methodical Notes

Funding Sources: no

COI: no

Notes:

Liou, J. Y. et al. Predicting the Best Fit: A Comparison of Response Surface Models for Midazolam and Alfentanil Sedation in Procedures With Varying Stimulation. Anesth Analg. 123. 299-308. 2016

Evidence level/Study Types	Population	Outcomes/Results
Evidence level: 1	Number of patients	Results: The effect-site concentrations tested ranged from 1 to 76 ng/mL and from 5 to

Study type: Response Surface Model Fit	samples: 33 Reference standard: yes Validation: NA Blinding: NA Inclusion of clinical information: NA Dealing with ambiguous clinical findings: NA	80 ng/mL for midazolam and alfentanil, respectively. Midazolam and alfentanil had synergistic effects in colonoscopy and EGD, but additivity was observed in the intersession group. Adequate prediction rates were 84% to 85% in the intersession group, 84% to 88% during colonoscopy, and 82% to 87% during EGD. The reduced Greco and Fixed alfentanil concentration required for 50% of the patients to achieve targeted response Hierarchy models performed better with comparable predictive strength. The reduced Greco model had the lowest AICc with strong correlation in all 3 phases of endoscopy. Dynamic, rather than fixed, γ and γ alf in the Hierarchy model improved model fit. Author conclusions: The reduced Greco model had the lowest objective function value and AICc and thus the best fit. This model was reliable with acceptable predictive ability based on adequate clinical correlation. We suggest that this model has practical clinical value for patients undergoing procedures with varying degrees of stimulation.
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Methodical Notes

Funding Sources: Funding: Taiwan National Science Council, Taipei City, Taiwan: National Science Council Grant NSC 102-2314-B-075-078 and NSC 103-2314-B-075-030

COI: none

Notes:

Prathanvanich, P. et al. The role of capnography during upper endoscopy in morbidly obese patients: a prospective study. Surg Obes Relat Dis. 11. 193-8. 2015

Evidence level/Study Types	Population	Outcomes/Results
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Evidence level: 3 Study type: Prospective consecutive cohort study in moribly obese patients	Number of patients / samples: 82 Reference standard: None Validation: Were determined Blinding: None Inclusion of clinical information: Demographic data of the patients are given. Dealing with ambiguous clinical findings:	Results: Mean BMI was 46,4 + 8,2 and the mean duration of the procedure was 9,4 + 2,5 minutes. Respiratory depression (PO ₂ < 90 % or etCO ₂ > 50 mmHg or any airway intervention was needed) occurred in in 40,2 % of the patients. No clinical significant complications (eg.g. ned for intubation or rescussitation) were noted.Abnormal EtCO ₂ -levels were deteced in all cases of respiratory depression. The sensitivity to detect respiratory depression by capnography was 81 % and the negative predictive value was 78 %. Author conclusions: Capnography provided a real time assessment of changes in ventilation and can detect early phases of respiratory depression. Utilization of propofol as a means for sedation, with extended advanced monoitoring technique, can allow for reduced adverse outcomes in morbidly obese patients undergoing upper GI-endoscopy.
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Methodical Notes

Funding Sources: none

COI: none

Notes:

Sato, M. et al. Safety and Effectiveness of Nurse-Administered Propofol Sedation in Outpatients Undergoing Gastrointestinal Endoscopy. Clin Gastroenterol Hepatol. 17. 1098-1104.e1. 2019

Evidence level/Study Types	Population	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: Data collection,</p>	<p>Number of patients / samples: EGD n=117661, Colonoscopy n=32550</p> <p>Reference standard: yes</p> <p>Validation: not given</p> <p>Blinding: no</p> <p>Inclusion of clinical information: no</p> <p>Dealing with ambiguous clinical findings: no</p>	<p>Results: Medium propofol dose for EGD was 77 mg, for colonoscopy 99 mg. Younger patients (< 41y) required more propofol than older (61-80) patients. Only Adverse event was the transient need for oxygen in n=1950 (1.3%). 44% of the patients were discharged within 60 minutes and 44% of the patients drove home themselves.</p> <p>Author conclusions: Nurse-administered propofol monosedation using an age-adjusted standard protocol up to a maximal of 200 mg is safe and practical for outpatient gastrointestinal endoscopy.</p>

Methodical Notes

Funding Sources: not given

COI: none

Notes: Large study, little content !
44% of the patients drove home with the car !

Schumann, R. et al. High-flow nasal oxygen availability for sedation decreases the use of general anesthesia during endoscopic retrograde cholangiopancreatography and endoscopic ultrasound. World J Gastroenterol. 22. 10398-10405. 2016

Evidence level/Study Types	Population	Outcomes/Results
<p>Evidence level: 4</p> <p>Study type: no</p>	<p>Number of patients / samples: 238</p> <p>Reference standard: no</p> <p>Validation: no</p> <p>Blinding: no</p> <p>Inclusion of clinical information: no</p> <p>Dealing with ambiguous clinical findings: no</p>	<p>Results: General anaesthesia was used less when high flow oxygen was available better oxygen saturation during procedures with high flow</p> <p>Author conclusions: High-flow nasal oxygen availability was associated with decreased GA utilization and improved oxygenation for ERCP and EUS during sedation.</p>

Methodical Notes

Funding Sources: none

COI: none

Notes: retrospective study

OXFORD (2011) Appraisal Sheet: Prognostic Studies: 1 Bewertung(en)

Obara, K. et al. Guidelines for sedation in gastroenterological endoscopy. Dig Endosc. 27. 435-449. 2015		
Population	Intervention	Outcomes/Results
Evidence level: 1 Study type: Guideline from the Japanese Soc: of GI-endoscopy; not censored Number of Patient: Recruitment Phase: Inclusion Criteria: Exclusion Criteria:	Intervention: Comparison:	Primary: Secondary: Results: Author's Conclusion:
Methodical Notes		
Funding Sources: COI: Randomization: Blinding: Dropout Rate/ITT-Analysis: Notes:		

NEWCASTLE - OTTAWA Checklist: Case Control: 18 Bewertung(en)

Finkelmeier, F. et al. ERCP in elderly patients: increased risk of sedation adverse events but low frequency of post-ERCP pancreatitis. Gastrointest Endosc. 82. 1051-9. 2015			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: retrospective cohort study	Funding sources: none Conflict of Interests: no Randomization: no, retrospective Blinding: no Dropout rates: n.a.	Total no. patients: 758 Patient characteristics: Inclusion criteria: ERCP Exclusion criteria: n.a.	Interventions: Comparison:
Notes:	retrospective analysis, indication, complications, seadtion in patients undergoing ERC, different age groups		

	Author's conclusion: ERC safe and effective careful with sedation in elderly	
Outcome Measures/results	Primary clinical description, indication, complications, sedation for ERC Secondary	Results: similar indications of ERC for different age groups similar efficacy more sedation complications in elderly (significant) post ERC pancreatitis less frequent in elderly

Garcia, C. J. et al. Endoscopic Retrograde Cholangiopancreatography in the Elderly. Am J Med Sci. 351. 84-90. 2016			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: retrospective cohort analysis, ERC in elderly patients	Funding sources: none Conflict of Interests: none Randomization: no, retrospective Blinding: no Dropout rates: no	Total no. patients: 89 Patient characteristics: 2004 - 2008 Inclusion criteria: ERCP in elderly Exclusion criteria: none	Interventions: Comparison:
Notes:	retrospective analysis, indication, complications, sedation in elderly undergoing ERC Author's conclusion: ERC safe and effective in elderly reduced sedation (midazolam and meperidine) in elderly		
Outcome Measures/results	Primary ERC complications, requirement of sedation Secondary	Results: 125 ERCPs performed in 89 patients (74 procedures in 54 patients older than 75 years, 51 procedures in 35 patients younger than 75 years). The average age was 76.0 (range: 65-94), 62.4% were female and 79.2% were Hispanic. Indications were similar between groups: jaundice (66.9%), abnormal liver tests (87.2%), abdominal pain (79.2%), cholangitis (24.0%), pancreatitis (32.8%) and stent change (12.9%). Concomitant illnesses were also similar. Lower doses of midazolam and meperidine were used for moderate sedation in the older group (Po0.01). ERCP findings were similar in both groups: stones (40.8%), stricture (18.4%) and stent placement (30.4%). Complications occurred in 6.4%.	

Goudra, B. et al. Association between Type of Sedation and the Adverse Events Associated with Gastrointestinal Endoscopy: An Analysis of 5 Years' Data from a Tertiary Center in the USA. Clin Endosc. 50. 161-169. 2017			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 2 Study type: retrospective analysis of 5 years' Data from a tertiary center in the USA comparing propofol-sedated patients vs. patients with another type of sedation in GI with regard to adverse events	Funding sources: not mentioned Conflict of Interests: The authors have no financial conflicts of interest. Randomization: no	Total no. patients: 73,029 procedures (GI endoscopy) Patient characteristics: September 8, 2008 until May 31, 2013 Inclusion criteria: patients undergoing GI endoscopy procedures under sedation	Interventions: EGD, ERCP, colonoscopy under propofol sedation or other sedation Comparison: Propofol sedation vs. other sedation with regard to adverse events Patient characteristics (esp.

	Blinding: no	Exclusion criteria: not mentioned	morbidity) with regard to adverse events
	Dropout rates: no		
Notes:	<p>study investigates the association between Type of Sedation and the Adverse Events Associated with Gastrointestinal Endoscopy</p> <p>Author's conclusion: The possible reasons for our results are the changing demographics, the worsening comorbidities of the patient population, and the increasing technical complexity of these procedures. Although extensive use of propofol has increased patient satisfaction and procedure acceptability, its use is also associated with more frequent adverse events.</p>		
Outcome Measures/results	<p>Primary adverse events</p> <p>Secondary</p>	<p>Results: A total of 163 adverse events were reported from 73,029 procedures. Frequencies of most adverse events were significantly higher in patients anesthetized with propofol. Automatic regression modeling showed that the type of sedation, the American Society of Anesthesiologists physical status classification, and the procedure type were some of the predictors of immediate life-threatening complications.</p>	

Hung, A. et al. Risk Factors and Outcomes of Reversal Agent Use in Moderate Sedation During Endoscopy and Colonoscopy. J Clin Gastroenterol. 50. e25-9. 2016			
Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 4</p> <p>Study type: case controll</p>	<p>Funding sources: From the Departments of *Gastroenterology; zAnesthesiology; and wDivision of Pharmacy, Beth Israel Deaconess Medical Center (BIDMC), Boston, MA.</p> <p>Conflict of Interests: The authors declare that they have nothing to disclose.</p> <p>Randomization: keine</p> <p>Blinding: keine</p> <p>Dropout rates: Analyse gespeicherter Daten (ITT)</p>	<p>Total no. patients: unter 130000 Endoskopie fanden sich 45 mit Gebrauch von Antidots; diese wurden gematsched mit 90 Endoskopien derselben Art und am selben Tag</p> <p>Patient characteristics: 2008 - 2013</p> <p>Inclusion criteria: Koloskopie und "Endoskopien"</p> <p>Exclusion criteria: EUS und ERCP</p>	<p>Interventions: keine</p> <p>Comparison: Gebrauch von Antidots zur Sedierung</p>
Notes:	<p>die Studie spricht von adverse events. Tatsächlich wurde aber nur nach dem Gebrauch von Antidoten gesucht. Bei den so gefundenen Patienten wurde erst dann nach adverse events unterschieden. Es wurde nur 45 unter 130000 Endoskopie gefunden. Es handelt sich also um ein serh seltenes Ereignis; detaillierte Ableitungen aus diesen Daten erscheinen fragwürdig</p> <p>Author's conclusion: Prevalence of reversal agent use during moderate sedation is low and outcomes are generally good. Several clinically relevant risk factors for reversal agent use were found suggesting that certain groups may benefit from closer monitoring.</p>		
Outcome Measures/results	<p>Primary n.a.</p> <p>Secondary n.a.</p>	<p>Results: Prevalence of reversal agent use was 0.03% [95% confidence interval (CI), 0.02-0.04]. Events triggering reversal use were oxygen desaturation (64.4%), respiration changes (24.4%), hypotension</p>	

	(8.9%), and bradycardia (6.7%). Two patients required escalation of care and the majority of patients were stabilized and discharged home. Compared with the control group, the reversal group was older (61±1.8 vs. 55±1.6, P=0.01), mostly female (82% vs. 50%, P<0.01), and had lower body mass index (24±0.8 vs. 27±0.7, P=0.03) but received similar dosages of sedation. When adjusted for age, race, sex, and body mass index, the odds of reversal agent patients having a higher ASA score than controls was 4.7 (95% CI, 1.7-13.1), and the odds of having a higher Mallampati score than controls was 5.0 (95% CI, 2.1-11.7) with P<0.01
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Kais, S. S. et al. Continuous negative external pressure (cNEP) reduces respiratory impairment during screening colonoscopy: a pilot study. Endoscopy. 48. 584-7. 2016

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 1 Study type: Case control	Funding sources: none Conflict of Interests: none Randomization: none Blinding: non Dropout rates: consecutive pat.	Total no. patients: 54 Patient characteristics: na Inclusion criteria: GI Endoscopy Exclusion criteria: na	Interventions: Screening colonoscopy in sedation with Midazolam plus mepreidine or fentni Comparison: application of negative external pressure versus no manipulation
Notes:	Author's conclusion: less respiratory impairment with negative external pressure		
Outcome Measures/results	Primary frequency of respiratory impairment Secondary na	Results: statistically significant less Respirator impairments in the negative pressure group	

Khoi, C. S. et al. Age correlates with hypotension during propofol-based anesthesia for endoscopic retrograde cholangiopancreatography. Acta Anaesthesiol Taiwan. 53. 131-4. 2015

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: Case Controll	Funding sources: k.A. Conflict of Interests: All authors have no conflicts of interest to dec Randomization: nicht zutreffend Blinding: nicht zutreffend Dropout rates: nicht zutreffend	Total no. patients: 552 Patient characteristics: 2006-2010 Inclusion criteria: we retrospectively reviewed the anesthetic records, history charts, and procedure records of the patients who underwent ERCP under propofol-based deep sedation from January 2006 to July 2010 at the Far Eastern Memorial Hospital. All propofol-based deep sedations were conducted by anesthesiologists.	Interventions: ERCP Comparison: kein Komparator

		Exclusion criteria: es wurde keine Fälle aus diesem Zeitraum ausgeschlossen
Notes:	es handelt sich um die deskriptive, retrospektive Analyse einer Kohorte ohne Komparator. Author's conclusion: Hypotension was the most frequent anesthetic complication during procedure under propofol-based deep sedation, but this method was safe and effective under appropriate monitoring. Age is the strongest predictor of hypotension and therefore propofol-based deep sedation should be conducted with caution in the elderly	
Outcome Measures/results	Primary patients with hypotension, hypertension, and desaturation during anesthesia Secondary	Results: Multivariate logistic regression identified sex and age as significantly associated with hypotension ($p < 0.05$). However, when age was excluded from analysis, hypertension and anesthetic time were identified as a significant predictor ($p = 0.002$ and $p = 0.03$, respectively), while sex remained a significant independent predictor ($p = 0.038$).

Kim, J. H. et al. Efficacy and Safety of Etomidate in Comparison with Propofol or Midazolam as Sedative for Upper Gastrointestinal Endoscopy. Clin Endosc. 53. 555-561. 2020			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 4 Study type: retrospective analysis of prospectively collected data	Funding sources: no Conflict of Interests: no Randomization: no Blinding: no Dropout rates: not clear	Total no. patients: 105 Patient characteristics: not clear Inclusion criteria: health check up endoscopy Exclusion criteria: history of adverse effects during a previous examination, chronic kidney disease, liver cirrhosis, heart failure, or sleep apnea, or who were taking medicines that interact with midazolam, propofol, or etomidate were excluded.	Interventions: Comparison:
Notes:	retrospective study, prospectively collected data comparison of etomidate, propofol or midazolam maintenance of sedation, induction with midazolam in every group inclusion in study not clear Author's conclusion: etomidate for maintenance after induction with midazolam for sedation in upper gastrointestinal endoscopy were not inferior to those following midazolam or propofol use from the perspectives of safety and efficacy.		
Outcome Measures/results	Primary cardiovascular and re-spiratory adverse events Secondary time to sedation procedure time	Results: Overall cardiovascular and respiratory adverse events were observed in 9 patients (25.7%) in the M + M group, 8 patients (23.5%) in the M + P group, and 10 patients (27.8%) in the M + E group no difference for all groups for primary end point	

Kim, S. I. et al. Conscious Sedation Using Midazolam and Sequential Flumazenil in Cirrhotic Patients for Prophylactic Endoscopic Variceal Ligation. Digestion. 92. 220-6. 2015			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 1	Funding sources: none	Total no. patients: 279	Interventions: sedation and EVL

Study type: case control	Conflict of Interests: Randomization: none Blinding: non Dropout rates: 20	Patient characteristics: 3 month Inclusion criteria: endoscopy with evl Exclusion criteria: < 18 yers, HE, congestive heart failure, chronic renal failure, Chronic obstructive disease	Comparison: with Midazolam and consecutive flumaceniil vs. no Sleep , 3:1
Notes:	Author's conclusion: Sedation during cirrothic patients endoscopy probaly safe		
Outcome Measures/results	Primary overt HE, Patient satisfaction and cooperation Secondary	Results: significant better patients satisfaction in the sedated group	

Kollmann, C. M. et al. Gastrointestinal endoscopy under sedation is associated with pneumonia in older inpatients-results of a retrospective case-control study. United European Gastroenterol J. 6. 382-390. 2018

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: Case controll	Funding sources: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors. Conflict of Interests: keine Randomization: nicht zutreffend Blinding: nicht zutreffend Dropout rates: nicht zutreffend	Total no. patients: 500 Patient characteristics: 2005-2015 Inclusion criteria: Laboratory parameters had to be available before (d0) gastrointestinal endoscopy under sedation (GIES) as well as three (d3) and/or seven days (d7) after endoscopy. Age- (2 years), gender- and time-matched (10%) inpatients who had neither obtained any invasive procedure nor sedation served as controls in a ratio of 1:1. Exclusion criteria: elevated inflammation parameters (WBC>10,000/ml or<4000/ml, CRP>2 mg/dl), preexisting antibiotic treatment, preexisting pneumonia and diseases or conditions accompanied by increased risk of aspiration Additional exclusion criteria for the control	Interventions: ÖGD oder ÖDG und Koloskopie Comparison: keine Endoskopie und keine andedre Sedierung

		group included any type of sedation.
Notes:	<p>die Studie wurde formal korrekt geplant. Doch zeigt die Auswertung, dass die Kontrollgruppe sich bereits in den untersuchten Parametern, z.B. in BMI und Karnowsky-Index, signifikant unterscheidet.</p> <p>Author's conclusion: Patients of advanced age carry an increased risk of pneumonia and LRI after GIES. Patients are generally more likely to feature inflammation and to receive antibiotic treatment.</p>	
Outcome Measures/results	<p>Primary Anteil von Patienten, die nach 3 Tagen eine Pneumonie entwickelt haben, besondere Auswertung für mindestens 65-Jährigen wird als Unterpunkt der primären Endpunktes aufgeführt</p> <p>Secondary</p>	<p>Results: Kein signifikanter Unterschied in der Gesamtgruppe. Signifikanter Unterschied bei den mindesten 65-Jährigen (Pneumonia (n=4 (2.6%) vs. 0 (0.0%), p=0.041) and LRI (n=12 (7.8%) vs. n=4 (2.5%), p=0.034)</p>

Mudambi, L. et al. Obstructive Sleep Apnea Is Not Associated with Higher Health Care Use after Colonoscopy under Conscious Sedation. Ann Am Thorac Soc. 13. 419-24. 2016			
Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 1</p> <p>Study type: Retrospective case-control study</p>	<p>Funding sources: Not found (available online)</p> <p>Conflict of Interests: Not found (available online)</p> <p>Randomization: None</p> <p>Blinding: None</p> <p>Dropout rates: None</p>	<p>Total no. patients: 6.690 (4316 OSA/ 2374 control group)</p> <p>Patient characteristics: 12 years (1999-2012)</p> <p>Inclusion criteria: Patients who undergone an elective colonoscopy. The control group was defined as patients without any sleep related diagnosis, defined by all ICD-9 codes related to sleep anytime during the study period. The OSA group was defined as patients who met all of the following criteria: OSA-related ICD-9 codes, codes for sleep testing, and at least one follow-up examination in the outpatient sleep clinic in all the years preceding and 3 years after the inception date.</p> <p>Exclusion criteria: All emergent colonoscopies, inpatient colonoscopies, and cases with general anesthesia were excluded.</p>	<p>Interventions:</p> <p>Comparison: OSA vs. control group</p>
Notes:	<p>Author's conclusion: Patients with and without OSA do not differ from in terms of hospital admissions, ICU admissions, and ER visits during the first 30 days after a colonoscopy with sedation. Patients with OSA can undergo moderate sedation during colonoscopy.</p>		
Outcome Measures/results	<p>Primary Terms of hospital admissions, ICU admissions, and ER visits during the first 30 days after a colonoscopy with sedation</p> <p>Secondary Subgroup</p>	<p>Results: There were no differences in hospitalizations, ICU admissions, or ER visits between the control and study groups at any period during the first 30 days after the procedure. The subgroup analysis shows as well no difference regarding to the outcome measures.</p>	

analysis: Polysomnogram
results available

Nonaka, S. et al. Safety and effectiveness of propofol-based monitored anesthesia care without intubation during endoscopic submucosal dissection for early gastric and esophageal cancers. Dig Endosc. 27. 665-73. 2015

Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 4</p> <p>Study type: Prospective cohort study</p>	<p>Funding sources: none</p> <p>Conflict of Interests: none</p> <p>Randomization: none</p> <p>Blinding: none</p> <p>Dropout rates: not given</p>	<p>Total no. patients: 794 pts under regular sedation and 219 pts. with MAC-sedation</p> <p>Patient characteristics: 2010-2014</p> <p>Inclusion criteria: Patients who underwent ESD - treatment for either early gastric or early esophageal cancer at a single institution</p> <p>Exclusion criteria: not mentioned</p>	<p>Interventions: Upper Gi-endoscopy with ESD under regular sedation by a nurse supervised by the endoscopist or MAC-sedation without intubation</p> <p>Comparison: Effectiveness regarding the body movements of the patients in both groups</p>
Notes:	<p>Author's conclusion: Propofol-based MAC-sedation without intubation provided a safer treatment environment by significantly reduced body movements and was very effective for difficult cases requiring longer procedure times or more powerful sedation.</p>		
Outcome Measures/results	<p>Primary Frequency of significant body movements noted by an independent observer in both groups</p> <p>Secondary Occurrence of hypoxemia</p>	<p>Results: Significant body movements were registered in 66/219 pts. under MAC-sedation whereas in 586/794 cases under regular sedation ($p < 0.0001$). The median minimum O₂-saturation was significantly lower under MAC-sedation than under regular sedation (96 % vs. 98 %, $P < 0.004$).</p>	

Ogawa, T. et al. Propofol sedation with a target-controlled infusion pump in elderly patients undergoing ERCP. Gastrointest Endosc. 92. 301-307. 2020

Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 2</p> <p>Study type: single-center, retrospective observational study</p>	<p>Funding sources: None</p> <p>Conflict of Interests:</p> <p>Randomization: None</p> <p>Blinding: None</p> <p>Dropout rates: stated above</p>	<p>Total no. patients: 469</p> <p>Patient characteristics: January 2014 and October 2016.</p> <p>Inclusion criteria: ERCP procedures</p> <p>Exclusion criteria: Repeated ERCP during study, additional drugs during intervention, hypotension not treatable before procedure.</p>	<p>Interventions: Propofol TCI after lokal pharyngeal anaesthesia and 15 mg pentazocine.</p> <p>Comparison: Patients were divided into 3 groups according to their age: group A, <70 years; group B, 70 and <85 years; and group C, 85 years.</p>
Notes:			

	Author's conclusion: NAAP sedation with a TCI system during ERCP may be acceptable in elderly patients with a lower dose of propofol than that used in younger patients.	
Outcome Measures/results	<p>Primary Associations between age group, propofol dose, and sedation-related adverse events (AEs) during ERCP were examined. In addition, the established target blood concentration and total infusion dose of propofol during the ERCP procedure were recorded. The minimum and maximum target blood concentrations were reviewed.</p> <p>Secondary Assessment of hypotension and hypoxemia, which are major AEs related to propofol sedation, that occurred during the induction period and the maintenance period of each procedure.</p>	Results: Median total infusion dose and minimum and maximum target blood concentrations of propofol were 336 mg, 2.2 mg/mL, and 2.2 mg/mL in group A; 184 mg, 1.0 mg/mL, and 1.4 mg/mL in group B; and 99 mg, .6 mg/mL, and 1.0 mg/mL in group C, respectively, with older groups requiring a lower dose ($P < .0001$). Hypotension was observed in 23 patients (4.8%), with no significant difference between groups (group A, 2.3%; group B, 6.3%; group C, 4.8%; $P = .24$). Hypoxemia was observed in 16 patients (3.3%), with no significant difference between groups (group A, 3.1%; group B, 4.9%; group C, .8%; $P = .17$). All AEs were immediately resolved, and no procedures were aborted.

Oshima, H. et al. Dexmedetomidine provides less body motion and respiratory depression during sedation in double-balloon enteroscopy than midazolam. SAGE Open Med. 5. 2050312117729920. 2017			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 2 Study type: prospective observational study with a historical control population	Funding sources: none Conflict of Interests: none Randomization: propensity score matching Blinding: none Dropout rates: none	Total no. patients: 182 Patient characteristics: 6 months Inclusion criteria: Indication for DBE Exclusion criteria: Age < 18 Years, severe organ failures	Interventions: DBE Comparison: Sedation with Dexmedetomidine in a prospective series, compared with historical collective sedated with Midazolam and pentazocine
Notes:	Author's conclusion: DEXsedation can reduce body motion rate and respiratory depression		
Outcome Measures/results	Primary cardiopulmonary adverse events and body motion rate Secondary	Results: less body movement in the DEX group and less respiratory depression, heart rate and blood pressure were not significantly different	

Park, C. H. et al. Outcomes of Propofol Sedation During Emergency Endoscopy Performed for Upper Gastrointestinal Bleeding. Dig Dis Sci. 61. 825-34. 2016			
Evidence level	Methodical Notes	Patient characteristics	Interventions

Evidence level: 3 Study type: Retrospective analysis	Funding sources: Supported by research fund of Hanyang University Guri/Korea Conflict of Interests: none Randomization: no Blinding: no Dropout rates: none	Total no. patients: 703 endoscopies, 539 non-variceal and 164 variceal bleeding Patient characteristics: 1/2012 - 4/2015 Inclusion criteria: Emergency endoscopy for variceal and non-variceal bleeding and sedation either with Propofol alone or Midazolam/Propofol Exclusion criteria: ASA V No sedation or Midazolam alone	Interventions: Emergency endoscopy Comparison: Sedation with P/M vs Propofol alone
Notes:	Variceal and non-variceal bleeding pts under sedation retrospectively analyzed Difficult judgement if not prospective Author's conclusion: Better understanding of the safety of propofol-based sedation and the risk of sedation-related adverse events during emergency endoscopy Shock more common in variceal bleeding Paradoxical reactions most common cause for procedure interruption		
Outcome Measures/results	Primary Sedative-related adverse events (shock, hypoxia, paradoxical reaction) Secondary Relationship between procedure time and Propofol dose	Results: Shock was more common in variceal bleeding $p < 0.001$, all recovered but 1 No difference of hypoxia and paradoxical reactions based on the source of bleeding Paradoxical reactions was the most common cause of procedure interruption Propofol dose much higher in non-variceal bleeding group when propofol alone was administered	

Sasala, L. et al. Cost Analysis of Intravenous Propofol Monotherapy versus Intravenous Combination Sedation in Patients Undergoing Outpatient Gastrointestinal Endoscopy. Aana j. 88. 373-379. 2020			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 4 Study type: Case Control study	Funding sources: Unknown. Only Abstract available. Conflict of Interests: Unknown. Only Abstract available. Randomization: None. Blinding: None. Dropout rates: Unknown. Only Abstract available.	Total no. patients: 277 Patient characteristics: Unknown. Only Abstract available. Inclusion criteria: Unknown. Only Abstract available. Exclusion criteria: Unknown. Only Abstract available.	Interventions: Sedation. Comparison: Propofol monotherapy compared with combination sedation consisting of propofol with any of the following: midazolam, fentanyl, dexmedetomidine, and/or ketamine.
Notes:	Only Abstract available. Author's conclusion: There were no significant differences in PACU length of stay, PACU cost, medication costs, and episodes of PONV between propofol monotherapy and combination sedation for outpatient GI endoscopy.		
Outcome Measures/results	Primary Cost analysis: PACU length of stay,	Results: The average PACU length of stay was 35.0 minutes for propofol monotherapy and 35.75 minutes for combination sedation	

episodes of postoperative nausea and vomiting (PONV), PACU costs, and medication costs.	(P = .918). The average PACU cost was \$566.37 for propofol monotherapy and \$578.44 for combination sedation (P = .918). The average cost for sedatives was \$3.13 for propofol monotherapy and \$3.34 for combination sedation (P = .964). There was 1 incident of nausea among all patients. .
Secondary Not specified.	

Twardowski, M. A. et al. Effects of Cannabis Use on Sedation Requirements for Endoscopic Procedures. J Am Osteopath Assoc. . . 2019			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 5 Study type: retrospective case control study	Funding sources: n.a Conflict of Interests: n.a. Randomization: no Blinding: no Dropout rates: n.a.	Total no. patients: 250 Patient characteristics: n.a. Inclusion criteria: Exclusion criteria:	Interventions: Comparison:
Notes:	retrospective chart review cannabis effect on sedation Author's conclusion: cannabis use with influence on sedative regimens		
Outcome Measures/results	Primary amount of sedation for endoscopic procedures, cannabis use Secondary	Results: more sedation needed for cannabis users	

Wahab, E. A. et al. Conscious sedation using propofol versus midazolam in cirrhotic patients during upper GI endoscopy: A comparative study. JGH Open. 3. 25-31. 2019			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 2 Study type: Comparative study	Funding sources: None Conflict of Interests: None Randomization: No Blinding: No Dropout rates: 362/450 eligible patients	Total no. patients: 90 Patient characteristics: November 2015 to April 2016. Inclusion criteria: Those educated, able to pass number connection test (NCT-A), compensated cirrhotic patients eligible for diagnostic and/or therapeutic UGIE. Exclusion criteria: known allergy or previous adverse reactions to midazolam and/or propofol, patients with significant respiratory airway disease or cardiac morbidity, and cirrhotic patients under categories Child B and C.	Interventions: the midazolam group, which included 30 patients who received IV weight- dependent midazolam (0.05 mg/kg with additional doses of 1 mg every 2 min when necessary, up to a maximum dose of 0.1 mg/kg or 10 mg); Comparison: he propofol group, which included 30 patients who received a propofol bolus dose according to age and weight (0.25 mg/kg with additional doses of 20–30 mg every 30–60 s when necessary, up to a maximum dose of 400 mg); and the combined group, which included 30 patients who received half a dose of midazolam and of propofol.

Notes:	Author's conclusion: Considering safety and efficacy issues, propofol is better than midazolam in gastrointestinal endoscopy, especially in patients with liver cirrhosis.	
Outcome Measures/results	Primary Drugs' efficacy Secondary recovery time, and endoscopy time	Results: Prolonged postendoscopy recovery times were reported in the midazolam group, while shorter recovery times were reported in the propofol and combined groups. All patients in the propofol and combined groups gained consciousness shortly postendoscopy; however, only half of the midazolam group's patients gained consciousness after the standard recovery time (10–30 min). Highly significant differences were found among the three groups regarding consciousness level according to the Glasgow coma scale, as well as regarding the occurrence of hypoxia during endoscopy.

Yoo, Y. C. et al. A comparison of sedation protocols for gastric endoscopic submucosal dissection: moderate sedation with analgesic supplementation vs analgesia targeted light sedation. Br J Anaesth. 115. 84-8. 2015

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 1 Study type: retrospective Study comparing two sedation protocols during ESD	Funding sources: none Conflict of Interests: none Randomization: consecutive protocol analysis Blinding: none Dropout rates: na	Total no. patients: 293 Patient characteristics: 6 month Inclusion criteria: ESD Exclusion criteria: no ESD	Interventions: seaatoin protocols during ESD Comparison: Dose of propofol in two protocols moderate sedation with analgesic supplementantation (ATLS) analgesia targeted light sedation(MSAS)
Notes:	Author's conclusion: ATLS good sedation mode for ESD		
Outcome Measures/results	Primary desaturation recovery time aspiration pneumonia Secondary	Results: ATLS reduced incidence of desaturation and a trend to low incidence of aspiration pneumonia	

NEWCASTLE - OTTAWA Checklist: Cohort: 38 Bewertung(en)

Andrade, C. M. et al. Safety of Gastrointestinal Endoscopy With Conscious Sedation in Patients With and Without Obstructive Sleep Apnea. J Clin Gastroenterol. 50. 198-201. 2016

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: Cohort study	Funding sources: NA Conflict of Interests: NA Randomization: no Blinding: no	Total no. patients: 500 Recruiting Phase: July 27, 2011 to October 22, 2013 Inclusion criteria: All patients at the James A. Haley VA	Interventions: Endoscopic procedure Comparison: OSA vs. non-OSA

	<p>Dropout rates: no</p>	<p>scheduled to undergo an endoscopic procedure with OSA were eligible for enrollment.</p> <p>Exclusion criteria: The exclusion criteria were age below 18 years, pregnancy, mild OSA, and patients scheduled with monitored anesthesia care (MAC).</p>
Notes:	<p>Author's conclusion: Despite the presumed increased risk of cardiopulmonary complications, patients with OSA who undergo endoscopy with conscious sedation have clinically insignificant variations in cardiopulmonary parameters that do not differ from those without OSA. Costly preventative measures in patients with OSA are not warranted.</p>	
Outcome Measures/results	<p>Primary Throughout the endoscopic procedure cardiopulmonary variables such as heart rate, blood pressure, and level of blood oxygen saturation were recorded electronically at 3-minute intervals.</p> <p>Secondary NA</p>	<p>Results: In total, 302 colonoscopies, 119 esophagogastroduodenoscopies, 6 flexible sigmoidoscopies, and 60 esophagogastroduodenoscopy/ colonoscopies were performed. None of the patients in the study required endotracheal intubation, pharmacologic reversal, or experienced an adverse outcome as a result of changes in blood pressure, heart rate, or blood oxygen saturation. There were no significant differences in the rate of tachycardia (P=0.749), bradycardia (P=0.438), hypotension (systolic/diastolic, P=0.460; mean arterial pressure, P=0.571), or hypoxia (P=0.787) between groups.</p> <p>The average length of time spent in each procedure and the average dose of sedation administered also did not differ significantly between the groups.</p>

Behrens, A. et al. [Safety of sedation during gastroscopy and colonoscopy in low-risk patients - results of a retrospective subgroup analysis of a registry study including over 170?000 endoscopies]. Z Gastroenterol. 54. 733-9. 2016

Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 3</p> <p>Study type: subgroup analysis of a registry study (database)</p>	<p>Funding sources: Fa. E&L medical systems GmbH, budget resources of the researchers</p> <p>Conflict of Interests: not mentioned</p> <p>Randomization: not relevant, comprehensive registry study</p>	<p>Total no. patients: 177944 patients of 39 research centers</p> <p>Recruiting Phase: December 2011 to June 2014</p> <p>Inclusion criteria: ASA 1 or ASA 2, esophagogastroduodenoscopy or colonoscopy with sedation</p> <p>Exclusion criteria: ASA 3 or higher, emergency endoscopies, therapeutic procedures, no sedation</p>	<p>Interventions: sedation (propofol alone in 64.4% of the sedations, a combination of propofol and midazolam in 22.4%, midazolam mono in 6.6%, midazolam and opiate in 5.1%, other 1.5%)</p> <p>Comparison:</p>

	Blinding: no	
	Dropout rates: none	
Notes:	Author's conclusion: Sedation can therefore be regarded as extremely safe in this group of patients. Even though this analysis did not include therapeutic colonoscopies (e.g. polypectomy), these data should lower the threshold for patients undergoing preventive check-up examinations and it should therefore be offered as a standard.	
Outcome Measures/results	Primary minor and major complications Secondary	Results: A total of 332 minor complications were documented (0.2%). No major complications or deaths occurred. The following risk factors were identified for the development of sedation-associated complications: Patients in ASA class 2 and sedation with midazolam in combination with an opiate

Bolat, E. et al. Effects of balanced propofol sedation on QT, corrected QT, and P-wave dispersion on upper endoscopy. Anatol J Cardiol. 16. 328-32. 2016			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: case control	Funding sources: none Conflict of Interests: none Randomization: no randomization Blinding: no blinding Dropout rates: 4 patients of 40	Total no. patients: 40 patients, 42 controls Recruiting Phase: June 1, 2013 and August 30, 2014 Inclusion criteria: EGD ASA 1-2 Exclusion criteria: arrhythmias of any form	Interventions: EGD in sedation or not, routine EGD Comparison: ECG
Notes:	case control, no blinding of ECG interpretation no randomization to sedation or not, patients will Author's conclusion: P-wave duration and Pwd values increased after endoscopy with a combination of midazolam and propofol sedation. Physicians should be made aware of the potential effects of BPS in terms on P-wave duration and Pwd values.		
Outcome Measures/results	Primary ECG changes Secondary	Results: Post-endoscopy P max duration and Pwd were prolonged compared with baseline values (86±13 ms vs. 92±10 ms and 29±12 ms vs. 33±12 ms, respectively; p<0.05). Post-endoscopy QTc and QTd were decreased compared with baseline values, but these decreases were not statistically significant	

Carvalho, P. H. et al. SEDATION IN COLONOSCOPY BY USING THREE DIFFERENT PROPOFOL INFUSION METHODS AND ANALYSIS OF PLASMA CONCENTRATION LEVELS: A PROSPECTIVE COMPARATIVE STUDY. Arq Bras Cir Dig. 29. 264-268. 2016			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: Cohort	Funding sources: NA Conflict of Interests: NA	Total no. patients: 50 Recruiting Phase: from April 2013 to December 2014 Inclusion criteria: Selection	Interventions: Colonoscopy Comparison: 1) intermittent bolus infusion; 2) continuous manually

	<p>Randomization: yes</p> <p>Blinding: no</p> <p>Dropout rates:</p>	<p>and assignment of patients were consecutive subjected to the colonoscopy schedule of the participating institutions. A different group was performed for every daily routine and, since the number of anesthesia procedures per day differed, anesthesia procedures were randomly performed in one or more groups in order to match the final sample number.</p> <p>Exclusion criteria: Patients with clinical condition classified as ASA class IV or higher were excluded. They were monitored by continuous electrocardiogram, pulse oximetry, aspiration capnography, noninvasive blood pressure devices and bispectral sensors (BIS).</p>	<p>controlled infusion; 3) continuous automatic infusion</p>
<p>Notes:</p>	<p>Author's conclusion: The use of propofol bolus administration for colonoscopies, through continuous manually controlled infusion or automatic infusion are similar regarding propofolemia and the clinical outcomes evaluated. The use of an innovative capnography catheter is liable and lowcost solution for the early detection of airway obstruction.</p>		
<p>Outcome Measures/results</p>	<p>Primary propofol plasma concentration</p> <p>Secondary cost</p>	<p>Results: Regarding clinical outcomes, statistical differences in agitation (higher in group 1, p=0.001) and initial blood pressure (p=0.008) were found. As for propofol serum levels, findings were similar in consumption per minute (p=0.748) and over time (p=0.830). In terms of cost analysis, group 1 cost was R\$7.00 (approximately US\$2,25); group2, R\$17.50 (approximately US\$5,64); and group 3, R\$112.70 (approximately US\$36,35, p<0.001). Capnography was able to predict 100% of the oxygen saturation drop (below 90%).</p>	

<p>Ching, H. L. et al. Paradigm shift: should the elderly undergo propofol sedation for DBE? A prospective cohort study. Frontline Gastroenterol. 9. 192-199. 2018</p>			
Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 1</p> <p>Study type: Cohort study</p>	<p>Funding sources: None</p> <p>Conflict of Interests: None</p> <p>Randomization: None</p> <p>Blinding: None</p> <p>Dropout rates: NA</p>	<p>Total no. patients: 161</p> <p>Recruiting Phase: Between March 2013 and December 2015</p> <p>Inclusion criteria: All patients undergoing DBE over a 30-month period were recruited at our tertiary centre.</p> <p>Exclusion criteria: NA</p>	<p>Interventions: Patients were subcategorised into four groups: elderly or young undergoing DBE with propofol or conventional sedation (with midazolam±fentanyl).</p> <p>Comparison: young vs. elderly patients</p>

Notes:	Author's conclusion: Compared with young patients, propofol-assisted DBE in the elderly is safe and has a high diagnostic yield.	
Outcome Measures/results	<p>Primary Patient demographics, comorbidities, procedural data, complications, diagnostic and therapeutic yield were compared.</p> <p>Secondary NA</p>	<p>Results: Cardiovascular disease and a higher American Society of Anaesthesiologists (ASA) status were more prevalent in elderly patients undergoing DBE with propofol ($p < 0.05$). Common indications for DBE were occult and overt obscure gastrointestinal bleeding and suspected Crohn's disease (elderly vs young: 50.7% vs 42.3%, 17.8% vs 12% and 19.2% vs 26.1%, respectively). Diagnostic yield was higher in elderly compared with young patients (75.3% vs 58.5%, $p = 0.016$). The most common findings in elderly and young patients were angioectasia (30.1% and 18.3%, respectively) and ulcers (17.8% and 9.2%, respectively), while therapeutic intervention rates were comparable (42.5% vs 32.4%, $p = 0.18$). ASA status did not affect propofol dose ($p = 0.55$) or procedure duration ($p = 0.31$). Tolerance scores were favourable in those receiving propofol compared with conventional sedation ($p < 0.05$). There was no difference in complications between the four groups ($p = 0.17$).</p>

Dumonceau, J. M. et al. Non-anesthesiologist administration of propofol for gastrointestinal endoscopy: European Society of Gastrointestinal Endoscopy, European Society of Gastroenterology and Endoscopy Nurses and Associates Guideline--Updated June 2015. Endoscopy. 47. 1175-89. 2015

Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 1</p> <p>Study type: Guideline-could not be censored</p>	<p>Funding sources:</p> <p>Conflict of Interests:</p> <p>Randomization:</p> <p>Blinding:</p> <p>Dropout rates:</p>	<p>Total no. patients:</p> <p>Recruiting Phase:</p> <p>Inclusion criteria:</p> <p>Exclusion criteria:</p>	<p>Interventions:</p> <p>Comparison:</p>
Notes:	<p>Guideline - could not be censored</p> <p>Author's conclusion:</p>		
Outcome Measures/results	<p>Primary</p> <p>Secondary</p>	Results:	

Ferreira, A. O. et al. Endoscopic sedation and monitoring practices in Portugal: a nationwide web-based survey. Eur J Gastroenterol Hepatol. 27. 265-70. 2015

Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 2</p> <p>Study type: 31-item survey</p>	<p>Funding sources: none</p> <p>Conflict of</p>	<p>Total no. patients: 129 of 490 members of the Portugese Soc. of Gastroenterology</p>	<p>Interventions: 31-item survey featuring questions regrading demographic data, procedural volume, sedation and monitoring practices,</p>

	<p>Interests: none</p> <p>Randomization: n/a</p> <p>Blinding: n/a</p> <p>Dropout rates: 74 % did not participate in the survey</p>	<p>responded (26 %)</p> <p>Recruiting Phase: April 2014</p> <p>Inclusion criteria: All 490 members of the Portugese Soc. of Gastroenterology were invited by mail to participate</p> <p>Exclusion criteria: none</p>	<p>personal preferences and opinion on NAAP-sedation (adopted from the German survey published 2013).</p> <p>Comparison: none</p>
Notes:	<p>This is a survey among Portugese endoscopists regardind their sedation proctice (adopted from the German survey published in 2013)</p> <p>Author's conclusion: The use of sedation is routine practice in colonoscopy, but not in EGD. The preferred agent is propofol and iits used almost exclusively by anesthesiologists.</p>		
Outcome Measures/results	<p>Primary Frequency of sedation during upper or lower GI-endoscopy. Use of propofol with NAAP or by MAC-sedation.</p> <p>Secondary Monitoring practices. Training issues.</p>	<p>Results: Upper GI-endoscopy was performed mainly without sedation (public 70 %, private practice 57 %), whereas colonoscopy was performed in the majorityx of cases under sedation (public - 64 %, private - 69 %). Propoofol was used by 77 % of the respondents, however, midazolam was used by 66 % of the respondents. In private practices propofol was the most used agent, wheras in public hospitals mainly midazolam was used for sedation. Prpofol was administerd mainly by anesthesiologists. However, 74 % of the respondents mentioned that they are willing to use propofol by itself if they had the opportunity of formal training. Monitoring was done by pulse oximetry by nearly all resondents (99 %) and oxygen supplementation is administerd in 81 % under propofol and in 42 % under traditional sedation. Blood pressure measurements were performed in 80 % and ecg recording was used routinely in 74 % of the respondents.</p>	

Finn, R. T., 3rd et al. Bolus Administration of Fentanyl and Midazolam for Colonoscopy Increases Endoscopy Unit Efficiency and Safety Compared With Titrated Sedation. Clin Gastroenterol Hepatol. 15. 1419-1426.e2. 2017

Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 2</p> <p>Study type: Retrospective analysis</p>	<p>Funding sources: Z.Gellad's effort is funded by Veterans Affairs Health Services Research and Development Career Development Award Study supported through Resident Research Grant from the Dept.of Medicine at Duke University Medical Center</p> <p>Conflict of Interests: none</p> <p>Randomization: No</p> <p>Blinding: No</p> <p>Dropout rates: No</p>	<p>Total no. patients: 966 Nurse directed titration of Fentanyl/Midazolam vs 699 physician directed bolus administration of the same sedativa</p> <p>Recruiting Phase: 4/2010 -4/2011 Nurse sedation until 10/2010; physician bolus administration after 10/2010</p> <p>Inclusion criteria: colonoscopies</p> <p>Exclusion criteria: Incomplete colonoscopies Critical time stamps missing Colonoscopies with other procedures more than 1 colonoscopyduring study period</p>	<p>Interventions: Diagnostic (?) colonoscopy only</p> <p>Comparison: 2 ways of sedative administration</p>
Notes:			

	Author's conclusion: Bolus dosing of sedativa improves endoscopy unit efficiency and safety and decreases amount of sedativa required	
Outcome Measures/results	Primary Sedation, recovery times Medication doses Adverse events Patient satisfaction Secondary Not specified	Results: Patients in bolus group had shorter sedation time $p < .01$ and slightly longer colonoscopy p in the titration group > lower doses of both fentanyl and midazolam in the bolus group More hypotension episodes in the bolus group $p < 0.1$ No difference for patients satisfaction and adverse events

García Guzzo, M. E. et al. Deep sedation using propofol target-controlled infusion for gastrointestinal endoscopic procedures: a retrospective cohort study. BMC Anesthesiol. 20. 195. 2020

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 4 Study type: retrospective case study	Funding sources: none Conflict of Interests: none Randomization: none Blinding: no Dropout rates: no	Total no. patients: 823 Recruiting Phase: 1 month Inclusion criteria: consecutive GI Endoscopy Exclusion criteria: no endoscopy	Interventions: Comparison: Documentation of adverse events no comparison
Notes:	Author's conclusion: propofol target control infusion is safe		
Outcome Measures/results	Primary adverse events and the necessity of therapeutic vasoactive management oder airway management Secondary	Results: oxygen desaturation $< 95\%$ 22.3 %; 19,2 % vasoactive drugs, 12,6% hypotension ,9,2% oxygen desaturation $< 90\%$	

Heron, V. et al. Endoscopist-Directed Propofol as an Adjunct to Standard Sedation: A Canadian Experience. J Can Assoc Gastroenterol. 3. 141-144. 2020

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: Retrospective, single-centre study	Funding sources: No data Conflict of Interests: None Randomization: None Blinding: None Dropout rates: None	Total no. patients: 4930 patients Recruiting Phase: 2004-2012 Inclusion criteria: Patients who had undergone gastrointestinal endoscopy (EGD, colonoscopy, PEG, ERCP) under sedation in which propofol was used. Exclusion criteria: Cases were excluded if propofol was administered by an anaesthetist or as an intravenous (IV) infusion in an intensive care unit (ICU) or emergency room setting.	Interventions: Comparison:
Notes:			

	Author's conclusion: The use of low-dose propofol as an adjunct to fentanyl and midazolam, administered by a registered nurse under the direction of the endoscopist was safe and effective in patients. a	
Outcome Measures/results	Primary Adverse events Secondary - drug combinations, dosage - need for reversal agents - endoscopic success	Results: - 0,45% AE. - mortality: 0% - 1 pts need for transfer to emergency unit - endoscopic success > 90% - reversal agents: 0,43%

Inatomi, O. et al. Dexmedetomidine is safe and reduces the additional dose of midazolam for sedation during endoscopic retrograde cholangiopancreatography in very elderly patients. BMC Gastroenterol. 18. 166. 2018

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 2 Study type: retrospective case control study	Funding sources: none Conflict of Interests: non Randomization: match ti historical cohort Blinding: none Dropout rates: none	Total no. patients: 140 Recruiting Phase: 12 month Inclusion criteria: Indication for ERCP , older than 85 Exclusion criteria:	Interventions: ERCP Comparison: midazolam sedation versus mida plus DEX
Notes:	Author's conclusion: DEX is a good alternative in sedation for very elderly with the indication for ERP		
Outcome Measures/results	Primary Adverse effects caripulmonary Secondary	Results: dex decreases the rate of adverse effects and the need for midazolam	

Ishibashi, C. et al. Effects of dexmedetomidine on hemodynamics and respiration in intubated, spontaneously breathing patients after endoscopic submucosal dissection for cervical esophageal or pharyngeal cancer. J Anesth. 30. 628-36. 2016

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 4 Study type: retrospective cohort analysis of patients after ESD receiving dexdor	Funding sources: none Conflict of Interests: none Randomization: no Blinding: no Dropout rates:	Total no. patients: 129 Recruiting Phase: May 2007 to December 2015, retrospective Inclusion criteria: ESD and dexdor Exclusion criteria: exubation in operating room, no dexdor	Interventions: retrospective, ESD, sedation with dexdor Comparison:
Notes:	retrospective analysis, cohort of patients after cervical esophageal or pharyngeal ESD sedation with dexmedetomidine after the procedure, influence on hemodynamics		

	Author's conclusion: Dexmedetomidine in intubated, spontaneously breathing patients after ESD was safe and effective. Patient baseline hemodynamics could significantly affect hemodynamics during drug infusion. progressive decrease in blood pressure and unchanged heart rate after an initial decrease	
Outcome Measures/results	Primary Secondary hemodynamics after ESD under dexdor sedation	Results: During infusion, blood pressure decreased progressively until 12h, whereas heart rate decreased only at 3h. Hemodynamic alterations during dexmedetomidine infusion greatly depended not only on its hemodynamic effects but also on baseline hemodynamics before anesthesia.

Jo, H. B. et al. Safety and effectiveness of midazolam for cirrhotic patients undergoing endoscopic variceal ligation. Turk J Gastroenterol. 29. 448-455. 2018

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 4 Study type: retrospective cohort	Funding sources: none Conflict of Interests: none Randomization: no Blinding: no Dropout rates:	Total no. patients: 325 Recruiting Phase: Inclusion criteria: The medical records of patients with cirrhosis who underwent EVL between October 2010 and December 2016 were reviewed retrospectively Exclusion criteria: Exclusion criteria comprised chronic use of benzodiazepines, overt HE, and state of cardiopulmonary dysfunction defined as follows: hypotension (systolic blood pressure<90 mm Hg and/or diastolic blood pressure<50 mm Hg), bradycardia (heart rate<55 beats per minute), and desaturation (<90% on pulse oximetry). Patients undergoing endoscopic screening were not included	Interventions: EVL Comparison: midazolam vs. non-midazolam
Notes:	Author's conclusion: Extreme caution should be taken when sedating patients with cirrhosis receiving EVL due to the AEs associated with the use of MDZ		
Outcome Measures/results	Primary The primary outcome of interest was treatment success. The secondary outcomes were procedure time, AEs, and mortality within 30 days. Secondary Risk factors and comorbidities affecting the development of AEs and HE were also evaluated	Results: No significant differences were found in treatment outcome and procedure time among 151 patients in the MDZ group and 169 patients in the non-MDZ group. Desaturation (23.2% vs. 7.7%, p<0.01), bradycardia (22.5% vs. 17.2%, p=0.03), and hepatic encephalopathy (HE) (6.6% vs. 0.6%, p<0.01) were more common in the MDZ group than in the non-MDZ group. Logistic regression analyses revealed that an Eastern Cooperative Oncology Group (ECOG) score of ≥ 2 (p<0.01) and the use of MDZ (p<0.01) were associated with the development of overall AEs. An ECOG score of ≥ 2 (p=0.01), high serum creatinine level (p=0.02), and the use of MDZ (p<0.01) were significant risk factors for HE.	

Jokelainen, J. et al. Assessment of sedation level for endoscopic retrograde cholangiopancreatography - a prospective validation study. Scand J Gastroenterol. 53. 370-375. 2018

Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 3</p> <p>Study type: Prospective validation study; comparison of 4 different methods to evaluate the depth of sedation in pts during ERCP</p>	<p>Funding sources: none</p> <p>Conflict of Interests: none</p> <p>Randomization: no</p> <p>Blinding: no</p> <p>Dropout rates: 1/200</p>	<p>Total no. patients: 200 pts ; 4 Groups:</p> <p>Bispectral index (BIS); modified Richmond Agitation/Sedation scale (mRASS); modified Ramsay Sedation Scale (mRSS); modified Observer Assessment of Alertness and Sedation (mOASS)</p> <p>Recruiting Phase: 11.12.2013 - 19.1.2016</p> <p>Inclusion criteria: Adult Patients for ERCP Further details not specified</p> <p>Exclusion criteria: Refusal to participate Incapability of giving informed consent</p>	<p>Interventions: ERCP 4 methods to assess the level of sedation (see above)</p> <p>Comparison: 200 pts 3 modes of sedation :</p> <ol style="list-style-type: none"> 1. Patient controlled sedation (PCS) 39 pts 2. Patient controlled sedation and anaesthesiologist administered (PCS): 9 pts 3. Anaesthesiologist administered sedation: 151 <p>134 received propofol, one Patient only as Bolus, the others propofol infusion and bolus</p>
Notes:	<p>ERCP procedures in general, not specified Inclusion criteria not stated in detail</p> <p>Author's conclusion: mOASS, mRSS and RASS were all found to be highly congruent with each other and slightly less so with BIS In clinical practice EEG-derived monitors are more useful in the clinical setting of ERCP sedation</p>		
Outcome Measures/results	<p>Primary The reliability in the assessment of the depth of sedation compared with each other and relationship to BIS. For Comparison : Cronbach's Alpha test Spearman's correlation and prediction probability used</p> <p>Secondary None</p>	<p>Results: All scales showed high reliability Better consistency between mOASS, mRASS and mRSS than with BIS PCS attempted 48x, successful 39x ; 81,3 % success rate No sedation related adverse effects</p>	

Joshi, D. et al. Experience of propofol sedation in a UK ERCP practice: lessons for service provision. Frontline Gastroenterol. 6. 32-37. 2015

Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 3</p> <p>Study type: retrospective cohort study with conscious sedation vs. propofol</p>	<p>Funding sources: none</p> <p>Conflict of Interests: none</p> <p>Randomization: no</p> <p>Blinding: no</p> <p>Dropout rates: n.a.</p>	<p>Total no. patients: 629</p> <p>Recruiting Phase: January 2013 and December 2013</p> <p>Inclusion criteria: ERCP, data available</p> <p>Exclusion criteria:</p>	<p>Interventions:</p> <p>Comparison:</p>

Notes:	retrospective data base analysis/cohort study ERCP: conscious sedation (midazolam/fentanyl) vs. propofol	
	Author's conclusion: PropERCP is safe and is associated with high endoscopic success.	
Outcome Measures/results	<p>Primary procedural information, patient demographics, ASA status, Cotton grade of endoscopic difficulty and endoscopic and anaesthetic complications.</p> <p>Secondary</p>	<p>Results: 744 ERCPs were performed in 629 patients (53% male). 161 ERCPs were performed under propofol. PropERCP patients were younger compared with the sedERCP group (54 vs 66 years, $p < 0.0001$). Indications for propERCP included sphincter of Oddi manometry (27%), previously poorly tolerated sedERCP (26%), cholangioscopy (21%) and patient request (8%). 77% of cases were elective, 12% were urgent day-case transfers and 11% were urgent inpatients. 59% of cases were tertiary referrals. ERCP was completed successfully in 95% of cases. Anaesthetic and endoscopic complications were comparable between the two groups (5% and 7% vs 3% and 5%). Where sedERCP had been unsuccessful due to patient intolerance, the procedure was completed successfully using propofol.</p>

Kikuchi, H. et al. Efficacy and safety of sedation during endoscopic submucosal dissection of gastric cancers using a comparative trial of propofol versus midazolam. Endosc Int Open. 6. E51-e57. 2018			
Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 4</p> <p>Study type: observational study</p>	<p>Funding sources: none</p> <p>Conflict of Interests: none</p> <p>Randomization: no</p> <p>Blinding: no</p> <p>Dropout rates: not stated</p>	<p>Total no. patients: 274</p> <p>Recruiting Phase: July 2013 and January 2014 and February 2014 and December 2015</p> <p>Inclusion criteria: early gastric cancer</p> <p>Exclusion criteria: not stated</p>	<p>Interventions: ESD gastric cancer, different sedation</p> <p>Comparison:</p>
Notes:	<p>observational study, ESD for early gastric cancer one time span midazolam and pentazocin sedation, next time span/following year propofol and pentazocin sedation.</p> <p>insecure end points like body movement during procedure 0 vs. 3... documentation? different group size</p> <p>Author's conclusion: efficacy and safety of propofol-based sedation for gastric ESD</p>		
Outcome Measures/results	<p>Primary frequency of body movement during ESD</p> <p>Secondary procedure time, en bloc resection rate, intraoperative change in cardiorespiratory dynamics, and postoperative awareness</p>	<p>Results: median frequency of body movement during ESD was significantly lower in group P (0 times) than in group M (3 times) ($P < 0.001$). No significant difference for the mean procedure time (117min in group P; 127min in group M)</p> <p>incidence of hypotension was significantly higher in group P (31.5%) than in group M (6.9%) ($P = 0.004$). Patients in group P had significantly higher postoperative awareness immediately after ESD and at 1 hour after ESD ($P = 0.002$ and 0.022, respectively).</p>	

Lee, H. S. et al. Nurse-Administered Propofol Continuous Infusion Sedation for Gastrointestinal Endoscopy in Patients Who Are Difficult to Sedate. Clin Gastroenterol Hepatol. 19. 180-188. 2021			
Evidence level	Methodical Notes	Patient characteristics	Interventions

Evidence level: 3 Study type: Cohort	Funding sources: NA Conflict of Interests: NA Randomization: none Blinding: none Dropout rates: NA	Total no. patients: 1427 Recruiting Phase: January 2018 through April 2018 Inclusion criteria: retrospective study of patients who underwent upper endoscopy or colonoscopy with NAPCIS at a single center Exclusion criteria: none	Interventions: We reviewed records from patients who were heavy users of alcohol (n [105), daily users of marijuana (n [267) or opioids (n [178), had a diagnosis of PTSD (n [91), or were none of these (controls, n [786). Comparison: NA
Notes:	Author's conclusion: NAPCIS seems to be a safe and effective means of providing sedation for endoscopy to patients who may be difficult to sedate owing to alcohol, marijuana, or opioid use, or PTSD.		
Outcome Measures/results	Primary We compared mean fentanyl and propofol doses (adjusted for body weight), procedure and recovery times, procedure success rates, and adverse events. Secondary NA	Results: Compared with the controls, the marijuana group required higher mean adjusted sedative doses for colonoscopies (0.6 vs 0.4 mcg/kg fentanyl and 5.0 vs 4.7 mg/kg propofol; P £ .025 for both) and upper endoscopies (0.8 vs 0.3 mcg/kg fentanyl and 3.7 vs 3.2 mg/kg propofol; P £ .021 for both), the PTSD group required a higher dose of fentanyl for colonoscopies (0.6 vs 0.4 mcg/kg; P [.009), and the alcohol group required a higher dose of fentanyl for upper endoscopies (0.7 vs 0.3 mcg/kg; P < .001). Procedure success rates were high (95.1%–100%) and did not differ significantly between the difficult-to-sedate groups and controls; mean procedure times (7.0–9.0 minutes for upper endoscopies, 21.1–22.9 minutes for colonoscopies) and recovery times (22.5–29.6 minutes) also were similar among groups. Upper endoscopies were associated with lower sedative doses and shorter procedure and recovery times than colonoscopies. Sedation-related adverse events were rare in all groups (only 26 cases total), and there were no serious complications or deaths.	

Lin, O. S. et al. One year experience with computer-assisted propofol sedation for colonoscopy. World J Gastroenterol. 23. 2964-2971. 2017

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: Case serie	Funding sources: none Conflict of Interests: none Randomization: none Blinding: none Dropout rates: not a	Total no. patients: 2677 Recruiting Phase: 3 month Inclusion criteria: consecutive Colonoscopy Exclusion criteria:	Interventions: comuter assisted propofol sedation Comparison: historical cohort
Notes:	Author's conclusion: CAPS is safe effective and efficient		
Outcome Measures/results	Primary ADR, Procedure Time, recovery Time Secondary	Results: Recovery Times shorter in comparison to historical population Procedure Times better completion of colonoscopy and adr were similar	

Lovett, P. et al. Propofol Versus Midazolam/Fentanyl Sedation for Colonoscopy in the Elderly Patient

Population. J Perianesth Nurs. 32. 210-214. 2017

Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 3</p> <p>Study type: cohort</p>	<p>Funding sources: none</p> <p>Conflict of Interests: none</p> <p>Randomization: none</p> <p>Blinding: none</p> <p>Dropout rates: NA</p>	<p>Total no. patients: 219</p> <p>Recruiting Phase: January to December 2013</p> <p>Inclusion criteria: This was a retrospective study of patients older than 65 years who underwent elective outpatient colonoscopies</p> <p>Exclusion criteria: NA</p>	<p>Interventions: NA</p> <p>Comparison: propofol vs. midazolam/fentanyl</p>
Notes:	<p>Author's conclusion: Propofol sedation was not associated with shorter recovery times. Further studies are needed to validate these findings</p>		
Outcome Measures/results	<p>Primary mean recovery times (in minutes)</p> <p>Secondary NA</p>	<p>Results: Propofol sedation was associated with longer recovery times compared with sedation with a combination of midazolam and fentanyl (mean: 50 minutes versus 31 minutes, P , .001).</p>	

Lucendo, A. J. et al. Gastrointestinal endoscopy sedation and monitoring practices in Spain: a nationwide survey in the year 2014. Endoscopy. 47. 383-90. 2015

Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 3</p> <p>Study type: Cohort study; Survey among Spanish endoscopists.</p>	<p>Funding sources: None</p> <p>Conflict of Interests: None</p> <p>Randomization: n/a</p> <p>Blinding: yes</p> <p>Dropout rates: n/a</p>	<p>Total no. patients: 2.476 spanish endoscopists received a 19-item survey via mail</p> <p>Recruiting Phase: 2014</p> <p>Inclusion criteria: Any member of the Spanish Soc. of Digestive Endoscopy, the Spanish Soc. of Gastroenterology or the Spanish Soc. of Digestive Diseases</p> <p>Exclusion criteria: none</p>	<p>Interventions: 19-item survey grouped in six categories: demographic data; material resources for sedation available; avtive participation in sedation; limitations in the enviroment for performing sedation; attitudes for sedation and impact of dedicated training.</p> <p>Comparison: none</p>
Notes:	<p>Survey among 2476 Spanish endoscopists with 23 % response rate</p> <p>Author's conclusion: The use of sedation in Spain varies widely but is on increase ans is more common in private hospitals. Propofol is the preferred sedative in all procedures.</p>		
Outcome Measures/results	<p>Primary Answers according to the six categories (see above)</p> <p>Secondary n/a</p>	<p>Results: 569/2476 endoscopists responded (23 %). Monitoring an resuscitation resources as well as a recovery room were universally available. Sedation was mainly performed by registered nurses (98,5 %). More tha half of upper Gi-endoscopies and 95 % of all colonoscopies were performed under sedation. Propofol was the most used sedative (70% in EGD, 80 % in colonoscopy). Sedation was more often used in private hospitals.</p>	

Maestro Antolín, S. et al. Severe cardiorespiratory complications derived from propofol sedation monitored by an endoscopist. Rev Esp Enferm Dig. 110. 237-239. 2018

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 4 Study type: Retrospective analysis	Funding sources: Unknown. Full text in Spain. Only Abstract analysed. Conflict of Interests: Unknown. Full text in Spain. Only Abstract analysed. Randomization: None. Blinding: None. Dropout rates: Unknown. Full text in Spain. Only Abstract analysed.	Total no. patients: 33195 Recruiting Phase: 2011 to 2016 Inclusion criteria: Various endoscopic examinations (gastroscopy, colonoscopy, endoscopic retrograde cholangiopancreatography [ERCP] and endoscopic ultrasound [EUS]) where sedation was controlled by an endoscopist within our unit. Exclusion criteria: Unknown. Full text in Spain. Only Abstract analysed.	Interventions: Sedation by endoscopist. Comparison: None.
Notes:	Full text in Spain, only abstract reviewed. Author's conclusion: Sedation controlled by a trained endoscopist is safe, effective and efficient.		
Outcome Measures/results	Primary Severe cardiorespiratory complications. Secondary Unknown.	Results: The rate of cardiorespiratory complications was 0.13% and the majority were severe desaturations. Most cases responded to an opening in the airway associated with the interruption of drug infusion and an ambu bag was required in a few cases. There were no statistically significant differences between the different groups, except for mean age, risk by type of examination and ASA risk, where the difference between ERCP and the rest of examinations was statistically significant.	

McVay, T. et al. Safety Analysis of Bariatric Patients Undergoing Outpatient Upper Endoscopy with Non-Anesthesia Administered Propofol Sedation. Obes Surg. 27. 1501-1507. 2017

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 2 Study type: Retrospective cohort study	Funding sources: This investigation was supported by the University of Utah Study Design and Biostatistics Center, with funding in part from the National Center for Research Resources and the National Center for Advancing Translational Sciences, National Institutes of Health, through Grant 5UL1TR001067-02 (formerly 8UL1TR000105 and UL1RR025764). Conflict of Interests: Dr. Fang is a consultant to Boston Scientific, Covidien, and Obalon Therapeutics. He is also the owner of Veritract.	Total no. patients: 395 (130 obese patients + 265non-obese-patients) Recruiting Phase: 03/2011-09/2015 Inclusion criteria: - pre-surgical outpatient EGD - severe obesity classes II and III Exclusion criteria: - EGD beside from EGD with biopsy - inpatient endoscopy	Interventions: NAAP sedation (propofol based plus fentanyl) Comparison: outcome in NAAP in non-obese vs. severe obesity patients

	Randomization: None Blinding: None Dropout rates: None	
Notes:	Author's conclusion: NAAP is a safe method of sedation in severely obese patients undergoing outpatient upper endoscopy	
Outcome Measures/results	Primary - sleep apnea - oxygen desaturation - chin lift maneuvers - advanced airway maneuvers Secondary	Results: Severely obese group vs. non-obese group: - sleep apnea (62 vs 8%; p < 0.001), - oxygen desaturations (22 vs 7%; p < 0.001) - chin lift maneuvers (20 vs 6%; p < 0.001) - Advanced airway interventions were rarely required in either group and not more frequent in the obese-group.

Mizrahi, M. et al. Minor Anesthesia-Related Events During Radiofrequency Ablation for Barrett's Esophagus Are Associated with an Increased Number of Treatment Sessions. Dig Dis Sci. 61. 1591-6. 2016			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 4 Study type: retrospective cohort study	Funding sources: none Conflict of Interests: none Randomization: no Blinding: no Dropout rates: n.a.	Total no. patients: 120 Recruiting Phase: 2008 - 2014 Inclusion criteria: RFA for barrett Exclusion criteria: not stated	Interventions: Comparison:
Notes:	retrospective single center cohort study adverse events linked to sedation for RFA of dysplastic barrett influence on number of RFA sessions? Author's conclusion: SRAE during RFA for dysplastic BE occurs at a rate typical of other advanced endoscopic procedures. Patients who experience minor events related to anesthesia during the first RFA are likely to require more RFA treatment sessions		
Outcome Measures/results	Primary frequency of sedation-related adverse events (SRAEs) during RFA for barrett Secondary occurrence of a SRAE during the first RFA session increased number of RFA sessions required to achieve complete eradication of dysplasia?	Results: SRAEs occurred in 32 %, most frequent SRAE was hypotension followed by hypoxia, arrhythmia and one unplanned intubation occurrence of a SRAE was associated with requiring more RFA sessions for ablation	

Nonaka, M. et al. Safety of gastroenterologist-guided sedation with propofol for upper gastrointestinal therapeutic endoscopy in elderly patients compared with younger patients. Gut Liver. 9. 38-42. 2015			
Evidence level	Methodical Notes	Patient characteristics	Interventions

<p>Evidence level: 3</p> <p>Study type: cohort</p>	<p>Funding sources: none reported</p> <p>Conflict of Interests: none</p> <p>Randomization: no</p> <p>Blinding: no</p> <p>Dropout rates:</p>	<p>Total no. patients: 160</p> <p>Recruiting Phase: NA</p> <p>Inclusion criteria: The records of 160 patients (181 procedures) who received endoscopic therapy for the treatment of cholangiopancreatic diseases and esophageal and gastric ESD at the Department of Gastroenterological Medicine of Akita Yuri Kumiai General Hospital (Yurihonjo, Akita, Japan) were analyzed</p> <p>Exclusion criteria: Patients who previously experienced hypersensitivity to 1% propofol (Diprivan®) or its constituents and pregnant women were excluded from the study</p>	<p>Interventions: therapeutic endoscopic procedures</p> <p>Comparison: patients <75 years old and elderly group, patients ≥75 years old</p>
<p>Notes:</p>	<p>Author's conclusion: Gastroenterologist-guided propofol sedation in elderly patients can be safely achieved in the same manner as that in younger patients, even for timeconsuming upper gastrointestinal therapeutic endoscopic procedures.</p>		
<p>Outcome Measures/results</p>	<p>Primary NA</p> <p>Secondary NA</p>	<p>Results: Although the number of patients with liver dysfunction was higher in the elderly group, there were no other significant differences in the baseline characteristics, including the American Society of Anesthesiologists classification, between the elderly and younger groups. The average maintenance rate of continuous propofol infusion was lower in the elderly patients. No statistically significant differences were found in the occurrence of adverse events between the elderly and younger groups. None of the patients returned to a resedated state after the initial recovery from sedation.</p>	

<p>Nonaka, T. et al. Feasibility of deep sedation with a combination of propofol and dexmedetomidine hydrochloride for esophageal endoscopic submucosal dissection. Dig Endosc. 28. 145-51. 2016</p>			
<p>Evidence level</p>	<p>Methodical Notes</p>	<p>Patient characteristics</p>	<p>Interventions</p>
<p>Evidence level: 4</p> <p>Study type: retrospective cohort study</p>	<p>Funding sources: NA</p> <p>Conflict of Interests: none</p> <p>Randomization: no</p> <p>Blinding: no</p> <p>Dropout rates:</p>	<p>Total no. patients: 40</p> <p>Recruiting Phase: between July 2012 and August 2014.</p> <p>Inclusion criteria: patients with superficial esophageal cancers who underwent esophageal ESD</p> <p>Exclusion criteria: NA</p>	<p>Interventions: endoscopic submucosal dissection</p> <p>Comparison: benzodiazepines vs. propofol and dexmedetomidine</p>
<p>Notes:</p>	<p>Author's conclusion: This retrospective study suggests that a combination of PF and DEX may provide stable deep sedation with less body movement than benzodiazepines during esophageal ESD</p>		

Outcome Measures/results	<p>Primary Clinical patient characteristics (including age, gender, body mass index, Brinkman index, alcohol consumption, treatment history of esophagus such as endoscopic resection or radiation therapy, underlying diseases and ASA physical status), endoscopic findings for esophageal neoplasm (including the lesion localized site and macroscopic type) and histopathological findings after ESD (including invasion depth of the lesion and resected specimen size) were reviewed.</p> <p>Secondary NA</p>	<p>Results: Median procedural times in the combination group were shorter than those in the conventional group (61min vs 89 min, P = 0.03), and the percentage of patients who showed restlessness in the combination group was significantly lower than that in the conventional group (25% vs 65%, P = 0.025). Incidences of hypotension and bradycardia in the combination group were higher than those in the conventional group (60% vs 15%, P=0.008, and 60% vs 15%, P=0.008, respectively).</p>
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<p>Okeke, F. C. et al. Safety of Propofol Used as a Rescue Agent During Colonoscopy. J Clin Gastroenterol. 50. e77-80. 2016</p>			
Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 3</p> <p>Study type: Retrospective cohort</p>	<p>Funding sources: NA</p> <p>Conflict of Interests: NA</p> <p>Randomization: no</p> <p>Blinding: no</p> <p>Dropout rates:</p>	<p>Total no. patients: 806</p> <p>Recruiting Phase: January 2006 to December 2009</p> <p>Inclusion criteria: NA</p> <p>Exclusion criteria: NA</p>	<p>Interventions: colonoscopy</p> <p>Comparison: propofol rescue vs. standard sedation</p>
<p>Notes:</p>	<p>Author's conclusion: Adjunctive propofol administered by gastroenterologist for conscious sedation was not associated with increased incidence of adverse events. It may be of value in patients who do not respond to conventional sedation.</p>		
Outcome Measures/results	<p>Primary We compared the rate of both major and minor complications between the 2 groups. Major complications included: prolonged hypotension (blood pressure of <90/60, which was unresponsive to 500mL of intravenous fluid), face-mask bagging, endotracheal intubation, and cardiopulmonary resuscitation. Minor complications included transient hypotension (blood pressure of <90/60, which</p>	<p>Results: There were no major adverse events in either group. The rates of minor adverse events in the propofol and control group were 0.02 and 0.01, respectively (P=0.56). Adverse effects in the propofol group included: transient hypotension (n=1), nausea/vomiting (n=3), agitation (n=2), and rash (n=1). Adverse effects seen with standard sedation included: transient hypotension (n=2), nausea/vomiting (n=1), and oversedation (n=2). Patients who received propofol were more likely to be younger, had a history of illicit drug use, and a longer procedure time (P<0.05).</p>	

was responsive to 500mL of intravenous fluid), hypoxia (oxygen saturation of <90%), nausea or vomiting, skin rash, and prolonged sedation requiring reversal agents).

Secondary NA

Patel, V. A. et al. Obstructive Sleep Apnea Increases the Risk of Cardiopulmonary Adverse Events Associated with Ambulatory Colonoscopy Independent of Body Mass Index. Dig Dis Sci. 62. 2834-2839. 2017

Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 2</p> <p>Study type: retrospective cohort</p>	<p>Funding sources: none</p> <p>Conflict of Interests: none</p> <p>Randomization: no</p> <p>Blinding: no</p> <p>Dropout rates: NA</p>	<p>Total no. patients: 418</p> <p>Recruiting Phase: between July 1, 2013, and July 1, 2014,</p> <p>Inclusion criteria: The VA clinical data warehouse was employed to identify 442 consecutive patients who underwent ambulatory colonoscopy</p> <p>Exclusion criteria: After excluding patients with unsedated procedures (n = 5), BMI <20 or missing BMI data (n = 14), and age over 75 years (n = 5), 418 patients were eligible for the study</p>	<p>Interventions: Colonoscopy</p> <p>Comparison: To assess the association of BMI and CAEs associated with ambulatory colonoscopy</p>
Notes:	<p>Author's conclusion: At least one CAE occurred in 46.4% of patients (220 events, 72.7% were hypoxia). The rate of CAEs (BMI <30: 43.8%, BMI 30–34: 48.0%, BMI C 35: 50.6%, p = 0.53) and rate of hypoxia (BMI <30: 34.8%, BMI 30–34: 40.9%, BMI C 35: 43.2%, p = 0.32) were numerically higher for obese and morbidly obese patients, but not statistically significant. Obese (OR 1.10, 95% CI 0.70–1.73) and morbidly obese (OR 1.07, 95% CI 0.61–1.85) patients did not have an increased risk of CAEs after adjusting for age, ASA class, obstructive sleep apnea (OSA), and type of sedation. OSA was independently associated with an increased risk of CAEs (OR 1.71, 95% CI 1.09–2.74, p = 0.02) after adjusting for BMI, age, ASA class, and type of sedation.</p>		
Outcome Measures/results	<p>Primary The primary aim of this study was to assess the independent effect of BMI on CAEs for outpatient colonoscopy, adjusting for clinically important covariates</p> <p>Secondary The secondary aim was to evaluate the need for an intervention for a CAE, as a measure of the CAE's clinical significance.</p>	<p>Results: At least one CAE occurred in 46.4% of patients (220 events, 72.7% were hypoxia). The rate of CAEs (BMI <30: 43.8%, BMI 30–34: 48.0%, BMI C 35: 50.6%, p = 0.53) and rate of hypoxia (BMI <30: 34.8%, BMI 30–34: 40.9%, BMI C 35: 43.2%, p = 0.32) were numerically higher for obese and morbidly obese patients, but not statistically significant. Obese (OR 1.10, 95% CI 0.70–1.73) and morbidly obese (OR 1.07, 95% CI 0.61–1.85) patients did not have an increased risk of CAEs after adjusting for age, ASA class, obstructive sleep apnea (OSA), and type of sedation. OSA was independently associated with an increased risk of CAEs (OR 1.71, 95% CI 1.09–2.74, p = 0.02) after adjusting for BMI, age, ASA class, and type of sedation.</p>	

Robertson, A. R. et al. Colonoscopy quality with Entonox(®)vs intravenous conscious sedation: 18608 colonoscopy retrospective study. World J Gastrointest Endosc. 9. 471-479. 2017

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 2 Study type: retrospective cohort study	Funding sources: none Conflict of Interests: none Randomization: no Patient's offer Blinding: none Dropout rates: none	Total no. patients: 18608 Recruiting Phase: 30 months Inclusion criteria: Colonoscopy Exclusion criteria: no colonoscopy possible	Interventions: Colonoscopy with intravenous conscious sedation (Midazolam plus opioid) vs. no sedation vs. Entonox gas Comparison: Quality of Colonoscopy
Notes:	standardized Database makes comparison possible		
	Author's conclusion:		
Outcome Measures/results	Primary Patient comfort Polyp detection rate caecal intubation rate Secondary	Results: Entonox not different from Sedatuin with Midazolam plus opioid	

Smischney, N. J. et al. Determinants of Endotracheal Intubation in Critically Ill Patients Undergoing Gastrointestinal Endoscopy Under Conscious Sedation. J Intensive Care Med. 34. 480-485. 2019

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 2 Study type: register/Cohort Study	Funding sources: Conflict of Interests: Randomization: Blinding: Dropout rates:	Total no. patients: 320 Recruiting Phase: 48 month Inclusion criteria: GI Endoscopy during ICU Stay Exclusion criteria:	Interventions: GI Endoscopy Comparison: primary intubation or not before GI Endoscopy
Notes:	Author's conclusion:		
Outcome Measures/results	Primary APACHE Score Secondary	Results: not relevANT FOR pROPOFOLSEDATION	

Turse, E. P. et al. Impact of moderate versus deep sedation on adenoma detection rate in index average-risk screening colonoscopies. Gastrointest Endosc. 90. 502-505. 2019

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: Retrospektive monozentrische Studie	Funding sources: nein Conflict of Interests: nein Randomization: nein Blinding: unklar Dropout rates: n. d.	Total no. patients: 585 Recruiting Phase: 6 Monate in 2015 (moderate Sedierung) und 6 Monate in 2016 (tiefe Sedierung) Inclusion criteria: Patienten mit Colonoskopie > 50 Jahre Exclusion criteria: Hochrisikopatienten, Darmblutungen, Konstipation, Diarrhoe, Abdominalschmerzen	Interventions: tiefe bzw. moderate Sedierung Comparison: tiefe versus moderate Sedierung
Notes:	Author's conclusion: Tiefe Sedierung hat keine Vorteil auf die Detektionsraten von Adenomen und Polypen		
Outcome Measures/results	Primary Qualitätsindikatoren (n. d.) Secondary Effekt unterschiedlicher Sedierungstiefen auf die Detektionsraten von Adenome und Polypen	Results: Kein signifikanter Einfluss der Sedierungstiefe auf die Detektionsraten von Adenomen und Polypen	

Urahama, R. et al. Polysomnographic assessment of respiratory disturbance during deep propofol sedation for endoscopic submucosal dissection of gastric tumors. World J Gastrointest Endosc. 10. 340-347. 2018

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 2 Study type: Cohort study	Funding sources: none Conflict of Interests: none Randomization: none Blinding: none Dropout rates: NA	Total no. patients: 10 Recruiting Phase: NA Inclusion criteria: Inclusion criteria were adult patients undergoing ESD surgery for early gastric cancer under propofol sedation with expected procedure duration of < 2 h. Exclusion criteria: Exclusion criteria were patients with severe comorbidities, including presence of high risk of aspiration and allergies to propofol and pentazocine	Interventions: endoscopic submucosal dissection (ESD) or endoscopic retrograde cholangiopancreatography. Comparison: Pulse oximetry vs. polysomnography
Notes:	Author's conclusion: Compared with pulse oximetry, PSG can better detect respiratory irregularities and thus provide superior		

	AHI values, leading to avoidance of fatal respiratory complications during ESD under propofol-induced sedation.	
Outcome Measures/results	<p>Primary Apnea hypopnea index (AHI), the primary outcome variable, was defined as the frequency of apnea and hypopnea episodes per hour of sedation.</p> <p>Secondary NA</p>	<p>Results: Polysomnography (PSG) detected 207 respiratory disturbances in the 10 patients. PSG yielded a significantly greater AHI ($10.44 \pm 5.68/h$) compared with pulse oximetry ($1.54 \pm 1.81/h$, $P < 0.001$), thus supporting our hypothesis. Obstructive AHI ($9.26 \pm 5.44/h$) was significantly greater than central AHI ($1.19 \pm 0.90/h$, $P < 0.001$). Compared with pulse oximetry, PSG detected the 25 instances of respiratory disturbances with hypoxemia 107.4 s earlier on average.</p>

Vaessen, H. et al. Clinical analysis of moderate-to-deep-sedation by nonmedical sedation practitioners in 597 patients undergoing gastrointestinal endoscopy: a retrospective study. Endosc Int Open. 4. E564-71. 2016

Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 3</p> <p>Study type: 30 months Retrospective Study and Analysis</p>	<p>Funding sources: none</p> <p>Conflict of Interests: none</p> <p>Randomization: no</p> <p>Blinding: no</p> <p>Dropout rates: none</p>	<p>Total no. patients: 597, but 5 excluded</p> <p>Recruiting Phase: Unclear; 30 months but 9/2013-7/2014 reported</p> <p>Inclusion criteria: 18 yrs compliance with fasting guidelines</p> <p>Exclusion criteria: Allergies Pregnancy Mental disability Acute GI Bleedinp</p>	<p>Interventions: Moderate to deep sedation with propofol and alfentanil in pts undergoing GI - endoscopy administered by non medical trained sedation practitioners</p> <p>Comparison: 4 groups of endoscopy procedures: Colonoscopy Colonoscopy and Gastroscopy Interventional gastroscopy ERCP/EUS</p>
Notes:	<p>30 months retrospective study</p> <p>Author's conclusion: Well trained non-medical sedation practitioners can be entrusted to take responsibility for the safe administration of moderate to deep sedation</p>		
Outcome Measures/results	<p>Primary Incidence of adverse effects affecting pat's ventilation and circulation Safety of administration by non medical personel</p> <p>Secondary see above</p>	<p>Results: Uneventfull recovery in all pts 89 / 597 (85 mild/4 severe) had complications All managed easily</p>	

Vargo, J. J. et al. Patient safety during sedation by anesthesia professionals during routine upper endoscopy and colonoscopy: an analysis of 1.38 million procedures. Gastrointest Endosc. 85. 101-108. 2017

Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 2</p> <p>Study type: cohort study</p>	<p>Funding sources: none</p> <p>Conflict of</p>	<p>Total no. patients: 1388235</p> <p>Recruiting Phase: 2002 and 2013</p>	<p>Interventions: routine upper endoscopy and colonoscopy</p>

	<p>Interests: The following authors disclosed financial relationships relevant to this publication: P. J. Niklewski, J. F. Martin: employees and developers of the SEDASYS System, Ethicon, Endo-Surgery Inc. All other authors disclosed no financial relationships relevant to this publication. P. J. Niklewski and J. F. Martin received research support as they were employed by Ethicon. J. L. Williams was paid by CORI, which received funding from Ethicon. Drs Vargo and Faigel received no funding support.</p> <p>Randomization: none</p> <p>Blinding: none</p> <p>Dropout rates: NA</p>	<p>Inclusion criteria: NA</p> <p>Exclusion criteria: NA</p>	<p>Comparison: anesthesia vs. endoscopist guided sedation</p>
<p>Notes:</p>	<p>Author's conclusion: Within the confines of the SAE definitions used, use of anesthesia professionals does not appear to bring a safety benefit to patients receiving colonoscopy and is associated with an increased SAE risk for ASA I, II, and III patients undergoing EGD.</p>		
<p>Outcome Measures/results</p>	<p>Primary The primary outcome variable was defined as a serious adverse event (SAE) requiring intervention. This was defined as any event requiring administration of cardiopulmonary resuscitation, hospital or emergency department admission, administration of</p>	<p>Results: There were 1,388,235 patients in this study that included 880,182 colonoscopy procedures (21% ADS) and 508,053 EGD procedures (23% ADS) between 2002 and 2013. When compared with EDS, the propensity adjusted SAE risk for patients receiving ADS was similar for colonoscopy (OR, .93; 95% CI, .82-1.06) but higher for EGD (OR, 1.33; 95% CI, 1.18-1.50). Additionally, with further stratification by American Society of Anesthesiologists (ASA) class, the use of ADS was associated with a higher SAE risk for ASA I/II and ASA III subjects undergoing EGD and showed no difference for either group undergoing colonoscopy. The sample size was not sufficient to make a conclusion regarding ASA IV/V patients.</p>	

	<p>rescue/reversal medication, emergency surgery, procedure termination because of an adverse event, intraprocedural adverse events requiring intervention, or blood transfusion.</p> <p>Secondary NA</p>
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Walter, S. et al. Evaluation of an Objective Measurement Tool for Stress Level Reduction by Individually Chosen Music During Colonoscopy-Results From the Study "ColoRelaxTone". Front Med (Lausanne). 7. 525. 2020

Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 3</p> <p>Study type: Prospektiv</p>	<p>Funding sources: n. d.</p> <p>Conflict of Interests: n. d.</p> <p>Randomization: n. d.</p> <p>Blinding: n. d.</p> <p>Dropout rates: n. d.</p>	<p>Total no. patients: 196</p> <p>Recruiting Phase: 2019 - 2020</p> <p>Inclusion criteria: Alter > 18 Jahre, Colonoskopie.</p> <p>Exclusion criteria: ASA III und höher, beeinträchtigte kognitive Funktionen, Schwangerschaft</p>	<p>Interventions: Messung von Vitalparametern und physiologischen Parametern, Erfassung Biosignalprozession, Fragebögen</p> <p>Comparison: Colonoskopie mit und ohne selbstgewählte Musik</p>
Notes:	<p>Es fehlt eine Erklärung wie die Patienten den jeweiligen Gruppen zugeordnet wurden. = Prospektive Studie; Randomisierung erfolgte nicht!?</p> <p>Author's conclusion: Musik sollte als ein nicht-medikamentöses Konzept zur Stressreduktion bei endoskopischen Prozeduren angewendet werden.</p>		
Outcome Measures/results	<p>Primary Wirkung von selbstausgewählter Musik auf die Stressreaktion während Colonoskopie.</p> <p>Secondary Prozessparameter, Bewertung der Prozedur anhand von Zufriedenheitsskalen für die Ärzte (CSSI) als auch die Patienten (PSSI), Messung physiologischer Parameter (EMG).</p>	<p>Results: Musik führt zu einer gesteigerten Zufriedenheit bei Patienten und Untersuchern. EMMG-Messungen belegen ein niedrigeres Stresslevel unter Musik.</p>	

Xiaoqian, Z. et al. Clinical comparative study on Nitrous Oxide inhalation versus intravenous propofol and Midazolam sedation in Transnasal Gastroscopy. Pak J Med Sci. 33. 891-894. 2017

Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 4</p> <p>Study type:</p>	<p>Funding sources: Guiyang City Health Bureau Funds</p>	<p>Total no. patients: 200 pts for gastroscopy 100 in each group</p>	<p>Interventions: Transnasal gastroscopy with P/M intravenous sedation or nitrous</p>

Prospective cohort study	Conflict of Interests: none Randomization: No Blinding: No Dropout rates: No	Recruiting Phase: 12/2012-4/2014 Inclusion criteria: Pats for transnasal gastroscopy Exclusion criteria: Allergies Relevant cardiovascular and pulmonary disease Former nasal Septum operation	oxide inhalation Comparison: see above
Notes:	Limited number of pts Very short time gastroscopy (149 and 152 sec), in contrast very high doses of propofol 1-2 mg/kg and midazolam 2mg/kg in combination No severe cardiovascular and pulmonary side effects despite the conclusion given Author's conclusion: Nitrous oxide Inhalation has higher safety and tolerance with a broader prospect for transnasal gastroscopy		
Outcome Measures/results	Primary Safety and patients comfort Secondary Not specified	Results: No significant difference in the duration of examination, satisfactory rate and safety; small tendency for higher cardiovascular side effects with P/M n.s.	

Xu, B. B. et al. Clinical study of anesthetization by dezocine combined with propofol for indolent colonoscopy. World J Gastroenterol. 22. 5609-15. 2016

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 4 Study type: Cross sectional survey	Funding sources: No Conflict of Interests: None Randomization: No Blinding: No Dropout rates: No	Total no. patients: 160 Recruiting Phase: 1.4.-30.4.2015 Inclusion criteria: ASA I-II 1-68 yrs Indolent colonoscopy Exclusion criteria: Severe organ damage Drug allergies	Interventions: Dezocine /Propofol for indolent colonoscopy Comparison: No comparison
Notes:	Anaesthetization with dezocine/propofol for indolent colonoscopy Data for pain Management and biochemical indicators of GI function The aim of the study is not completely clear and not well expressed Author's conclusion: Dezocine in combination with propofol can successfully be used in colonoscopy patients for sedation without pain in particular for mid- to older aged pts Increased gastric mucosal blood flow suggesting regulative effect on GI function		
Outcome Measures/results	Primary Survey to collect patient General Information and anaesthesia data, pain Management. Biochemical indicators 30 min after colonoscopy from venous blood to analyze GI function	Results: 2 cases of Body movements, 2 cases of respiratory Depression Gastric and vasoactive intestinal Peptide levels slightly increased, somatostatin and endothelin levels slightly decreased	

Secondary not specified

Yoshio, T. et al. Efficacy of novel sedation using the combination of dexmedetomidine and midazolam during endoscopic submucosal dissection for esophageal squamous cell carcinoma. Esophagus. 16. 285-291. 2019

Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 3</p> <p>Study type: single arm prospective, cohort study comparison to historic control</p>	<p>Funding sources: none</p> <p>Conflict of Interests: none</p> <p>Randomization: no</p> <p>Blinding: no</p> <p>Dropout rates: n.a.</p>	<p>Total no. patients: 65</p> <p>Recruiting Phase: October 2014 to September 2015</p> <p>Inclusion criteria: histological diagnosis of squamous cell carcinoma, obtained by endoscopic biopsy; a tumor invasion \leq SM1 on pre-operative diagnosis; location of the tumor in upper, middle or lower thoracic (Ut, Mt, and Lt, respectively) or abdominal (Ae) esophagus; indication for ESD without intubation; absence of lymph node or distant metastasis on pre-operative computed tomography; age between 20 and 80 years; a performance status between 0 and 2; and absence of severe organ dysfunction.</p> <p>Exclusion criteria: uncontrolled hypertension; heart disease or arrhythmia; respiratory disease requiring oxygen at rest; unstable angina (newly occurring or a worsening over the 3 weeks prior to ESD); myocardial infarction within 6 months prior to ESD; difficulty with discontinuing antithrombotic drugs during the pre-operative period; and severe infectious disease requiring systemic treatment.</p>	<p>Interventions:</p> <p>Comparison:</p>
Notes:	<p>prospective, single arm confirmatory study of ESD with sedation of midazolam and dexmedetomidine, comparison to historic controls</p> <p>Author's conclusion: combination of DEX and midazolam provided effective sedation for ESD for ESCC</p>		
Outcome Measures/results	<p>Primary proportion of patients who did not move or require restraint during ESD</p> <p>Secondary frequency of complications and self-report questionnaires from patients and endoscopists.</p>	<p>Results: Restraint was not required in 97% of patients sedated using the combination of DEX and midazolam. Depressed respiration, low blood pressure, and bradycardia occurred in 23, 37, and 26% of patients. All patients recovered without severe complication. Occurrence of low blood pressure and bradycardia were higher, while respiratory depression was lower for the combination group than for the historical control group. The amount of midazolam used was significantly lower. Endoscopists were satisfied with the sedation in 94% of cases. All lesions were resected in en bloc fashion, without perforation</p>	

Yurtlu, D. A. et al. Propofol-Based Sedation Versus General Anesthesia for Endoscopic Submucosal Dissection. Medicine (Baltimore). 95. e3680. 2016

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3	Funding sources: Not reported.	Total no. patients: 91	Interventions: General anesthesia or propofol-based

Study type: Retrospective analysis	Conflict of Interests: Not reported. Randomization: None. Blinding: None. Dropout rates: Patients were excluded from the analysis.	Recruiting Phase: Between 2013 and 2015 Inclusion criteria: ASA 1 to 3 patients receiving gastric ESD Exclusion criteria: Not reported.	sedation methods at gastric endoscopic submucosal dissection (ESD) procedures. Comparison: General anesthesia versus propofol-based sedation
Notes:	Author's conclusion: general anesthesia administration may prevent an increase in procedure time due to frequent breaks caused by gag reflex, cough, mobilization, and oropharyngeal suctioning needs of the patient, and thus reduce the dissection time. Finally, ensuring the reliability of the airway with endotracheal intubation increases the comfort of the endoscopist, in addition to preventing respiratory problems for the anesthesiologist, creating a safe reliable alternative to sedation methods for gastric ESD procedures.		
Outcome Measures/results	Primary Procedure time, lesion size, dissection speed, anesthesia time, adverse effects such as gag reflex, nausea, vomiting, cough, number of desaturation episodes (SpO ₂) Secondary Primary and secondary endpoints not clearly stated.	Results: The calculated dissection speed was significantly high in group general anesthesia (G) (36.02±20.96mm ² /min) compared with the propofol sedation group (S) (26.04±17.56 mm ² /min; P=0.010). The incidence of nausea, cough, number of oropharyngeal suctioning, and desaturation episodes were significantly high in group S compared with that in group G (P	

Literatursammlung:

AG 3 - Literatur 2013 - 2014

Inhalt: 10 Literaturstellen

Literaturstelle	Evidenzlevel	Studientyp
Behrens, A. 2016	3	prospective multicenter registry
Behrens, A. 2013	2	Prospective multicenter Data collection of sedation associated complications in gastrointestinal endoscopy
Björkman, I. 2013	2	RCT
Friedrich-Rust, M. 2014	2	Prospective randomized study
Gotoda, T. 2014	3	Retrospective single center study, comparison of elderly and younger patients
Park, W. Y. 2014	2	Randomized controlled study
Slagelse, C. 2011	4	Retrospective assesment of side effects during propofol sedation with NAPS by eight trained nurses
Slagelse, C. 2013	2	Randomized controlled trial
Wall, B. F. 2017	1	Systematic review (Cochrane)
Yu, Y. H. 2013	3	Prospective, Randomized Controlled Trial

OXFORD (2011) Appraisal Sheet: Systematic Reviews: 1 Bewertung(en)

Wall, B. F. et al. Capnography versus standard monitoring for emergency department procedural sedation and analgesia. Cochrane Database Syst Rev. 3. Cd010698. 2017			
Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 1</p> <p>Study type: Systematic review (Cochrane)</p> <p>Databases: Cochrane Central Register od Controlled Trials, Medline, Embase, CINAHL, Meta-Registers</p> <p>Search period: February 2016</p> <p>Inclusion Criteria:</p>	<p>Population: Threee trials involving 1272 patients</p> <p>Intervention:</p> <p>Comparison: Oxygen desaturation, hypotension, emesis, Pulmanory aspiration, Airway intervention, Recovery time</p>	<p>Primary: Oxygen desaturation</p> <p>Secondary: hypotension, emesis, Pulmanory aspiration, Airway intervention, Recovery time</p> <p>Results: No diKerences in the rates of oxygen desaturation (RR 0.89, 95% CI 0.48 to 1.63; n = 1272, 3 trials) and hypotension (RR 2.36, 95% CI 0.98 to 5.69; n = 986, 1 trial). no differences in the rate of airway interventions performed (RR 1.26, 95% CI 0.94 to 1.69; n</p>	<p>Campbell 2016 {published and unpublished data}</p> <p>CampbellSG, MageeKD, ZedPJ, FroeseP, EtsellG, LaPierreA, et al. End-tidal capnometry during emergency department procedural sedation and analgesia: a randomized trial. World Journal of Emergency Medicine 2016;7(1):13-8. [PUBMED: 27006732]</p> <p>Deitch 2010 {published data only}</p>

<p>Randomized controlled trials and quasi randomized trial comparing capnography and standad monitoring for patients receiving procedural sedation and analgesia</p> <p>Exclusion Criteria:</p>	<p>= 1272). In the subgroup analysis, we found a higher rate of airway interventions for adults in the capnography group (RR 1.44, 95% CI 1.16 to 1.79; n = 1118, 2 trials; moderate quality evidence).</p> <p>Author's Conclusion: No convincing evidence that capnography reduces the rate of clinically adverse events in comparison to standard monitoring in PSA. Overall moderate quality of evidence due to population and outcome definition heterogeneity and limited reporting bias.</p>	<p>DeitchK, MinerJ, ChudnofskyCR, DominiciP, LattaD. Does end tidal CO2 monitoring during emergency department procedural sedation and analgesia with propofol decrease the incidence of hypoxic events? A randomized, controlled trial. Annals of Emergency Medicine 2010;5(3):258-64. [DOI: 10.1016/j.annemergmed.2009.07.030; PUBMED: 19783324] Langhan 2015 {published data only} * LanghanML, ShabanovaV, LiFY, BernsteinSL, ShapiroED. A randomized controlled trial of capnography during sedation in a pediatric emergency setting. American Journal of Emergency Medicine 2015;33(1):25-30. [PUBMED: 25445871]</p>
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Methodical Notes

Funding Sources: Cochrane Library

COI: none

Study Quality: 3 randomized controlled trials

Heterogeneity: high heterogeneity

Publication Bias: Evidence for publication bias

Notes:

OXFORD (2011) Appraisal Sheet: RCT: 5 Bewertung(en)

Björkman, I. et al. Gender differences when using sedative music during colonoscopy. Gastroenterol Nurs. 36. 14-20. 2013

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: RCT</p> <p>Number of Patient: 120</p> <p>Recruitment Phase: n.a.</p> <p>Inclusion Criteria: Adult outpatients on the waiting list for colonoscopy, over 18 years old, with normal hearing, sight, and ability to</p>	<p>Intervention: All patients in the intervention group listened to sedative instrumental music with a slow tempo, with 60-80 beats/minute, which had been reported to be calming and relaxing. The music was played on a CD player with earphones. The patients could control the volume themselves.</p>	<p>Primary: The questionnaire contained questions that were developed for this study, regarding demographic variables such as gender, age, and previous experience of colonoscopy. Age was divided into five different groups, 18-30 years, 31-50 years, 51-65 years, 66- 80 years and >80 years. The intervention group was also asked to answer questions regarding their desire to listen to music again if undergoing a new colonoscopy, and in that case, if they would then want to choose the music themselves.</p> <p>Secondary: The STAI short form consists of six</p>

<p>read and understand the Swedish language.</p> <p>Exclusion Criteria: Patients with dementia were excluded in order to minimise the risk of misunderstanding.</p>	<p>Comparison: The control group received the usual care with drugs administered when needed (Midazolam, Kerogen, Rapifen).</p>	<p>statements regarding anxiety, being calm, tense, upset, relaxed, content, or worried.</p> <p>Visual Analogue Scales (VAS), where the participants marked their answer on a line graded from 1- 100mm, were used to measure anxiety, well-being, relaxation and pain during the colonoscopy.</p> <p>Results: Women in the intervention group had a lower level of anxiety during the colonoscopy than those in the control group ($p = .007$) and well-being was significantly higher in the intervention group, especially among men, than in the controls ($p = .006$ and $p = .025$, respectively). Men in the intervention group were more relaxed during the colonoscopy than those in the control group ($p = .065$). Listening to sedative music decreased anxiety among women and increased well-being among men during colonoscopy.</p> <p>Author's Conclusion: Listening to sedative music decreased anxiety among women and increased well-being among men during colonoscopy. This simple procedure, which improves well-being, should be offered to every patient prior to colonoscopy.</p>
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Methodical Notes

Funding Sources:

COI: None

Randomization: Sealed envelope

Blinding: No

Dropout Rate/ITT-Analysis: None

Notes:

Friedrich-Rust, M. et al. Capnographic monitoring of propofol-based sedation during colonoscopy. Endoscopy. 46. 236-44. 2014

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: Prospective randomized study</p> <p>Number of Patient: 533</p> <p>Recruitment Phase: Patient enrollment started in June 2012 and ended in May 2013.</p> <p>Inclusion Criteria: Patients presenting for colonoscopy at the two study sites (Endoscopy Unit of the Department of Internal Medicine 1, University Hospital Frankfurt, Germany; Endoscopy outpatient clinic of the Praxisklinik für Diagnostik am Staedel, Frankfurt, Germany) were enrolled if they fulfilled all of the following inclusion criteria: (1)</p>	<p>Intervention: Standard monitoring alone (standard monitoring group) or standard monitoring with additional capnography (capnography monitoring group) for propofol-based sedation for colonoscopy.</p> <p>Comparison: Standard monitoring alone (standard monitoring group) or standard monitoring with additional capnography (capnography monitoring group).</p>	<p>Primary: Incidence of oxygen desaturation (hypoxemia), defined as an SO_2 drop to</p> <p>Secondary: (1) incidence of severe hypoxia ($SO_2 < 2L/min$), (3) episodes of apnea (end-tidal CO_2 at 0mmHg for >10 seconds), (4) time difference between apnea and hypoxemia in patients randomized to the capnography monitoring group, (5) assisted ventilation, (6) incidence of hypotension (systolic blood pressure</p> <p>Results: The incidence of hypoxemia was significantly lower in patients with capnography monitoring compared with those receiving standard monitoring (18 % vs. 32 %; $P = 0.00091$). Independent risk factors for hypoxemia were age ($P = 0.00015$), high body mass index ($P = 0.0044$), history of sleep apnea ($P = 0.025$), standard monitoring group ($P = 0.000069$), total dose of propofol ($P = 0.031$), and dose of ketamine</p>

age ≥ 18 years, (2) sedation requested during endoscopy, (3) ability to give written informed consent.

Exclusion Criteria: (1) ASA class 4 or 5, (2) unable to give informed consent themselves or by the appointed legal guardian, (3) pregnant or breastfeeding women, (4) contraindication for colonoscopy, (5) allergic to propofol, peanuts, soya products, chicken egg protein or sulfite.

(P

Author's Conclusion: In patients undergoing colonoscopy during propofol-based sedation capnography monitoring with a simple and inexpensive device reduced the incidence of hypoxemia.

Methodical Notes

Funding Sources: Not reported.

COI: None.

Randomization: An online randomization was prepared by the Department of Biostatistics (E.H.). The randomization list was calculated using R from the R Foundation for Statistical Computing (Vienna, Austria) and the R package blockrand by Schwarzer (version 2.12.0) and implemented in an online allocation of the included patients. Blockwise randomization was stratified according to the following criteria: (1) ASA class 1, 2 or 3, (2) planned sedation with either "propofol monotherapy" or "propofol + ketamine," (3) endoscopy planned with either "colonoscopy only" or "colonoscopy+gastroscopy," (4) center of study with either "University Hospital" or "PKD."

Blinding: None.

Dropout Rate/ITT-Analysis: ITT not reported. PPA done.

Notes:

Park, W. Y. et al. Bispectral index monitoring during anesthesiologist-directed propofol and remifentanyl sedation for endoscopic submucosal dissection: a prospective randomized controlled trial. Yonsei Med J. 55. 1421-9. 2014

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: Randomized controlled study</p> <p>Number of Patient: n=180</p> <p>Recruitment Phase: mai 2011 btill February 2012</p> <p>Inclusion Criteria: Patients undergoing gastric ESD Adult patients aged 20-80 years ASA class 1-3</p> <p>Exclusion Criteria: BMI > 35 kg/m2, severe hepatic or renal insufficiency, mental incompetence, allergy to drugs, use of antidepressants or anticonvulsant, baseline oxygen saturation < 90% on room air, baseline systolic blood pressure < 80 mmHg</p>	<p>Intervention: upper GI endoscopy with gastric ESD Sedation with Modified observer assessment of alertness and Sedation scale (MOAA/S) or bispectral imaging (BIS)</p> <p>Comparison:</p>	<p>Primary: The total doses of Propofol and remifentanyl, number of rescue doses of propofol, Complications</p> <p>Secondary:</p> <p>Results: The number of patients who needed rescue propofol was significantly higher in the control group (MOAA/S)47.8% vs 30.0 % in the BIS group. There were no differences in the total doses of propofol and remifentanyl and in the incidence of sedation or procedure related complications.</p> <p>Author's Conclusion: BIS guided sedation with propofol and remifentanyl reduced the number of patients requiring rescue propofol in ESD procedures. However, this finding did not lead to clinical benefits, thus BIS is of limited use during anesthesiologist directed sedation.</p>

Methodical Notes

Funding Sources: none

COI: none

Randomization: yes, blinded envelope

Blinding: no

Dropout Rate/ITT-Analysis:

Notes:

Slagelse, C. et al. The role of capnography in endoscopy patients undergoing nurse-administered propofol sedation: a randomized study. Scand J Gastroenterol. 48. 1222-30. 2013

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: Randomized controlled trial</p> <p>Number of Patient: 540</p> <p>Recruitment Phase:</p> <p>Inclusion Criteria: Patients, aged 18 or above and referred to endoscopy at Gentofte Hospital, who were compliant with the criteria of NAPS.</p> <p>Exclusion Criteria: NAPS exclusion criteria were ASA physical status classification >3, sleep apnoea, allergy against soya, eggs, and peanuts, body mass index (BMI) >35 kg/m², Mallampati score ≥4, acute gastrointestinal bleeding, subileus, gastric retention, and severe cold (30% ≤ Forced Expired Volume in 1 second < 50%).</p>	<p>Intervention: Patients were randomized into a control group and an intervention group with and without capnography, respectively. EtCO₂ was registered by a nasal cannula (Smart CapnoLine Guardian™) in the intervention group in addition to the standard monitoring in both groups.</p> <p>Comparison: Patients were randomized into a control group and an intervention group with and without capnography, respectively. EtCO₂ was registered by a nasal cannula (Smart CapnoLine Guardian™) in the intervention group in addition to the standard monitoring in both groups.</p>	<p>Primary: Hypoxia defined as the number, duration, and level of hypoxic events, with hypoxia divided into three levels: saturation <92–90%, <90–88%, <88%.</p> <p>Secondary: Number of actions taken to restore normo-ventilation.</p> <p>Results: The number and total duration of hypoxia was reduced by 39.3% and 21.1% in the intervention group compared to the control group (p > 0.05). No differences in actions taken against insufficient respiration were found. Changes in end-tidal carbon dioxide (R = 0.177, p-value < 0.001) and respiratory rate (R = 0.092, p-value < 0.001) were correlated to oxygen saturation (SpO₂) up to 36 s prior to changes in SpO₂.</p> <p>Author's Conclusion: Capnography seems to reduce the number and duration of hypoxic events in patients undergoing endoscopy with NAPS, but the results are not significant. Capnographic measurements are of assistance as an objective estimation of respiratory status in procedures exceeding 25 min compared with standard visual monitoring. EtCO₂ as well as awRR are correlated to changes in SpO₂ demonstrating that capnography is able to predict early changes in respiration (36 s) that may lead to hypoxia. However, due to a limited clinical benefit, lack of evidence of increased safety, and the additional costs associated with capnography, we do not find capnography necessary during routine endoscopy in a selected patient population undergoing NAPS.</p>

Methodical Notes

Funding Sources: Public funding: The Danish Agency for Science, Technology and Innovation has supported the project with 72,170.00 DKK as a scholarship of seven months. Private funding: "Snedkermester Sophus Jacobsen og hustrus Astrid Jacobsens Fond" has supported the project with 20,000 DKK as part of a one-year scholarship.

COI: Vicare Medical has provided one out of three capnographic monitors (Phillips MP20) and part of the specialized bite blocks/nasal cannulas (Smart CapnoLine Guardian™) was provided by the Danish company Medidane. The funders had no role in study design, data collection, and analysis, decision to publish, or preparation of the manuscript.

Randomization: For allocation of participants a computerized random number generator (<http://stattrek.com/Tables/Random.aspx>) was used to produce a table with 600 numbers either one (intervention group) or zero (control group). For every 50 patients there was an equal number of ones and zeros and the table

with 600 numbers was produced to compensate for patients lost for follow-up. Patients were distributed by simple randomization between groups according to the sequence in the table after verbal information and acceptance of inclusion in the study by phone (by nurse or investigator). The table was produced by an external person not involved in the study through the above-mentioned computerized random number generator and assigned to the investigator.

Blinding: None.

Dropout Rate/ITT-Analysis: 24 and 27 patients lost to F/U.

Notes:

Negative study for capnography (Primary endpoint to reduce hypoxemia by one tenth).

Yu, Y. H. et al. Efficacy of bispectral index monitoring during balanced propofol sedation for colonoscopy: a prospective, randomized controlled trial. Dig Dis Sci. 58. 3576-83. 2013

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: Prospective, Randomized Controlled Trial</p> <p>Number of Patient: 30 (pilot) + 122 (randomized)</p> <p>Recruiting Phase: Between May 2010 and July 2012.</p> <p>Inclusion Criteria: Patients over age of 18 scheduled to undergo outpatient colonoscopy under BPS in the Division of Gastroenterology of Hanyang University Guri Hospital.</p> <p>Exclusion Criteria: Exclusion criteria included patients with American Society of Anesthesiologists (ASA) status IV or higher, and those who refused sedation during colonoscopy, who were hospitalized, or who were pregnant or lactating, as well as patients with allergies to eggs, beans, or latex, those with a previous history of alcohol or sedative overdose, or of adverse events associated with propofol, and those with sleep apnea or acute gastrointestinal hemorrhage or with a recent history of central nervous system (CNS) abnormalities (e.g., stroke).</p>	<p>Intervention: Patients who were scheduled to undergo outpatient colonoscopy were prospectively randomized to either a BIS or control group.</p> <p>Comparison: Patients who were scheduled to undergo outpatient colonoscopy were prospectively randomized to either a BIS or control group.</p>	<p>Primary: Doses of propofol, and satisfaction of patients and endoscopists, were compared between the BIS group and the non-BIS group to evaluate the efficacy of BIS. Mean sedation induction time, cecal intubation time, total procedure time, recovery time, and frequency of adverse cardiopulmonary events were evaluated. Recovery time was assessed by using modified Aldrete score.</p> <p>Secondary: -</p> <p>Results: The BIS values and the modified observer's assessment of alertness/sedation scores (MOAA/S) were positively correlated ($r = 0.66$ and $p < 0.001$). The optimal cut-off value of BIS for maintaining moderate sedation was 81, and the area under the ROC curve was 0.88 (95 % CI 0.82–0.93), indicating high prediction accuracy. However, there was no difference between the BIS group and the control group in levels of satisfaction of either patients or endoscopists. In addition, there was no difference in the complication and the required dose of propofol between both groups.</p> <p>Author's Conclusion: BIS and clinical sedation scores, MOAA/S scores, showed a high level of correlation. However, no significant efficacy was observed in the BIS group who underwent outpatient colonoscopy.</p>

Methodical Notes

Funding Sources: Research fund of the Hanyang University Institute of Aging, Society in 2011.

COI: None.

Randomization: Not sufficient. For allocation of the participants, Microsoft Excel was used. The patients were randomly allocated into a BIS group and a non-BIS group to evaluate the efficacy of BIS.

Blinding: The patient was blinded to the allocation assignment, but the endoscopist and sedation nurse were not blinded.

Dropout Rate/ITT-Analysis: 7 patients were excluded from the analysis (5 patients in whom cecal intubation failed

and 2 patients whose bowel preparation was not properly carried out). A total of 115 patients completed the study, 59 patients in the BIS group and 56 patients in the control group

Notes:

Severe methodological flaws.

NEWCASTLE - OTTAWA Checklist: Cohort: 4 Bewertung(en)

Behrens, A. et al. Safety of sedation during gastroscopy and colonoscopy in low-risk patients – results of a retrospective subgroup analysis of a registry study including over 170?000 endoscopies. Z Gastroenterol. 54. 733-739. 2016

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: prospective multicenter registry	Funding sources: none Conflict of Interests: none Randomization: no Blinding: no Dropout rates: not relevant	Total no. patients: 177944 Recruiting Phase: 12/2011 to 6/2014 Inclusion criteria: Endoscopy with sedation, ASA grade I and II, upper GI and colonoscopy, diagnostik endoscopy, patients > 17 years Exclusion criteria: emergency endoscopy, therapeutic intervention	Interventions: upper GI and colonoscopy under sedation Comparison:
Notes:	Retrospective analysis of low risk patients for complication with sedation Author's conclusion: No major complications oder death occured and minor comlications are very rare. Sedation can be regarded as extremely safe in this group of patients		
Outcome Measures/results	Primary Minorcomplications (paradoxe reaction, respiratory depression wur sO2 < 90% for > 10 sec, systolic Hypotension with drop of RR > 25%, drop of heart rate > 20%and Majorcomplications Secondary Sedation used, duration of procedure, actions afer complications, airway intervention, outcome	Results: Minor complications in 0.2% (n=332), no major oder death occurred. Risk factory for developement of sedatioon associated complications were ASA class 2 and sedation wih midazolam in combination with an opiate	

Behrens, A. et al. Wie sicher ist die Sedierung in der gastrointestinalen Endoskopie? Eine multizentrische Auswertung von 388?404 Endoskopien und Auswertung der Daten aus prospektiv geführten Komplikationsregistern von Mitgliedern der Arbeitsgemeinschaft leitender Gastroente. Z Gastroenterol. 51. 432-436. 2013

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 2 Study type: Prospective multicenter Data collection of sedation associated complications in gastrointestinal endoscopy	Funding sources: Conflict of Interests: none Randomization:	Total no. patients: 388404 endoscopies with sedation Recruiting Phase: january 2000 till Spetember 2011 Inclusion criteria:	Interventions: Gastrointestinal endoscopies with sedation Comparison:

	Blinding: no Dropout rates:	Gastrointestinal endoscopy with sedation in 15 representative Units with a endoscopy register Exclusion criteria:
Notes:	Multicenter Data-collection of a cohort of patients undergoing gastrointestinal endoscopy Author's conclusion: Large study with low rates of complication and mortality in sedated gastrointestinal endoscopy. Risk factor for complication and mortality was emergency procedures and ASA classification \geq	
Outcome Measures/results	Primary Severe complications Mortality Secondary Surveillance modalities Distribution in ASA Classifications	Results: n=57 severe complications (0.01%), 36 with no long termin defizit n=20 died (0.005%), N=16 due to complication, all with ASA3-5 n=22 post interventional surveillance in ICU 21 with reanimation n=14 with intubation

Gotoda, T. et al. Non-anesthesiologist administrated propofol (NAAP) during endoscopic submucosal dissection for elderly patients with early gastric cancer. Gastric Cancer. 17. 686-91. 2014

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: Retrospective single center study, comparison of elderly and younger patients	Funding sources: none Conflict of Interests: none Randomization: no Blinding: no Dropout rates:	Total no. patients: n=121 Recruiting Phase: Inclusion criteria: Patients undergoing endoscopic submucosal dissection (ESD) Exclusion criteria:	Interventions: Sedation for endoscopic submucosal dissection Comparison: Older versus younger patients
Notes:	Author's conclusion: Gastroenterologist guided propofol sedation during gastric ESD may be acceptable even in elderly with ASA I/II class under carefull monitoring of vital signs and oxygen saturation		
Outcome Measures/results	Primary Propofol usage (dose) Haemodynamics Secondary Adverse events	Results: No difference in the maintenance or total dose of propofol n=7 adverse events (5,8%), n=3 cases of hypotension (< 80 mmHg) No differences between the elderly and younger group	

Slagelse, C. et al. Nurse-administered propofol sedation for gastrointestinal endoscopic procedures: first Nordic results from implementation of a structured training program. Scand J Gastroenterol. 46. 1503-9. 2011

Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 4</p> <p>Study type: Retrospective assesment of side effects during propofol sedation with NAPS by eight trained nurses</p>	<p>Funding sources: none</p> <p>Conflict of Interests: none</p> <p>Randomization: none</p> <p>Blinding: none</p> <p>Dropout rates: not reported</p>	<p>Total no. patients: 2522</p> <p>Recruiting Phase: 2007-2009</p> <p>Inclusion criteria: All pts. who received NAPS-sedation by eight trained nurses.</p> <p>Exclusion criteria: ASA>2, pregnant women, Mallampatti class 3 or higher</p>	<p>Interventions: Recording of pulse frequency, blood pressure and pulse oxymetry</p> <p>Comparison: none</p>
<p>Notes:</p>	<p>Author's conclusion: NAPS by trained nurses is safe and effective.</p>		
<p>Outcome Measures/results</p>	<p>Primary Occurence of hypoxemia or hypotension</p> <p>Secondary</p>	<p>Results: Hypocxemic episodes werde registered in 4.7 %, no relevant side effects occurred.</p>	

Literatursammlung:**AG 3 - Literatur 2015 - 2020****Inhalt: 49 Literaturstellen**

Literaturstelle	Evidenzlevel	Studientyp
Bakry, M. 2019	3	Observational study of consecutive patients undergoing gastrointestinal endoscopy
Behrens, A. 2019	1	Prospective multicenter (n=39) data collection
Conigliaro, R. 2017	1	Position paper of the Italian Soc. of Digestive Endoscopy, no systematic review. Not censored.
Dumonceau, J. M. 2015	1	Guideline-could not be censored
Early, D. S. 2018	1	Guideline, not censored
Ferreira, A. O. 2016	1	RCT
Ferreira, A. O. 2015	2	31-item survey
Garbe, J. 2021	2	yes
Gouda, B. 2017	2	Meta-analysis of the published literature
Goudra, B. G. 2015	2	Meta analysis of the literature
Han, S. J. 2017	2	Randomised, prospective controlled study
Heo, J. 2016	2	RCT
Heron, V. 2020	3	Retrospective, single-centre study
Holley, K. 2016	2	Yes
Holton, J. 2016	5	
Jensen, J. T. 2016	2	Retrospective case series; single-center
Jensen, J. T. 2015	2	Retrospective case control study
Jensen, J. T. 2016	1	
Jopling, M. W. 2017	3	Retrospective data base analysis
Kashiwagi, K. 2016	1	RCT
Kim, S. H. 2018	2	Metaanalysis comparing capnography and standard care for sedation
Lapidus, A. 2019	5	Retrospective data analysis
Lee, C. K. 2016	2	Survey
Lieber, S. R. 2020	2	retrospective register-study
Lin, Y. J. 2020	2	Randomized, prospective Study

Lucendo, A. J. 2015	3	Cohort study; Survey among Spanish endoscopists.
Manno, M. 2021	3	Single-center, observational, prospective study
Mathews, D. M. 2018	3	Randomized controlled study
McVay, T. 2017	2	Retrospective cohort study
Mehta, P. P. 2016	1	RCT
Michael, F. A. 2020	1	Prospective, randomized study
Mohanaruban, A. 2015	4	Survey among gastroenterology trainees by the British Soc of Gastroenterology (BSG).
Obara, K. 2015	1	Guideline from the Japanese Soc: of GI-endoscopy; not censored
Ooi, M. 2015	3	Retrospective analysis
Peveling-Oberhag, J. 2020	2	Randomized controlled study comparing standard monitoring vs. capnography
Phan, A. D. 2020	1	prospective, diagnostic accuracy study
Prathanvanich, P. 2015	3	Prospective consecutive cohort study in moribly obese patients
Riphaus, A. 2016	1	Guideline: no analysis necessary
Sargin, M. 2019	2	Randomized controlled
Sathananthan, D. 2017	3	prospective design
Sato, M. 2019	3	Data collection,
Takamaru, H. 2020	1	retrospective study
Takimoto, Y. 2019	5	prospective
Teng, W. N. 2018	3	Observational study in patients undergoing propofol-sedated diagnostic EGD (MAC-sedation)
Touw, H. R. W. 2017	1	prospective study
Wadhwa, V. 2019	2	Prospective study
Yamamoto, H. 2015	3	Randomised controlled trial
Yang, J. F. 2016	2	Retrospective case series
Zhang, H. 2019	2	Metanalyse and trial sequential analysis

OXFORD (2011) Appraisal Sheet: Systematic Reviews: 6 Bewertung(en)

Conigliaro, R. et al. Italian Society of Digestive Endoscopy (SIED) position paper on the non-anaesthesiologist administration of propofol for gastrointestinal endoscopy. Dig Liver Dis. 49. 1185-1190. 2017			
Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
Evidence level: 1 Study type: Position paper of the Italian Soc. of Digestive Endoscopy, no systematic review. Not censored.	Intervention: Comparison:	Primary: Secondary: Results:	

Databases:		Author's Conclusion:	
Search period:			
Inclusion Criteria:			
Exclusion Criteria:			
Methodical Notes			
Funding Sources:			
COI:			
Study Quality:			
Heterogeneity:			
Publication Bias:			
Notes:			

Gouda, B. et al. Safety of non-anesthesia provider administered propofol sedation in non-advanced gastrointestinal endoscopic procedures: A meta-analysis. Saudi J Gastroenterol. 23. 133-143. 2017

Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 2</p> <p>Study type: Meta-analysis of the published literature</p> <p>Databases: Pubmed, Embase, Cochrane library, Scopus, Web of Science.</p> <p>Search period: Until April 2015</p> <p>Inclusion Criteria: Propofol sedation for EGD, Colonoscopy or both by using the search terms "Propofol sedation endoscopy", "Propofol sedation colonoscopy" and "Nurse-administered propofol sedation.</p> <p>Exclusion Criteria: Studies who addressed non-propofol based sedation, studies who included advanced endoscopic procedures (e.G. ESD, ERCP, EUS, small bowel enteroscopy, stenting etc.). Duplicated publications were removed by using the "Endnote" program.</p>	<p>Population: 137.087 pts.</p> <p>Intervention: A total of 25 publications were analyzed, 9 studies evaluated sedation for colonoscopy, 5 studies for upper Gi-endoscopy and 11 studies for both procedures.</p> <p>Comparison:</p>	<p>Primary: No. of hypoxemic events (desaturation > 90% assessed by pulse oximetry), no. of any airway interventions (e.g. Chin lift, bag ventilation) and airway complication rates were analyzed.</p> <p>Secondary: Need for endotracheal intubation and conversion rate to general anesthesia.</p> <p>Results: 2.931 hypoxia episodes were registered, with a pooled hypoxia rate of 0.014 %. Pooled airway intervention rate was 0.002 % and the pooled airway complication rate was 0.001 %. None of the Studies reported a need for endotracheal intubation and the conversion rate to endotracheal intubation was zero.</p> <p>Author's Conclusion: The rate of adverse events in patients undergoing non-advanced endoscopic procedures with NAAP sedation are extremely small. Similar data for anesthesia-providers are not available. It is prudent for anesthesia-providers to demonstrate their superiority in prospective randomized controlled trials, if they like to retain exclusive ownership over propofol sedation in patients undergoing GI endoscopy.</p>	<p>608 records were analyzed, 288 remained after duplicates have been removed ("Endnote"). In the references 55 citations were provided.</p>

Methodical Notes
<p>Funding Sources: Nil.</p> <p>COI: None.</p> <p>Study Quality: High quality meta-analysis</p> <p>Heterogeneity: 90 % for colonoscopy trials. 98 % for upper Gi-endoscopy trials. 99 % for trials evaluating both procedures.</p> <p>Publication Bias: Showed asymmetric distribution for the hypoxia rates as well as for the airway interventions. Symmetric distribution was found for airway-related complications.</p> <p>Notes:</p>

<p>Holton, J. et al. Capnography compared to pulse oximetry for early detection of respiratory compromise in non-intubated patients undergoing gastrointestinal endoscopy procedures: a systematic review protocol. JBI Database System Rev Implement Rep. 14. 38-47. 2016</p>			
Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 5</p> <p>Study type:</p> <p>Databases:</p> <p>Search period:</p> <p>Inclusion Criteria:</p> <p>Exclusion Criteria:</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary:</p> <p>Secondary:</p> <p>Results:</p> <p>Author's Conclusion:</p>	
Methodical Notes			
<p>Funding Sources:</p> <p>COI:</p> <p>Study Quality:</p> <p>Heterogeneity:</p> <p>Publication Bias:</p> <p>Notes: Systematic review protocol. No results yet published.</p>			

<p>Kim, S. H. et al. The addition of capnography to standard monitoring reduces hypoxemic events during gastrointestinal endoscopic sedation: a systematic review and meta-analysis. Ther Clin Risk Manag. 14. 1605-1614. 2018</p>			
Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 2</p> <p>Study type: Metaanalysis comparing capnography and</p>	<p>Population: 9 RCT with n=3088 patients</p> <p>Intervention: Capnography</p>	<p>Primary: Incidence of hypoxemia and severe hypoxemia</p> <p>Secondary:</p> <p>Results: Capnography monitoring reduced the</p>	27 citations

standard care for sedation Databases: Medlin, EMBASE, Cochrane Central, RCT Search period: till January 2018 Inclusion Criteria: RCT Exclusion Criteria:	versus standard monitoring Comparison: Capnography versus standard monitoring	incidence of hypoxemia OR 0.61 (95% CI 0.49-0.77) and severe hypoxemia 0.53 (95 CI 0.35 - 0.81). There were no significant difference in other outcomes including incidence of apnea, assisted ventilation, supplemental oxygen and changes in vital signs, early procedure termination and patients satisfactions related outcomes. Author's Conclusion: Capnography is an important addition for detection of hypoxemia during gastrointestinal procedural sedation and should be considered in routine monitoring
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Methodical Notes

Funding Sources: none

COI: none

Study Quality: no

Heterogeneity: medium

Publication Bias: yes

Notes:

Riphaus, A. et al. Update S3-guideline: "sedation for gastrointestinal endoscopy" 2014 (AWMF-register-no. 021/014). Z Gastroenterol. 54. 58-95. 2016

Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
Evidence level: 1 Study type: Guideline: no analysis necessary Databases: Search period: Inclusion Criteria: Exclusion Criteria:	Intervention: Comparison:	Primary: Secondary: Results: Author's Conclusion:	

Methodical Notes

Funding Sources:

COI:

Study Quality:

Heterogeneity:

Publication Bias:

Notes:

Guideline: not censored

Zhang, H. et al. Bispectral index monitoring of sedation depth during endoscopy: a meta-analysis with trial sequential analysis of randomized controlled trials. Minerva Anesthesiol. 85. 412-432. 2019

Evidence Types	level/Study	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 2</p> <p>Study type: Metanalyse and trial sequential analysis</p> <p>Databases: PubMed, EMBASE, CENTRAL, CINAHL,</p> <p>Search period: till May 31st 2018</p> <p>Inclusion Criteria: BIS monitoring in endoscopy in adults, no language restrictions. Studies using BIS versus standard clinical practice</p> <p>Exclusion Criteria: Non-RCT, pediatric patients receiving general anesthesia, study outcome not available.</p>		<p>Population: 13 RCT with n=1372 patients</p> <p>Intervention: Bispectral index monitoring compared to clinical signs</p> <p>Comparison: Bispectral index monitoring compared to clinical signs</p>	<p>Primary: Intraprocedural safety, haemodynamic stability, cardiorespiratory complications(hypoxemia, hypertension, hypotension, bradycardia.</p> <p>Secondary: Procedure duration, recovery time and patients'2 and endoscopists satisfaction</p> <p>Results: BIS monitoring of sedation depth was associated with lower incidence of intraprocedural hypoxia, which was not confirmed by TSA. Procedure time, recovery time, satisfactions scores and haemodynamic parameters were similar</p> <p>Author's Conclusion: More RCT studies are needed</p>	Citation n=56

Methodical Notes

Funding Sources: not given

COI: none

Study Quality: Meta analysis of RCT

Heterogeneity:

Publication Bias:

Notes:

OXFORD (2011) Appraisal Sheet: RCT: 10 Bewertung(en)

Ferreira, A. O. et al. Non-anesthesiologist administration of propofol sedation for colonoscopy is safe in low risk patients: results of a noninferiority randomized controlled trial. Endoscopy. 48. 747-53. 2016		
Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 277</p> <p>Recruiting Phase: 1/2014 and 2/2015</p> <p>Inclusion Criteria: patients 18-80 years . ASA I and II , elective colonoscopy</p>	<p>Intervention: sedation non-anaesthesiologist administered / NAAP</p> <p>Comparison: comparing NAAP (group A) with anaesthesiologist administered sedation group (group B)</p>	<p>Primary: incidence of adverse events, minor an de sentinel. to evaluate sedation safety, colonoscopy quality and patient satisfaction with NAAP.</p> <p>Secondary: propofol dose, patient satisfaction, pain, colonoscopy quality indicators, and procedure and recovera times.</p> <p>Results: there were no differences in mean propofol dose, withdrawal time, painless colonoscopy, satisfaction, and amnesia. There were no sentinel</p>

<p>Exclusion Criteria: ASA > II, pregnancy, patients with intravenous drug use, predicted difficult airway and ventilation, as defined</p>		<p>adverse events. There were no differences in cecal intubation and adenoma detection rate.</p> <p>Author's Conclusion: NAAP is equivalent to anaesthesiologist-administered sedation in the rate of adverse events in a low risk population</p>
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<p>Methodical Notes</p>		
<p>Funding Sources:</p> <p>COI: none</p> <p>Randomization: www.randomization .com</p> <p>Blinding: single blinded , only patients were kept blind</p> <p>Dropout Rate/ITT-Analysis: none attendance n-5, respiratory infection n-3 at the time of procedure</p> <p>Notes:</p>		

<p>Han, S. J. et al. Efficacy of midazolam- versus propofol-based sedations by non-anesthesiologists during therapeutic endoscopic retrograde cholangiopancreatography in patients aged over 80 years. Dig Endosc. 29. 369-376. 2017</p>		
<p>Population</p>	<p>Intervention Comparison</p>	<p>Outcomes/Results</p>
<p>Evidence level: 2</p> <p>Study type: Randomised, prospective controlled study</p> <p>Number of Patient: 109</p> <p>Recruiting Phase: 2,5 years</p> <p>Inclusion Criteria: - Patients aged 80 years or older - ASA I-IV - naive papilla</p> <p>Exclusion Criteria: - uncontrolled coagulopathy - allergy to the study drugs - sedative or alcohol abuse - history of a sedation-associated complication - inability to provide informed consent</p>	<p>Intervention: Midazolam vs. propofol-based sedation plus fentanyl</p> <p>Comparison: safety and efficacy</p>	<p>Primary: Safety: cardiopulmonary components: - hypoxia - increased oxygen supply - bradycardia - tachycardia - hypotension</p> <p>Efficacy: - satisfaction with sedation (patient, endoscopist, nurse) - pain (10 points VAS)</p> <p>Secondary: - recovery time - ERCP-related complications - procedure outcome</p> <p>Results: No significant difference regarding safety and efficacy, recovering time, ERCP related complications, procedure outcome.</p> <p>Author's Conclusion: Midazolam and propofol based sedation are safe and effective in patients aged 80yrs and older in therapeutic ERCP. Based on the availability of an antidote and the tendency for sedation safety, midazolambased sedation may be preferred in patients over 80 years of age undergoing non-anesthesiologist-induced sedation.</p>

<p>Methodical Notes</p>		
<p>Funding Sources: Soonchunhyang University Research Fund</p> <p>COI: None</p>		

Randomization: computer based

Blinding: Blinding of the nurse and endoscopist only partly present, 100% to the patient

Dropout Rate/ITT-Analysis: 9 drop outs /109 enrolled pts.

Notes:

Good methodological quality of this study

Limitations: number of patients too small for capturing rare complications, single center study, asian population, low sedation depth, mean low body weight, delayed complications e.g. falls were not recorded

Heo, J. et al. Effects of bispectral index monitoring as an adjunct to nurse-administered propofol combined sedation during colonoscopy: a randomized clinical trial. Korean J Intern Med. 31. 260-6. 2016

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: RCT</p> <p>Number of Patient: 300</p> <p>Recruitment Phase: Feb 2012 - Aug 2013</p> <p>Inclusion Criteria: consecutive patients requiring colonoscopy</p> <p>Exclusion Criteria: age below 18 yrs ASA > 3</p>	<p>Intervention: BIS monitoring</p> <p>Comparison: modified observer's assessment of alertness/sedation scale</p>	<p>Primary: Total dose of propofol and midazolam, procedure time, patient pain level during colonoscopy, satisfaction level of patients and endoscopists</p> <p>Secondary:</p> <p>Results: mean propofol dose significantly higher in BIS group</p> <p>Author's Conclusion: BIS doesn't seem like better than MOAA/S</p>

Methodical Notes

Funding Sources: none

COI: none

Randomization: yes

Blinding:

Dropout Rate/ITT-Analysis:

Notes:

Nur ASA I + II Patienten

Kashiwagi, K. et al. Prospective, randomized, placebo-controlled trial evaluating the efficacy and safety of propofol sedation by anesthesiologists and gastroenterologist-led teams using computer-assisted personalized sedation during upper and lower gastrointestinal endoscopy. Dig Endosc. 28. 657-64. 2016

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 272</p>	<p>Intervention: Propofol Sedierung über SEDASYS-System oder Infusion mit Sojabohnenöl (Intralipid fluid solution Fresenius)</p>	<p>Primary: ability to maintain moderate sedation (MOAA/S scores of 2-4 bei > 50% von allen Messungen)</p> <p>Secondary: patient and clinical</p>

<p>Recruitment Phase: Oktober 2013-März 2014</p> <p>Inclusion Criteria: > 20 Jahre, ASA I-II, geplante ÖGD oder Colo</p> <p>Exclusion Criteria: Allergie Propofol/Soja, Alkohol-Drogenabusus, Sättigung < 90% bei Raumluft, Schwangerschaft/Stillen, BMI > 35</p>	<p>Comparison: safety and efficacy of propofol sedation vs. no sedation</p>	<p>satisfaction</p> <p>Results: proportion of subjects maintained in moderate sedation was significantly higher than in the no sedation group</p> <p>Author's Conclusion: Moderate sedation can be achieved an maintained with propofol, improving both patient and physicians satisfaction</p>
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Methodical Notes

Funding Sources: Fa. Ethicon

COI: no

Randomization: yes

Blinding: yes

Dropout Rate/ITT-Analysis: 11 patients

Notes:

Lin, Y. J. et al. Target-controlled propofol infusion with or without bispectral index monitoring of sedation during advanced gastrointestinal endoscopy. J Gastroenterol Hepatol. 35. 1189-1195. 2020

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: Randomized, prospective Study</p> <p>Number of Patient: 200, 100 BIS-open group, 100 BIS blind group</p> <p>Recruitment Phase:</p> <p>Inclusion Criteria: patients undergoing advanced endoscopy</p> <p>Exclusion Criteria:</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary: Total amount of propofol required to maintain anesthesia</p> <p>Secondary: Sedation induced adverse events, recovery, and quality of sedation (endoscopist and patient satisfaction)</p> <p>Results: Propofol mean infusion rate were higher in patients without BIS</p> <p>Author's Conclusion:</p>

Methodical Notes

Funding Sources:

COI: none

Randomization:

Blinding:

Dropout Rate/ITT-Analysis:

Notes:

Treatment not blinded for endoscopist

Mathews, D. M. et al. Improving patient safety during procedural sedation via respiratory volume monitoring: A randomized controlled trial. J Clin Anesth. 46. 118-123. 2018

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: Randomized controlled study</p> <p>Number of Patient: n=73, n=41 with respiratory volume monitoring, 32 without RVM</p> <p>Recruitment Phase:</p> <p>Inclusion Criteria: Patients undergoing endoscopy with ASAI-III</p> <p>Exclusion Criteria:</p>	<p>Intervention: In patients without RVM anesthetists were blinded to the RVM</p> <p>Comparison:</p>	<p>Primary: Percentage of time with low RV, defined as < 40% of the baseline RV</p> <p>Secondary: Judgement as not useful, useful or very useful</p> <p>Results: Control patients (without RVM) had twice as much Low MV compared to RVM patients (15.3±2.8% vs. 7.1±1.4%, P=0.020). The "not useful" (13.7±3.8%) group showed no improvement over the Control group (p=0.81). However, both the "very useful" (4.7±1.4%) and "somewhat useful" (4.9±1.7%) groups showed significant improvement over the "not useful" group (p<0.05).</p> <p>Author's Conclusion: Patients without RVM spent more than double the amount of time with Low MV. This difference was more pronounced when anesthesiologist found RVM useful for managing care, lending credibility to the usage of minute ventilation monitoring in procedural sedation.</p>
Methodical Notes		
<p>Funding Sources: not given</p> <p>COI: not given</p> <p>Randomization: yes</p> <p>Blinding:</p> <p>Dropout Rate/ITT-Analysis: not given</p> <p>Notes: It is not clear how the RVM was integrated in the regular sedation regime</p>		

Mehta, P. P. et al. Capnographic Monitoring in Routine EGD and Colonoscopy With Moderate Sedation: A Prospective, Randomized, Controlled Trial. Am J Gastroenterol. 111. 395-404. 2016

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 452</p> <p>Recruitment Phase: 12/2013-01/2015</p> <p>Inclusion Criteria: ASA I, II moderate sedation (fenta/benzo) elective EGD or colonoscopy</p>	<p>Intervention: capnographic monitoring</p> <p>Comparison: capnographic monitoring blind vs. open alarm</p>	<p>Primary: hypoxemia rates (sO₂<90%, >10sec.)</p> <p>Secondary: severe hypoxemia, hypotension, bradycardia, early procedure termination for any cause, disordered respiration, apnea</p> <p>Results: hypoxemia rates blind vs. open EGD: 54,1 vs. 49,5% colonoscopy: 53,8 vs. 52,1%</p> <p>Author's Conclusion: Capnographic monitoring does not reduce the incidence of hypoxemia.</p>

Exclusion Criteria: ASA >2 allergie to medication sleep apnea	
Methodical Notes	
Funding Sources: ACG	
COI: None	
Randomization: yes	
Blinding: yes	
Dropout Rate/ITT-Analysis: drop out: 218/452 ITT hypoxemia EGD: 113, colonoscopy 124	
Notes:	

Peveling-Oberhag, J. et al. Capnography monitoring of non-anesthesiologist provided sedation during percutaneous endoscopic gastrostomy placement: A prospective, controlled, randomized trial. J Gastroenterol Hepatol. 35. 401-407. 2020		
Population	Intervention - Comparison	Outcomes/Results
Evidence level: 2 Study type: Randomized controlled study comparing standard monitoring vs. capnography Number of Patient: 150 Recruitment Phase: Inclusion Criteria: Patients undergoing placement of PEG tube (Push and pull method) Exclusion Criteria: Presence of head neck tumor, tracheostomie	Intervention: Patients undergoing PEG placement with or without capnography Comparison: Rate of hypoxemia with standard management care (SM) and capnography(CA). CA was performed in all patients but blinded for the staff in the SM group	Primary: Frequency of hypoemia (SpO2 <)=% for > 15 sec)and severe hypoxemia (SpO2 < 85% for > 15 sec) Secondary: Results: significantly more episodes of hypoxemia and severe hypoxemia in the SM (57% and 41%) group compared to the capnography (CA) group (28% and 20%). OR was 0.29 and 0.35 in favor of the CA group. CA was able to detect mild and severe hypoxemia 83 und 99 s before SM Author's Conclusion: Respiratory complications during PEG placement are frequent. CA is able to detect imminent hypoxemia at an earl time point. CA monitoring can be recommended particularly during PEG placement.
Methodical Notes		
Funding Sources:		
COI:		
Randomization: 1:1		
Blinding: Staff and endoscopist were blinded to capnography in the SM group		
Dropout Rate/ITT-Analysis:		
Notes:		

Sargin, M. et al. The effect of bispectral index monitoring on cognitive performance following sedation for outpatient colonoscopy: a randomized controlled trial. Sao Paulo Med J. 137. 305-311. 2019

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: Randomized controlled</p> <p>Number of Patient: n=100, 50 patients with and 50 without Bispectral imaging</p> <p>Recruitment Phase: 30.January 2017-15.January 2018</p> <p>Inclusion Criteria: Patients undergoing colonscopy, 18-70 years, ASA I-III,</p> <p>Exclusion Criteria: minimal mental state ≤ 23, ASA IV-V, allergies, CNS affections</p>	<p>Intervention: Colonoscopy with propofol sedation with and without bispectral imaging</p> <p>Comparison:</p>	<p>Primary: Cognitive performance (MMSE, TDT, CDT) after der procedure (colonoscopy with propofol)</p> <p>Secondary: Effect of BIS monitoring on total propofol use, duration of sedation and patient satisfaction</p> <p>Results: No differences in the sedation, procedure and recovery characteristics, duration of the sedation or in patients satisfaction between groups. The total amount of propofol used for sedation was significantly lower in the BIS monitored group. There was no difference in the cognitive baseline performance, MMSE and CDT were significantly higher in the BIS monitored group. TDT was significantly higher in the monitored group.</p> <p>Author's Conclusion: BIS monitoring gives rise to a decrease in the amount of propofol use during the procedure and with a smaller (shorter) decline of cognitive function</p>

Methodical Notes

Funding Sources: not given

COI: no

Randomization: computer generated

Blinding: yes

Dropout Rate/ITT-Analysis: none

Notes:

Yamamoto, H. et al. Clinical impact of gastroenterologist-administered propofol during esophagogastroduodenoscopy: a randomized comparison at a single medical clinic. Gastric Cancer. 18. 326-31. 2015

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: Randomised controlled trial</p> <p>Number of Patient: 106, 54 underwent sedation with propofol, whereas 52 had sedation with midazolam</p> <p>Recruitment Phase: 10/2012 until 5/2013</p>	<p>Intervention: Patients who underwent diagnostic EGD under either propofol bolus sedation by registered nurses under supervision of the endoscopist (NAPS) vs. sedation with midazolam by the same team.</p> <p>Comparison: Sedation level and tolerability as well as recovery times were assessed in both groups. They assumed that 50 % of the midazolam group will have</p>	<p>Primary: The sample size was calculated from the expected frequency of recovery within 30 minutes.</p> <p>Secondary: Patient tolerability of the procedure and assessment of the sedation level.</p> <p>Results: No severe complications occurred, oxygen desaturation was found in only 1 pts. No significant differences were detected regarding sedation level and patient tolerability. Full recovery time was significant</p>

<p>Inclusion Criteria: All patients with suspected gastric cancer who underwent diagnostic upper GI-endoscopy (EGD).</p> <p>Exclusion Criteria: Age < 20 years, Age > 69 years, ASA-class > 2, body weight > 100 kg, pregnant patients, allergy to soybean or eggs, those with former cerebral infarction or psychiatric disorders.</p>	<p>full recovery after 30 minutes and tried to detect a 30 % difference by propofol sedation.</p>	<p>shorter in the propofol group (4,7 Min) than in the midazolam group (24 min, p< 0.01).</p> <p>Author's Conclusion: Regarding post-procedure management of patients propofol use might not necessitate a recovery room and excessive assessment tasks because of rapid recovery time without any prolonged reaction, which causes patient compliance.</p>
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Methodical Notes

Funding Sources: none

COI: none

Randomization: Yes

Blinding: none

Dropout Rate/ITT-Analysis: From 117 pts. invited to participate in the study 9 refused to participate and 2 pts. were canceled.

Notes:

OXFORD (2011) Appraisal Sheet: Diagnostic Studies: 16 Bewertung(en)

Bakry, M. et al. Changes in topographic electroencephalogram during deepening levels of propofol sedation based on alertness/sedation scale under bispectral index guidance. Anaesthesiol Intensive Ther. 51. 224-229. 2019

Evidence level/Study Types	Population	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: Observational study of consecutive patients undergoing gastrointestinal endoscopy</p>	<p>Number of patients / samples: n=50</p> <p>Reference standard: yes</p> <p>Validation: Correlation of the EEG changes with the levels of propofol sedation</p> <p>Blinding: unclear</p> <p>Inclusion of clinical information: Neurological or cognitive normal patients</p> <p>Dealing with ambiguous clinical findings:</p>	<p>Results: In mild sedation increased spectral power in the delta and beta ranges and decreased power in the occipital alpha ranges.</p> <p>Deep sedation: sustained increase in the global delta power. Maximum increase in the theta and beta ranges.</p> <p>Recovery: decreased power in the alpha ranges mainly observed in the frontal and occipital regions.</p> <p>Author conclusions: Distinct patterns of EEG changes associated with deepening sedation induced with propofol. Even though there are similarities there are also changes to natural sleep suggesting different mechanism</p>

Methodical Notes

Funding Sources:

COI: none

Notes:

Behrens, A. et al. Acute sedation-associated complications in GI endoscopy (ProSed 2 Study): results from the prospective multicentre electronic registry of sedation-associated complications. Gut. 68. 445-452. 2019

Evidence level/Study Types	Population	Outcomes/Results
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<p>Evidence level: 1</p> <p>Study type: Prospective multicenter (n=39) data collection</p>	<p>Number of patients / samples: n=368206 endoscopies recorded, 11 % without sedation</p> <p>Reference standard: no</p> <p>Validation: not given</p> <p>Blinding: no</p> <p>Inclusion of clinical information: no</p> <p>Dealing with ambiguous clinical findings: not clear</p>	<p>Results: Major complication in 38 (0.01%) and minor complications in 0.3% of the sedated patients Overall mortality was 0.005% (n=15). Risk factors for complications: ASA class > II (OR 2.29) and type and duration of endoscopy. Propofol monosedation had lowest rate (OR 0.75) for complications. Tertiary referral centres had higher complication rates (OR 1.61) when compared to primary care hospitals. Compared with sedation by a two-person endoscopy team (endoscopist/assistant; 53.5% of all procedures), adding another person for sedation (nurse, physician) was associated with higher complication rates (ORs 1.40-4.46), probably due to higher complexity.</p> <p>Author conclusions: This large multicentre registry study confirmed that severe acute sedation-related complications are rare during GI endoscopy with a very low mortality.</p>
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Methodical Notes**Funding Sources:**

COI: None

Notes: Prospective multicenter study

Garbe, J. et al. Capability of processed EEG parameters to monitor conscious sedation in endoscopy is similar to general anaesthesia. United European Gastroenterol J. . . 2021

Evidence level/Study Types	Population	Outcomes/Results
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<p>Evidence level: 2</p> <p>Study type: yes</p>	<p>Number of patients / samples: 171, yes</p> <p>Reference standard: yes</p> <p>Validation: feasibility study</p> <p>Blinding: no</p> <p>Inclusion of clinical information: yes</p> <p>Dealing with ambiguous clinical findings: yes</p>	<p>Results: Using processed EEG parameters is feasible with many limitations.</p> <p>Author conclusions: The results are insufficient for clinical application and maybe increased with optimization and modelling.</p>
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Methodical Notes

Funding Sources: Not documented

COI: None

Notes: The study shows the feasibility of processed EEG in GI endoscopy with many limitations. Especially good-quality signals are difficult to register in the endoscopy setting. Further improvements have to be made.

Holley, K. et al. Monitoring minute ventilation versus respiratory rate to measure the adequacy of ventilation in patients undergoing upper endoscopic procedures. J Clin Monit Comput. 30. 33-9. 2016

Evidence level/Study Types	Population	Outcomes/Results
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Evidence level: 2 Study type: Yes	Number of patients / samples: 51 patients Reference standard: Conventional monitoring with pulse oximetry, capnography and ecg as well as blood pressure measurement. Validation: Blinding: The sedation team was unaware of the results from the bio-impedance monitor Inclusion of clinical information: Demographic data and character of the endoscopic procedure are given. Dealing with ambiguous clinical findings:	Results: There was a weak correlation between the respiratory rate (RR) and the minute volume (MV) ($r = 0.05$). Simulating a variety of RR alarms showed that a substantial fraction of a low MV remains undetected ($> 70\%$). Author conclusions: Low RR measurements are not adequate to detect low MV measurements and the new respiratory volume monitor provides a new way for non-invasive measurement of the MV during procedural sedation.
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Methodical Notes

Funding Sources: The study was supported from the producer of the respiratory minute volume monitor (Respiratory Motion Inc.)

COI: One of the co-authors was an employee from Respiratory Motion Inc., the other authors had no conflicts to declare.

Notes: Prospective cohort study to evaluate the diagnostic capability of a bio-impedance device to assess the respiratory minute volume in propofol-sedated patients undergoing upper GI-endoscopy.

Jopling, M. W. et al. Capnography sensor use is associated with reduction of adverse outcomes during gastrointestinal endoscopic procedures with sedation administration. BMC Anesthesiol. 17. 157. 2017

Evidence level/Study Types	Population	Outcomes/Results
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Evidence level: 3 Study type: Retrospective data base analysis	Number of patients / samples: n=258262 inpatients, n=3807151 outpatients Reference standard:	Results: For inpatients, capnography monitoring was associated with a reduction of death rate at discharge (OR: 0.53 [95% CI: 0.40-0.70]; $P < 0.0001$). For outpatients, capnography monitoring was associated with a 61% estimated reduction in the odds of pharmacological rescue event at discharge (0.39 [0.29, 0.52]; $P < 0.0001$) and a non-significant 82%
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	no	estimated reduction in the odds of death at discharge (0.18 [0.02, 1.99]; P = 0.16).
	Validation: possible	Author conclusions: capnography monitoring was associated with a reduced likelihood of pharmacological rescue events in outpatients and death in inpatients when assessed at discharge. Despite the limitations of the retrospective data analysis methodology, the use of capnography during these procedures is recommended.
	Blinding: no	
	Inclusion of clinical information: Patients undergoing endoscopy	
	Dealing with ambiguous findings:	

Methodical Notes

Funding Sources: no given

COI: none

Notes: Large study on the possible use of Capnography

Lapidus, A. et al. Safety and efficacy of endoscopist-directed balanced propofol sedation during endoscopic retrograde cholangiopancreatography. *Ann Gastroenterol.* 32. 303-311. 2019

Evidence level/Study Types	Population	Outcomes/Results
Evidence level: 5 Study type: Retrospective data analysis	Number of patients / samples: n=501 Reference standard: unclear Validation: not given Blinding: no Inclusion of clinical information: no Dealing with ambiguous findings: unclear	Results: No complications during endoscopists administered propofol Author conclusions: Endoscopists directed BPS appears safe, efficacious and feasible for ASAI-III patients undergoing inpatient and ambulatory ERCP

Methodical Notes

Funding Sources: Not given

COI: No

Notes:

Michael, F. A. et al. Evaluation of the Integrated Pulmonary Index® during non-anesthesiologist sedation for percutaneous endoscopic gastrostomy. *J Clin Monit Comput.* . . 2020

Evidence level/Study Types	Population	Outcomes/Results
Evidence level: 1	Number of patients / samples: 147 patients underwent PEG within the trial protocol and	Results: Hypoxic events (total 62 [42%]; SM 43 [58%] vs. CM 19 [26%]; p < 0.05) as well as severe hypoxic events (total 44 [29%]; SM 31 [42%] vs. CM 13 [18%]; p <

<p>Study type: Prospective, randomized study</p>	<p>underwent per protocol analysis (73 in the capnography group with IPI [IM] and 74 in the standard monitoring group [SM]).</p> <p>Reference standard: yes</p> <p>Validation: Analysis showed that IPI < 7 as well as IPI = 1 have a high sensitivity in predicting hypoxic as well as severe hypoxic events (sensitivity >80%, specificity <14%).</p> <p>Blinding: No blinding</p> <p>Inclusion of clinical information: Yes</p> <p>Dealing with ambiguous clinical findings: No</p>	<p>0.05) were significantly reduced in CM compared to SM. SM=standard monitoring, CM= capnography monitoring The subgroup analysis showed that IPI < 7 as well as IPI = 1 have a high sensitivity in predicting hypoxic as well as severe hypoxic events, specificity was low (< 14%).</p> <p>Author conclusions: IPI can be a useful metric to assess respiratory status during propofol-sedation in PEG-placement. However, IPI was not superior to PetCO2 and apnea > 10 s.</p>
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Methodical Notes

Funding Sources: The Company Medtronic, USA provided the capnography monitor (Capnostream™ 20) and mouthpieces for capnographic measurements

COI: None

Notes:

Phan, A. D. et al. Noninvasive continuous monitoring versus intermittent oscillometric measurements for the detection of hypotension during digestive endoscopy. PLoS One. 15. e0240241. 2020

Evidence level/Study Types	Population	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: prospective, diagnostic accuracy study</p>	<p>Number of patients / samples: 20</p> <p>Reference standard: yes</p> <p>Validation:</p> <p>Blinding: None</p> <p>Inclusion of clinical information: yes</p> <p>Dealing with ambiguous clinical findings: no</p>	<p>Results: Mean arterial pressure decreased significantly at the end of GI endoscopy and during colonoscopy. These variations were more pronounced according to noninvasive continuous monitoring (ClearSight™, Edwards) in comparison to intermittent oscillometric pressure measurements. Stroke volume also diminished during the procedure under propofol sedation, especially during gastric insufflation.</p> <p>Author conclusions: Noninvasive continuous monitoring in high-risk patients undergoing digestive endoscopy under sedation could help in detecting hypoperfusion earlier than the usual intermittent blood pressure measurements.</p>

Methodical Notes

Funding Sources: Edwards Laboratories provided the ClearSight™ sensors free of charge but had no role in designing the study, collecting or analyzing the data, writing the manuscript or participating in the decision to submit it for publication.

COI: None

Notes:

Prathanvanich, P. et al. The role of capnography during upper endoscopy in morbidly obese patients: a prospective study. Surg Obes Relat Dis. 11. 193-8. 2015

Evidence level/Study Types	Population	Outcomes/Results
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<p>Evidence level: 3</p> <p>Study type: Prospective consecutive cohort study in moribly obese patients</p>	<p>Number of patients / samples: 82</p> <p>Reference standard: None</p> <p>Validation: Were determined</p> <p>Blinding: None</p> <p>Inclusion of clinical information: Demographic data of the patients are given.</p> <p>Dealing with ambiguous clinical findings:</p>	<p>Results: Mean BMI was 46,4 + 8,2 and the mean duration of the procedure was 9,4 + 2,5 minutes. Respiratory depression (PO₂ < 90 % or etCO₂ > 50 mmHg or any airway intervention was needed) occurred in in 40,2 % of the patients. No clinical significant complications (eg.g. ned for intubation or rescussitation) were noted.Abnormal EtCO₂-levels were deteced in all cases of respiratory depression. The sensitivity to detect respiratory depression by capnography was 81 % and the negative predictive value was 78 %.</p> <p>Author conclusions: Capnography provided a real time assesment of changes in ventilation and can detect early phases of respiratory depression. Utilization of propofol as a means for sedation, with extended advanced monoitoring technique, can allow for reduced adverse outcomes in morbidly obese patients undergoing upper GI-endoscopy.</p>
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Methodical Notes

Funding Sources: none

COI: none

Notes:

Sathananthan, D. et al. Assessing the safety of physician-directed nurse-administered propofol sedation in low-risk patients undergoing endoscopy and colonoscopy. Endosc Int Open. 5. E110-e115. 2017

Evidence level/Study Types	Population	Outcomes/Results
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<p>Evidence level: 3</p> <p>Study type: prospective design</p>	<p>Number of patients / samples: 1000</p> <p>Reference standard: yes</p> <p>Validation: not possible</p> <p>Blinding: no</p> <p>Inclusion of clinical information: yes</p> <p>Dealing with</p>	<p>Results: Major complications: 0% Minor cardiorespiratory; 6,42% - 41 cases of hypotension (4.18%) - 22 cases of bradycardia (2.24 %) - 1 brief episode of apnea and hypotension.</p> <p>Author conclusions: PhD NAPS is safe in endoscopy and colonoscopy when the endoscopist and nursing staff involved are appropriately trained and strict patient selection criteria are employed.</p>
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ambiguous clinical findings: no

Methodical Notes

Funding Sources: None

COI: None

Notes: Prospective study to assess the safety of PhD NAPS in low-risk patients undergoing endoscopy and/or colonoscopy.

Limitations: Single center study, formally PhD NAPS- sedation, but in fact four persons (endoscopist, endoscopy assistance, 2 NAPS) involved instead of a common PhD NAPS sedation team with three people involved

Sato, M. et al. Safety and Effectiveness of Nurse-Administered Propofol Sedation in Outpatients Undergoing Gastrointestinal Endoscopy. Clin Gastroenterol Hepatol. 17. 1098-1104.e1. 2019

Evidence level/Study Types

Population

Outcomes/Results

Evidence level: 3

Study type: Data collection,

Number of patients / samples: EGD n=117661, Colonoscopy n=32550

Reference standard: yes

Validation: not given

Blinding: no

Inclusion of clinical information: no

Dealing with ambiguous clinical findings: no

Results: Medium propofol dose for EGD was 77 mg, for colonoscopy 99 mg.

Younger patients (< 41y) required more propofol than older (61-80) patients.

Only Adverse event was the transient need for oxygen in n=1950 (1.3%). 44% of the patients were discharged within 60 minutes and 44% of the patients drove home themselves.

Author conclusions: Nurse-administered propofol monosedation using an age-adjusted standard protocol up to a maximal of 200 mg is safe and practical for outpatient gastrointestinal endoscopy.

Methodical Notes

Funding Sources: not given

COI: none

Notes: Large study, little content !
44% of the patients drove home with the car !

Takamaru, H. et al. A new reliable acoustic respiratory monitoring technology during upper gastrointestinal tract therapeutic endoscopy with CO(2) insufflation. J Clin Monit Comput. . . 2020

Evidence level/Study Types

Population

Outcomes/Results

Evidence level: 1

Study type: retrospective study

Number of patients / samples: 49 patients

Reference standard: yes

Validation: Not documented

Results: The mean ratio of the unmeasurable time during the overall procedure time for capnography was 36.9%, while only 21.6% were unmeasurable by RRa. When comparing capnography monitoring to RRa, the mean ratio of unmeasurable time was significantly lower in RRa (p < 0.01).

Prior to the hypoxia, depressed respiratory rate was observed by RRa. There were no severe or adverse events (more than grade 2) in all 49 patients.

Author conclusions: The acoustic monitoring technology provides a

	Blinding: yes Inclusion of clinical information: yes Dealing with ambiguous clinical findings: no	more reliable respiratory monitoring when compared to standard capnography during endoscopic resection of upper gastrointestinal tract cancers under CO ₂ insufflation, even if the procedures were prolonged and complex.
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Methodical Notes

Funding Sources: This work was supported in part by the National Cancer Center Research and Development Fund (25-A-12, 28-K-1, and 29-A-13) to Dr Saito.

COI: None

Notes:

Takimoto, Y. et al. Novel mainstream capnometer system is safe and feasible even under CO₂ insufflation during ERCP-related procedure: a pilot study. BMJ Open Gastroenterol. 6. e000266. 2019

Evidence level/Study Types	Population	Outcomes/Results
Evidence level: 5 Study type: prospective	Number of patients / samples: 11 Reference standard: yes Validation: not clear Blinding: no Inclusion of clinical information: Patients undergoing ERCP Dealing with ambiguous clinical findings:	Results: Apnoe was detected earlier with capnography when compared to percutaneous oxygen monitoring. Capnography is feasible even with Co ₂ insufflation. Author conclusions: Apnoe was detected earlier with capnography when compared to percutaneous oxygen monitoring. Capnography is feasible even with Co ₂ insufflation.

Methodical Notes

Funding Sources: unclear

COI: not given

Notes:

Teng, W. N. et al. Oral capnography is more effective than nasal capnography during sedative upper gastrointestinal endoscopy. J Clin Monit Comput. 32. 321-326. 2018

Evidence level/Study Types	Population	Outcomes/Results
Evidence level: 3 Study type:	Number of patients / samples: 119 pts.; 89 with use of a mandibular advanced (MA) bit block	Results: In conscious patients (prior to administration of propofol) is conducted to 95 % over the nostrils. After sedation and insertion of the

<p>Observational study in patients undergoing propofol-sedated diagnostic EGD (MAC-sedation)</p>	<p>allowing both, nasal and oral capnography.</p> <p>Reference standard: Yes. Standard monitoring with pulse oximetry, blood pressure measurement and ecg recording was performed in all patients. In the control group only transnasal capnography was added, whereas the MA bite block allows both nasal as well as oral capnography.</p> <p>Validation: not given</p> <p>Blinding: None</p> <p>Inclusion of clinical information: Demographic and procedural patient were given.</p> <p>Dealing with ambiguous clinical findings:</p>	<p>endoscope nasal breathing significantly decreased to 47 %. With oral capnography, however, sufficient respiratory data could be obtained in 100 % of the cases. Therefore capnography via oral cannula increases the measurement accuracy and efficacy.</p> <p>Author conclusions: Capnography via oral cannula increases the measurement accuracy and efficacy. The lack of capnographic measurement via the nasal route indicated a lack of airway patency during open mouth endoscopic examinations. Further studies will be needed.</p>
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Methodical Notes

Funding Sources: One author received funding by the SPARK-program of his University.

COI: none.

Notes:

Touw, H. R. W. et al. Photoplethysmography respiratory rate monitoring in patients receiving procedural sedation and analgesia for upper gastrointestinal endoscopy. J Clin Monit Comput. 31. 747-754. 2017

Evidence level/Study Types

Population

Outcomes/Results

<p>Evidence level: 1</p> <p>Study type: prospective study</p>	<p>Number of patients / samples: 26</p> <p>Reference standard: yes (capnography, pulse oximetry)</p> <p>Validation:</p> <p>Blinding: yes</p> <p>Inclusion of clinical information: yes</p> <p>Dealing with ambiguous clinical findings: yes</p>	<p>Results: The study shows a low level of agreement between capnography and the plethysmography respiratory rate during procedural sedation for UGI endoscopy. Moreover, respiratory rate derived from both the capnogram and photoplethysmogram showed a limited ability to provide warning signs for a hypoxaemic event during the sedation procedure.</p> <p>Author conclusions: The plethysmography respiratory rate failed in detecting hypoxaemic events.</p>
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Methodical Notes

Funding Sources: Covidien/Medtronic (Zaltbommel, the Netherlands) provided the Nellcor 2.0 machine for the study period of 4 months on a free loan. The Nellcor sensors were ordered and paid for by the Anaesthesiology Department of VUmc. Data were analysed without interference of Covidien.

COI: None

Notes:

Wadhwa, V. et al. Novel device for monitoring respiratory rate during endoscopy-A thermodynamic sensor. World J Gastrointest Pharmacol Ther. 10. 57-66. 2019

Evidence level/Study Types	Population	Outcomes/Results
Evidence level: 2 Study type: Prospective study	Number of patients / samples: n=12 Reference standard: yes Validation: Not given Blinding: No blinding Inclusion of clinical information: yes Dealing with ambiguous clinical findings:	Results: Respiration was measured with capnography and with a novel LRMD (Lindsholm respiratory monitoring device). LRMD monitoring correlated with capnography with respect to respiratory rate detection and apnea events Author conclusions: The LRMD could be used as an alternative to capnography for measuring respiration in endoscopy

Methodical Notes

Funding Sources: not given

COI: not given

Notes: Relatively small study (n=12) of a new device

OXFORD (2011) Appraisal Sheet: Prognostic Studies: 6 Bewertung(en)

Early, D. S. et al. Guidelines for sedation and anesthesia in GI endoscopy. Gastrointest Endosc. 87. 327-337. 2018

Population	Intervention	Outcomes/Results
Evidence level: 1 Study type: Guideline, not censored Number of Patient: Recruitment Phase: Inclusion Criteria: Exclusion Criteria:	Intervention: Comparison:	Primary: Secondary: Results: Author's Conclusion:

Methodical Notes

Funding Sources:

COI:

Randomization:

Blinding:

Dropout Rate/ITT-Analysis:

Notes:

Goudra, B. G. et al. Safety of Non-anesthesia Provider-Administered Propofol (NAAP) Sedation in Advanced Gastrointestinal Endoscopic Procedures: Comparative Meta-Analysis of Pooled Results. Dig Dis Sci. 60. 2612-27. 2015

Population	Intervention	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: Meta analysis of the literature</p> <p>Number of Patient: 3.018 for NAAP and 2.374 for AAP included in prospective observational trials</p> <p>Recruitment Phase: 2013</p> <p>Inclusion Criteria: All published (PubMed, embase) prospective observational trials for NAAP or AAP in patients undergoing advanced upper Gi-procedures (EUS, ERCP, enteroscopy) using propofol as the main sedative agent.</p> <p>Exclusion Criteria: n/a</p>	<p>Intervention:</p> <p>Comparison: 16 studies performing NAAP vs. 10 studies performing AAP</p>	<p>Primary: Occurrence of side effects</p> <p>Secondary: Reported patient satisfaction and endoscopist satisfaction rates</p> <p>Results: Pooled hypoxia rate was 0.133 in NAAP and 0.143 in AAP, respectively. Pooled airway intervention was 0.035 for NAAP and 0.133 for AAP. Patient satisfaction and endoscopist satisfaction were better in AAP than in NAAP. However, also the mean propofol dose used was higher in AAP than in the NAAP group.</p> <p>Author's Conclusion: The safety of naap compared favourably with AAP sedation in patients undergoing advanced endoscopic procedures. However, it came at the cost of decreased patient and endoscopist satisfaction.</p>

Methodical Notes

Funding Sources: None

COI: None

Randomization: n/a

Blinding: n/a

Dropout Rate/ITT-Analysis:

Notes: The study represents a meta-analysis of the literature between the outcome of non-anesthetologist administered (NAAP) and anesthetologist-administered (AAP) propofol sedation during GI-endoscopy.

Jensen, J. T. et al. High efficacy with deep nurse-administered propofol sedation for advanced gastroenterologic endoscopic procedures. Endosc Int Open. 4. E107-11. 2016

Population	Intervention	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: Retrospective case series; single-center</p> <p>Number of Patient: 1899</p>	<p>Intervention: NAPS-sedation with propofol (repeated bolus administration) under monitoring with pulse oximetry, blood pressure and ecg.</p>	<p>Primary: Disruption of the procedure due to sedation-related side effects</p> <p>Secondary: oxygen saturation < 92 % Drop of blood pressure < 50 mmHg from baseline Occurrence of arrhythmia as detected by ecg-</p>

<p>Recruitment Phase: 66 months (5 1/2 years)</p> <p>Inclusion Criteria: All patients who underwent ERCP, EUS or double-balloon enteroscopy (DBE) under intermittent (bolus dose) NAPS sedation with propofol (inpatients)</p> <p>Exclusion Criteria: ASA-class > 3, BMI > 35, pts with difficult airways (Mallampati etc.), pregnancy, < 17 years, sleep apnea</p>	<p>Comparison: Occurrence of side-effects</p>	<p>monitoring Need for assisted ventilation</p> <p>Results: All but one procedure were successfully completed under NAPS sedation (0.05% drop out rate). Hypoxia occurred in 4,3 %, hypotension in 5,6 % of the cases. Need for assisted ventilation was recorded in 20 cases (1,1%).</p> <p>Author's Conclusion: NAPS with propofol allowed a nearly 100% success rate in selected patients. The rate of hypoxia, hypotension and respiratory support was higher compared with previously published data, but the method was still assessed as safe.</p>
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Methodical Notes

Funding Sources: Funding by Arvid Nilssons fund

COI: None

Randomization: None

Blinding: None

Dropout Rate/ITT-Analysis: Unknown

Notes:

Obara, K. et al. Guidelines for sedation in gastroenterological endoscopy. Dig Endosc. 27. 435-449. 2015

Population	Intervention	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: Guideline from the Japanese Soc: of GI-endoscopy; not censored</p> <p>Number of Patient:</p> <p>Recruitment Phase:</p> <p>Inclusion Criteria:</p> <p>Exclusion Criteria:</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary:</p> <p>Secondary:</p> <p>Results:</p> <p>Author's Conclusion:</p>

Methodical Notes

Funding Sources:

COI:

Randomization:

Blinding:

Dropout Rate/ITT-Analysis:

Notes:

Ooi, M. et al. Morbidity and mortality of endoscopist-directed nurse-administered propofol sedation (EDNAPS) in a tertiary referral center. Endosc Int Open. 3. E393-7. 2015

Population	Intervention	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: Retrospective analysis</p> <p>Number of Patient: A total of 27.989 pts. underwent mainly diagnostic upper and lower GI-endoscopy. Analyzed in detail were 23 cases in whom an emergency call during endoscopic sedation occurred.</p> <p>Recruitment Phase: 11/2004 - 11/2012</p> <p>Inclusion Criteria: Patients who underwent NAPS sedation (by using bolus titrated propofol plus a pre-medication with midazolam and/or fentanyl) by an registered nurse during upper and lower GI-endoscopies.</p> <p>Exclusion Criteria: < 18 years; BMI > 35; soy allergy; prior complications with sedation; any planned endoscopic interventions (ESD, EUS, enterocopy etc.); difficult airways, significant mentalhealth issues; sleep apnoe</p>	<p>Intervention: Analysis of those 23 cases in whom an medical emergency team (MET) were informed due to complications during endoscopist-directed NAPS sedation (e.g. threatened airway, cardiac or respiratory arrest, seizure, oxygen saturation < 90 %, arrythmia, drop of blood pressure < 90 mmHg or heart rate < 40 bpm)</p> <p>Comparison:</p>	<p>Primary: Number of patients in whom the MET-team were informed and causes of the emergency calls.</p> <p>Secondary:</p> <p>Results: In 23 pts. the MET-team were informed. There were 20 males and 3 females. 18 pts. underwent upper and 5 pts. lower GI-endoscopy. 16 pts. had ASA-scors II or IV. 11 pts. underwent EGD for GI-hemorrhage, 5 pts. for dysphagia, and one patient each for PEG-removal or dyspepsia. 7 pts. had to be intubated from whom 2 pts. died. 5 of these 7 pts. were emergency cases for upper GI-bleeding.</p> <p>Author's Conclusion: Endoscopist-directed NAPS sedation is safe for patients with ASA class I or lower unedoing upper or lower Gi-endoscopy. Upper Gi-endoscopy is associated with a greater risk than colonoscopy and those with ASA > II needing urgent upper GI-endoscopy for GI-hemorrhage are at particular risk of cardio-respiratory complications.</p>
<p>Methodical Notes</p>		
<p>Funding Sources: None</p> <p>COI: None</p> <p>Randomization: None</p> <p>Blinding: n/a</p> <p>Dropout Rate/ITT-Analysis: n/a</p> <p>Notes:</p>		

Yang, J. F. et al. Efficacy and Safety of Propofol-Mediated Sedation for Outpatient Endoscopic Retrograde Cholangiopancreatography (ERCP). Dig Dis Sci. 61. 1686-91. 2016

Population	Intervention	Outcomes/Results
<p>Evidence level: 2</p>	<p>Intervention: ERCP und deep sedation with propofol by</p>	<p>Primary: Occurence of Sedation-related adverse events (SAE):</p>

<p>Study type: Retrospective case series</p> <p>Number of Patient: 3041</p> <p>Recruitment Phase: 72 months</p> <p>Inclusion Criteria: All patients who underwent outpatient ERCP</p> <p>Exclusion Criteria: not mentioned</p>	<p>anesthesiologists (MAC-sedation)</p> <p>Comparison: Occurrence of side effects under monitoring with pulse oximetry, nasal capnography, blood pressure monitoring</p>	<p>1. Hypoxia (pO₂<90%) requiring airway manipulation 2. Need to cease the ERCP-procedure</p> <p>These data were related to demographic data of the patients</p> <p>Secondary:</p> <p>Results: Hypoxia occurred in 28% of the cases, early termination of the procedure in 0,3% of the cases. Multivariate analysis showed that older age, ASA equal or higher than class III, higher BMI and female sex are independent risk factors</p> <p>Author's Conclusion: Propofol can be used safely for MAC-sedation during ERCP. Age, female sex, ASA > 2 and BMI are independent risk factors for the occurrence of SAE</p>
Methodical Notes		
<p>Funding Sources: none</p> <p>COI: none</p> <p>Randomization: none</p> <p>Blinding: none</p> <p>Dropout Rate/ITT-Analysis: unknown</p> <p>Notes:</p>		

NEWCASTLE - OTTAWA Checklist: Case Control: 2 Bewertung(en)

Jensen, J. T. et al. Moderate and deep nurse-administered propofol sedation is safe. Dan Med J. 62. A5049. 2015			
Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 2</p> <p>Study type: Retrospective case control study</p>	<p>Funding sources: Arvid Nilsson foundation</p> <p>Conflict of Interests: none</p> <p>Randomization: none</p> <p>Blinding: none</p> <p>Dropout rates: n =1 needed total intravenous anesthesia and could not be managed with NAAP-sedation</p>	<p>Total no. patients: 6.840</p> <p>Patient characteristics: 5/2007 until 12/2012</p> <p>Inclusion criteria: Consecutive patients who underwent upper or lower Gi-endoscopy (incl. partial colonoscopy) under nurse-administered propofol sedation</p> <p>Exclusion criteria: Age < 13 years, BMI > 35; history of soy or egg allergy; prior complications with sedation; difficult airway; pregnancy; massive ventricular retention</p>	<p>Interventions: NAAP sedation</p> <p>Comparison: Patients without complications vs. patients with sedation</p>
Notes:			
<p>Author's conclusion: Safety during NAAP-sedation was good. Age, ASA-class III and the</p>			

	total propofol dose were correlated with a higher rate of adverse events. Patients aged 60 years or more needed more handling during adverse events.	
Outcome Measures/results	<p>Primary Occurrence of complications:</p> <ol style="list-style-type: none"> 1. oxygen desaturation < 92 % 2. hypotension with drop from baseline > 50 mmHg 3. any intervention to resolve an adverse event (e.g. assisted ventilation mandatory) <p>Secondary Risk factor analysis for demographic patient data</p>	<p>Results: The hypoxia rate was 3.2 %, the rate of hypotension was 3,1 %. Assisted ventilation was mandatory in 0,5 % of the cases.</p> <p>Age (p < 0.001), ASA-class III (p<0.017), and the total propofol dose (p=0.001) were associated with a higher complication rate.</p>

Jensen, J. T. et al. Development and validation of a theoretical test in non-anaesthesiologist-administered propofol sedation for gastrointestinal endoscopy. Scand J Gastroenterol. 51. 872-9. 2016			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 1 Study type:	Funding sources: Conflict of Interests: Randomization: Blinding: Dropout rates:	Total no. patients: Patient characteristics: Inclusion criteria: Exclusion criteria:	Interventions: Comparison:
Notes:	nicht beurteilbar nur Abstract vorhanden		
	Author's conclusion:		
Outcome Measures/results	Primary Secondary	Results:	

NEWCASTLE - OTTAWA Checklist: Cohort: 9 Bewertung(en)

Dumonceau, J. M. et al. Non-anesthesiologist administration of propofol for gastrointestinal endoscopy: European Society of Gastrointestinal Endoscopy, European Society of Gastroenterology and Endoscopy Nurses and Associates Guideline--Updated June 2015. Endoscopy. 47. 1175-89. 2015			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 1 Study type: Guideline-could not be censored	Funding sources: Conflict of Interests: Randomization: Blinding: Dropout rates:	Total no. patients: Recruiting Phase: Inclusion criteria: Exclusion criteria:	Interventions: Comparison:

Notes:	Guideline - could not be censored	
	Author's conclusion:	
Outcome Measures/results	Primary	Results:
	Secondary	

Ferreira, A. O. et al. Endoscopic sedation and monitoring practices in Portugal: a nationwide web-based survey. Eur J Gastroenterol Hepatol. 27. 265-70. 2015

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 2 Study type: 31-item survey	Funding sources: none Conflict of Interests: none Randomization: n/a Blinding: n/a Dropout rates: 74 % did not participate in the survey	Total no. patients: 129 of 490 members of the Portugese Soc. of Gastroenterology responded (26 %) Recruiting Phase: April 2014 Inclusion criteria: All 490 members of the Portugese Soc. of Gastroenterology were invited by mail to participate Exclusion criteria: none	Interventions: 31-item survey featuring questions regrading demographic data, procedural volume, sedation and monitoring practices, personal preferences and opinion on NAAP-sedation (adopted from the German survey published 2013). Comparison: none
Notes:	This is a survey among Portugese endoscopists regardind their sedation proctice (adopted from the German survey published in 2013) Author's conclusion: The use of sedation is routine practice in colonoscopy, but not in EGD. The preferred agent is propofol and iits used almost exclusively by anesthesiologists.		
Outcome Measures/results	Primary Frequency of sedation during upper or lower GI-endoscopy. Use of propofol with NAAP or by MAC-sedation. Secondary Monitoring practices. Training issues.	Results: Upper GI-endoscopy was performed mainly without sedation (public 70 %, private practice 57 %), whereas colonoscopy was performed in the majorityx of cases under sedation (public - 64 %, private - 69 %). Propoofol was used by 77 % of the respondents, however, midazolam was used by 66 % of the respondents. In private practices propofol was the most used agent, wheras in public hospitals mainly midazolam was used for sedation. Prpofol was administerd mainly by anesthesiologists. However, 74 % of the respondents mentioned that they are willing to use propofol by itself if they had the opportunity of formal training. Monitoring was done by pulse oximetry by nearly all resondents (99 %) and oxygen supplementation is administerd in 81 % under propofol and in 42 % under traditional sedation. Blood pressure measurements were performed in 80 % and ecg recording was used routinely in 74 % of the respondents.	

Heron, V. et al. Endoscopist-Directed Propofol as an Adjunct to Standard Sedation: A Canadian Experience. J Can Assoc Gastroenterol. 3. 141-144. 2020

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: Retrospective, single-centre study	Funding sources: No data Conflict of Interests: None Randomization:	Total no. patients: 4930 patients Recruiting Phase: 2004-2012 Inclusion criteria: Patients who had undergone gastrointestinal endoscopy (EGD, colonoscopy, PEG, ERCP) under sedation in	Interventions: Comparison:

	None	which propofol was used.
	Blinding: None	Exclusion criteria: Cases were excluded if propofol was administered by an anaesthetist or as an intravenous (IV) infusion in an intensive care unit (ICU) or emergency room setting.
	Dropout rates: None	
Notes:	Author's conclusion: The use of low-dose propofol as an adjunct to fentanyl and midazolam, administered by a registered nurse under the direction of the endoscopist was safe and effective in patients. a	
Outcome Measures/results	Primary Adverse events Secondary - drug combinations, dosage - need for reversal agents - endoscopic success	Results: - 0,45% AE. - mortality: 0% - 1 pts need for transfer to emergency unit - endoscopic success > 90% - reversal agents: 0,43%

Lee, C. K. et al. Room for Quality Improvement in Endoscopist-Directed Sedation: Results from the First Nationwide Survey in Korea. Gut Liver. 10. 83-94. 2016

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 2 Study type: Survey	Funding sources: Grant from the Korean society of GI-endoscopy Conflict of Interests: None Randomization: None Blinding: Yes Dropout rates: 73% of all Korean endoscopists did not participate in the survey.	Total no. patients: 1.332 Korean endoscopists responded Recruiting Phase: Inclusion criteria: Invited to participate were all members of the Korean Soc. of Gastrointestinal Endoscopy (n=5.860) in 2014, from whom 1.332 endoscopists participated in the survey (22,7%). Exclusion criteria: None	Interventions: To assess the sedation practice of Korean endoscopists in 2014 with a 35-items questionnaire. Comparison:
Notes:	Comparable survey to two German surveys from 2010 and 2013. Author's conclusion: Endoscopist-directed propofol sedation is the predominant sedation in Korea. The survey strongly suggest that there is much room for quality improvement regarding sedation training and patient vigilance in endoscopist directed sedation.		
Outcome Measures/results	Primary Sedation frequency and use of different sedative drugs. Secondary Monitoring practice and training.	Results: Overall sedation was used in > 90 of all cases. Propofol-sedation (mainly as Endoscopist-directed sedation) was the predominant sedation method, reported from nearly 56 % of the endoscopists, however, midazolam was used by nearly one third. Pulse oximetry was used by > 90 % of all respondents, risk stratification by use of the ASA-classification by only 67 % and supplemental oxygen was given routinely by 43 %. Formal training for sedation was not reported from 9 % of the participants.	

Lieber, S. R. et al. Complications of Anesthesia Services in Gastrointestinal Endoscopic Procedures. Clin Gastroenterol Hepatol. 18. 2118-2127.e4. 2020

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 2 Study type: retrospective register-study	Funding sources: grants from National Institutes of Health Conflict of Interests: none Randomization: none Blinding: none Dropout rates: none	Total no. patients: 428,947 endoscopic procedures Recruiting Phase: 2010-2015 Inclusion criteria: in - and outpatient, anesthesia service during gastrointestinal procedure, age>17 yrs Exclusion criteria: gastrointestinal endoscopic procedures during surgery	Interventions: anesthesia service during gastrointestinal endoscopic procedure Comparison: none
Notes:	safety of anesthesia services in gastrointestinal endoscopic procedures, bias in patients receiving ADS Author's conclusion: ADS during endoscopy is safe with a few serious complications		
Outcome Measures/results	Primary safety of anesthesia /complication rate Secondary risk factors for the occurrence of complications	Results: 4441 complications (1,09%), serious complications (0,34%) risk factors: older age, ASA 4/5, EGD, general anesthesia, case performed on an overnight shift, longer duration	

Lucendo, A. J. et al. Gastrointestinal endoscopy sedation and monitoring practices in Spain: a nationwide survey in the year 2014. Endoscopy. 47. 383-90. 2015

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: Cohort study; Survey among Spanish endoscopists.	Funding sources: None Conflict of Interests: None Randomization: n/a Blinding: yes Dropout rates: n/a	Total no. patients: 2.476 spanish endoscopists received a 19-item survey via mail Recruiting Phase: 2014 Inclusion criteria: Any member of the Spanish Soc. of Digestive Endoscopy, the Spanish Soc. of Gastroenterology or the Spanish Soc. of Digestive Diseases Exclusion criteria: none	Interventions: 19-item survey grouped in six categories: demographic data; material resources for sedation available; active participation in sedation; limitations in the environment for performing sedation; attitudes for sedation and impact of dedicated training. Comparison: none
Notes:	Survey among 2476 Spanish endoscopists with 23 % response rate Author's conclusion: The use of sedation in Spain varies widely but is on increase and is more common in private hospitals. Propofol is the preferred sedative in all procedures.		
Outcome Measures/results	Primary Answers according to the six categories (see above)	Results: 569/2476 endoscopists responded (23 %). Monitoring an resuscitation resources as well as a recovery room were universally available. Sedation was mainly performed by registered nurses (98,5 %). More than half of upper Gi-endoscopies and 95 % of all colonoscopies were performed under sedation. Propofol was the	

Secondary n/a

most used sedative (70% in EGD, 80 % in colonoscopy). Sedation was more often used in private hospitals.

Manno, M. et al. Implementation of the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA) sedation training course in a regular endoscopy unit. Endoscopy. 53. 65-71. 2021

Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 3</p> <p>Study type: Single-center, observational, prospective study</p>	<p>Funding sources: Unknown.</p> <p>Conflict of Interests: None.</p> <p>Randomization: None.</p> <p>Blinding: None.</p> <p>Dropout rates: See patient number.</p>	<p>Total no. patients: 12 132 patients underwent endoscopic procedures, 10755 (88.6 %) of which were performed in a non-anesthesiological setting. Of these, about 20 % used moderate sedation with midazolam + fentanyl and 80 % used deep sedation with additional propofol.</p> <p>Recruiting Phase: January 2017 to August 2018</p> <p>Inclusion criteria: Consecutive endoscopic procedures in adults (≥ 18 years) performed at endoscopy unit of Capri.</p> <p>Exclusion criteria: Patients were excluded from the analysis if they refused sedation, were pregnant or breast-feeding, underwent procedures performed with primary involvement of an anesthesiologist (e. g. urgent setting, estimated long-lasting and/or therapeutic procedures such as endoscopic retrograde cholangiopancreatography, endoscopic submucosal dissection, or endoscopic ultrasound-guided drainage), or took regular narcotic analgesics or psychotropic drugs for chronic conditions</p>	<p>Interventions: Propofol-balanced sedation (PBS) by adequately trained personnel after implementation of the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA) sedation training program.</p> <p>Comparison: None.</p>
Notes:	<p>Author's conclusion: After completing the ESGE-ESGENA sedation training program, the rate of adverse events was very low in the authors` institution.</p>		
Outcome Measures/results	<p>Primary Occurrence of adverse events.</p> <p>Secondary None.</p>	<p>Results: A total of 23 adverse events (0.21 %) were registered: 5/2284 (0.22 %) during moderate sedation, and 18/8471 (0.21 %) during deep sedation.</p>	

McVay, T. et al. Safety Analysis of Bariatric Patients Undergoing Outpatient Upper Endoscopy with Non-Anesthesia Administered Propofol Sedation. Obes Surg. 27. 1501-1507. 2017

Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 2</p> <p>Study type: Retrospective cohort study</p>	<p>Funding sources: This investigation was supported by the University of Utah Study Design and Biostatistics Center, with funding in part from the National Center</p>	<p>Total no. patients: 395 (130 obese patients + 265non-obese-patients)</p> <p>Recruiting Phase: 03/2011-09/2015</p>	<p>Interventions: NAAP sedation (propofol based plus fentanyl)</p> <p>Comparison: outcome</p>

	<p>for Research Resources and the National Center for Advancing Translational Sciences, National Institutes of Health, through Grant 5UL1TR001067-02 (formerly 8UL1TR000105 and UL1RR025764).</p> <p>Conflict of Interests: Dr. Fang is a consultant to Boston Scientific, Covidien, and Obalon Therapeutics. He is also the owner of Veritract.</p> <p>Randomization: None</p> <p>Blinding: None</p> <p>Dropout rates: None</p>	<p>Inclusion criteria: - pre-surgical outpatient EGD - severe obesity classes II and III</p> <p>Exclusion criteria: - EGD beside from EGD with biopsy - inpatient endoscopy</p>	<p>in NAAP in non-obese vs. severe obesity patients</p>
Notes:	<p>Author's conclusion: NAAP is a safe method of sedation in severely obese patients undergoing outpatient upper endoscopy</p>		
Outcome Measures/results	<p>Primary - sleep apnea - oxygen desaturation - chin lift maneuvers - advanced airway maneuvers</p> <p>Secondary</p>	<p>Results: Severely obese group vs. non-obese group: - sleep apnea (62 vs 8%; p < 0.001), - oxygen desaturations (22 vs 7%; p < 0.001) - chin lift maneuvers (20 vs 6%; p < 0.001) - Advanced airway interventions were rarely required in either group and not more frequent in the obese-group.</p>	

Mohanaruban, A. et al. Safe sedation practices among gastroenterology registrars: do we need more training?. Frontline Gastroenterol. 6. 223-228. 2015			
Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 4</p> <p>Study type: Survey among gastroenterology trainees by the British Soc of Gastroenterology (BSG).</p>	<p>Funding sources: none</p> <p>Conflict of Interests: none</p> <p>Randomization: none</p> <p>Blinding: none</p> <p>Dropout rates: 90 %</p>	<p>Total no. patients: 78 of 758 GI-trainees took part.</p> <p>Recruiting Phase: 12/2013 - 6/2014</p> <p>Inclusion criteria: Trainees members of the BSG</p> <p>Exclusion criteria: n/a</p>	<p>Interventions: 19-item questionnaire was send out by mail and by post.</p> <p>Comparison: n/a</p>
Notes:	<p>Survey on GI-trainees of the British Soc. of Gastroenterolgy with 10 % response rate, assumed to be low (in other surveys resonse rate by 20-30 %).</p> <p>Author's conclusion: The authors propose that a formal training session in sedation or an e-learning module could be incoporated as part of deanery or trust induction for gastroenterology trainees and kept under regular review.</p>		
Outcome Measures/results	<p>Primary If structured training was offered.</p> <p>Secondary Trainees knowledge of the action of</p>	<p>Results: 51 % of the trainess had not yet finished a structured training on safe sedation, but 92 % felt such a structured training course beneficial. The survey detect some gaps in trainees knowledge of the action of sedative agents.</p>	

some sedative agents
(midazolam and fentanyl, no
propofol-related questions)

Literatursammlung:

AG 4 - Literatur 2013 - 2014

Inhalt: 11 Literaturstellen

Literaturstelle	Evidenzlevel	Studientyp
Cabrini, L. 2013	5	Systematic review
Frieling, T. 2013	4	Prospective multicentre survey
Hafner, S. 2015	1	systematic review of 16 randomised controlled trials consisting of 2933 colonoscopies
Hammami, Muhammad B. 2019	3	RCT
Kilgert, B. 2014	4	Prospective, double-blind controlled trial data collection
Kim, Hyunil 2020	1	RCT
Lee, S. J. 2015	3	RCT
Müller, M. 2014	3	Prospective cohort study
Suh, S. J. 2014	4	Cohort study
Teshima, C. W. 2014	2	
Yoo J?J, kim SG, Kim YS 2019	1	

OXFORD (2011) Appraisal Sheet: Systematic Reviews: 2 Bewertung(en)

Cabrini, L. et al. Non-invasive ventilation during upper endoscopies in adult patients. A systematic review. Minerva Anesthesiol. 79. 683-94. 2013			
Evidence level/Study Types	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 5</p> <p>Study type: Systematic review</p> <p>Databases: Biomed Central, Embase, Pubmed, Cochrane Clinical Trials Register. Further searches involved conference Proceedings.</p> <p>Search period: Up to September 1, 2012</p> <p>Inclusion Criteria:</p> <p>Exclusion Criteria:</p>	<p>Intervention:</p> <p>Comparison:</p>	<p>Primary:</p> <p>Secondary:</p> <p>Results:</p> <p>Author's Conclusion:</p>	
Methodical Notes			

Funding Sources:

COI:

Study Quality:**Heterogeneity:****Publication Bias:****Notes:**

Ten studies reported the use without complications of NIV to assist fiberoptic bronchoscopy (FOB) and broncho-alveolar lavage (BAL). Ten studies described the use of NIV in fiberoptic-guided tracheal intubations. The authors reported no complications, even in hypoxemic patients and they observed only one failure (0.4%). Three studies evaluated the effectiveness of NIV during placement of percutaneous endoscopic gastrostomy in patients with neuromuscular diseases. In this group the failure rate was 4.4%. One study described the successful use of NIV in sedated patients undergoing gastroscopy. Three studies reported the successful application of NIV during trans-esophageal echocardiography.

Therefore, only 4 of the included studies are related to GI endoscopy. No further Analysis of the systematic review.

Hafner, S. et al. Water infusion versus air insufflation for colonoscopy. Cochrane Database Syst Rev. . CD009863. 2015

Evidence Types	level/Study	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 1</p> <p>Study type: systematic review of 16 randomised controlled trials consisting of 2933 colonoscopies</p> <p>Databases: Cochrane Colorectal Cancer Group Specialized Register (searched February 2014)</p> <ul style="list-style-type: none"> • Cochrane Central Register of Controlled Trials (CENTRAL; 2014, Issue 1); • Ovid MEDLINE (1950 to February 2014); • Ovid EMBASE (1974 to February 2014); • ClinicalTrials.gov (1999 to February 2014) <p>In addition: the references from all identified studies as well as review articles on this topic for more eligible trials screening of published meeting abstracts of international scientific conferences such as the Digestive Disease Week, the United European Gastroenterology Week, the European Crohn's and Colitis Organisation meeting, and the annual meeting of the American College of Gastroenterology to identify studies published</p>	<p>Population: 2933 colonoscopies with male and female participants, regardless of the indication (screening, surveillance, symptoms).</p> <p>Intervention: water infusion (water exchange or water immersion methods) against standard air insufflation during the insertion phase of the colonoscopy</p> <p>Comparison: comparison of 16 RCT with regard to cecal intubation rate, adenoma detection, and pain in 2933 colonoscopies performed either with water infusion (water exchange or water immersion methods) or with standard air insufflation</p>	<p>Primary: 1. Cecal intubation rate 2. Adenoma detection a. Number of participants with at least one adenoma detected (adenoma detection rate) b. Number of adenomas detected per participant</p> <p>Secondary: 1. The time needed to reach the cecum 2. Maximum pain score reported by the participants 3. Completing cecal intubation without sedation/analgesia 4. Adverse events (side effects from sedatives/analgesics used or procedure-related complications)</p> <p>Results: Completeness of colonoscopy (cecal intubation rate) was similar between water infusion and standard air insufflation (risk ratio 1.00, 95% confidence interval (CI) 0.97 to 1.03, P = 0.93). Adenoma detection rate was slightly improved with water infusion (risk ratio 1.16, 95% CI 1.04 to 1.30, P = 0.007). With water infusion participants experienced significantly less pain (mean difference in pain score on a 0 to 10 scale: -1.57, 95% CI -2.00 to -1.14, P < 0.00001) and a significantly lower proportion of participants requested on-demand sedation or analgesia, or both (risk ratio 1.20, 95% CI 1.14 to 1.27, P <</p>		

<p>in abstract form only</p> <p>Ovid EMBASE (1974 to February 2014), ClinicalTrials.gov (1999 to February 2014)</p> <p>Search period: 1950 to 2014</p> <p>Inclusion Criteria: Randomised controlled trials comparing water infusion (water exchange or water immersion methods) against standard air insufflation during the insertion phase of the colonoscopy were included. RCTs irrespective of language and publication status no discrimination between water immersion and water exchange methods</p> <p>Exclusion Criteria: Studies with water-related methods as adjuncts to usual air insufflation were excluded.</p>		<p>0.00001)</p> <p>Author's Conclusion: Improved adenoma detection might be due to the cleansing effects of water infusions on the mucosa. Detection of premalignant lesions during standard colonoscopy is suboptimal, and so improvements in adenoma detection by water infusion colonoscopy, although small, may help to reduce the risk of interval colorectal carcinoma. The most obvious benefit of water infusion colonoscopy was reduction of procedure-related abdominal pain, which may enhance the acceptance of screening/surveillance colonoscopy.</p>	
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Methodical Notes

Funding Sources: not mentioned

COI: none

Study Quality: heterogeneity and reporting biases systematically assessed and transparently dealt with

Heterogeneity: huge between-study variability, outliers excluded

Sensitivity analysis revealed that the result was heavily determined by one trial that had a particularly long procedure time (at least three times longer than the other trials) (Leung FW 2010). Exclusion of this study reduced heterogeneity markedly

Publication Bias: investigation of potential publication bias using the funnel plot. As inspection of funnel plots did not reveal signs of asymmetry, no additional tests such as Egger's linear regression test were performed

Notes:

systematic review of 16 randomised controlled trials consisting of 2933 colonoscopies

OXFORD (2011) Appraisal Sheet: RCT: 4 Bewertung(en)

Hammami, Muhammad B. et al. Sequence of same-day upper and lower gastrointestinal endoscopy does not affect total procedure' time or medication use: A randomized trial. JGH Open. 3. 488-493. 2019

Population

**Intervention
Comparison**

Outcomes/Results

<p>Evidence level: 3</p> <p>Study type: RCT</p> <p>Number of Patient:</p> <p>Recruitment Phase: July 2016 to November 2017</p> <p>Inclusion Criteria: nicht kritisch kranke Erwachsenen zwischen 18 und 90 Jahren mit geplanter Doppeluntersuchung mit Sedierung/Anästhesie innerhalb der Endoskopieabteilung</p> <p>Exclusion Criteria: Untersuchung außerhalb der Endoskopieabteilung, Schwangere, "no decision-making capacity"</p>	<p>Intervention: ÖGD gefolgt von Koloskopie</p> <p>Comparison: Koloskopie gefolgt von ÖGD</p>	<p>Primary: nicht adjustierte mittlere Untersuchungszeit</p> <p>Secondary: mittlere Differenz in der Medikamentendosis.</p> <p>Results: kein signifikanter Unterschied in primärem und in sekundären Endpunkten</p> <p>Author's Conclusion: The sequence of same-day double gastrointestinal endoscopy does not affect total procedure time or medication use.</p>
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<p>Methodical Notes</p>
<p>Funding Sources: k.A.</p> <p>COI: keine</p> <p>Randomization: ja: website Randomization.com (http://randomization.com).</p> <p>Blinding: nein</p> <p>Dropout Rate/ITT-Analysis: 0; ITT</p> <p>Notes: Ein signifikanter Unterschied war nicht zu erwarten. Es wurde Raumluft insuffliert und kein CO2 verwendet</p>

<p>Kim, Hyunil et al. Oxygenation before Endoscopic Sedation Reduces the Hypoxic Event during Endoscopy in Elderly Patients: A Randomized Controlled Trial. Journal of Clinical Medicine. 9. . 2020</p>		
<p>Population</p>	<p>Intervention - Comparison</p>	<p>Outcomes/Results</p>
<p>Evidence level: 1</p> <p>Study type: RCT</p> <p>Number of Patient: 70 (Studiengröße wurde zuvor berechnet)</p> <p>Recruitment Phase: 1 Jahr 8/2018/2019</p> <p>Inclusion Criteria: Alter 65 oder höher; ASA unter 3; ÖGD oder orale EUS</p> <p>Exclusion Criteria: ASA 3 oder höher, Alter unter 65</p>	<p>Intervention: Oxygenisierung vor und während der Endoskopie mit 2 l O₂/min</p> <p>Comparison: keine prophylaktische O₂-Gabe</p>	<p>Primary: Hypoxämie mit O₂-Sättigung unter 90%</p> <p>Secondary: differences in demographic factors between the hypoxia and non-hypoxia groups and compare the underlying disease and endoscopy-related factors</p> <p>Results: hypoxia occurred in 28 (80%) patients in the non-oxygenated group versus no patient in the oxygenated group</p> <p>Author's Conclusion: The incidence of hypoxia during sedation endoscopy is high in patients over 65 years, but oxygenation during endoscopic sedation in elderly people can significantly reduce the incidence of intraprocedural hypoxic events</p>
<p>Methodical Notes</p>		
<p>Funding Sources: grant from the Korea Health Technology R&D Project through the Korea Health Industry Development Institute (KHIDI), funded by the Ministry of Health & Welfare, Republic of Korea (grant number: HI19C0062).</p>		
<p>COI: The authors declare no conflict of interest</p>		

Randomization: ja: sequential sealed opaque envelope method

Blinding: nein (aber O2-Saettigung als objektiver Parameter)

Dropout Rate/ITT-Analysis: 0

Notes:

Lee, S. J. et al. Efficacy of carbon dioxide versus air insufflation according to different sedation protocols during therapeutic endoscopic retrograde cholangiopancreatography: prospective, randomized, double-blind study. Dig Endosc. 27. 512-521. 2015

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: RCT</p> <p>Number of Patient: 160</p> <p>Recruiting Phase: Mai 2013 - Februar 2014</p> <p>Inclusion Criteria: therapeutische ERCP bei Patienten mit naiver Papille</p> <p>Exclusion Criteria: inability to provide informed consent, age under 18 years, abdominal pain with a severity of >2 on a 10-point visual analogue scale (VAS) ASA V, neurological impairment, narcotic use during the previous 12 h, uncontrolled chronic obstructive pulmonarydisease (COPD), severe acute pancreatitis, acute exacerbation of chronic pancreatitis, pregnancy, poor general status (performance status 4), early completion of procedure for anatomical reasons prior to attempted cannulation.</p>	<p>Intervention: Insufflation von CO2-Gas anstelle von Raumluft bei Patienten mit BPS (balanced propofol sedation, Midazolam + Opioid) oder PS (Propofol + Opioid)</p> <p>Comparison: Insufflation von Raumluft</p>	<p>Primary: immediate post-ERCP abdominal pain after recovery</p> <p>Secondary: abdominal pain at 3 h and 24 h, abdominal distension, nausea, overall satisfaction with sedation, abdominal radiography, sedation efficacy, endoscopic procedure outcomes procedurerelevant complications.</p> <p>Results: signifikant weniger Schmerz (VAS) nach Erholung in der CO2-BPS-Gruppe (p=0,002)</p> <p>Author's Conclusion: CO2 with BPS showed the lowest VAS score for early abdominal pain, distension and GVS, and had a higher score for overall satisfaction for sedation.</p>

Methodical Notes

Funding Sources: Soonchunhyang University Research Fund (No.20130619).

COI: keine

Randomization: ja

Blinding: ja

Dropout Rate/ITT-Analysis: 0

Notes:

Die statistische Abgrenzung von BPS und PS geht aus den Daten nicht hervor. Der Einfluss der unterschiedlichen Erholungszeit nach Midazolam im Vergleich zu Propofol wird nicht diskutiert

Teshima, C. W. et al. Magnetic imaging-assisted colonoscopy vs conventional colonoscopy: a randomized controlled trial. World J Gastroenterol. 20. 13178-84. 2014

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type:</p> <p>Number of Patient: 253</p> <p>Recruitment Phase: Between September 2011 and October 2012.</p> <p>Inclusion Criteria: Consecutive, adult patients (18 years or older) referred for elective, outpatient colonoscopy at the University of Alberta Hospital (Edmonton, Canada) were considered for enrollment.</p> <p>Exclusion Criteria: Patients were excluded if they were admitted to hospital or if they had active, ongoing lower gastrointestinal bleeding, if they were undergoing colonoscopy without prior purgative bowel preparation or if they required anesthetist-administered propofol, if they had a history of previous colonic surgery, cardiac pacemaker or implantable cardioverter-defibrillator, or if the colonoscopy was to be performed by a trainee under staff supervision.</p>	<p>Intervention: Eligible patients who provided informed consent were then randomized to undergo conventional colonoscopy (CC) or MIC using the new ScopeGuide system, with patients, but not endoscopists, blinded to the randomization status.</p> <p>Comparison: See above.</p>	<p>Primary: Patient experience during colonoscopy, defined by patient comfort as expressed by the mean pain score. The pain score was determined using the post-procedure visual analogue pain scale</p> <p>Secondary: Amount of sedation used during the procedure was then quantified by calculating a sedation score derived from the doses of the conscious sedation medications. Since the conscious sedation consisted of two different drugs, the doses of these drugs were converted into a single numerical score.</p> <p>Results: There were no differences in cecal intubation rates (100% vs 99%), insertion distance-to-cecum (82 cm vs 83 cm), time-to-cecum (6.5 min vs 7.2 min), or polyp detection rate (47% vs 52%) between the MIC and CC groups. The primary outcome of mean pain score (1.0 vs 0.9 out of 10, P = 0.41) did not differ between MIC and CC groups, nor did the mean sedation score (8.2 vs 8.5, P = 0.34). Within the subgroup of cases considered more challenging or difficult, time-to-cecum was significantly faster with MIC compared to CC, 10.1 min vs 13.4 min respectively (P = 0.01). Sensitivity analyses confirmed a similar pattern of overall findings when each endoscopist was considered separately, demonstrating that the mean results for the entire group were not unduly influenced by outlier results from any one endoscopist.</p> <p>Author's Conclusion: Although the latest version of MIC resulted in faster times-to-cecum within a subgroup of more challenging cases, overall it was no better than CC in terms of patient comfort, sedation requirements and endoscopic procedural metrics, when performed in experienced hands.</p>

Methodical Notes

Funding Sources: None.

COI: ScopeGuide-enabled colonoscopes and the ScopeGuide system used in this study were provided free-of-charge on temporary loan from Olympus America.

Randomization: Simple, non-restricted randomization was performed using a computerized random-number generator immediately prior to the procedure.

Blinding: Patients, not endoscopists.

Dropout Rate/ITT-Analysis: ITT.

Notes:

The primary endpoint of pain score (0.9 vs 1.0, P = 0.41) did not differ between the CC and MIC groups, nor did the secondary endpoints of sedation score (8.5 vs 8.2, P = 0.34) and pain difference (-1.3 vs -1.8, P = 0.14).

OXFORD (2011) Appraisal Sheet: Prognostic Studies: 1 Bewertung(en)

Frieling, T. et al. Sedation-associated complications in endoscopy--prospective multicentre survey of 191142 patients. Z Gastroenterol. 51. 568-72. 2013

Population	Intervention	Outcomes/Results
<p>Evidence level: 4</p> <p>Study type: Prospective multicentre survey</p> <p>Number of Patient: 191,142 patients</p> <p>Recruiting Phase: From 02/2010 to 01/2012</p> <p>Inclusion Criteria: The analysis included all endoscopies performed during this investigation period independent of the applied moderate sedation (propofol, midazolam, pethidine, dipidolor, diazepam, flumazenil) and independent of the profession of the applying person (endoscopist, endoscopy nurse, person trained for NAAP).</p> <p>Exclusion Criteria: None.</p>	<p>Intervention: Sedation for endoscopy.</p> <p>Comparison: None.</p>	<p>Primary: Safety of sedation for endoscopy.</p> <p>Secondary: None.</p> <p>Results: Clinical relevant endoscopy related complication rate was 0.0022 % (n = 424). These complications included 82 sedation related complications (0.00 042 %). The overall and the sedation related complication rate between the participating clinics ranged from 0.00047 % to 0.0078 % and from 0 % to 0.00246 %, respectively. During the observation period sedation related complication caused death in 6 patients (0.00003 %) because of cardiopulmonary arrest and/or respiratory failure ([Table 2]). 50 % of fatal outcomes occurred during emergency endoscopies and all affected patients showed ASA class 3. All endoscopies with fatal outcome were performed in the presence of an additional person responsible for NAAP. In 2 patients, respiratory failure and death occurred several days after stabilization on the intensive care unit and transfer to a normal internal ward.≤</p> <p>Author's Conclusion: In everyday hospital work, moderate sedation with propofol during gastrointestinal endoscopies is a safe procedure with a low potential of risk. We, therefore believe, that the regular attendance of an additional person for NAAP is not justified in daily routine. In contrast, high risk patients (ASA ≥ 3) have to be identified, especially before emergency endoscopy and should be managed under intensive care condition.</p>

Methodical Notes

Funding Sources: Helios Hospitals.

COI: Not reported.

Randomization: None.

Blinding: None.

Dropout Rate/ITT-Analysis: Not reported.

Notes: Authors`conclusions are only in part supported by results.

NEWCASTLE - OTTAWA Checklist: Cohort: 4 Bewertung(en)

Kilgert, B. et al. Prospective long-term assessment of sedation-related adverse events and patient satisfaction for upper endoscopy and colonoscopy. Digestion. 90. 42-8. 2014

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 4 Study type: Prospective, double-blind controlled trial data collection	Funding sources: Not reported. Conflict of Interests: None. Randomization: None. Blinding: None. Dropout rates: Not reported.	Total no. patients: 307 Recruiting Phase: During June 2012 till April 2013. Inclusion criteria: >18 years, sufficient linguistic and cognitive qualifications, literacy and patient's agreement to the study. Exclusion criteria: <18 years, illiteracy, limited language skills, dementia or other diseases limiting cognitive qualifications, hearing loss or deficiency, absent or refused patient's agreement and emergency examinations.	Interventions: Different sedation protocols for varying endoscopic procedures. Comparison: Different sedation protocols for varying endoscopic procedures.
Notes:	Severe methodological flaws. Allocation to sedation protocols not reported. Authors' conclusions cannot be drawn from results. Author's conclusion: Propofol in monosedation should preferably be used for patient sedation in screening and surveillance endoscopies.		
Outcome Measures/results	Primary Patient satisfaction, fear and pain. Secondary Safety.	Results: Different types of sedation were assessed: propofol in monosedation (6.5%), combination of propofol + meperidine (41.0%), combination of midazolam + meperidine (48.5%) and other combinations (3.9%). Patient satisfaction was significantly reduced regarding fear and pain during the endoscopic procedure ($p = 0.001$ and $p = 0.0001$, respectively). All patients receiving propofol monosedation indicated significantly less pain in comparison to other sedation groups ($p < 0.0001$). Moreover, sedation with midazolam + meperidine increased the fear during the procedure significantly in comparison to monosedation with propofol ($p = 0.082$). Propofol/meperidine in combination and midazolam/meperidine increased the probability for cardiovascular events in comparison to monosedation with propofol ($p = 0.005$; $p = 0.039$).	

Müller, M. et al. Prospective evaluation of the routine use of a nasopharyngeal airway (Wendl Tube) during endoscopic propofol-based sedation. Digestion. 89. 247-52. 2014

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: Prospective cohort study	Funding sources: None. Conflict of Interests: None. Randomization: None. Blinding: None. Dropout rates: ITT done.	Total no. patients: 216 Recruiting Phase: Between July 2009 and April 2012 Inclusion criteria: All adult patients scheduled for colonoscopy or expected longer lasting or therapeutic upper GI endoscopy (e.g. endoscopic ultrasound, enteroscopy, dilation of the esophagus) under sedation with propofol, performed by three experienced endoscopists at the German Diagnostic Clinic, Wiesbaden.	Interventions: Insertion of a nasopharyngeal airway (NPA) during endoscopic sedation Comparison: NPA versus None.

		Exclusion criteria: Age under 18 years, pregnancy, allergies to topical anesthetics, nasal deformities (known deformation of the nasal septum, visible distortion or deviation from the midline of the nasal septum), ASA IV, patients on anticoagulants including non-steroidal anti-inflammatory drugs and lack of informed consent.
Notes:	Author's conclusion: The routine placement of an NPA can reduce the frequency of hypoxemic events during endoscopic sedation with minor risks for nasopharyngeal injury.	
Outcome Measures/results	<p>Primary Frequency of respiratory depression (SaO₂ <90% detected by pulse oximetry)</p> <p>Secondary Occurrence of nasopharyngeal damage after NPA insertion, hypotension (SBP <90 mm Hg), bradycardia (heart rate <40 beats/min) and the total frequency of such adverse events.</p>	Results: In 105 patients an NPA was used (intervention group). Five (4.7%) of those patients showed minor nasopharyngeal injury. Respiratory depression (13.5 vs. 1.9%, p = 0.002) and hypotension (11 vs. 5%, p = 0.09) occurred more frequently in the control than in the intervention group.

Suh, S. J. et al. Is propofol safe when administered to cirrhotic patients during sedative endoscopy?. Korean J Intern Med. 29. 57-65. 2014			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 4 Study type: Cohort study	<p>Funding sources: Supported by a grant from the Korea Healthcare technology R&D Project, Ministry of Health and Welfare, Republic of Korea (HI10C2020).</p> <p>Conflict of Interests: None.</p> <p>Randomization: None.</p> <p>Blinding: None.</p> <p>Dropout rates: ITT.</p>	<p>Total no. patients: 40</p> <p>Recruiting Phase: Unknown.</p> <p>Inclusion criteria: Inclusion criteria for the cirrhotic patients group consisted of patients aged 20 to 65 years with liver cirrhosis. Diagnosis of liver cirrhosis was based on the results of liver biopsy or abdominal sonography along with compatible clinical history and laboratory findings.</p> <p>Exclusion criteria: Patients who were over 65 years of age or had visual impairment, a history of hepatic encephalopathy or GI bleeding within a past month, active neurological impairment, any current psychiatric illness, symptomatic cardiopulmonary disease, or who were unwilling to participate were excluded.</p>	<p>Interventions: Propofol sedation.</p> <p>Comparison: Group 1 with cirrhosis, Group 2 without cirrhosis</p>
Notes:	Improper design for evaluating the hypothesis. Author's conclusion: Sedation with propofol was well tolerated in cirrhotic patients. No newly developed hepatic encephalopathy was observed.		
Outcome Measures/results	<p>Primary Not clearly specified: To evaluate the efficacy and safety of</p>	<p>Results: sedation with propofol did not affect cognitive and psychomotor functions and was not related to the development of hepatic encephalopathy during upper GI endoscopy for the</p>	

	sedative endoscopy with propofol in Korean patients with liver cirrhosis.	evaluation of complications in Korean cirrhotic patients. Also, propofol use was safe under proper monitoring and was effective for sedation in this population.
	Secondary -	

Yoo J?J, kim SG, Kim YS . Optimal selection of sedative drug during endoscopy in cirrhotic patients to avoid minimal encephalopathy. Journal of hepatology. 70(1). e696?e697. 2019			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 1 Study type:	Funding sources: Conflict of Interests: Randomization: Blinding: Dropout rates:	Total no. patients: Recruiting Phase: Inclusion criteria: Exclusion criteria:	Interventions: Comparison:
Notes:	Article and Abstract cannot be found in Pubmed. No Access to Journal 2019 articles. Author's conclusion:		
Outcome Measures/results	Primary Secondary	Results:	

Literatursammlung:**AG 4 - Literatur 2015 - 2020****Inhalt:** 35 Literaturstellen

Literaturstelle	Evidenzlevel	Studientyp
Allampati, S. 2019	4	Comparative study
Ayuse, T. 2020	5	RCT
Ball, A. J. 2015	3	database analysis
Banno, S. 2018	3	Respective data base analysis
Baykal Total, Z. 2016	4	RCT.
Behrens, A. 2016	3	subgroup analysis of a registry study (database)
Behrens, A. 2019	1	Prospective multcenter (n=39) data collection
Bielawska, B. 2018	2	Retrospective population-based cohort study analyzed from coding data (demographic data, diagnostic and procedure codes) in the Ontario region.
Cassell, B. E. 2020	3	Observational study.
Da?kaya, H. 2016	2	RCT
Dimou, F. 2019	4	Prospective observational study.
Dossa, F. 2020	1	
Dossa, F. 2020	2	Systematic review and meta-analysis
Geng, W. 2019	4	prospective observational study
Goudra, B. 2017	2	retrospective analysis of 5 years' Data from a tertiary center in the USA comparing propofol-sedated patients vs. patients with another type of sedation in GI with regard to adverse events
Goudra, B. 2015	3	A Single-Center Retrospective Analysis of 73,029 Procedures of GI endoscopy
Grilo-Bensusan, I. 2018	4	a prospective, single-center, descriptive study of 300 patients undergoing ambulatory colonoscopy under conscious sedation
Hendel, K. 2020	4	Observational study.
Jensen, J. T. 2016	1	
Jirapinyo, P. 2015	1	Case Controll
Kawano, S. 2015	4	Prospective cohort study
Khoi, C. S. 2015	3	Case Controll
Kim, D. B. 2021	2	Randomized study.
Lauriola, M. 2019	5	

Maestro Antolín, S. 2018	4	Retrospective analysis
McCain, J. D. 2020	4	Case control study
Sachar, H. 2018	2	Randomized double-blind trial
Sasala, L. 2020	4	Case Control study
Shin, S. 2017	2	RCT
Shirota, Y. 2020	4	Retrospective study
Smith, Z. L. 2020	1	
Theivanayagam, S. 2017	4	Retrospektive Datenanalyse
Tian, L. 2020	2	Randomized, double-blinded, and controlled study
Ullman, D. A. 2019	3	Double-blind, randomized, placebo-controlled trial
Wadhwa, V. 2019	2	Prospective study

OXFORD (2011) Appraisal Sheet: Systematic Reviews: 1 Bewertung(en)

Dossa, F. et al. Propofol versus midazolam with or without short-acting opioids for sedation in colonoscopy: a systematic review and meta-analysis of safety, satisfaction, and efficiency outcomes. Gastrointest Endosc. 91. 1015-1026.e7. 2020				
Evidence Types	level/Study	P - I - C	Outcomes/Results	Literature References
<p>Evidence level: 2</p> <p>Study type: Systematic review and meta-analysis</p> <p>Databases: Medline, Embase, and the Cochrane library</p> <p>Search period: to July 30, 2018</p> <p>Inclusion Criteria: RCTs comparing propofol (\pm short-acting opioids) and midazolam (\pm short-acting opioids) for elective colonoscopy.</p> <p>Exclusion Criteria: Studies reporting the results of emergency or upper/advanced endoscopic procedures and those that combined propofol or midazolam with longer-acting opioids (ie, meperidine), used uncommon formulations of either study drug (eg, fospropofol), compared</p>		<p>Population: Nine studies of 1427 patients.</p> <p>Intervention: Colonoscopies performed with propofol versus midazolam (\pm short-acting opioids).</p> <p>Comparison: Propofol versus midazolam (\pm short-acting opioids).</p>	<p>Primary: Cardiopulmonary safety.</p> <p>Secondary: Satisfaction and efficiency measures.</p> <p>Results: There were no significant differences in cardiorespiratory outcomes (hypotension, hypoxia, bradycardia) between sedative groups. Patient satisfaction was high in both groups, with most patients reporting willingness to undergo a future colonoscopy with the same sedative regimen. In the meta-analysis, patients sedated with propofol had greater satisfaction than those sedated with midazolam (\pm short-acting opioids) (SMD, .54; 95% confidence interval [CI], .30-.79); however, there was considerable heterogeneity. Procedure time was similar between groups (SMD, .15; 95% CI, .04-.27), but recovery time was shorter in the propofol group (SMD, .41; 95% CI, .08-.74).</p> <p>Author's Conclusion: Both propofol and midazolam (\pm short-acting opioids) result in high patient</p>	<p>Bastaki M. Douzinas E.E. Fotis T.G. et al. A randomized double-blind trial of anesthesia provided for colonoscopy by university-degreed anesthesia nurses in Greece: safety and efficacy. Gastroenterol Nurs. 2013; 36: 223-230</p> <p>Eberl S. Polderman J. Preckel B. et al. Is "really conscious" sedation with solely an opioid an alternative to every day used sedation regimes for colonoscopies in a teaching hospital? Midazolam/fentanyl, propofol/alfentanil, or alfentanil only for colonoscopy: a randomized trial. Techn Coloproctol. 2014;</p>

alternative sedative combinations, or evaluated special populations (patients with cirrhosis, sleep apnea, obesity, patients ≥80 years of age, pregnant women, children). We also excluded conference abstracts, non-English language studies, and studies that did not report at least 1 of outcomes of interest.

satisfaction and appear to be safe for use in colonoscopy. The marginal benefits to propofol are small improvements in satisfaction and recovery time.

18: 745-752

Fanti L.
Gemma M.
Agostoni M.
et al.
Target Controlled Infusion for non-anaesthesiologist propofol sedation during gastrointestinal endoscopy: the first double blind randomized controlled trial.
Dig Liver Dis. 2015; 47: 566-571

Kostash M.A.
Johnston R.
Bailey R.
et al.
Sedation for colonoscopy: a double-blind comparison of diazepam/meperidine, midazolam/fentanyl and propofol/fentanyl combinations.
Can J Gastroenterol Hepatol. 1994; 8: 27-31

Tanner J.W.
Lichtenstein G.R.
et al.
A randomized, controlled, double-blind trial of patient-controlled sedation with propofol/remifentanyl versus midazolam/fentanyl for colonoscopy.
Anesth Analg. 2008; 106: 434-439

Ng J.-M.
Kong C.-F.
Nyam D.
Patient-controlled sedation with propofol for colonoscopy.
Gastrointest Endosc. 2001; 54: 8-13

Padmanabhan A.
Frangopoulos C.
Shaffer L.E.
Patient satisfaction with propofol for outpatient colonoscopy: a prospective, randomized, double-blind study.
Dis Colon Rectum. 2017; 60: 1102-1108

Schroeder C.
Kaoutzanis C.
Tocco-Bradley R.
et al.
Patients prefer propofol to

		<p>midazolam plus fentanyl for sedation for colonoscopy. Dis Colon Rectum. 2016; 59: 62-69</p> <p>Ulmer B.J. Hansen J.J. Overley C.A. et al. Propofol versus midazolam/fentanyl for outpatient colonoscopy: administration by nurses supervised by endoscopists. Clin Gastroenterol Hepatol. 2003; 1: 425-432</p>
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Methodical Notes

Funding Sources: Research support for this study was provided by the Canadian Institutes of Health Research (CIHR) Foundation Grant (grant no. 148470) and with the support of Cancer Care Ontario through funding provided by the Government of Ontario.

COI: One author received speaker honorarium from Pendopharm.

Study Quality: N/A

Heterogeneity: Statistical heterogeneity was assessed using the I2 statistic. Authors were unable to perform subgroup analyses or meta-regression to explore sources of heterogeneity because of the small number of studies. Where single studies appeared to contribute excessively to heterogeneity, authors performed sensitivity analyses using the leave-one-out method to test the robustness of our findings after exclusion of these studies.

Publication Bias: One study by Spie et al GIE Endoscopy 2002 not included.

Notes:

Exclusion of some studies not clear. Included studies with other endpoints than the primary endpoint of the meta-analysis.

OXFORD (2011) Appraisal Sheet: RCT: 8 Bewertung(en)

Ayuse, T. et al. Study on prevention of hypercapnia by Nasal High Flow in patients with endoscopic submucosal dissection during intravenous anesthesia. <i>Medicine (Baltimore)</i> . 99. e20038. 2020		
Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 5</p> <p>Study type: RCT</p> <p>Number of Patient: Not reported.</p> <p>Recruitment Phase: Not reported.</p> <p>Inclusion Criteria: Adult patients between the ages of 20 and 85, that gave informed consent after a thorough explanation of all details of this clinical trial.</p> <p>Exclusion Criteria: The exclusion criteria were as follows:</p>	<p>Intervention: Nasal high flow.</p> <p>Comparison: Rate of occurrence of hypercapnia in the NHF device group and the control group were calculated.</p>	<p>Primary: Rate of occurrence of hypercapnia.</p> <p>Secondary: Incidence of hypoxemia was evaluated as defined by a transcutaneous oxygen saturation value of 90% or lower.</p> <p>Results: Not reported.</p> <p>Author's Conclusion: Inconclusive.</p>

(1) continuous administration of oxygen by nasal cannula (home oxygen therapy),
 (2) inability to breathe through the nose,
 (3) use of antithrombotic drugs that could not be reduced or discontinued on the day before the endoscope,
 (4) a history of pneumothorax,
 (5) judged inappropriate as study subjects.

Methodical Notes

Funding Sources: The AIRVO device and the AIRVO information were provided by Fisher & Paykel Healthcare Ltd, Auckland, New Zealand.

COI: The AIRVO device and the AIRVO information were provided by Fisher & Paykel Healthcare Ltd, Auckland, New Zealand.

Randomization: Allocation method: Research Electronic Data Capture (REDCap) was used to randomly allocate participants to “NHF-using” and “non-NHF-using” groups at a ratio of 1:1 (stratified block method). Allocation factor: Allocation was based on the presence or absence of COPD. If a participant had a history of smoking and the respiratory function test (spirogram) recorded a 1-second rate of less than 70%, it was determined that COPD was present and allocation was performed.

Blinding: Not reported.

Dropout Rate/ITT-Analysis: Still Recruiting.

Notes:
 Only study description, study ongoing.

Baykal Tatal, Z. et al. Propofol-ketamine combination: a choice with less complications and better hemodynamic stability compared to propofol? On a prospective study in a group of colonoscopy patients. Ir J Med Sci. 185. 699-704. 2016

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 4</p> <p>Study type: RCT.</p> <p>Number of Patient: 95 patients were included.</p> <p>Recruitment Phase: 01.05.2013 and 01.01.2014</p> <p>Inclusion Criteria: Colonoscopy.</p> <p>Exclusion Criteria: Preoperative American Society of Anesthesiologists (ASA) physical status classification 3–4, <18 or >70 years old, previous coronary heart disease, hypertension, arterial aneurysm, epilepsy, intracranial mass of benign or malign nature, respiratory–hepatic or renal impairment, and propofol or ketamine allergy history.</p>	<p>Intervention: Patients were block randomized to either sedation with propofol (GroupP) or propofol-ketamine (GroupPK) for colonoscopy.</p> <p>Comparison: Propofol or propofol-ketamine.</p>	<p>Primary: Duration for reaching desired Ramsay Sedation Score (RSS ≥ 4).</p> <p>Secondary: Postoperative recovery duration according to Modified Aldrete Scores (MAS ≥ 9), rates of cardiovascular (hypertension, hypotension, bradycardia), respiratory depression, laryngospasm, visual side effects, nausea/vomiting complications.</p> <p>Results: GroupPK patients needed shorter duration for achieving RSS ≥ 4 (3.3 ± 4.2 vs 2.4 ± 1.6 min, p: 0.038).</p> <p>GroupPK patients had longer recovery duration (MAS ≥ 9, 1 vs 5 min, p: 0.005).</p> <p>Author's Conclusion: Propofol-ketamine combination is an advantageous choice compared to propofol alone in colonoscopy patients in means of achieving desired sedation level in a shorter period of time with lower dose requirements. Propofol-ketamine also provides a</p>

better hemodynamic stability, less nausea and vomiting, and respiratory complication rates. Yet it seems that this choice might be related with longer recovery duration.

Methodical Notes

Funding Sources: Not reported.

COI: Not reported.

Randomization: Block wise.

Blinding: Correct.

Dropout Rate/ITT-Analysis: Not done.

Notes:

Da?kaya, H. et al. Use of the gastro-laryngeal tube in endoscopic retrograde cholangiopancreatography cases under sedation/analgesia. Turk J Gastroenterol. 27. 246-51. 2016

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: RCT</p> <p>Number of Patient: 80 patients between the ages of 20 and 75 years, ASA status 1-2, who were scheduled for elective ERCP</p> <p>Recruiting Phase: The study was completed within a period of three months.</p> <p>Inclusion Criteria: patients aged between 20 and 75 years, ASA status 1-2, undergoing elective ERC</p> <p>Exclusion Criteria: emergency operations, morbidly obese patients (BMI>35), patients with previous neurologic disease or symptoms (transient ischemic attack, syncope, dementia, etc.) patients with allergies to the drugs to be used</p>	<p>Intervention: ERCP with odr without airway management with GLT</p> <p>Comparison: procedure with sedation without any airway instruments vs. procedure after sedation and airway management with GLT. Intraoperative and postoperative vital signs as well as the satisfaction of the patients and the endoscopist were recorded.</p>	<p>Primary: patient and endoscopist satisfaction</p> <p>Secondary: duration of the ERCP, incidents of desaturation</p> <p>Results: The duration to esophageal visualization was found to be significantly higher in group N (16 s) than in group G (7 s) (p=0.001). The mean Visual Analogue Scale for Pain (VAS) was significantly higher in group G (1.85) than in group N (0.45) (p=0.016). Group G had higher endoscopist satisfaction scores than group N. The incidence of desaturation during ERCP was significantly higher in group N (60%) than in group G (0%) (p=0.000).</p> <p>Author's Conclusion: ERCP should be performed under optimal conditions to avoid the occurrence of unwanted complications, such as aspiration-related disorders. herefore, according to the structural properties of GLT, sedation anesthesia application with GLT in ERCP will be safer, more comfortable, and more effective.</p>

Methodical Notes

Funding Sources: The authors declared that this study has received no financial support.

COI: none

Randomization: yes

Blinding: no

Dropout Rate/ITT-Analysis:

Notes:
RCT

Kim, D. B. et al. Propofol compared with bolus and titrated midazolam for sedation in outpatient colonoscopy: a prospective randomized double-blind study. *Gastrointest Endosc.* 93. 201-208. 2021

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: Randomized study.</p> <p>Number of Patient: 267</p> <p>Recruiting Phase: Unknown. Only Abstract accessible.</p> <p>Inclusion Criteria: Unknown. Only Abstract accessible.</p> <p>Exclusion Criteria: Unknown. Only Abstract accessible.</p>	<p>Intervention: Sedation for outpatient colonoscopy</p> <p>Comparison: Propofol group, bolus midazolam group, and titrated midazolam group.</p>	<p>Primary: Total procedure time, induction time, recovery time, and discharge time among the 3 groups.</p> <p>Secondary: Patient satisfaction and the incidence of adverse events.</p> <p>Results: Patients in the propofol group had a shorter total procedure time (39.5 vs 59.4 vs 58.1 minutes; $P < .001$), induction time (4.6 vs 6.3 vs 7.6 minutes; $P < .001$), recovery time (11.5 vs 29.5 vs 29.2 minutes; $P < .001$), and discharge time (20.6 vs 34.9 vs 34.7 minutes; $P < .001$) than patients in the bolus midazolam group and titrated midazolam group. Patients in the propofol group reported higher degrees of satisfaction than patients in the bolus or titrated midazolam plus meperidine groups (9.9 vs 9.6 vs 9.6 [$P = .007$] and 4.9 vs 4.7 vs 4.8 [$P = .008$], respectively). Adverse events were not significantly different between groups.</p> <p>Author's Conclusion: Propofol was superior to bolus or titrated midazolam in terms of endoscopy unit efficiency and patient satisfaction during outpatient colonoscopy.</p>

Methodical Notes

Funding Sources: Unknown. Only Abstract accessible.

COI: Unknown. Only Abstract accessible.

Randomization: Unknown. Only Abstract accessible.

Blinding: Unknown. Only Abstract accessible.

Dropout Rate/ITT-Analysis: Unknown. Only Abstract accessible.

Notes:
Only abstract accessible.

Sachar, H. et al. Continued midazolam versus diphenhydramine in difficult-to-sedate patients: a randomized double-blind trial. *Gastrointest Endosc.* 87. 1297-1303. 2018

Population	Intervention Comparison	Outcomes/Results
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<p>Evidence level: 2</p> <p>Study type: Randomized double-blind trial</p> <p>Number of Patient: 200</p> <p>Recruitment Phase: Between February 2013 and June 2015.</p> <p>Inclusion Criteria: Patients undergoing elective colonoscopy with moderate sedation were eligible.</p> <p>Exclusion Criteria: Patients were excluded if they had a documented allergy or adverse reaction to prior use of diphenhydramine, closed angle glaucoma, were unable or unwilling to provide informed consent, or were pregnant.</p>	<p>Intervention: Moderate sedation for elective colonoscopy. Patients were randomly assigned to receive intravenous diphenhydramine 25 mg versus midazolam 1.5 mg.</p> <p>Comparison: Patients not adequately sedated with midazolam 5 mg and fentanyl 100 mcg were randomly assigned to diphenhydramine 25 mg versus continued midazolam 1.5 mg.</p>	<p>Primary: Adequate sedation. Adequate sedation, assessed 3 minutes after the last dose of study medication was given and before initiation of the colonoscopy. Adequacy of sedation was assessed 3 minutes after each study medication dose. If MOAA/S was 4 to 5, study medication was repeated, to a maximum of 3 doses.</p> <p>Secondary: Safety endpoints were (1) oxygen desaturation (<90% for ≥1 minute), (2) hypotension (systolic blood pressure <90 mm Hg), or (3) use of a reversal agent. Other endpoints included (1) time from first dose of study drug to discharge from recovery room; (2) need for additional sedation drugs after study drugs were administered (before or during colonoscopy); (3) post-procedural assessment of adequate procedural sedation by endoscopist; (4) post-procedural assessment of adequate procedural sedation by patient; and 5) patient willingness to repeat colonoscopy assessed 24 hours after the procedure. Endoscopists' and patients' assessment of adequate sedation were performed by asking if they felt adequate sedation was achieved (adequate vs inadequate).</p> <p>Results: Adequate sedation was achieved less often with diphenhydramine than midazolam: 27% versus 65%, difference = -38%; 95% CI, -50% to -24%; p<0.0001. After study medications were completed, more patients required additional medication for sedation or analgesia with diphenhydramine versus midazolam (84% vs 68%, p=0.008), whereas the time to discharge from the recovery unit was similar (134 vs 129 minutes).</p> <p>Author's Conclusion: Endoscopists performing moderate sedation should continue midazolam rather than switching to diphenhydramine in patients who do not achieve adequate sedation with usual doses of midazolam and an opioid.</p>
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Methodical Notes

Funding Sources: Grant Support: NIH T32 DK007017, P30 DK34989.

COI: None.

Randomization: The randomization schedule was computer-generated by an individual uninvolved in the conduct of the study. The assignments were concealed using opaque coverings that were removed only at the time of randomization.

Blinding: A separate individual, who was uninvolved in patient care or assessment, determined the randomization assignment, obtained the study medication (clear, colorless solutions in identical 5 mL syringes) in a separate room, and then administered the study medication.

Dropout Rate/ITT-Analysis: ITT done.

Notes:

Shin, S. et al. Patient satisfaction after endoscopic submucosal dissection under propofol-based sedation: a small premedication makes all the difference. Surg Endosc. 31. 2636-2644. 2017

Population	Intervention - Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: RCT</p>	<p>Intervention: Midazolam vs. Plazebo, ESD unter Sedierung mit Propfol und Fentanyl b. Bed.</p>	<p>Primary: Patienten- und Untersucherzufriedenheit.</p>

<p>Number of Patient: 72 von 81</p> <p>Recruitment Phase: 2014 - 2015</p> <p>Inclusion Criteria: Patienten mit Magenkarzinom oder Adenom mit Indikation zur ESD. ASA I - III, ECOG 0 oder 1.</p> <p>Exclusion Criteria: Vorherige MAgenresektion oder ESDs. Allergie. 3 oder mehr Läsionen (unklar welche gemeint sind), SEdierung innerhalb 24 h vor der INtervention.</p>	<p>unter Bestimmung der Sedierungstiefe mit MOAA/S (Ziel 3 oder 4).</p> <p>Comparison: Vergleich von Prämedikation mit Midazolam vs. Plazebo anhand Satisfaction-Scores NRS, VAS und Wong-Baker FACES</p>	<p>Secondary: Untersuchungsvariablen (Medikamentenverbrauch etc.), Medikamentenverbräuche, Akzeptanz der Patienten, die gleiche Sedierungsmethode erneut zu erhalten.</p> <p>Results: Nach Interimsanalyse abgebrochen, da Patienten hochsignifikant die Sedierung mit Midazolam bevorzugten. Alle anderen Parameter ohne Gruppenunterschiede.</p> <p>Author's Conclusion: Eine Prämedikation mit einer geringen Dosis von Midazolam steigert den Patientenkomfort ohne die Prozedurqualität oder Komplikationsraten zu verändern.</p>
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Methodical Notes

Funding Sources: nein

COI: nein

Randomization: ja

Blinding: ja

Dropout Rate/ITT-Analysis: 9 von 81

Notes:

Tian, L. et al. A randomized controlled trial for measuring effects on cognitive functions of adding ketamine to propofol during sedation for colonoscopy. *Medicine (Baltimore)*. 99. e21859. 2020

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: Randomized, double-blinded, and controlled study</p> <p>Number of Patient: 200</p> <p>Recruitment Phase: Not reported.</p> <p>Inclusion Criteria: Patients aged above 18 years, who were of physical status I-II according to the American Society of Anesthesiologists (ASA), and were scheduled for elective colonoscopy procedure.</p> <p>Exclusion Criteria: Patient refusal, Mini-Mental Test (MMT) scores of <26, advanced cardiopulmonary or psychiatric disease, alcohol or drug addiction, morbid obesity (body mass index >30kg/m),</p>	<p>Intervention: Sedation.</p> <p>Comparison: Allocation to ketamine/propofol admixture group (Group KP, n= 100), and propofol group (Group P, n= 100). Patients in Group KP received 0.25 mg/kg of ketamine and 0.5 mg/kg of propofol. Patients in Group P received 0.5mg/kg propofol.</p>	<p>Primary: Cognitive impairment: Difference in accuracy on CogState tests between the discharge and baseline assessments between the 2 experimental groups.</p> <p>Secondary: Operating conditions, complications, recovery times, and satisfaction with care</p> <p>Results: one-card learning accuracy and One-back memory was only impaired in Group KP patients (P=.006, P=.040) after the endoscopy but left intact in Group P patients. Group KP patients showed more severe impairment in one-card learning accuracy compared with Group P patients (P=.044). Group KP patients have better 5 minutes MAP (P=.005) and were also less likely to suffer from complications such as respiratory depression (P=.023) and hypotension (P=.015). OAA/S scores, BIS, MAP, complications, recovery times, and endoscopist and patient satisfaction were similar between the 2 groups.</p> <p>Author's Conclusion: Although adding ketamine to propofol for sedation in colonoscopy provided fewer complications such as respiratory depression and hypotension, it also causes more impairment in cognitive functions.</p>

history of undergoing anesthesia in the last 7 days, and known allergy to the drugs studied.

Methodical Notes

Funding Sources: Hansoh Foundation of Lianyungang (QN1706).

COI: None.

Randomization: By using random numbers generated by computer placed in sealed envelopes.

Blinding: Blinding was provided by an anesthesiologist who did not participate in anesthesia application. He had access to the randomization list when the patient was admitted to the colonoscopy suite and met criteria for study inclusion. He prepared appropriate anesthesia-inducing drugs for each group.

Dropout Rate/ITT-Analysis: Ninety five patients in Group KP and 92 patients in Group P had completed the CogStates tests and were included in the data analysis.

Notes:

Ullman, D. A. et al. Relation of viscous lidocaine combined with propofol deep sedation during elective upper gastrointestinal endoscopy to discharge. Proc (Bayl Univ Med Cent). 32. 505-509. 2019

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: Double-blind, randomized, placebo-controlled trial</p> <p>Number of Patient: 93</p> <p>Recruiting Phase: From September 2015 to October 2016.</p> <p>Inclusion Criteria: Individuals aged 18 to 75 years scheduled for an elective EGD.</p> <p>Exclusion Criteria: Intolerance to lidocaine or propofol, impaired swallowing reflex, current pregnancy, dementia, and urgent, emergent, or therapeutic EGDs. Patients with an ASA status of 4 or higher were excluded.</p>	<p>Intervention: 7.5 mL 2% lidocaine viscous solution and 7.5 mL placebo solution (3% methylcellulose) in addition to propofol sedation.</p> <p>Comparison: Lidocaine vs. placebo.</p>	<p>Primary: Association of topical pharyngeal anesthetics (TPA) with patient recovery time, post-EGD to discharge: Time from arrival to the postanesthesia care unit to discharge ("recovery time") for TPAs combined with propofol sedation versus propofol alone.</p> <p>Secondary: Gastroenterologist's satisfaction with endoscope insertion, observed patient discomfort during the procedure, and patient pain ratings.</p> <p>Results: There were no statistically significant differences between the lidocaine (n = 46) and placebo (n = 47) groups with respect to recovery time (42 ± 17.8 vs 39 ± 15.9 minutes; P = 0.23), procedure time (6.5 ± 2.7 vs 7 ± 3.6 minutes; P = 0.77), endoscopist satisfaction (83.2 ± 24.4 vs 77 ± 27.7, P = 0.23), patient discomfort (16.6 ± 19.8 vs 24.0 ± 29.7, P = 0.37), or total propofol administered (2.3 ± 1.3 vs 2.3 ± 1.0 mg/kg, P = 0.55).</p> <p>Author's Conclusion: Compared to placebo, topical viscous lidocaine does not appear to delay recovery time or adversely affect sedation-related outcomes.</p>

Methodical Notes

Funding Sources: Grant from The E. Donnell Thomas Resident Research Program, Bassett Research Institute, Cooperstown, NY

COI: Not reported.

Randomization: 1:1 ratio according to a randomization schedule. This schedule was prepared by the study statistician using SAS version 9.3 and was shared with the study pharmacist.

Blinding: Both lidocaine and placebo solutions, prepared by the pharmacist, were cherry flavored and sweetened with a small quantity of saccharin to improve palatability. The characteristics of lidocaine and placebo were indistinguishable by an independent examiner. The solutions were administered via an oral syringe in the posterior pharynx by a certified registered nurse anesthetist.

Dropout Rate/ITT-Analysis: PPA done. No ITT.

Notes:

Results do not support conclusions: Lidocaine with no additional effect for Propofol sedation.

OXFORD (2011) Appraisal Sheet: Diagnostic Studies: 5 Bewertung(en)

Banno, S. et al. Risk Factor for Vital Signs Fluctuation during Colonoscopy under Conscious Sedation Consisting of Midazolam and Meperidine. Dig Dis. 36. 113-117. 2018

Evidence level/Study Types	Population	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: Respective data base analysis</p>	<p>Number of patients / samples: n=755</p> <p>Reference standard: Sedation with Midazolam, meperidine or combination of both</p> <p>Validation:</p> <p>Blinding: no</p> <p>Inclusion of clinical information: Consecutive patients undergoing endoscopy</p> <p>Dealing with ambiguous clinical findings:</p>	<p>Results: Vital sign fluctuation (VSF) was observed in 17%; hypotension and oxygen desaturation was observed in 13 and 5%, respectively.</p> <p>Multivariate analysis revealed age (OR 1.05 [95% CI 1.04-1.07]), female gender (OR 1.78 [95% CI 1.19-2.70]), and use of midazolam (OR 5.06 [95% CI 3.18-8.08]) as independent risk factors for VSF.</p> <p>Author conclusions:</p>
Methodical Notes		
Funding Sources: not given		
COI: none		
Notes:		

Behrens, A. et al. Acute sedation-associated complications in GI endoscopy (ProSed 2 Study): results from the prospective multicentre electronic registry of sedation-associated complications. Gut. 68. 445-452. 2019

Evidence level/Study Types	Population	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: Prospective multicenter (n=39) data collection</p>	<p>Number of patients / samples: n=368206 endoscopies recorded, 11 % without sedation</p> <p>Reference standard: no</p>	<p>Results: Major complication in 38 (0.01%) and minor complications in 0.3% of the sedated patients Overall mortality was 0.005% (n=15).</p> <p>Risk factors for complications: ASA class > II (OR 2.29) and type and duration of endoscopy.</p> <p>Propofol monosedation had lowest rate (OR 0.75) for</p>

<p>Validation: not given</p> <p>Blinding: no</p> <p>Inclusion of clinical information: no</p> <p>Dealing with ambiguous clinical findings: not clear</p>	<p>complications.</p> <p>Tertiary referral centres had higher complication rates (OR 1.61) when compared to primary care hospitals.</p> <p>Compared with sedation by a two-person endoscopy team (endoscopist/assistant; 53.5% of all procedures), adding another person for sedation (nurse, physician) was associated with higher complication rates (ORs 1.40-4.46), probably due to higher complexity.</p> <p>Author conclusions: This large multicentre registry study confirmed that severe acute sedation-related complications are rare during GI endoscopy with a very low mortality.</p>
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Methodical Notes

Funding Sources:

COI: None

Notes: Prospective multicenter study

Goudra, B. et al. Cardiac arrests in patients undergoing gastrointestinal endoscopy: A retrospective analysis of 73,029 procedures. Saudi J Gastroenterol. 21. 400-11. 2015

Evidence level/Study Types	Population	Outcomes/Results
<p>Evidence level: 3</p> <p>Study type: A Single-Center Retrospective Analysis of 73,029 Procedures of GI endoscopy</p>	<p>Number of patients / samples: 73029 procedures, data obtained from the clinical quality improvement and local registry over 5 years</p> <p>Reference standard:</p> <p>Validation:</p> <p>Blinding: none</p> <p>Inclusion of clinical information: The information of patients who sustained cardiac arrest attributable to sedation was studied in detail. Analysis included comparison of cardiac arrests due to all causes until discharge (or death) versus the cardiac arrests and death occurring during the procedure and in the recovery area.</p> <p>Statistical comparisons were made between the cardiac arrest events recorded (all causes, irrespective of outcome) in either the propofol or nonpropofol sedation groups. Where available, data was analyzed to find relationships between the frequency of cardiac arrest and the American Society of Anesthesiology (ASA) physical status, Modified Mallampatti (MMP) airway classification, and Body Mass Index (BMI) of the patients.</p> <p>Dealing with ambiguous clinical findings: statistical analysis of all cases</p>	<p>Results: The incidence of cardiac arrest and death (all causes, until discharge) was 6.07 and 4.28 per 10,000 in patients sedated with propofol, compared with non-propofol-based sedation (0.67 and 0.44). The incidence of cardiac arrest during and immediately after the procedure (recovery area) for all endoscopies was 3.92 per 10,000; of which, 72% were airway management related. About 90.0% of all peri-procedural cardiac arrests occurred in patients who received propofol.</p> <p>Author conclusions: The incidence of cardiac arrest and death is about 10 times higher in patients receiving propofol-based sedation compared with those receiving midazolam-fentanyl sedation. More than two thirds of these events occur during EGD and ERCP.</p>

Methodical Notes

Funding Sources: none

COI: none

Notes: A Single-Center Retrospective Analysis of 73,029 Procedures of GI endoscopy

Grilo-Bensusan, I. et al. Prospective study of the factors associated with poor tolerance to ambulatory colonoscopy under conscious sedation. Rev Esp Enferm Dig. 110. 223-230. 2018

Evidence level/Study Types

Population

Outcomes/Results

Evidence level: 4

Study type: a prospective, single-center, descriptive study of 300 patients undergoing ambulatory colonoscopy under conscious sedation

Number of patients / samples: A total of 343 patients were included, of which 337 had a full colonoscopy indication. Of these, 319 were performed under conscious sedation, and finally 300 colonoscopies (94%) were deemed valid for the study

Reference standard:

Validation: to determine the factors which are related to poor tolerance to colonoscopy under conscious sedation since it could permit an a priori selection of patients who might require deep sedation with propofol

Blinding:

no
The endoscopist and the nurse also assessed the patients' pain during the procedure "blindly", without knowing the response of the others.

Inclusion of clinical information:

Patients' general variables (age, gender, weight, height, BMI, comorbidity and reason for examination) were recorded. If a colonoscopy had been previously performed, the pain experienced by the patient was assessed quantitatively by means of a 0 to 100 mm VAS, as well as qualitatively as "bad" or "good".

Dealing with ambiguous clinical findings: The correlation between the

Results: Tolerance was good in 273 cases (91%). The median value of tolerance was 13 (p25-p75: 4-33). Pain was considered as mild in 215 (71.7%), moderate in 57 (19%) and intense in 28 (9.3%). In the univariate study, greater pain was associated with females, anxiety, the indication for the procedure, the length of time and difficulty of the examination, and the doses of sedatives. In the multivariate study, both the indication (OR 2.92, 95% CI = 1.03-8.2, p < 0.05) and the difficulty of the examination (OR 4.68, 95% CI = 1.6-13.6, p < 0.01) were significant. Complications were found in 16 patients (5.3%), although all of them were insignificant.

Author conclusions: Conclusions: tolerance of patients undergoing ambulatory colonoscopy under conscious sedation is good in most cases and complications are infrequent and minor. A worse tolerance to the test is associated with women patients, individuals with anxiety prior to colonoscopy, indication, difficult and longer exploration and lower doses of sedatives.

variables was studied using the Spearman's correlation coefficient

Methodical Notes

Funding Sources: not mentioned

COI: not mentioned

Notes: a prospective, single-center, descriptive study of 300 patients undergoing ambulatory colonoscopy under conscious sedation

Wadhwa, V. et al. Novel device for monitoring respiratory rate during endoscopy-A thermodynamic sensor. World J Gastrointest Pharmacol Ther. 10. 57-66. 2019

Evidence level/Study Types

Population

Outcomes/Results

<p>Evidence level: 2</p> <p>Study type: Prospective study</p>	<p>Number of patients / samples: n=12</p> <p>Reference standard: yes</p> <p>Validation: Not given</p> <p>Blinding: No blinding</p> <p>Inclusion of clinical information: yes</p> <p>Dealing with ambiguous clinical findings:</p>	<p>Results: Respiration was measured with capnography and with a novel LRMD (Lindsholm respiratory monitoring device). LRMD monitoring correlated with capnography with respect to respiratory rate detection and apnea events</p> <p>Author conclusions: The LRMD could be used as an alternative to capnography for measuring respiration in endoscopy</p>
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Methodical Notes

Funding Sources: not given

COI: not given

Notes: Relatively small study (n=12) of a new device

OXFORD (2011) Appraisal Sheet: Prognostic Studies: 5 Bewertung(en)

Bielawska, B. et al. Anesthesia Assistance in Outpatient Colonoscopy and Risk of Aspiration Pneumonia, Bowel Perforation, and Splenic Injury. Gastroenterology. 154. 77-85.e3. 2018

Population

Intervention

Outcomes/Results

<p>Evidence level: 2</p> <p>Study type: Retrospective population-based cohort study analyzed from coding data (demographic data, diagnostic and procedure codes) in the Ontario region.</p>	<p>Intervention: Colonoscopy performed under endoscopist-directed sedation with midazolam plus opiates vs. Anesthsists-directed sedation with propofol analyzed by propensity-matched cohorts</p>	<p>Primary: Coding of bowel perforation, splenic injury or aspiration pneumonia in both groups.</p> <p>Secondary:</p> <p>Results: AA was provided in 862.817 cases (28,2 %) of the cohort. After propensity-matching 793.073 pts were analyzed for each group. The</p>
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<p>Number of Patient: 3.834.927 pts. underwent outpatient colonoscopy</p> <p>Recruiting Phase: 1/2005 until 12/2012</p> <p>Inclusion Criteria: Patients underwent outpatient colonoscopy in the Ontario region either under sedation with benzo's and narcotics by the endoscopist or with propofol by an anesthetist (AA-group).</p> <p>Exclusion Criteria: Patients < 18 years, inpatient colonoscopy, concurrent EGD additionally performed.</p>	<p>Comparison: Outcome of Anesthesia-assisted colonoscopy vs. unassisted colonoscopy</p>	<p>risk for perforation (OR 0,99) and for splenic injury (OR 1,09) did not differ significantly between both groups. However, AA was associated with an increased risk of aspiration pneumonia (OR 1,63).</p> <p>Author's Conclusion: In a population-based cohort study, AA for outpatient colonoscopy was associated with a significantly increased risk for aspiration pneumonia, but not for bowel perforation or splenic injury. Endoscopists should warn patients, especially those with respiratory compromise, of this risk.</p>
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Methodical Notes

Funding Sources: partially funded by Physicians Services Inc.

COI: none

Randomization: Pseudo-randomization by propensity matching.

Blinding: none

Dropout Rate/ITT-Analysis: n/a

Notes:

Cassell, B. E. et al. Predictors of Failed Conscious Sedation in Patients Undergoing an Outpatient Colonoscopy and Implications for the Adenoma Detection Rate. *Sci Rep.* 10. 2167. 2020

Population	Intervention	Outcomes/Results
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Evidence level: 3

Study type: Observational study.

Number of Patient: 766

Recruiting Phase: Between July 1, 2015 and November 12, 2015

Inclusion Criteria: Consecutive adult outpatients presenting for colonoscopy at an academic hospital-based endoscopy unit between July 1, 2015 and November 12, 2015 were included in the study.

Exclusion Criteria: Patients who had unsedated procedures,

Intervention: Conscious sedation.

Comparison: None.

Primary: To identify the conscious sedation (CS) failure rate, predictors of failure, and its impact on the adenoma detection rate (ADR).

Secondary: None.

Results: Multivariable logistic regression identified predictors for CS failure and the ADR. Among 766 patients, 29 (3.8%) and 175 (22.8%) patients failed CS by strict and expanded definitions, respectively. Female gender (OR 3.50; 95% CI: 1.37–8.94) and fellow involvement (OR 4.15; 95% CI: 1.79–9.58) were associated with failed CS by the strict definition. Younger age (OR 1.27, 95% CI: 1.07–1.49), outpatient opiate use (OR 1.71; 95% CI 1.03–2.84), use of an adjunct medication (OR 3.34; 95% CI: 1.94–5.73), and fellow involvement (OR 2.20; 95% CI: 1.31–3.71) were associated with failed CS by the expanded definition. Patients meeting strict failure criteria had a lower ADR (OR 0.30; 95% CI: 0.12–0.77).

Author's Conclusion: Several clinical factors may be useful for triaging to MAC. The ADR is lower in patients meeting strict criteria for failed CS.

had an EGD in addition to their colonoscopy in the same endoscopy session, or who had missing study variables were excluded.

Methodical Notes

Funding Sources: None.

COI: Not reported.

Randomization: None.

Blinding: None.

Dropout Rate/ITT-Analysis: None.

Notes: Identification of factors that lead to failure of conscious sedation.

Dossa, F. et al. Practice recommendations for the use of sedation in routine hospital-based colonoscopy. BMJ Open Gastroenterol. 7. e000348. 2020

Population	Intervention	Outcomes/Results
Evidence level: 1 Study type: Number of Patient: Recruiting Phase: Inclusion Criteria: Exclusion Criteria:	Intervention: Comparison:	Primary: Secondary: Results: Author's Conclusion:

Methodical Notes

Funding Sources:

COI:

Randomization:

Blinding:

Dropout Rate/ITT-Analysis:

Notes:

Geng, W. et al. An artificial neural network model for prediction of hypoxemia during sedation for gastrointestinal endoscopy. J Int Med Res. 47. 2097-2103. 2019

Population	Intervention	Outcomes/Results
Evidence level: 4 Study type: prospective observational study Number of Patient: 220 Recruiting Phase: 5 July, 2017, and	Intervention: Development of artificial network Analysis (ANN) Comparison: None.	Primary: Develop an ANN model for prediction of hypoxemia. Secondary: None. Results: Univariate analysis indicated that body mass index (BMI), habitual snoring and neck circumference were associated with hypoxemia. An

31 July, 2017

Inclusion Criteria: Patients with American Society of Anesthesiologists (ASA) status I–III undergoing routine gastroscopy and/or colonoscopy examination were enrolled.

Exclusion Criteria: Therapeutic endoscopy, prior gastric or colonic resection, inadequate bowel preparation, severe cardiopulmonary diseases before data collection, patients with ASA class of 4 or higher and lack of complete data availability.

ANN model was developed with three variables (BMI, habitual snoring and neck circumference). The area under the receiver operating characteristic curve for the ANN model was 0.80.

Author's Conclusion: The ANN model developed here, comprising BMI, habitual snoring and neck circumference, was useful for prediction of hypoxemia during sedation for gastrointestinal endoscopy.

Methodical Notes

Funding Sources: The work was partly supported by the National Natural Science Foundation of China (81774109), Zhejiang Provincial Department of Education (Y201839270) and Wenzhou Science and Technology Plan Project (Y20180508).

COI: None.

Randomization: None.

Blinding: None.

Dropout Rate/ITT-Analysis: None.

Notes: ANN was not prospectively evaluated.

Hendel, K. et al. Pain perception during colonoscopy in relation to gender and equipment: a clinical study. *Scand J Pain.* 20. 747-753. 2020

Population	Intervention	Outcomes/Results
<p>Evidence level: 4</p> <p>Study type: Observational study.</p> <p>Number of Patient: 391 patients</p> <p>Recruiting Phase: Unknown. Only Abstract accessible.</p> <p>Inclusion Criteria: Unknown. Only Abstract accessible.</p> <p>Exclusion Criteria: Unknown. Only Abstract accessible.</p>	<p>Intervention: VAS for pain.</p> <p>Comparison: None.</p>	<p>Primary: To investigate gender-related differences during the colonoscopy procedure, and the impact of endoscopic equipment and psychological factors on pain management.</p> <p>Secondary: Unknown. Only Abstract accessible.</p> <p>Results: No overall gender-related difference in VAS reports was found. There was no reduction in VAS when alternate instructions were given. Female patients were, however, more likely to benefit from light sedation ($p=0.012$). When compared with previous-generation endoscopes, the current generation equipment resulted in a VAS drop of 1.9 points for women and 1.6 for men ($p<0.009$) and washed out a previously observed gender-related difference.</p> <p>Author's Conclusion: No overall gender-related differences were found for pain experience during the colonoscopy procedure. Access to up-to-date endoscopic equipment can reduce procedure-related patient discomfort considerably, even at the expert level of a consultant physician.</p>

Methodical Notes

Funding Sources: Unknown. Only Abstract accessible.

COI: Unknown. Only Abstract accessible.

Randomization: None.

Blinding: None.

Dropout Rate/ITT-Analysis: Unknown. Only Abstract accessible.

Notes: Full text not accessible. Only Abstract.

NEWCASTLE - OTTAWA Checklist: Case Control: 7 Bewertung(en)

Allampati, S. et al. Recovery of cognitive function after sedation with propofol for outpatient gastrointestinal endoscopy. Saudi J Gastroenterol. 25. 188-193. 2019

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 4 Study type: Comparative study	Funding sources: None. Conflict of Interests: None. Randomization: None. Blinding: None. Dropout rates: None.	Total no. patients: 169 Patient characteristics: Not reported Inclusion criteria: Patients who presented to the outpatient endoscopy suite at West Virginia University Hospitals (WVUH) for EGD, colonoscopy, EGD and colonoscopy, or endoscopic ultrasound (EUS) were randomly recruited to the study. 50 healthy controls (controls) were randomly recruited to the study from waiting areas at the WVUH. Exclusion criteria: Patients undergoing endoscopic retrograde cholangiopancreatography were excluded.	Interventions: Propofol sedation. Comparison: Patients after Propofol sedation for endoscopy vs. healthy controls.
Notes:	No clear result. Author's conclusion: Our study supports the return of cognitive flexibility to baseline within 30–45 min after propofol sedation for outpatient GI endoscopy despite delayed return of psychomotor speed and reaction time.		
Outcome Measures/results	Primary Cognitive function 30-45 min after endoscopy using EncephalApp, a smartphone-based Stroop app. Secondary	Results: Recovery after Propofol similar to controls. However, results severely flared and not conclusive.	

Goudra, B. et al. Association between Type of Sedation and the Adverse Events Associated with Gastrointestinal Endoscopy: An Analysis of 5 Years' Data from a Tertiary Center in the USA. Clin Endosc. 50. 161-169. 2017

Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 2 Study type: retrospective	Funding sources: not mentioned	Total no. patients: 73,029 procedures (GI endoscopy)	Interventions: EGD, ERCP, colonoscopy unter propofol sedation or other

analysis of 5 years' Data from a tertiary center in the USA comparing propofol-sedated patients vs. patients with another type of sedation in GI with regard to adverse events	Conflict of Interests: The authors have no financial conflicts of interest. Randomization: no Blinding: no Dropout rates: no	Patient characteristics: September 8, 2008 until May 31, 2013 Inclusion criteria: patients undergoing GI endoscopy procedures under sedation Exclusion criteria: not mentioned	sedation Comparison: Propofol sedation vs. other sedation with regard to adverse events Pateint characteristics (esp. morbidity) with regard to adverse events
Notes:	study investigates the association between Type of Sedation and the Adverse Events Associated with Gastrointestinal Endoscopy Author's conclusion: The possible reasons for our results are the changing demographics, the worsening comorbidities of the patient population, and the increasing technical complexity of these procedures. Although extensive use of propofol has increased patient satisfaction and procedure acceptability, its use is also associated with more frequent adverse events.		
Outcome Measures/results	Primary adverse events Secondary	Results: A total of 163 adverse events were reported from 73,029 procedures. Frequencies of most adverse events were significantly higher in patients anesthetized with propofol. Automatic regression modeling showed that the type of sedation, the American Society of Anesthesiologists physical status classification, and the procedure type were some of the predictors of immediate life-threatening complications.	

Jensen, J. T. et al. Development and validation of a theoretical test in non-anaesthesiologist-administered propofol sedation for gastrointestinal endoscopy. Scand J Gastroenterol. 51. 872-9. 2016			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 1 Study type:	Funding sources: Conflict of Interests: Randomization: Blinding: Dropout rates:	Total no. patients: Patient characteristics: Inclusion criteria: Exclusion criteria:	Interventions: Comparison:
Notes:	nicht beurteilbar nur Abstract vorhanden Author's conclusion:		
Outcome Measures/results	Primary Secondary	Results:	

Jirapinyo, P. et al. Patients With Roux-en-Y Gastric Bypass Require Increased Sedation During Upper Endoscopy. Clin Gastroenterol Hepatol. 13. 1432-6. 2015			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 1 Study type: Case Controll	Funding sources: Supported by Harvard Digestive Diseases Center at Harvard Medical School	Total no. patients: 400 Patient characteristics: retrospektiv 2005 - 2010	Interventions: Sedierungsbedarf bei ÖGD

	(DK034854). Conflict of Interests: The authors disclose no conflicts. Randomization: nicht zutreffend Blinding: nicht zutreffend Dropout rates: retrospektive Studie, dropout nicht möglich	Inclusion criteria: Patienten mit Roux-Y-Magenbypass und gematched solche ohne diesen Eingriff als Kontrollen Exclusion criteria: keine	Comparison: Patienten mit und ohne Magenbypass-OP
Notes:	sauberes Studiendesign, insbesondere wurde gematched für Alter, Geschlecht und BMI Author's conclusion: This study demonstrated that RYGB patients required higher sedation doses during EGD than the non-RYGB patients with similar age, gender, and BMI. In addition, for a subgroup of patients who underwent EGD both before and after RYGB, sedation requirement increased significantly after gastric bypass, despite weight loss. In addition to a history of RYGB, our study also demonstrated that ASA classification and therapeutic endoscopic procedure were independent predictors of higher sedation doses.		
Outcome Measures/results	Primary Sedierungsbedarf Fentanyl und Midazolam Secondary Subgruppenanalyse für die Patienten mit ÖGD vor und nach der Bypass-OP	Results: RYGB patients required higher doses of fentanyl and midazolam during EGD than the non-RYGB patients with similar age, gender, and BMI. The RYGB group took significantly longer than the control to be sedated ($P < .001$, =Sedierung zur und während der ÖGD)	

Khoi, C. S. et al. Age correlates with hypotension during propofol-based anesthesia for endoscopic retrograde cholangiopancreatography. Acta Anaesthesiol Taiwan. 53. 131-4. 2015			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: Case Controll	Funding sources: k.A. Conflict of Interests: All authors have no conflicts of interest to dec Randomization: nicht zutreffend Blinding: nicht zutreffend Dropout rates: nicht zutreffend	Total no. patients: 552 Patient characteristics: 2006-2010 Inclusion criteria: we retrospectively reviewed the anesthetic records, history charts, and procedure records of the patients who underwent ERCP under propofol-based deep sedation from January 2006 to July 2010 at the Far Eastern Memorial Hospital. All propofol-based deep sedations were conducted by anesthesiologists. Exclusion criteria: es wurde keine Fälle aus diesem Zeitraum ausgeschlossen	Interventions: ERCP Comparison: kein Komparator
Notes:	es handelt sich um die deskriptive, retrospektive Analyse einer Kohorte ohne Komparator. Author's conclusion: Hypotension was the most frequent anesthetic complication during procedure under propofol-based deep sedation, but this method was safe and effective under appropriate monitoring. Age is the strongest predictor of hypotension and therefore propofol-based deep sedation should be conducted with caution in the elderly		

Outcome Measures/results	Primary patients with hypotension, hypertension, and desaturation during anesthesia Secondary	Results: Multivariate logistic regression identified sex and age as significantly associated with hypotension ($p < 0.05$;). However, when age was excluded from analysis, hypertension and anesthetic time were identified as a significant predictor ($p = 0.002$ and $p = 0.03$, respectively), while sex remained a significant independent predictor ($p = 0.038$).
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McCain, J. D. et al. Creation of a score to predict risk of high conscious sedation requirements in patients undergoing endoscopy. Gastrointest Endosc. 91. 595-605.e3. 2020			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 4 Study type: Case control study	Funding sources: none Conflict of Interests: none Randomization: no Blinding: no Dropout rates: no	Total no. patients: 488 Patient characteristics: November 2011- Mai 2017 Inclusion criteria: Outpatient EGD, colonoscopy or both Met at least 1 of the criteria for the score Exclusion criteria:	Interventions: Comparison: matched in a 1:2 fashion with patients from the same sample without criteria of the score
Notes:	Author's conclusion: The risk score can funktion as a useful tool for physicians when discussing sedation options before endoscopy.		
Outcome Measures/results	Primary occurrence of high conscious sedation requirements during GI endoscopy. one of the following criteria: > 10 mg midazolam, >200 mikrog fentayl, > 100 mg meperidine, need for reversal agent, incomplete procedure, aborted procedure, poorly tolerated procedure Secondary	Results: Significant associations with sedation failure for age, sex, nonclonazepam benzodiazepin use, opioid use, procedure type. Based on this a score was created with predicted the rist of sedation failure with an AUC of 0,70.	

Sasala, L. et al. Cost Analysis of Intravenous Propofol Monotherapy versus Intravenous Combination Sedation in Patients Undergoing Outpatient Gastrointestinal Endoscopy. Aana j. 88. 373-379. 2020			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 4 Study type: Case Control study	Funding sources: Unknown. Only Abstract available. Conflict of Interests: Unknown. Only Abstract available. Randomization: None.	Total no. patients: 277 Patient characteristics: Unknown. Only Abstract available. Inclusion criteria: Unknown. Only	Interventions: Sedation. Comparison: Propofol monotherapy compared with combination sedation consisting of propofol with any of the following: midazolam, fentanyl, dexmedetomidine, and/or ketamine.

	Blinding: None.	Abstract available.
	Dropout rates: Unknown. Only Abstract available.	Exclusion criteria: Unknown. Only Abstract available.
Notes:	Only Abstract available.	
	Author's conclusion: There were no significant differences in PACU length of stay, PACU cost, medication costs, and episodes of PONV between propofol monotherapy and combination sedation for outpatient GI endoscopy.	
Outcome Measures/results	Primary Cost analysis: PACU length of stay, episodes of postoperative nausea and vomiting (PONV), PACU costs, and medication costs. Secondary Not specified.	Results: The average PACU length of stay was 35.0 minutes for propofol monotherapy and 35.75 minutes for combination sedation (P = .918). The average PACU cost was \$566.37 for propofol monotherapy and \$578.44 for combination sedation (P = .918). The average cost for sedatives was \$3.13 for propofol monotherapy and \$3.34 for combination sedation (P = .964). There was 1 incident of nausea among all patients. .

NEWCASTLE - OTTAWA Checklist: Cohort: 9 Bewertung(en)

Ball, A. J. et al. Sedation practice and comfort during colonoscopy: lessons learnt from a national screening programme. Eur J Gastroenterol Hepatol. 27. 741-6. 2015			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: database analysis	Funding sources: not mentioned Conflict of Interests: The authors declare that there is no conflict of interest. Randomization: not relevant, comprehensive database analysis Blinding: Dropout rates:	Total no. patients: 113.316 colonoscopy examinations were performed (99.044 screening and 14.272 surveillance examinations). Recruiting Phase: 1 January 2010 to 31 December 2012 Inclusion criteria: Exclusion criteria: none	Interventions: intravenous sedation and opiate analgesia in screening and surveillance colonoscopies Comparison: Correlations between the proportion of examinations associated with significant discomfort and the amounts of medication used by colonoscopists were assessed using Spearman'sp. Logistic regression modelling examined the independent predictors of significant discomfort
Notes:	Dataset: The Bowel Cancer Screening System (BCSS) is a national database related to all colonoscopy examinations performed within the English Bowel Cancer Screening Programme (BCSP). An Specialist Screening Practitioner (SSP) attends each examination and rates patient comfort, independent of the colonoscopist, using the urse-rated Modified Gloucester Comfort Scale (MGCS). Studies have shown that the BCSS has a high level of completeness and accuracy. Author's conclusion: Comfort ratings vary widely between colonoscopists and appear to be unrelated to medication practice. Tailoring medication use to achieve comfortable procedures, while minimizing risk and inconvenience, remains an important area for future research.		
Outcome Measures/results	Primary discomfort rated on the five-point Modified Gloucester Comfort Scale: 1, no discomfort; 5, severe discomfort. Scores of 4	Results: In 91% of examinations, there was no significant discomfort reported during examination; however, there was considerable variation between individual colonoscopists (range 76.1–99.2%). Intravenous sedation and opiate analgesia were used during most examinations, but there was wide variation between colonoscopists, with a median (range) usage of 95.1%	

	and 5 were considered to indicate significant discomfort.	(4.1–100%) and 97.3% (5.6–100%), respectively. There was no association between the amount of sedation and analgesia used and significant discomfort ($p < 0.2$). On multivariate analysis, significant discomfort was found to be more common among female individuals [odds ratio (OR)=2.0], on incomplete examinations (OR=6.7), and among patients with diverticulosis (OR=1.4).
	Secondary	

Behrens, A. et al. [Safety of sedation during gastroscopy and colonoscopy in low-risk patients - results of a retrospective subgroup analysis of a registry study including over 170?000 endoscopies]. Z Gastroenterol. 54. 733-9. 2016			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 3 Study type: subgroup analysis of a registry study (database)	Funding sources: Fa. E&L medical systems GmbH, budget resources of the researchers Conflict of Interests: not mentioned Randomization: not relevant, comprehensive registry study Blinding: no Dropout rates: none	Total no. patients: 177944 patients of 39 research centers Recruiting Phase: December 2011 to June 2014 Inclusion criteria: ASA 1 or ASA 2, esophagogastroduodenoscopy or colonoscopy with sedation Exclusion criteria: ASA 3 or higher, emergency endoscopies, therapeutic procedures, no sedation	Interventions: sedation (propofol alone in 64.4% of the sedations, a combination of propofol and midazolam in 22.4%, midazolam mono in 6.6%, midazolam and opiate in 5.1%, other 1.5%) Comparison:
Notes:	Author's conclusion: Sedation can therefore be regarded as extremely safe in this group of patients. Even though this analysis did not include therapeutic colonoscopies (e.g. polypectomy), these data should lower the threshold for patients undergoing preventive check-up examinations and it should therefore be offered as a standard.		
Outcome Measures/results	Primary minor and major complications Secondary	Results: A total of 332 minor complications were documented (0.2%). No major complications or deaths occurred. The following risk factors were identified for the development of sedation-associated complications: Patients in ASA class 2 and sedation with midazolam in combination with an opiate	

Dimou, F. et al. Nasal positive pressure with the SuperNO(2)VA™ device decreases sedation-related hypoxemia during pre-bariatric surgery EGD. Surg Endosc. 33. 3828-3832. 2019			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 4 Study type: Prospective observational study.	Funding sources: Unknown, only Abstract available. Full text not accessible. Conflict of Interests: Unknown, only Abstract available. Full text not accessible.	Total no. patients: 56 consecutive patients. Recruiting Phase: Between June 2016 and August 2017 Inclusion criteria: EGD prior to bariatric surgery. Exclusion criteria:	Interventions: SuperNO2VA™ device, a sealed nasal positive airway pressure mask designed to deliver high-fraction inhaled oxygen and titratable positive pressure. Comparison: SuperNO2VA™ device, a sealed nasal positive airway pressure mask designed to deliver high-fraction inhaled oxygen and titratable positive pressure compared to conventional nasal cannula.

	<p>Randomization: None.</p> <p>Blinding: None.</p> <p>Dropout rates: Unknown, only Abstract available. Full text not accessible.</p>	<p>Unknown, only Abstract available.</p>
Notes:	<p>Based on the abstract. Full text not available.</p> <p>Author's conclusion: Patients with higher BMI, higher ASA classification, and OSA were more likely to have the SuperNO2VA™ device used; yet, paradoxically, these patients were less likely to have issues with desaturation events. Use of this device can optimize care in this challenging patient population by minimizing the risks of hypoventilation.</p>	
Outcome Measures/results	<p>Primary Desaturation events.</p> <p>Secondary None.</p>	<p>Results: The SuperNO2VA™ group had a lower median age compared to the control group (38.5 vs. 48.5 years, $p = 0.04$). These patients had a higher body mass index (BMI) (47.4 vs. 40.5, IQR, $p < 0.0001$), higher ASA class ($p = 0.03$), and were more likely to have OSA (53.9% vs. 26.7%, $p = 0.04$). Desaturation events were significantly lower in the SuperNO2VA™ group (11.5% vs. 46.7%, $p = 0.004$) and the median lowest oxygen saturation was higher in the SuperNO2VA™ group (100% vs. 90.5%, $p < 0.0001$).</p>

Kawano, S. et al. An effective and safe sedation technique combining target-controlled infusion pump with propofol, intravenous pentazocine, and bispectral index monitoring for peroral double-balloon endoscopy. Digestion. 91. 112-6. 2015

Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 4</p> <p>Study type: Prospective cohort study</p>	<p>Funding sources: Not reported.</p> <p>Conflict of Interests: Not reported.</p> <p>Randomization: None.</p> <p>Blinding: None.</p> <p>Dropout rates: None.</p>	<p>Total no. patients: 34</p> <p>Recruiting Phase: November 2011 to October 2013</p> <p>Inclusion criteria: Consecutive patients who underwent DBE by the oral approach at Okayama University Hospital</p> <p>Exclusion criteria: (1) patients 18 years or younger, (2) patients with an American Society of Anesthesiologists physical status classification system score of 3 or more, or (3) patients with a positive history of allergy to propofol and/or eggs.</p>	<p>Interventions: Sedation protocol for peroral DBE, which consisted of target-controlled infusion (TCI) anesthesia with propofol, an intravenous bolus of pentazocine, and bispectral index (BIS) monitoring.</p> <p>Comparison: None.</p>
Notes:	<p>Case series.</p> <p>Author's conclusion: A combination of propofol via TCI pump, bolus injection of pentazocine as needed, and BIS monitoring was a safe and effective procedure for peroral DBE. Reasonable satisfaction indices were obtained from both patients and endoscopists. Pentazocine was required for young patients and in cases with longer procedure times.</p>		
Outcome Measures/results	<p>Primary Safety and efficacy.</p> <p>Secondary Additional Need of</p>	<p>Results: Five patients (14.7%) required a reduction in the dose of propofol. No patient experienced serious adverse events. All patients (100%) and 80.6% (25/31) of endoscopists answered that the sedation protocol was 'excellent' or 'enough' for peroral DBE. Eleven patients (32.3%) required a bolus injection of pentazocine. Age <60</p>	

	intravenous bolus of pentazocine.	years and a total procedure time of >70 min were significant risk-factors for pentazocine use.
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Lauriola, M. et al. Intolerance of Uncertainty and Anxiety-Related Dispositions Predict Pain During Upper Endoscopy. Front Psychol. 10. 1112. 2019			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 5 Study type:	Funding sources: Conflict of Interests: Randomization: Blinding: Dropout rates:	Total no. patients: Recruiting Phase: Inclusion criteria: Exclusion criteria:	Interventions: Comparison:
Notes:	Es handelt sich nicht um eine Kohortenstudie im eigentlichen Sinne mit Vergleiche zweier Kohorten über die Zeit. Verglichen wurde der psychologische Status/Stress vor einer ÖGD mit den selbstberichteten Symptomen/Schmerz nach der ÖGD. Hoher Stress-Level zuvorkorreliert mit negativer Wahrnehmung. Author's conclusion:		
Outcome Measures/results	Primary Secondary	Results:	

Maestro Antolín, S. et al. Severe cardiorespiratory complications derived from propofol sedation monitored by an endoscopist. Rev Esp Enferm Dig. 110. 237-239. 2018			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 4 Study type: Retrospective analysis	Funding sources: Unknown. Full text in Spain. Only Abstract analysed. Conflict of Interests: Unknown. Full text in Spain. Only Abstract analysed. Randomization: None. Blinding: None. Dropout rates: Unknown. Full text in Spain. Only Abstract analysed.	Total no. patients: 33195 Recruiting Phase: 2011 to 2016 Inclusion criteria: Various endoscopic examinations (gastroscopy, colonoscopy, endoscopic retrograde cholangiopancreatography [ERCP] and endoscopic ultrasound [EUS]) where sedation was controlled by an endoscopist within our unit. Exclusion criteria: Unknown. Full text in Spain. Only Abstract analysed.	Interventions: Sedation by endoscopist. Comparison: None.
Notes:	Full text in Spain, only abstract reviewed. Author's conclusion: Sedation controlled by a trained endoscopist is safe, effective and efficient.		
Outcome Measures/results	Primary Severe cardiorespiratory complications.	Results: The rate of cardiorespiratory complications was 0.13% and the majority were severe desaturations. Most cases responded to an opening in the airway associated with the interruption of drug infusion and an ambu bag was required in a few cases. There were no	

	Secondary Unknown.	statistically significant differences between the different groups, except for mean age, risk by type of examination and ASA risk, where the difference between ERCP and the rest of examinations was statistically significant.
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Shirota, Y. et al. More than half of hypoxemia cases occurred during the recovery period after completion of esophagogastroduodenoscopy with planned moderate sedation. Sci Rep. 10. 4312. 2020			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 4 Study type: Retrospective study	Funding sources: Not reported. Conflict of Interests: None. Randomization: None. Blinding: None. Dropout rates: None.	Total no. patients: 4065 consecutive esophagogastroduodenoscopy (EGD) procedures Recruiting Phase: Between April 1, 2015 and December 31, 2016 Inclusion criteria: 4065 consecutive outpatient EGD procedures conducted under sedation in 2890 unique patients. Exclusion criteria: Not reported.	Interventions: Outpatient EGD procedures conducted under sedation. Comparison: None.
Notes:	Author's conclusion: The lack of risk factors is no guarantee that hypoxemia will not occur. Therefore, continuous monitoring by pulse oximetry is more important during the recovery period and is recommended in all EGD procedures under planned moderate sedation.		
Outcome Measures/results	Primary Incidence of adverse events during the recovery period and to assess the effectiveness of continuous monitoring Secondary None.	Results: 84 (2.1%) procedures developed unexpected hypoxemia (SpO ₂ ≤ 90%). Hypoxemia was observed during the procedure, at the end of the procedure, and during the recovery period in 21, 17, and 46 (1.1%) procedures, respectively. More than half of the hypoxemia cases occurred during the recovery period. Many hypoxemia cases were characterized by neither serious co-morbid illness nor low body mass index which have been reported as risk factors of hypoxemia.	

Smith, Z. L. et al. Type of sedation and the need for unplanned interventions during ERCP: analysis of the clinical outcomes research initiative national endoscopic database (CORI-NED). Frontline Gastroenterol. 11. 104-110. 2020			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 1 Study type:	Funding sources: Conflict of Interests: Randomization: Blinding: Dropout rates:	Total no. patients: Recruiting Phase: Inclusion criteria: Exclusion criteria:	Interventions: Comparison:
Notes:	Originalpaper nicht verfügbar Author's conclusion:		
Outcome Measures/results	Primary Secondary	Results:	

Theivanayagam, S. et al. ASA Classification Pre-Endoscopic Procedures: A Retrospective Analysis on the Accuracy of Gastroenterologists. South Med J. 110. 79-82. 2017

Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 4</p> <p>Study type: Retrospektive Datenanalyse</p>	<p>Funding sources: n. d.</p> <p>Conflict of Interests: n. d.</p> <p>Randomization: nein</p> <p>Blinding: n. d.</p> <p>Dropout rates: n. d.</p>	<p>Total no. patients: n. d.</p> <p>Recruiting Phase: 2012 - 2013</p> <p>Inclusion criteria: ÖGD</p> <p>Exclusion criteria: n. d.</p>	<p>Interventions: Evaluation der ASA-Scores</p> <p>Comparison: keine</p>
<p>Notes:</p>	<p>Für diese Studie liegt nur das Abstrakt vor, das Originalpaper konnte nicht aufgefunden werden.</p> <p>Author's conclusion: Die ASA-Klassifikation ist gemäß diesen Studienergebnissen nur von unzureichendem Wert für die Risikoeinschätzung.</p>		
<p>Outcome Measures/results</p>	<p>Primary Korrektheit der prä-diagnostischen ASA-Klassifikation durch verschiedene Untersucher</p> <p>Secondary n. d.</p>	<p>Results: Die Einschätzung des Patientenrisikos anhand der ASA-Klassifikation ist moderat vergleichbar zwischen Gastroenterologen und Anästhesisten, unzureichend zwischen unterschiedlichen Gastroenterologen und in moderater Übereinstimmung mit sich selber (?).</p>	

Literatursammlung:

AG 5 - Literatur 2013 - 2014

Inhalt: 2 Literaturstellen

Literaturstelle	Evidenzlevel	Studientyp
Nguyen, Nam Q. 2016	1	Randomized, double-blind, placebo- controlled, crossover manner
Watkins, T. J. 2014	2	Randomized, controlled.

OXFORD (2011) Appraisal Sheet: RCT: 2 Bewertung(en)

Nguyen, Nam Q. et al. Psychomotor and cognitive effects of 15-minute inhalation of methoxyflurane in healthy volunteers: implication for post-colonoscopy care. <i>Endosc Int Open</i> . 04. E1171-E1177. 2016		
Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 1</p> <p>Study type: Randomized, double-blind, placebo- controlled, crossover manner</p> <p>Number of Patient: 60</p> <p>Recruiting Phase: 12 month.</p> <p>Inclusion Criteria: Volunteers who were able to give informed consent, able to understand adequately use of the methoxyflurane (Pentrox) inhaler, and who had no contraindication to use of methoxyflurane were recruited.</p> <p>Exclusion Criteria: Exclusion criteria were: (1) a history of significant alcohol (> 40 g/d for males, 20 g/d for females) or narcotic use; (2) previous history of significant liver, cardiac or respiratory illnesses (i. e. ischemic heart disease, chronic obstructive pulmonary disease, chronic liver disease); (3) body mass index less than 19 kg/m²; (4) any renal impairment; (5) previous possible allergy to the medication by the patient or a relative; (6) hypersensitivity to fluorinated agents; (7) previous head injury; (8) difficulty in following instructions (including language barrier); (9) concurrent use of any potential nephrotoxic drugs (e.g. aminoglycosides) or tetracyclines; and (10) personal or family history of malignant hyperthermia.</p>	<p>Intervention: The subjects were then asked to inhale through a portable green inhaler containing either 3 mL of saline (placebo) or methoxyflurane over 15 minutes. The subjects were asked to take 10 inhalations of methoxyflurane at the beginning and 1 inhalation every 3 breaths thereafter for the rest of the 15-minute duration.</p> <p>Comparison: "placebo" consisted of 3 mL of normal saline, the solution had the smell of methoxyflurane to "blind" the subject from distinguishing placebo from active methoxyflurane.</p>	<p>Primary: (1) the differences in psychomotor functions between inhaled methoxyflurane and placebo in healthy volunteers; and (2) the intra-subject and inter-subject variability in these outcomes for planning a definitive equivalence study.</p> <p>Secondary: (1) the duration and severity of adverse impact of inhaled methoxyflurane on psychomotor functions in healthy volunteers; and (2) the influence of age on the effects of methoxyflurane on the psychomotor function in healthy subjects.</p> <p>Results: Compared to placebo, a 15-minute Pentrox inhalation led to an immediate but small impairment of DSST (P < 0.001), ART (P < 0.001), EHC (P < 0.01), TMT (P = 0.02) and LRT (P = 0.04). In all subjects, the performance of all 5 tests normalized by 30 minutes after inhalation, and was comparable to that with placebo. Although increasing age was associated with a small deterioration in psychomotor testing performance, the magnitude of Pentrox effects remained comparable among all age groups.</p> <p>Author's Conclusion: In all age groups, a 15-minute Pentrox inhalation induces acute but short-lasting</p>

impairment of psychomotor and cognitive performance, which returns to normal within 30 minutes, indicating that subjects who have colonoscopy with Pentrox can return to highly skilled psychomotor skills tasks such as driving and daily work the same day.

Methodical Notes

Funding Sources:

COI: None

Randomization: Randomization of the order of the studied drug and placebo was done in blocks of 10 using a computer program (GraphPad Software Inc., La Jolla, CA, USA). Results of the randomization were enclosed in envelopes labelled from subjects 1 to 60.

Blinding: Yes

Dropout Rate/ITT-Analysis: None

Notes:

Watkins, T. J. et al. Evaluation of postprocedure cognitive function using 3 distinct standard sedation regimens for endoscopic procedures. Aana j. 82. 133-9. 2014

Population	Intervention Comparison	Outcomes/Results
<p>Evidence level: 2</p> <p>Study type: Randomized, controlled.</p> <p>Number of Patient: 96; 92 analyzed after 4 dropouts</p> <p>Recruiting Phase: not stated</p> <p>Inclusion Criteria: ASA class 1 or 2. The minimum inclusion age was 18 years.</p> <p>Exclusion Criteria: patients unable to give informed consent; patients with hearing, visual, or communication impairments; patients with allergies to the medications used in the investigation; pregnant or breastfeeding women; and patients with a history of seizure disorders or sleep apnea.</p>	<p>Intervention: postprocedure cognitive function associated with 1. propofol alone</p> <p>Comparison: 2. propofol plus fentanyl 3. and fentanyl plus midazolam.</p>	<p>Primary: To evaluate postprocedure cognitive function associated with 3 distinct standard sedation regimens used for endoscopic procedures.</p> <p>Secondary: To identify complications requiring provider interventions.</p> <p>Results: The propofol plus fentanyl group had a mean TICS score of 34.53 at 24 hours compared with 34.96 at 48 hours (P = .017). The midazolam plus fentanyl group had a mean TICS score of 34.76 at 24 hours compared with 36.26 at 48 hours (P = .004). The propofol-alone group had a mean TICS score of 35.09 at 24 hours compared with 35.98 at 48 hours (P = .924).</p> <p>Author's Conclusion: The results of this investigation indicate that the sedation regimen of propofol alone has the least impact on postprocedure cognitive function. Additionally, the number of jaw lift interventions was significantly higher in both groups who received fentanyl.</p>

Methodical Notes

Funding Sources: not stated

COI: not stated

Randomization: not stated

Blinding: The study used 3 ordinal groups for level of sedation (mild, moderate, and deep) and tested 3 groups for difference in proportion (propofol alone, propofol plus fentanyl, and fentanyl plus midazolam). The goal of this investigation was to test the research hypothesis that the proportion of cases falling into each sedation category

(mild, moderate, and deep) is not identical for each treatment group (propofol alone, propofol plus fentanyl, and fentanyl plus midazolam).

Dropout Rate/ITT-Analysis: Ninety-six patients were enrolled in this investigation. Four patients were excluded from the final statistical analysis because they were unavailable for follow-up at the 24-hour or 48-hour reassessments.

Notes:

Literatursammlung:

AG 5 - Literatur 2015 - 2020

Inhalt: 2 Literaturstellen

Literaturstelle	Evidenzlevel	Studientyp
Riphaus, A. 2017	2	Prospective observational study
Trevisani, L. 2013	4	Prospective, non-randomized cohort study

NEWCASTLE - OTTAWA Checklist: Case Control: 1 Bewertung(en)

Riphaus, A. et al. Women awaken faster than men after electroencephalogram-monitored propofol sedation for colonoscopy: A prospective observational study. Eur J Anaesthesiol. 34. 681-687. 2017			
Evidence level	Methodical Notes	Patient characteristics	Interventions
Evidence level: 2 Study type: Prospective observational study	Funding sources: none Conflict of Interests: none Randomization: none Blinding: None Dropout rates: 5/224	Total no. patients: 219 Patient characteristics: May 2014 till June 2016 Inclusion criteria: Patients aged more than 18 years who were scheduled for colonoscopy for diagnostic and therapeutic colonoscopy. Exclusion criteria: Patients from whom informed consent could not be obtained due to an emergency situation (lower gastrointestinal bleeding), patients with ASA class 4 or 5, those with pre-existing hypoxaemia (SpO ₂	Interventions: Propofol sedation using electroencephalogram monitoring during a constant level of sedation depth (D0 to D2) performed by trained nurses or physicians after a body-weight-adjusted loading dose. Comparison: gender-specific differences
Notes:	Author's conclusion: The effect of gender aspects should be considered when propofol is used as sedation for gastrointestinal endoscopy. That includes adequate dosing for women as well as caution regarding potential overdosing of male patients.		
Outcome Measures/results	Primary Presence of gender-specific differences in awakening time (time from end of sedation to eye-opening and complete orientation); Secondary Total dose of propofol, sedation-associated	Results: Women awakened significantly faster than men, with a time to eye-opening of 7.3	

complications (bradycardia, hypotension, hypoxaemia and apnoea), patient cooperation and patient satisfaction. Multivariate analysis was performed to correct confounding factors such as age and BMI.

NEWCASTLE - OTTAWA Checklist: Cohort: 1 Bewertung(en)

Trevisani, L. et al. Post-Anaesthetic Discharge Scoring System to assess patient recovery and discharge after colonoscopy. World J Gastrointest Endosc. 5. 502-7. 2013

Evidence level	Methodical Notes	Patient characteristics	Interventions
<p>Evidence level: 4</p> <p>Study type: Prospective, non-randomized cohort study</p>	<p>Funding sources: Not reported.</p> <p>Conflict of Interests: Not reported.</p> <p>Randomization: None.</p> <p>Blinding: None.</p> <p>Dropout rates: Reported.</p>	<p>Total no. patients: 220</p> <p>Recruiting Phase: Not reported.</p> <p>Inclusion criteria: Consecutive outpatients undergoing ambulatory elective colonoscopy in an Italian Digestive Endoscopy Centre. Age range 18 to 75 years, patients scheduled for elective sedated colonoscopy, and capability (evaluated by the endoscopist) of fully understanding the questionnaire.</p> <p>Exclusion criteria: American Society of Anesthesiology (ASA) risk class 3 or higher[12], previous colonic surgical procedure, willingness to undergo unsedated colonoscopy, inpatient status, planned endoscopic therapy, psychiatric diseases or long-term psychiatric drug addiction, concomitant neoplastic diseases, pregnancy or lactation.</p>	<p>Interventions: In the Control-group (110 subjects) discharge decision was based on the clinical assessment; in Post-Anaesthetic Discharge Scoring System (PADSS)-group (110 subjects) discharge decision was based on the modified PADSS.</p> <p>Comparison: Time to discharge.</p>
<p>Notes:</p>	<p>Methodologically flawed. No Gold Standard for cognitive recovery used. Discharge was set equally to cognitive recovery.</p> <p>Author's conclusion: The Post-Anaesthetic Discharge Scoring System is as safe as the clinical assessment and allows for an earlier patient discharge after colonoscopy performed under sedation.</p>		
<p>Outcome Measures/results</p>	<p>Primary Recovery from sedation.</p> <p>Secondary Post endoscopy complications.</p>	<p>Results: Recovery from sedation was faster in PADSS-group than in Control-group (58.75 ± 18.67 min vs 95.14 ± 10.85 min, respectively; P < 0.001). Recovery time resulted shorter than 60 min in 39 patients of PADSS-group (37.5%), and in no patient of Control-group (P < 0.001). At follow-up phone call, no patient declared any hospital re-admission because of problems related to colonoscopy and/or sedation. Mild delayed post-discharge symptoms occurred in 57 patients in Control-group (55.3%) and in 32 in PADSS-group (30.7%). The most common symptoms were drowsiness, weakness, abdominal distension, and headache. Only 3 subjects needed to take some drugs because of post-discharge symptoms.</p>	

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