Metaanalysis of ^{68}Ga-PSMA-11 PET Accuracy for the Detection of Prostate Cancer Validated by Histopathology

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[68]Ga-PSMA-11 PET is used to stage patients with prostate cancer. We performed an updated metaanalysis that separates imaging at the time of diagnosis and at the time of biochemical recurrence and focuses on pathology correlation in both populations. **Methods:** We searched the MEDLINE and EMBASE databases using the PRISMA statement. Quality was assessed using the Quality Assessment of Diagnostic Accuracy Studies tool 2. In total, 1,811 studies were screened, 58 were analyzed, 41 were included for qualitative synthesis, and 29 were included for quantitative analysis. A random-effect model and a hierarchical summary receiver-operating-characteristic model were used to summarize the sensitivity, specificity, positive predictive value (PPV), negative predictive value, and accuracy for pelvic lymph nodes in initial staging compared with pathology at prostatectomy and the PPV for lesions with pathologic correlation in those with biochemical recurrence. We also summarized the detection rate of ^{68}Ga-PSMA-11 in those with biochemical recurrence stratified by prostate-specific antigen (PSA) at the time of imaging. **Results:** The metaanalysis of ^{68}Ga-PSMA-11 at initial staging demonstrated a sensitivity and specificity of 0.74 (95% confidence interval [95% CI], 0.51–0.89) and 0.96 (95% CI, 0.85–0.99), respectively, using nodal pathology at prostatectomy as a gold standard. At biochemical recurrence, the PPV was 0.99 (95% CI, 0.96–1.00). The detection rate was 0.63 (95% CI, 0.55–0.70), with a PSA of less than 2.0 and 0.94 (95% CI, 0.91–0.96) with a PSA of more than 2.0. **Conclusion:** ^{68}Ga-PSMA-11 performed well for the localization of metastatic prostate cancer at initial staging and at the time of biochemical recurrence.

Key Words: molecular imaging; oncology; GU; PET; PSMA; prostate cancer

Staging of patients with prostate cancer using conventional imaging, typically MRI, CT, and bone scans, is limited by a low sensitivity for metastatic disease. Imaging using small molecules targeting the prostate-specific membrane antigen (PSMA) has demonstrated higher detection sensitivity than conventional imaging and other radiotracers such a choline-based agents (*1–3*). Although there is a large number of radiotracers that target PSMA, ^{68}Ga-PSMA-11 constitutes most of the literature.

Paralleling its widespread clinical adoption, a large number of publications on ^{68}Ga-PSMA-11 PET emerged over the past 4 y. Several metaanalyses have been performed. However, prior metaanalyses are limited by the heterogeneity of included studies: patients at initial diagnosis and at biochemical recurrence were combined, and the reference standard for lesion validation ranged from clinical experience and imaging without predefined criteria to surgery or biopsy in a few cases (*4,5*). However, to achieve the approval of PSMA ligands for PET imaging, systematic analysis of categorized evidence using histopathology validation is needed. Additionally, since the publication of initial metaanalyses, nearly 3 times as many patients have been reported in the literature.

We therefore focused on the 2 indications for which ^{68}Ga-PSMA-11 PET is most likely to be used clinically: initial staging of those with intermediate- to high-risk prostate cancer and localization of metastatic disease in those with biochemical recurrence after definitive therapy. We performed an updated metaanalysis, separating such patients and correlating findings with pathologic validation. We specifically focused on lesions with pathologic validation to support the potential approval of this drug.

MATERIALS AND METHODS

Search Strategy

The aim of this systematic review and metaanalysis was to summarize studies of staging and restaging ^{68}Ga-PSMA PET/CT or PET/MRI in patients with either localized or metastatic prostate cancer. A second aim was to determine the imaging test accuracy of the new PET/CT and PET/MRI method using tissue samples obtained through biopsy or surgery as the reference standard. We followed the PRISMA guidelines (*6*). The protocol for this metaanalysis was registered with PROSPERO (Centre for Reviews and Dissemination temporary identification number 99828).

The scientific literature databases MEDLINE and EMBASE were systematically searched in April 2018. Our systematic review included original research studies of initial staging and biochemical recurrence patients with ^{68}Ga-PSMA-11 PET. The search used several key words, including "prostate" or "prostate cancer" or "prostate neoplasm" or "prostate malignancy"; "positron emission tomography" or "PET"; and "prostate specific membrane antigen" or "PSMA" and "PSMA

PET" with "prostate." The search and article selection were performed by 2 independent evaluators. Each screened the titles and abstracts of the reports and selected appropriate original research articles that were published in English. Papers that were excluded included those published before 2012, studies of laboratory results, studies of neoplasms other than prostate cancer, studies of radiotracers that were not ^{68}Ga-PSMA-11, bioavailability studies, case studies, and studies with small sample sizes (<20 patients). Risk for bias in the studies was assessed using the QUADAS-2 methodology (7).

Outcome Measures

We looked at several outcome measurements from the papers reviewed. We calculated imaging test characteristics (sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy) for the detection of lesions in the prostate and pelvic lymph nodes and compared those values with the results of histopathologic biopsy or radical prostatectomy lymph node dissection. Sensitivity is defined as true-positives divided by true-positives plus false-negatives. Specificity is defined as true-negatives divided by true-negatives plus false-positives. PPV is defined as true-positives divided by true-positives plus false-positives. NPV is defined as true-negatives divided by true-negatives plus false-negatives. Accuracy is defined as true-positives plus false-positives divided by the population. We also calculated detection rate in patients by prostate-specific antigen (PSA) cutoffs that had positive imaging results by ^{68}Ga-PSMA-11. Detection rate is defined as the percentage of patients who have focal uptake on ^{68}Ga-PSMA-11 PET that is interpreted as being consistent with cancer.

Data Collection

Two reviewers independently extracted from the studies the radiation dose and uptake time for ^{68}Ga-PSMA PET/CT and PET/MRI. The reviewers also extracted the number of patients in each study, their age (median and mean), PSA (median and range), Gleason score, and initial treatment (androgen deprivation therapy, radiation therapy, or radical prostatectomy). The number of patients detected with PET imaging and the location of the metastases were also extracted.

Metaanalytic Methods

In our metaanalysis, we used a random-effect model (8) and a hierarchical summary receiver-operating-characteristic model (Stata, version 14.0; StataCorp). We summarized the sensitivity, specificity, PPV, NPV, and accuracy for pelvic lymph nodes in initial staging using pathology at prostatectomy as a gold standard, and for any lesion with pathologic correlation in biochemical recurrence patients. We also summarized the detection rate of ^{68}Ga-PSMA-11 in those with biochemical recurrence stratified by PSA at the time of imaging. All point estimates from the metaanalysis regression are reported as the mean and 95% confidence interval (95% CI).

RESULTS

Eligible Studies

Electronic searching of PubMed and EMBASE resulted in 2,178 articles (Fig. 1). Of these, 367 were duplicates, and 1,811 were reviewed at the abstract level, of which 1,763 were excluded. Subsequently, 59 papers were reviewed in full text, and 18 studies were excluded. Forty-one articles were deemed eligible for inclusion in the metaanalysis (Table 1). Nearly all papers imaged patients roughly 60 min after injection with a dose of 120–230 MBq. Risk for bias and applicability were assessed using the QUADAS-2 tool (Supplemental Fig. 1; supplemental materials are available at http://jnm.snmjournals.org). Significant biases existed in most papers reviewed. Bias concerned the selection of patients, as nearly all studies reported retrospective cohorts without predefined inclusion criteria, and lack of a histologic reference standard, with, again, most papers reporting only detection rates and only a few reporting results compared with histology. Overall, the performance of ^{68}Ga-PSMA-11 PET was fairly consistent across papers, with uptake times and doses in similar ranges. Most of the included papers were retrospective studies that had patients not enrolled on the basis of defined inclusion criteria, and only 4 of the studies were prospectively acquired (Table 1).

Initial Staging

Six studies in the metaanalysis included patients imaged at initial staging, of which 5 papers correlated pelvic nodal disease to pathology at radical prostatectomy, reporting a total of 266 patients between the 5 studies (Table 2). Most of the papers included only patients who were classified as at intermediate to high risk by the D'Amico classification (Table 2). Across the 5 studies, the metaanalysis of the sensitivity, specificity, PPV, NPV, and accuracy was 0.74 (95% CI, 0.51–0.89), 0.96 (95% CI, 0.85–0.99), 0.93 (95% CI, 0.86–0.99), 0.85 (95% CI, 0.75–0.93), and 0.86 (95% CI, 0.79–0.92), respectively (Fig. 1).

Biochemical Recurrence

Thirty-four studies in the metaanalysis included patients imaged at biochemical recurrence. First, we reviewed all included papers to determine whether results were reported using pathology as a gold standard and selected all patients for whom a pathology correlation was reported. Most papers on patients with biochemical recurrence did not have pathologic correlation for PSMA-avid lesions, and only detection rates were reported. In total, 256 patients were included across 15 studies with pathologic correlation, of which 233 were reported as true-positive lesions (Table 3). The metaanalysis of the sensitivity, specificity, PPV, NPV, and
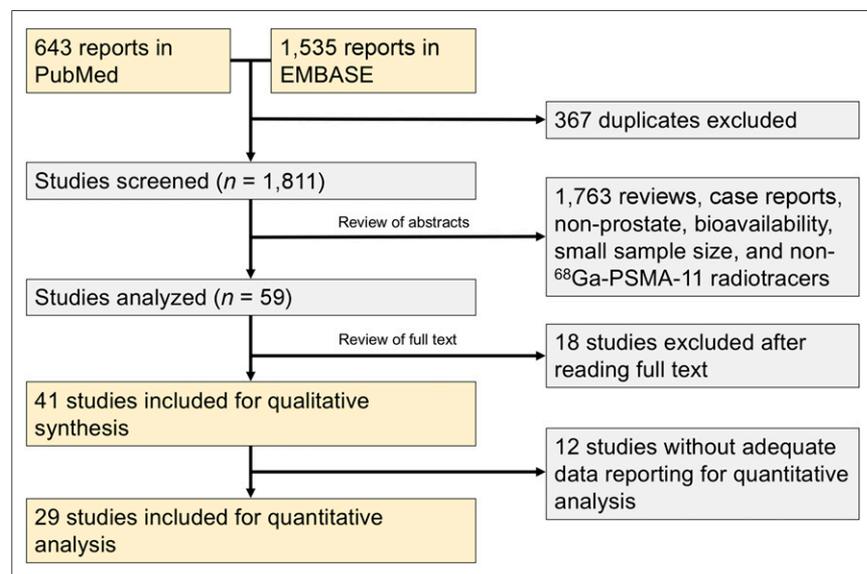
FIGURE 1. PRISMA flow diagram depicting process for selecting papers included in this metaanalysis.

TABLE 1
Characteristics of Studies Included

Study	Year	Patients (n)	Indication	Age (y)	PSA (ng/mL)	PSA range	Design	PET protocol Injected activity	Uptake time (min)
Afaq (*18*)	2018	100	BCR	67.9	NR	NR	R	159 MBq	60
Afshar-Oromieh (*19*)	2013	37	BCR	70	3.3	0.01–148	NR	121.0 MBq	60
Afshar-Oromieh (*3*)	2014	37	BCR	69.3	11.1	0.01–116	R	132.0 MBq	60
Afshar-Oromieh (*20*)	2014	20	BCR	69.6	2.62	0.51–73.60	NR	149.0 MBq	60
Afshar-Oromieh (*14*)	2015	319	IS + BCR	68	4.59	0.01–41395	R	168 MBq	60
Afshar-Oromieh (*13*)	2017	1007	BCR	68	12.1	0.01–1237	R	227 MBq	68
Afshar-Oromieh (*21*)	2017	112	IS + BCR	70	6.39	0.01–176.0	R	207 MBq	60
Bluemel (*22*)	2016	32	BCR	69	5.4	0.2–126.65	R	133 MBq	60
Budaus (*23*)	2016	30	IS	62	38.9	1.4–376	R	169.4 MBq	60
Byrne (*24*)	2018	81	BCR	63	0.87	0.22–8.7	NR	2 MBq/kg	60
Ceci (*25*)	2015	70	BCR	67	3.5	0.2–32.2	R	146.3 MBq	60
Demirkol (*26*)	2015	22	BCR	68	4.15	0.2–191.5	R	166.0 MBq	45
Eiber (*1*)	2015	248	BCR	70	1.99	0.2–59.4	R	155 MBq	54.2
Einspieler (*27*)	2017	118	BCR	72	6.4	2.2–158.4	R	2 MBq/kg	60
Fendler (*28*)	2016	21	IS	NR	NR	NR	R	192 MBq	58
Giesel (*29*)	2015	21	BCR	70	6.84	0.6–45	NR	176 MBq	60
Grubmüller (*30*)	2018	117	BCR	74	1.04	0.58–1.87	R	2 MBq/kg	60
Gupta (*12*)	2017	179	BCR	70	4.7	0.01–963	R	149 MBq	50
Habl (*31*)	2017	100	BCR	64	1	0.12–14.7	R	146 MBq	56
Henkenberens (*32*)	2017	23	BCR	80	2.75	0.52–8.92	R	79 MBq	60
Herlemann (*33*)	2016	34	IS + BCR	NR	NR	NR	R	NR	60
Herlemann (*34*)	2017	35	BCR	64	4.1	NR	R	NR	NR
Hope (*10*)	2017	126	BCR	69	5.9	NR	PR	199.8 MBq	63
Hruby (*35*)	2017	48	BCR	NR	5	2.04–39	NR	2.0 MBq/kg	60
Kranzbuhler (*9*)	2018	56	BCR	69	0.99	0.05–30	R	123 MBq	60
Lake (*36*)	2017	55	BCR	68.3	11.2	4–88	R	201.5 MBq	65
Maurer (*37*)	2016	130	IS	66	11.5	6.85–24.5	R	1.76 MBq/kg	59.8
Morigi (*2*)	2015	38	BCR	68	15.6	0.04–12.0	PR	2 MBq/kg	60
Pfister (*38*)	2016	28	BCR	67	2.35	0.04–8	R	2 MBq/kg	45
Rauscher (*39*)	2016	48	BCR	71	1.31	0.75–2.55	R	154 MBq	57
Rauscher (*40*)	2016	22	BCR	68	1.03	0.2–.72	R	147 MBq	60
Sachpekidis (*41*)	2016	31	BCR	71	2	0.1–130	NR	236 MBq	60
Sanli (*42*)	2017	109	BCR	71	6.5	0.2–640	R	185 MBq	60
Schiller (*43*)	2017	31	BCR	64	2.19	0.12–14.7	R	135 MBq	60
Schmidt-Hegemann (*44*)	2017	129	BCR	72	6.04	0.13–150.00	R	189 MBq	60
Siriwardana (*45*)	2017	35	BCR	67	0.2	0–1	R	NR	NR
Uprimny (*46*)	2017	203	BCR	68	1.44	0.14–96.0	R	150 MBq	60
Van Leeuwen (*11*)	2016	70	BCR	67	0.2	0.12–.32	PR	NR	NR
Van Leeuwen (*47*)	2017	30	IS	65	8.1	5.2–10.1	PR	NR	60
Verburg (*48*)	2016	155	BCR	70	4	0–2,000	R	190 MBq	60
Zhang (*49*)	2017	42	IS + BCR	69	52.31	7.20–348	R	131.7 MBq	60

BCR = biochemical recurrence; IS = initial staging; R = retrospective; PR = prospective; NR = not reported.
Means are provided when available; otherwise, medians reported.

TABLE 2
Overview of Included Initial Staging in 5 Studies Reporting Total of 266 Patients

Study	Year	D'Amico risk	n	Nodes/patient	TP	FP	TN	FN
Budaus (23)	2016	N	30	20.3	4	0	18	8
Herlemann (33)	2016	N	34	14.2	20	4	8	2
Maurer (37)	2016	Y	130	21*	27	1	88	14
Van Leeuwen (47)	2017	Y	30	17.8	7	1	18	4
Zhang (49)	2017	Y	42	14.8	14	1	26	1

*Reported as median.
TP = true positive; FP = false positive; TN = true negative; FN = false negative.
Number of nodes resected per patient is reported as mean. Papers that use intermediate to high risk by D'Amico classification for inclusion criteria are noted.

accuracy in all patients with pathology correlation were 0.99 (95% CI, 0.96–1.00), 0.76 (95% CI, 0.02–1.00), 0.99 (95% CI, 0.96–1.00), 0.76 (95% CI, 0.02–1.00), and 0.98 (95% CI, 0.94–1.00), respectively. Given that only PSMA-positive lesions were biopsied and the resultant low number of true- and false-negative lesions, the most relevant measurement in this population is the PPV (Fig. 2).

The reporting of detection rate was heterogeneous across PSA levels, and comparisons across all papers is limited within specific

TABLE 3
Overview of Included Biochemical Recurrence Studies Reporting 256 Patients in Total with Pathology Correlation

Study	Year	n	TP	FP	TN	FN
Afaq (18)	2018	11	10	1	0	0
Afshar-Oromieh (19)	2013	6	6	0	0	0
Afshar-Oromieh (3)	2014	7	7	0	0	0
Afshar-Oromieh (14)	2015	42	37	0	0	5
Ceci (25)	2015	7	6	1	0	0
Demirkol (26)	2015	3	3	0	0	0
Einspieler (27)	2017	6	6	0	0	0
Morigi (2)	2015	10	9	0	1	0
Eiber (1)	2015	12	12	0	0	0
Grubmüller (30)	2018	16	16	0	0	0
Pfister (38)	2016	28	22	6	0	0
Rauscher (39)	2016	22	22	0	0	0
Rauscher (50)	2016	48	42	3	3	0
Siriwardana (45)	2017	35	32	0	3	0
Van Leeuwen (11)	2016	3	3	0	0	0

TP = true positive; FP = false positive; TN = true negative; FN = false negative.
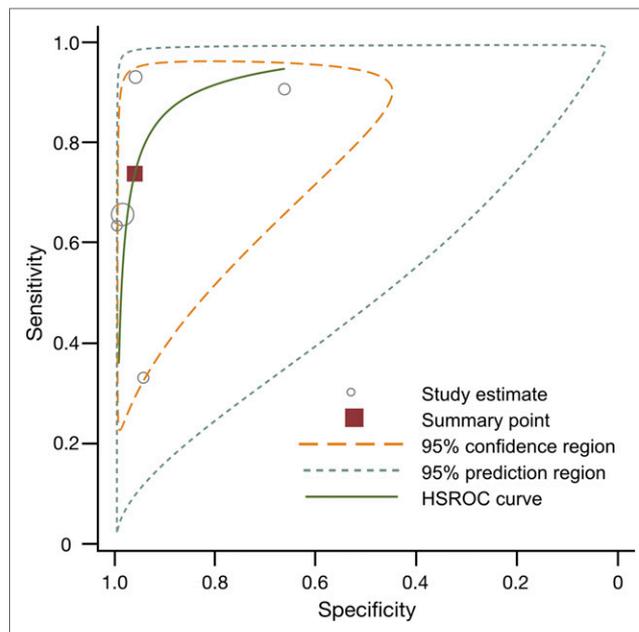
FIGURE 2. Summary of sensitivity, specificity, and hierarchical summary receiver-operating-characteristic (HSROC) curve for ^{68}Ga-PSMA-11 for initial staging of intermediate- to high-risk prostate cancer patients before prostatectomy for malignancy in pelvic nodes, with pathology at time of prostatectomy as gold standard. Effect size for sensitivity and specificity was 0.74 (95% CI, 0.51–0.89) and 0.96 (95% CI, 0.85–0.99), respectively. Size of circles represents size of individual studies.

PSA ranges. We grouped papers that reported results with a PSA of less than 2.0 ng/dL, between 2.0 and 5.0 ng/dL, and more than 5.0 ng/dL (Table 4). The metaanalysis for the detection rate for PSAs of less than 2.0 was 0.63 95% CI, (0.55–0.70). For PSAs of 2.0–5.0 the estimate was 0.89 (95% CI, 0.85–0.93) (Fig. 4), and for PSAs of more than 5.0 the estimate was 0.95 (95% CI, 0.92–0.97). We grouped papers that reported detection rates above and below PSAs of 2.0 ng/mL, and we provide a Forest plot of the results (Fig. 3).

Six papers reported detection sensitivity in patients with a PSA of less than 0.2 ng/mL, although few data were reported on pathology correlation in these papers (9–14). In these papers, 61 of 153 patients were reported as being positive for disease on PSMA PET, and the metaanalysis for the detection rate for PSAs of less than 0.2 was 0.4 (95% CI, 0.24–0.57). The largest study reported 32 of 68 positive for disease when the PSA level was less than 0.2 nd/dL (13).

DISCUSSION

This metaanalysis reaffirms the utility of ^{68}Ga-PSMA-11 PET for imaging of intermediate- to high-risk patients before definitive therapy and those who develop subsequent biochemical recurrence. In initial staging with pathology as a gold standard, ^{68}Ga-PSMA-11 had a sensitivity and specificity of 0.74 (95% CI, 0.51–0.89) and 0.96 (95% CI, 0.85–0.99), respectively, and in biochemical recurrence, the PPV was 0.99 (95% CI, 0.96–1.00). For those patients with biochemical recurrence, the detection rate was 0.63 (95% CI, 0.55–0.70) with a PSA of less than 2.0 and 0.94 (95% CI, 0.91–0.96) with a PSA of more than 2.0.

The sensitivity and specificity results in our study can be difficult to compare with other studies. Perera et al. reported a sensitivity and

TABLE 4

Overview of Detection Sensitivity for ^{68}Ga-PSMA-11 PET Stratified by PSA Level at Time of Imaging in 2,616 Patients

Study	Year	n	Positive patients/total			Detection rate by PSA		
			<2	2–5	>5	<2	2–5	>5
Afshar-Oromieh (19)	2013	37	9/10	9/13	14/14	90%	69%	100%
Afshar-Oromieh (14)	2015	311	55/90	64/73	140/148	61%	88%	95%
Afshar-Oromieh (13)	2017	960	301/451	201/227	266/282	67%	89%	94%
Bluemel (22)	2016	32	9/25	5/7		36%	71%	
Ceci (25)	2015	51	17/20	29/31		85%	94%	
Demirkol (26)	2015	22	5/7	15/15		71%	100%	
Eiber (1)	2015	248	102/124	120/124		82%	97%	
Einspieler (27)	2017	118	NR	36/44	71/74	NR	82%	96%
Gupta (12)	2017	177	24/56	117/121		43%	97%	
Habl (31)	2017	100	56/80	20/20		70%	100%	
Kranzbuhler (9)	2018	56	24/35	20/21		69%	95%	
Lake (36)	2017	55	14/18	35/37		78%	95%	
Hope (10)	2017	121	41/55	20/21	42/45	75%	95%	93%
Morigi (2)	2015	38	18/30	7/8		60%	88%	
Sachpekidis (41)	2016	31	7/15	12/16		47%	75%	
Sanli (42)	2017	25	5/16	9/9	NR	31%	100%	NR
Van Leeuwen (11)	2016	70	25/70	NR	NR	36%	NR	NR
Verburg (48)	2016	155	27/46	97/109		59%	89%	

PSA is in ng/mL.
NR = not reported.

specificity of 0.86 (95% CI, 0.37–0.98) and 0.86 (95% CI, 0.03–1.00), respectively, but merged data from both biochemical recurrence and initial staging patients (5). A second, more recent, metaanalysis performed only on the initial staging population closely mirrored our results, with estimated sensitivity and specificity of 0.71 (95% CI, 0.59–0.81) and 0.95 (95% CI, 0.87–0.99), respectively (15). von Eyben et al. reported the sensitivity and specificity for initial staging alone—0.70 (95% CI, 0.53–0.83)—and pooled specificity was 0.84 (95% CI, 24–99) (4). The point estimates from von Eyben more closely mirror our results, although our confidence intervals are narrower because of a greater number of patients published since the von Eyben article. von Eyben et al. did not perform a metaanalysis compared with histopathology in the biochemical recurrence setting.

In biochemical recurrence, we chose to report a PPV and not the sensitivity and specificity, as only PSMA-avid lesions are typically biopsied and therefore the subsequent calculated sensitivity and specificity are not relevant. Given that all patients with biochemical recurrence are considered to have disease, the detection rates may be used to approximate the sensitivity for metastatic disease in these patients. It is not possible to biopsy numerous nodes in patients, and therefore the accuracy of ^{68}Ga-PSMA-11 PET outside biopsied lesions is unknown. It is possible that ^{68}Ga-PSMA-11
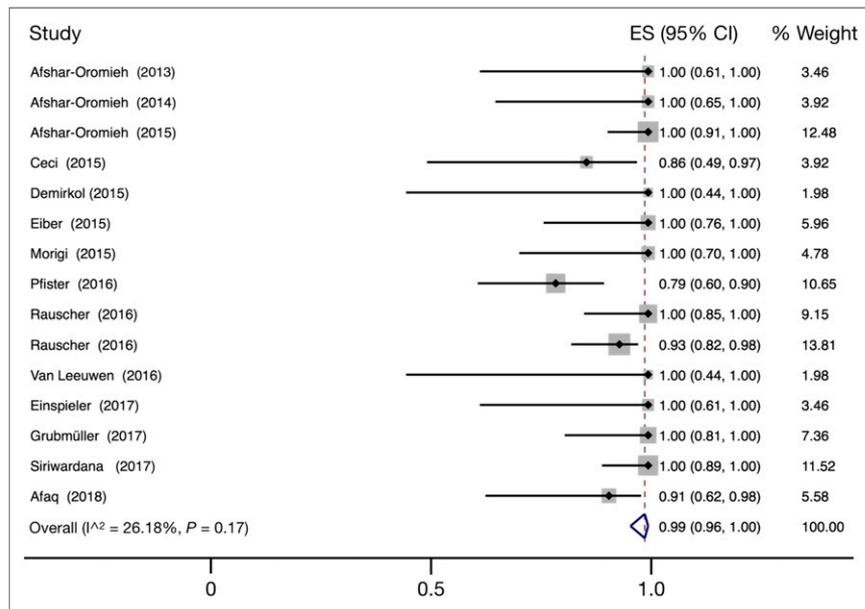
FIGURE 3. Forest plot of PPV for ^{68}Ga-PSMA-11 in biochemical recurrence patients who have pathologic correlation for gold standard comparison. Overall effect size (ES) for PPV is 0.99 (95% CI, 0.96–1.00). Size of squares represents size of individual studies. Reference numbers are in Table 3.
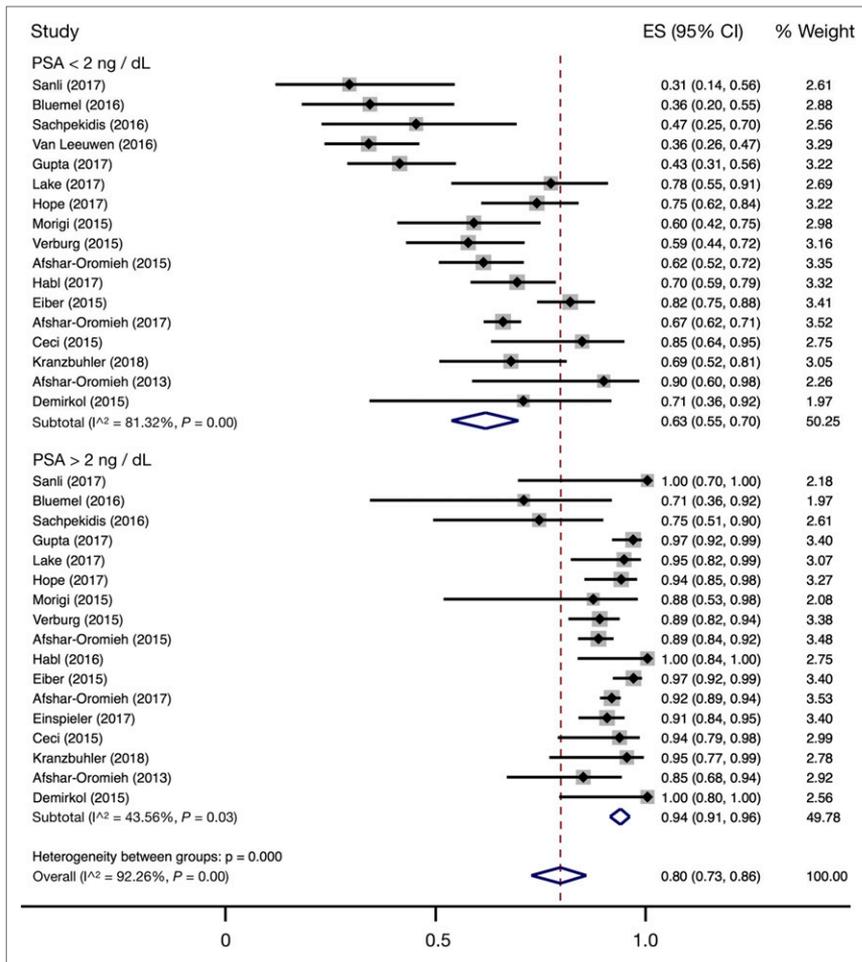
FIGURE 4. Forest plot of detection rate for ⁶⁸Ga-PSMA-11 in biochemical recurrence patients. Effect size (ES) for detection rate is 0.63 (95% CI, 0.55–0.70) for PSA < 2.0 ng/dL and 0.94 (95% CI, 0.91–0.96) for PSA > 2.0 ng/dL. Size of squares represents size of individual studies. Reference numbers are in Table 3.

PET sees only the tip of the iceberg in a large number of patients and that there may be several negative lesions that are not detected and not biopsied.

We chose to limit our analysis to lesions that have a biopsy correlate, because the definition of reference standards varied across the papers that used a composite endpoint of clinical and imaging follow-up. One of the main reasons for the lack of pathology correlation is the difficulty in obtaining a biopsy of lesions in patients with biochemical recurrence at low PSAs. The absence of gold-standard verification makes measurements of accuracy in this population difficult. Given that there is no agreed-upon follow-up composite gold standard, it is not possible to pool data from patients who do not have pathologic validation. Nonetheless, there was a relatively large number of patients (256) reported in the literature with pathologic correlation.

When reporting the results of research radiopharmaceuticals, it is important to consider how the data included may be used to support the subsequent radiopharmaceutical approval. In some cases, literature-based metaanalysis can be used in lieu of a second registration trial, and therefore the quality of studies is critical in support of future approvals. There are several things that are frequently not reported, including safety, inclusion and exclusion criteria, radiopharmaceutical synthesis methods, and quality control method. Using multiple readers and reporting interreader variability is also important in strengthening the value of the results. Dose ranges and uptake times are frequently reported by what is defined in the imaging protocol and not what occurred in individual patients. Another factor that is frequently underdescribed in the literature is the chemistry process (source of the precursor, synthesis module used, generator type, and quality assurance process used), which are important in the registration process so that regulatory bodies know that identical compounds were used across studies. There may be value in developing standard reporting guidelines for studies that evaluate the role of radiopharmaceuticals to ensure high-quality data in the literature moving forward. Furthermore, there may be value in developing harmonized release criteria across sites using the same compound in the research setting to help keep radiopharmaceutical products consistent across sites.

In addition to improved harmonization of reporting in PSMA PET articles, what would greatly strengthen the results in the literature are well-designed prospective studies that include a well-defined gold standard that can be used to measure accuracy. Although this is an optimistic goal, we readily admit that in the setting of biochemical recurrence, this goal may be difficult to achieve given the general frequent inability to obtain histologic verification.

The main limitation of our study is the heterogeneity that exists within the included studies. For example, patients are grouped by varying PSA ranges in the literature, which makes determining the reported sensitivities within various PSA ranges difficult to pool across articles. Additionally, most studies assessing imaging in those with biochemical recurrence did not include pathology correlation and simply reported detection sensitivities. Finally, the interpretive criteria are not defined in all papers, and in the past year reporting standards have been proposed that may limit variability in readings (*16,17*). One of the main reasons for the heterogeneity across studies using ⁶⁸Ga-PSMA-11 is that most reports are from institutions using the compound under a compassionate-use setting, and so no formal prospective protocols were developed or followed.

CONCLUSION

⁶⁸Ga-PSMA-11 performed well for the localization of metastatic prostate cancer. In initial staging, with pathology as a gold standard, ⁶⁸Ga-PSMA-11 had a sensitivity and specificity of 0.74 (95% CI, 0.51–0.89) and 0.96 (95% CI, 0.85–0.99). In biochemical recurrence, with pathology as a gold standard, the PPV was 0.99 (95% CI, 0.96–1.00). The detection rate was 0.63 (95% CI,

0.55–0.70) with a PSA less than 2.0 and 0.94 (95% CI, 0.91–0.96) with a PSA greater than 2.0.

DISCLOSURE

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