

Evidenztabelle (68)Ga-PSMA-PET

Ref-ID	authors, title	population	intervention	study design	results	methodological validity	LoE
initial staging (+ histological verification)							
23503	Maurer T. Diagnostic Efficacy of (68)Gallium-PSMA Positron Emission Tomography Compared to Conventional Imaging for Lymph Node Staging of 130 Consecutive Patients with Intermediate to High Risk Prostate Cancer. J Urol 2016;195(5):1436-43.	pat.s before RPx + pLND median 66y (range 61-72); PSA 11,55 ng/mL (0,57-244); GSC 7 (6-10); 56,7% ≥cT3 2012-2014 single-center study (Germany)	68Ga-PSMA (median dose 1,76MBq/kg), PET(/MR or /CT, n=95 vs. 35) 1h after injection	retrospective study (n=130 pat.s, 734 regional LNs dissected) comparison: CT, MRT control: histology	detection of LNMs in 31,5% of pat.s (histologically detected metastases in 15,9% of dissected LNs) pat.-based sensitivity 65,9%; specificity 98,9%; PPV 96,4%; NPV 86,3%; accuracy 88,5% with PSMA (vs. morphological imaging: 43,9%; 85,4%; 58,1%; 76,8%; 72,3%) (p=0,002) template-based sensitivity of PSMA-PET: 73,5%; specificity 99,2%; PPV 94,5%; NPV 95,2%; accuracy 95,1% (vs. morphological imaging: 28,2%; 97,1; 64,7%; 87,7%; 86,1%) (p<0,001) lesion detection in primary tumor: tracer uptake in 91,6%. in pat.s where PET was false-negative for LNMs, there was no PSMA uptake in primary tumor either. mean maximum size of LNMs missed in PET was 3±1mm (range 1-5)	Pat.-Charakteristika beschrieben - ja ausbalanciert zwischen den Gruppen - n/a drop-out beschrieben - n/a statist. Methoden beschrieben - ja Methoden, Definitionen beschrieben - ja ITT-Analyse - ja / n/a Col /Sponsoring angegeben - nein Quadas: low - low - low - low	3
23509	Budaus L. Initial Experience of (68)Ga-PSMA PET/CT Imaging in High-risk Prostate Cancer Patients Prior to Radical Prostatectomy. Eur Urol 2016;69(3):393-6.	pat.s before RPx +epLND (LNM risk >20%) mean 62,3y, median 63y (44-75); PSA mean 38,9 ng/mL, median 8,8 (1,4-376); GSC 7: 63,3% (>7: 36,7%); 63,3% ≥cT3 2014-2015 multi-center / pat.s from 5 sites (Germany)	68Ga-PSMA (mean dose 169 MBq, range 106-269), PET ?h after injection (maybe different at incl. sites)	retrospective study (n=30 pat.s, 608 LN systematically dissected during prostatectomy) (pat.s pre-selected for homogeneity: risk for LNMs >20% each) control: histology	detection of LNMs in 40% of pat.s (metastases in 8,7% of dissected LNs) pat.based sensitivity 33,3%; specificity 100%; PPV 100%; NPV 69,2%; accuracy 73,3% lesion-based sensitivity 27,3%; specificity 100%; PPV 100%; NPV 52,9% correct prediction of prostate tumor foci in 92,9% pat.s [33,3% of pat.s true positive with Ga-PSMA, false negative: 66,7%]; median size of Ga-PSMA-detected vs. undetected LNMs: 13,6 vs 4,3 mm (p<0,05) conclusion: <u>substantial influence of LNM size on the diagnostic accuracy of 68Ga-PSMA PET/CT</u>	Pat.-Charakteristika beschrieben - ja ausbalanciert zwischen den Gruppen - n/a drop-out beschrieben - n/a statist. Methoden beschrieben - nein Methoden, Definitionen beschrieben - nein ITT-Analyse - ja / n/a Col /Sponsoring angegeben - ja Quadas: high - low - low - low	3-
23494	van Leeuwen PJ. Prospective Evaluation of 68Gallium-PSMA Positron Emission Tomography/Computerized Tomography for Preoperative Lymph Node Staging in Prostate Cancer. BJU Int 2016.	pat.s before RP+LND mean/median 65y (range 60-71), PSA mean 8,2 ng/mL, median 8,1 (5,2-10,1); GSC 7: 17% (8-9: 83%); 20% cT3 / 60% cT2 / 20% cT1c 2015 single-center study (Australia)	68Ga-PSMA (mean dose 150 MBq) PET 1h after injection	prospective study (n=30 pat.s, 536 resected LNs following standard procedure) control: histology	detection rates: 37% of pat.s with LNMs (metastases in 4,9% of dissected LNs) pat.-based sensitivity 64%, specificity 95%, PPV 88%, NPV 82% LN-based: sensitivity 58%, specificity 100%, PPV 94%, NPV 98% conclusion: <i>In patients with intermediate to high-risk PC, 68Ga-PSMA PET/CT has a high specificity and a moderate sensitivity for LNM detection. [detection depends on LNM size (sensitivity better if >5mm) (mean size true positive: 4,7mm, false negative 2,7mm)]</i>	Pat.-Charakteristika beschrieben - ja ausbalanciert zwischen den Gruppen - n/a drop-out beschrieben - n/a statist. Methoden beschrieben - ja Methoden, Definitionen beschrieben - ja ITT-Analyse - ja / n/a Col /Sponsoring angegeben - ja Quadas: low - low - low - low	2(+/-)
23499	Herlemann A. Ga-PSMA Positron Emission Tomography/Computed Tomography Provides Accurate Staging of Lymph Node Regions Prior to Lymph Node Dissection in Patients with Prostate Cancer. Eur Urol 2016.	pat.s for LN staging before RP+LND, or before secondary LND; primary LND: mean 70,5y (59-80); mean PSA 55,9 ng/mL (3,3-363); GSC ≥7: 90% [data split for initial (here) / recurrent (below)] 2014-2015 single-center study (Germany)	68Ga-PSMA (mean dose ?MBq) PET 1h after injection	prospective study (n=34 pat.s total, primary LND pat. n=20, 235 dissected LNMs from 40 regions) comparison: CT control: histology	(overall (pLND+sLND) detection of LNM: sensitivity 84%, specificity 82%, PPV 84%, NPV 82% for PSMA-PET (vs. 65%, 76%, 75%, 67% for CT)) primary LND per region: sensitivity 86%; specificity 88%; PPV 80%; NPV 92%; accuracy 88% (vs CT before pLND: 64%; 81%; 64%; 81%; 75%)	Pat.-Charakteristika beschrieben - ja ausbalanciert zwischen den Gruppen - n/a drop-out beschrieben - ja statist. Methoden beschrieben - nein Methoden, Definitionen beschrieben - ja ITT-Analyse - ja / n/a Col /Sponsoring angegeben - ja Quadas: low - low - low - low	2(+/-)

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23493	Rhee H. PSMA PET May Improve the Diagnostic Accuracy of mpMRI in Localised Prostate Cancer as Confirmed by Whole-Mount Histopathology. J Urol 2016.	pat.s with PCa before RP; median 62y (41-71); PSA 6 ng/mL (3,5-45); GSC 7: 80%, GSC9: 20% single-center study (Australia)	68Ga-PSMA (mean dose 150 MBq), PET 90 min after injection	prospective study (n=20 pat.s, 50 significant lesions within prostate) comparison: MRI control: histology (prostate)	diagnostic accuracy with PSMA-PET: sensitivity 49%, specificity 95%, PPV 85%, NPV 88% (vs MRI: 44%, 94%, 81%, 76%) <i>PSMA PET yielded higher specificity and PPV due to a lower false negative rate</i> (no p values provided) conclusion: <i>A significant proportion of cancers are potentially missed and underestimated by both imaging modalities. PSMA PET may be used in addition to mpMRI to help improve the local staging of those undergoing retropubic radical prostatectomy.</i>	Pat.-Charakteristika beschrieben - ja ausbalanciert zwischen den Gruppen - n/a drop-out beschrieben - ja statist. Methoden beschrieben - ja Methoden, Definitionen beschrieben - ja ITT-Analyse - ja Col /Sponsoring angegeben - ja Quadas: low - low - low - low	2(+/-)
23500	Eiber M. Simultaneous Ga-PSMA HBED-CC PET/MRI Improves the Localization of Primary Prostate Cancer. Eur Urol 2016.	pat.s with histolog. proven PCa with intermediate or high risk before RPx; median 66y (62-72); PSA 12ng/mL (6,9-18,8); GSC 7: 66%, 8-10: 28% 2013-2014 single-center study (Germany)	68Ga-PSMA (mean dose 141 MBq) PET/CT ~1h after injection	retrospective study (n=53 pat.s, 318 prostate sextants) comparison: MRI control: histology (prostate)	diagnostic accuracy (pat.-based): sensitivity with PSMA-PET 92% vs 66% with MRI (combined PET/MRI: 98%) (PET vs MRI, combined vs MRI: p<0,001) sextant-based: sensitivity with PSMA-PET 64% vs 58% with MRI (combined PET/MRI: 76%); specificity 94% vs 82% (vs combined: 97%) conclusion: <i>We found that 68Ga-PSMA HBED-CC PET/MRI increases the diagnostic accuracy for localization of PCa in patients selected for RP.</i>	Pat.-Charakteristika beschrieben - ja ausbalanciert zwischen den Gruppen - n/a drop-out beschrieben - ja statist. Methoden beschrieben - ja Methoden, Definitionen beschrieben - ja ITT-Analyse - n/a Col /Sponsoring angegeben - ja Quadas: low - low - low - low	3
recurrent disease (+ / - histological verification)							
23495	Pfister D. Detection of recurrent prostate cancer lesions before salvage lymphadenectomy is more accurate with Ga-PSMA-HBED-CC than with F-Fluoroethylcholine PET/CT. Eur J Nucl Med Mol Imaging 2016.	pat.s with recurrent PCa before salvage lymphadenectomy; median 67 vs 65y; PSA 2,35 vs 2,7 (n.s.) 2009-2015 single-center study (Germany)	68Ga-PSMA (2 MBq/kg), PET 45 min after injection; 18FEC (3 MBq/kg), 1h after injection	retrospective study (n=28 PSMA vs 38 FEC, 308 vs. 378 LNs+local lesions) [tracer: 2009-2013 FEC, 2013-2015 PSMA] comparator: Fluoroethylcholine PET (different pat.) control: histology	detection rate / PPV (per pat.): 82,1% with PSMA-PET vs 78,9% with FEC-PET PSMA vs. FEC (lesion-based): sensitivity 86,9 vs 71,2; specificity 93,1 vs 86,9; PPV 75,7 vs 67,3; NPV 96,6 vs 88,8 (statistically significant: NPV) (accuracy: 91,9% vs 82,5%, significant)	Pat.-Charakteristika beschrieben - ja ausbalanciert zwischen den Gruppen - ja drop-out beschrieben - n/a statist. Methoden beschrieben - ja Methoden, Definitionen beschrieben - ja ITT-Analyse - ja Col /Sponsoring angegeben - ja Quadas: low - low - low - low	3

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23499	Herlemann A. Ga-PSMA Positron Emission Tomography/Computed Tomography Provides Accurate Staging of Lymph Node Regions Prior to Lymph Node Dissection in Patients with Prostate Cancer. Eur Urol 2016.	pat.s for LN staging before RP+LND, or before secondary LND; secondary: mean 62,8y (50-76); mean PSA 5,3 (0,3-18,8) [data split for initial (above) / recurrent (here)]	68Ga-PSMA (mean dose ?MBq) PET 1h after injection	prospective study (n=34 pat.s total, secondary LND n=14; 249 dissected LNs from 31 regions) comparison: CT control: histology	(overall (pLND+sLND) detection of LNM: sensitivity 84%, specificity 82%, PPV 84%, NPV 82% for PSMA-PET (vs. 65%, 76%, 75%, 67% for CT)) secondary LND per region: sensitivity 83%; specificity 63%; PPV 86%; NPV 56%; accuracy 77% (vs CT: 65%; 63%; 83%; 38%; 65%)	Pat.-Charakteristika beschrieben - ja ausbalanciert zwischen den Gruppen - n/a drop-out beschrieben - ja statist. Methoden beschrieben - nein Methoden, Definitionen beschrieben - ja ITT-Analyse - ja / n/a Col /Sponsoring angegeben - ja Quadas: low - low - low - low	2(+/-)
23510	Morigi JJ. Prospective Comparison of 18F-Fluoromethylcholine Versus 68Ga-PSMA PET/CT in Prostate Cancer Patients Who Have Rising PSA After Curative Treatment and Are Being Considered for Targeted Therapy. J Nucl Med 2015;56(8):1185-90.	pat.s with biochemical recurrence (initially managed with RP, RTx, or both) and considered for targeted Tx; mean 68y (54-81); PSA 1,74 (0,04-12); risk group: all intermed.-high	68Ga-PSMA (2 MBq/kg) vs. 18F-FMC (3,5 MBq/kg) scans 45 min after injection (first FMC, then PSMA within 30 d)	prospective cohort study (n=38) in-patient control comparator: Fluoromethylcholine PET no systematic histology control	detection: 68% of pat.s PET-positive scans, of these 54% PSMA-positive, 42% both PSMA- and FMC-positive, 4% (n=1) FMC-positive alone. overall detection rate in pat.s with PSMA significantly higher (p<0,001), correlated with PSA levels (<0,5ng/mL: 50% with PSMA vs. 12,5% with FEC; 0,5-2ng/mL: 69% vs. 31%; >2ng/mL: 86% vs. 57%) (predictor analysis: p<0,001 for both tracers) tumor-to-background ratio: higher for Ga-PSMA (28,6 vs. 9,4; p<0,001) histology (9 pat.s): all Ga-PSMA scans true-positive; FMC-only scan: false-positive (Ga-PSMA true-negative) impact on management (not detailed): in 63% of pat.s, in 54% due to PSMA results alone conclusion: <i>In patients with a low PSA (<0,5 ng/mL) evaluated for Tx with curative intent, Ga-PSMA-PET demonstrated a significantly higher detection rate for recurrent disease than FMC.</i>	Pat.-Charakteristika beschrieben - ja ausbalanciert zwischen den Gruppen - n/a drop-out beschrieben - n/a statist. Methoden beschrieben - ja Methoden, Definitionen beschrieben - ja ITT-Analyse - ja Col /Sponsoring angegeben - ja Quadas: low - low - low - low	2(+/-)
mixed initial, recurrent (histological verification in selected pat.s)							
23506	Hijazi S. Pelvic lymph node dissection for nodal oligometastatic prostate cancer detected by 68Ga-PSMA-positron emission tomography/computerized tomography. Prostate 2015;75(16):1934-40.	pat.s with biochemical recurrence after curative treatment (n=23) or before primary tx of high-risk PCa (n=12); mean 71y (49-77)	68Ga-PSMA (mean dose 300 MBq, range 140-392), PET 1h and 2h after injection	retrospective study (n=35 pat.s, 213 LNs from 17 pat.s with PET-positive nodal lesions) control: histology after pLND (in 17 pat.s - selected dependent on PET/CT outcome)	detection of indicative lesions: in 91,4% of pat.s (32 of 35) diagnostic accuracy: (based on 17 PET-positive pat.s with LND) sensitivity 94%; specificity 99%; PPV 89%; NPV 99,5% [no subgroup analysis for recurrent vs. initial]	Pat.-Charakteristika beschrieben - ja ausbalanciert zwischen den Gruppen - n/a drop-out beschrieben - n/a statist. Methoden beschrieben - ja Methoden, Definitionen beschrieben - ja ITT-Analyse - ja Col /Sponsoring angegeben - nein Quadas: unclear - low - low - low	3
23514	Afshar-Oromieh A. The diagnostic value of PET/CT imaging with the (68)Ga-labelled PSMA ligand HBED-CC in the diagnosis of recurrent prostate cancer. Eur J Nucl Med Mol Imaging 2015;42(2):197-209.	pat.: majority (92%) with suspected progressive disease (others: to exclude metastases before initial Tx); mean 67,6y±7,1 /median 68y; PSA 161,1±2347,1 /median 4,59)	68Ga-PSMA (median 161 MBq, range 40–400 MBq) PET 1h after injection	retrospective cohort study (n=319; 8% initial staging) control: histology (in 42 pat.s / 456 lesions - all of these pat.s with pathological tracer uptake)	detection of at least 1 PCa-characteristic lesion: in 82,8% of patients diagnostic accuracy (histology after LND in selected pat.s): 76,6% sensitivity; 100% specificity; 100% PPV; 91,4% NPV pat.-based sensitivity: 88,1% [no subgroup analysis for recurrent vs. initial] (8% primary in entire cohort - unknown regarding pat.s with LND + histology)	Pat.-Charakteristika beschrieben - ja ausbalanciert zwischen den Gruppen - n/a drop-out beschrieben - ja / n/a statist. Methoden beschrieben - ja Methoden, Definitionen beschrieben - ja ITT-Analyse - n/a Col /Sponsoring angegeben - ja Quadas: unclear - low - low - unclear	3

impact on patient management (no histology control)

23505	Sterzing F. (68)Ga-PSMA-11 PET/CT: a new technique with high potential for the radiotherapeutic management of prostate cancer patients. Eur J Nucl Med Mol Imaging 2016;43(1):34-41.	pat. for radiotherapy planning: 42 (74%) with biochemical recurrence after RT, 15 at initial diagnosis; median 70y (53-83); median PSA 3,0 (0,16-113) [mixed recurrent and Initial , no subgroup analyses] single-center study (Germany)	68Ga-PSMA (mean dose 175 MBq, range 77-350) PET/CT 1h after injection	retrospective cohort study (n=57 pat.) (comparison: CIM -bone scintigraphy, CT or MRI - not detailed)	lesion detection: 85 in 34 pat. (25=73,5% with recurrence, 9=26,5% initial) detection in conventional CT: at least 1 lesion in 12 (10 recurrent, 2 initial) of 57 (=21.1 %) pat.s influence on radiotherapeutic management: TNM staging of 29 of 57 (50.8 %) patients was changed after PSMA-11 PET/CT imaging. This included 4 (13.7 %) patients with changes at initial diagnosis and 25 (86.3 %) patients at the time of recurrence. changes: additional LN radiation in 62,1%, enlarged field irradiation+boost in 27,5%, systemic Tx instead of RT in 13,8%	Pat.-Charakteristika beschrieben - ja ausbalanciert zwischen den Gruppen - n/a drop-out beschrieben - n/a / nein statist. Methoden beschrieben - nein Methoden, Definitionen beschrieben - ja ITT-Analyse - n/a Col /Sponsoring angegeben - ja Quadas: low - low - unclear - low	3
23502	van Leeuwen PJ. (68) Ga-PSMA has a high detection rate of prostate cancer recurrence outside the prostatic fossa in patients being considered for salvage radiation treatment. BJU Int 2016;117(5):732-9.	pat.s with biochemical recurrence after RP, considered for RT, with no findings in CT; median 62y (57-67); PSA 0,2 (0,12-0,32) 2015 single-center study (Australia)	68Ga-PSMA (mean dose 169 MBq) PET 45 min after injection	retrospective study (n=70 pat.s) no direct comparison with CIM: all pat.s previously CT-negative	detection rates: PSMA-positive lesions, (n=53 detected) in 54% of pat.s impact of outcomes on pat.management: all pat.s were being considered for salvage RT to the prostate fossa - change of management directly attributable to PSMA-PET findings in n=20 (28,6%) of pat.s: enlarged volume of salvage RT in 25%, salvage LND instead of radiation in 5% (n=1), salvage RT to pLNs alone + ADT in 30%, stereotactic RT to a solitary LN alone in 20%, stereotactic RT to a lesion outside pelvis with or without ADT in 15%, salvage RT+ extrapelvic stereotactic RT in 5% changes in management defined as: none; moderate = change in delivery dose, site or volume of salvage RT; major = change of selected tx	Pat.-Charakteristika beschrieben - ja ausbalanciert zwischen den Gruppen - n/a drop-out beschrieben - n/a statist. Methoden beschrieben - ja Methoden, Definitionen beschrieben - ja ITT-Analyse - ja / n/a Col /Sponsoring angegeben - ja Quadas: unclear - low - low - low	3
23504	Shakespeare TP. Effect of prostate-specific membrane antigen positron emission tomography on the decision-making of radiation oncologists. Radiat Oncol 2015;10:233.	pat.s with indefinite convent. imaging, or high suspicion, or considered RTx; median 69y (52.83) [mixed recurrent and Initial , no subgroup analyses] 2015 single-center study (Australia)	68Ga-PSMA (mean dose 169 MBq) PET ?h after injection	retrospective study (n=54 pat.s) comparison: CIM	PSMA-PET vs CIM outcomes: in 46,3% PET positive, CIM negative; in 13% PSMA neg, conv.scans positive (31,5% double neg, 9,3% double pos) intended pat. management after CIM (following dept. protocol) vs. change in management after PSMA-PET: 53,7% of pat.s had a change in management due to PSMA-PET: of 50% planned for observation -> 18,5%, 9,3% planned for oligometastasis treatment -> 37%; change in RT management 46,3%, in ADT management 33,3%	Pat.-Charakteristika beschrieben - ja ausbalanciert zwischen den Gruppen - n/a drop-out beschrieben - n/a statist. Methoden beschrieben - nein Methoden, Definitionen beschrieben - nein ITT-Analyse - ja Col /Sponsoring angegeben - ja Quadas: low - unclear - low - low	3