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Pilot Trial Comparing the Performance of ^{68}Ga-PSMA-11 PET/CT to ^{18}F-PSMA-1007 PET/CT in the Detection of Prostate Cancer Recurrence in Men with Rising PSA Following Radical Prostatectomy

Jesse Ende[1,4]; Amer Amin[2,3,4]; Gemma Sheehan-Dare[1]; Thomas Cusick[2]; Bao Ho[1]; Joanne Keane[1]; Andrew Nguyen[1]; Victor Liu[1]; Jonathan Lee[1]; Lyn Chan[1]; Peter Lin[4,5,6]; Andrew Chen[1]; Karen Fullard[1]; Phillip Stricker[2,4]; Louise Emmett[1,4]*

[1]Nuclear Medicine Department, St Vincent's Hospital Sydney, Sydney, Australia.

[2]St Vincent's Prostate Cancer Centre, Sydney, Australia.

[3]Garvan Institute of Medical Research, Sydney, Australia.

[4]School of Medicine, University of New South Wales, Sydney, Australia.

[5]Department of Nuclear Medicine and PET, Liverpool Hospital Sydney, Sydney, Australia.

[6]School of Medicine, Western Sydney University, Sydney, Australia.

***Corresponding Author(s): Louise Emmett**

Department of Nuclear Medicine, St Vincent's Hospital Sydney, 390 Victoria Street Darlinghurst, 2010, NSW, Australia.

Tel: +61-02-8382-1111, Fax: +61-02-8382-1824;

Email: louise.emmett@svha.org.au

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Abstract

Objective: Prostate-Specific Membrane Antigen (PSMA) PET/CT is increasingly used in the staging and management of prostate cancer. The most published tracer in PSMA PET/CT is ^{68}Ga-PSMA-11 (PSMA-11). However, ^{18}F-PSMA-1007 (PSMA-1007) has several potential advantages over PSMA-11, including non-urinary clearance, which may improve accuracy of prostate cancer detection in the prostate fossa. The aim of this study is to prospectively compare the diagnostic accuracy of PSMA-11 with PSMA-1007 in the detection of locally recurrent and metastatic prostate cancer in men with Biochemical Recurrence (BCR) following Radical Prostatectomy (RP).

Materials and methods: Men with a rising PSA after RP were prospectively recruited to undergo both PSMA-11 and PSMA-1007 PET/CT. Images were reported by two experienced readers (a third in the case of discordance) blind to clinical and imaging information. Clinical, pathological, and follow-up data were recorded. PSMA-11 was used to guide treatment, and a composite reference standard formulated to evaluate diagnostic value.

Keywords: ^{68}Ga-PSMA-11 PET/CT; ^{18}F-PSMA-1007 PET/CT; PSMA PET; radical prostatectomy; prostate cancer; biochemical recurrence.

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Results: 14 men underwent both PSMA-11 and PSMA-1007 PET/CT within two weeks (mean PSA at imaging 0.21 ± 0.15 ng/mL). 8/14 men had negative results on both modalities. 2/14 men had lesions on PSMA-11 alone, 1/14 had a lesion on PSMA 1007 alone (false positive) and 3/14 men had lesions on both. 8 lesions were detected. PSMA-11 detected 7, whilst PSMA-1007 detected 5. Based on the reference standard, 7/8 were considered true positives; a bone lesion on PSMA-1007 alone was considered false positive. 3 lesions were identified in the prostate fossa on PSMA-11 compared with one on PSMA-1007. Kappa scores for inter-observer agreement were higher in PSMA-11 compared to PSMA-1007 group.

Conclusion: Detection rates in PSMA-1007 PET/CT were not superior to PSMA-11 in men with BCR post-RP. Despite low renal excretion, detection of local recurrences in the prostate fossa was not improved with PSMA-1007.

Introduction

Prostate Specific Membrane Antigen (PSMA) is a cell surface protein which is significantly overexpressed in prostate cancer cells when compared to other PSMA expressing tissues or normal prostate tissue. PSMA PET/CT has shown promising results in detecting men with Biochemical Recurrence (BCR) and is now recommended in those with a PSA >0.2 ng/mL after Radical Prostatectomy (RP) [1].

^{68}Ga-PSMA-11 (PSMA-11) is the most published radiopharmaceutical used worldwide in PET scanning for the detection of prostate cancer [2]. However, PSMA-11 has a number of characteristics that limit its potential as the ideal imaging agent. It is renally excreted with high bladder activity, which may conceal low volume, low intensity recurrences in the prostate fossa. Significant ureteric activity may also lead to false positive results [3].

^{18}F-PSMA-1007 (PSMA-1007) is a small molecule peptide with a moderate lipophilic profile, and is primarily excreted via the hepatobiliary route. It has the advantage of non-urinary excretion over PSMA-11, which technically allows for better visualisation of the prostate fossa and pelvis. Furthermore, Fluorine-18 has a shorter positron range and longer half-life (110 minutes) then Gallium-68, with the potential to increase Tumour to background activity and subsequently improve tumoral detection rates [4,5].

Although PSMA-1007 and PSMA-11 have been compared in the staging setting [6], at present there has been no direct comparison in men with BCR post-RP. This prospective pilot study aimed to assess the detection rate of PSMA-1007 PET/CT compared to PSMA-11 PET/CT in the setting of low PSA biochemical recurrence, particularly in the surgical fossa.

Methods

Study population and protocol

Institutional ethics approval was granted for this prospective study (HREC/18/SVH/55) and informed consent was obtained from all participants between April and July 2019. Men with biochemical relapse after RP were recruited. Fourteen men were recruited for this pilot study. All men underwent both PSMA-11 and PSMA-1007 PET/CT within a two week period. Men then underwent standard of care treatment after multidisciplinary team discussion and were followed up with PSA measurements at 6 months and 12 months. Subsequent treatments undertaken were documented.

Radiopharmacy and PET acquisition

Radiopharmaceutical production of PSMA-1007 and PSMA-11 was undertaken in accordance with good local production quality control requirements, and release criteria. PSMA-11 was produced on-site with a Good Laboratory Practices compliant procedure using a TRASIS® automated radio-pharmacy cassette. ^{18}F-PSMA-1007 was produced using a single-step radiofluorination GMP-compliant automated synthesis module (ABX, Radeberg, Germany) on a GE FastLab. Radiopharmacy quality control for both tracers was undertaken including high-pressure liquid chromatography and thin-layer chromatography methods to test the radiochemical and chemical purity.

A dose of 3.5 MBq/kg of ^{18}F-PSMA-1007 was injected intravenously into the patient. This was followed by whole body imaging at a mean time of 109 ± 25 minutes, after which whole body PET/CT image acquisition was performed.

For ^{68}Ga-PSMA-11 PET/CT a dose of 2 MBq/kg was used. Scanning was undertaken after a mean time of 71 ± 18 minutes. Patients were encouraged to remain well hydrated and to void urine before their study. Furosemide 20mg intravenously was given to all men undergoing PSMA-11 scanning at the time of radioisotope injection where it was not clinically contraindicated (administered to twelve patients).

All PET/CT imaging was undertaken using a Phillips® Ingenuity TOF – PET / 64 slice CT scanner (Phillips, Amsterdam, Netherlands). A non-contrast-enhanced CT scan was performed 45 minutes post tracer injection using the following CT parameters: Slice thickness of 2 mm, soft tissue reconstruction kernel, 120 keV and 50 mAs, pitch of 0.828, 600 mm FOV, and a 512 matrix. Immediately after CT scanning, a whole-body PET scan was acquired for 2 minutes per bed position. The emission data were corrected for randoms, scatter, and decay using Phillips® Body-dynamic.xml and Body.xml reconstruction protocol.

Reporting of imaging

Both the PSMA-1007 and PSMA-11 PET images were reported prospectively by two experienced nuclear medicine consultants who were blinded to clinical and imaging results. In the event of discordance, a third reader reviewed the images and the results of the majority of reviewers was viewed as final. All images were viewed and reported using Phillips® Fusion Viewer. Data for all PSMA scans was analysed visually and semi-quantitatively. Visual analysis included a four-point certainty scoring scale (definitely negative, equivocal probably negative, equivocal probably positive, and definitely positive), as well as anatomical site and size of lesions. Semi-quantitative analysis was undertaken using an automated standardized maximum uptake value (SUV max). Additionally, the SUV max of the ureter, bladder, gluteus maximus, and liver was measured in each patient to obtain background SUV readings. For each detected lesion the Tumour-To-Background Ratio (TBR) was calculated using the ratio between SUV max of the lesion and SUV max of gluteus maximus. Both SUV max and TBR were utilised in data analysis.

Treatments

For the purposes of the study, the PSMA-11 PET/CT was taken as standard practice and the PSMA-1007 PET/CT was considered exploratory. PSMA-11 results were provided to the investigating clinicians. In the event that the PSMA-1007

detected a lesion that was not detected on the PSMA-11 PET/CT, the treating clinician was informed. If a biopsy was undertaken and further management ensued, this data was collected by the trial investigators.

Composite reference standard

To evaluate the accuracy of PSMA-1007 and PSMA-11 PET/CT in detecting recurrence, a composite reference standard was developed using clinical outcome data (Figure 1). In summary, a scan was defined as true positive, false positive, true negative, and true positive by comparing imaging findings with targeted treatment response data. Biopsy correlation was intended, but not undertaken in this patient cohort due to small volume disease. Treatment response was taken as a greater than 50% reduction in PSA to targeted therapy from baseline to latest follow up. A true positive was determined if PSA declined following therapy at a site that was positive on the PSMA PET. If the PSA declined in the absence of therapy, this was interpreted as a false positive or true negative result depending on the imaging findings.

Statistical analysis

Baseline characteristics are reported as mean ± SD. Cohen's kappa was used to measure inter-observer agreement for both modalities. SUV max of lesions were compared using non-parametric paired testing and reported as mean ± SD, while background SUV max and TBR were compared with parametric paired testing and reported as mean ± SD. Where a lesion was absent on one modality, but not the other, the SUV max was set as 1.0 (background) for paired testing comparison. All tests were two-sided and a p-value of 0.05 or less was taken as statistically significant.

Results

Baseline characteristics

Patient characteristics are summarised in table 1. All 14 men enrolled onto the study had undergone radical prostatectomy. Two men had undergone adjuvant radiotherapy after RP. No men were on ADT at the time of imaging. All 14 men underwent both PSMA-1007 and PSMA-11 PET/CT for a rising PSA at a mean of 61.6 ± 59.6 months after their primary RP. Mean PSA at the time of PET scanning was 0.21 ± 0.15 ng/mL.

Comparison of ^{18}F-PSMA-1007 to ^{68}Ga-PSMA-11

6/14 men (43%) had positive PET scans. Of these, 5/14 (36%) patients had positive PSMA-11 scans, and 4/14 (29%) had positive PSMA-1007 scans. 8/14 (57%) were negative on both scans.

On lesional analysis, 8 lesions were detected across both modalities, with 2 patients having 2 lesions identified and the remainder having a single lesion. 3 lesions were in the prostate fossa, 2 in regional lymph nodes, 2 in vertebral bodies and one in the liver.

PSMA-11 detected 7 lesions, whilst PSMA-1007 detected 5. 3 lesions identified on PSMA-11 but not PSMA-1007 were in the pelvis (2 in the prostate fossa). The single lesion seen on PSMA-1007 but not PSMA-11 was in the T5 vertebral body (false positive on reference standard). Specifically, no additional lesions were identified in the prostate fossa on PSMA-1007 that were not also identified on PSMA-11. Anatomical sites of disease are detailed in (Table 2).

Using the reference standard 7/8 lesions were classified as true positives. The remaining lesion was only detected by PSMA-1007 (vertebral) and was determined to be a false positive as PSA declined during follow-up without treatment.

Treatment response

8/14 men underwent targeted therapy after PSMA imaging. Of the 8 men that had negative scans on both PSMA-1007 and PSMA-11, 2/8 underwent salvage fossa radiotherapy, and 1/8 received radiotherapy and ADT. All 3 men had a positive treatment response with a PSA reduction >50%. The remaining 5/8 did not undergo definitive treatment and have instead had their PSA monitored. All 5 had an increase in PSA by 0.18+/-0.19 ng/mL (mean follow-up PSA 0.36 ± 0.33).

Of the 6 men with a positive finding on PSMA PET, 3/6 underwent salvage fossa radiotherapy, 1/6 had stereotactic radiotherapy to a presacral lymph node and 1/6 underwent a hemihepatectomy and is now on hormone therapy. The only patient with a positive PSMA-1007 but negative PSMA-11 scan (in the T5 vertebral body) had a decline in PSA without any treatment.

Tumour and background measurements

There was no significant difference between the SUV max of those lesions detected on both PSMA-1007 and PSMA-11 scans (SUV max 5.4 ± 7.0 vs 7.0 ± 10.2, p= 0.469) (Figure 2). Similarly, there was no significant difference in the TBR for lesions identified on both scans (9.3 ± 12.7 vs 17.1 ± 24.1, p= 0.167) (Figure 3). The background SUV readings of the ureter and bladder were significantly lower for PSMA-1007 compared to PSMA-11 (ureter 1.45 ± 0.56 vs 2.25 ± 1.02, p= 0.0038; bladder 3.46 ± 2.28 vs 9.67 ± 6.47, p = 0.0042). Conversely, the liver and gluteus maximus had significantly higher background SUV measurements on the PSMA-1007 images (liver 11.82 ± 4.21 vs 5.37 ± 1.30, p<0.0001; gluteus maximus 0.55 ± 0.20 vs 0.36 ± 0.08, p= 0.004) (Figure 4).

Inter-observer variation

The Kappa score between the two readers was 0.44 (95%CI 0-0.907) for PSMA- 1007 compared to 0.84 (95%CI 0.534-1.0) for PSMA-11. A third read was required for 6 patients due to discordance regarding the presence of lesions between the first two readers; five for PSMA-1007 and two for PSMA-11 (one patient required a third read for both).

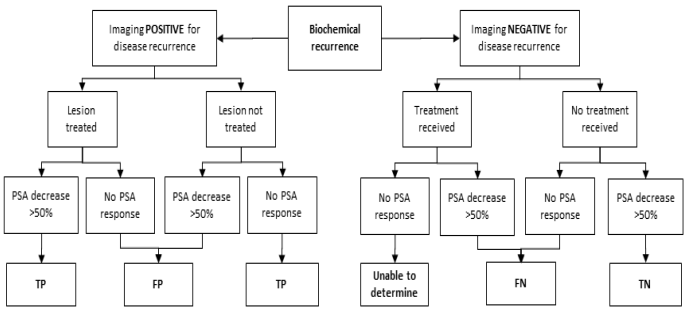

Figure 1: The composite reference standard used to classify detected lesions as either true positive, true negative, false positive, or false negative based on imaging findings and PSA outcome data.

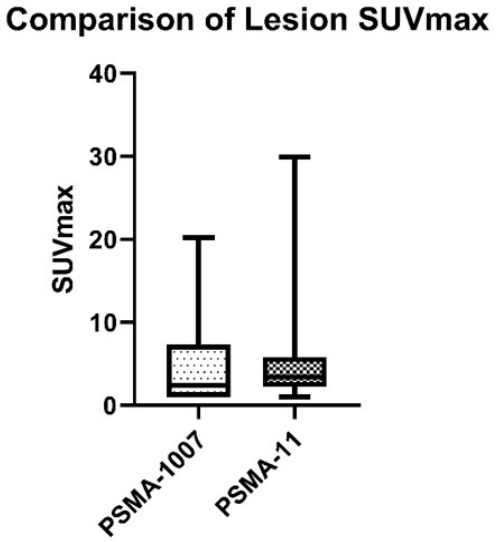

Figure 2: Comparison of the SUV max measurements for lesions detected on PSMA-1007 and PSMA-11 imaging.

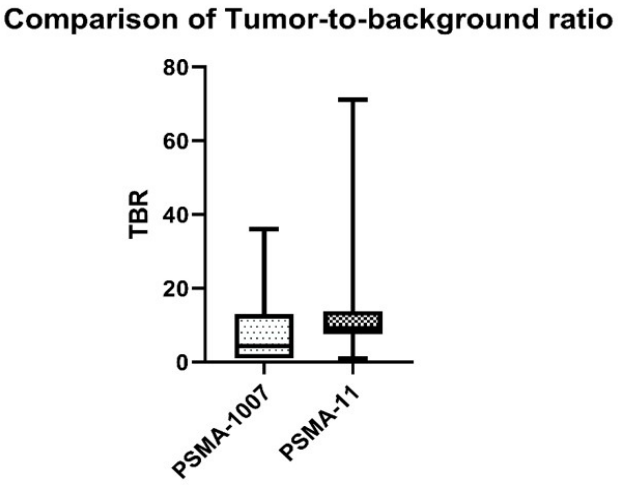

Figure 3: Comparison of the tumour-to-background ratio for lesions detected on PSMA-1007 and PSMA-11 imaging.

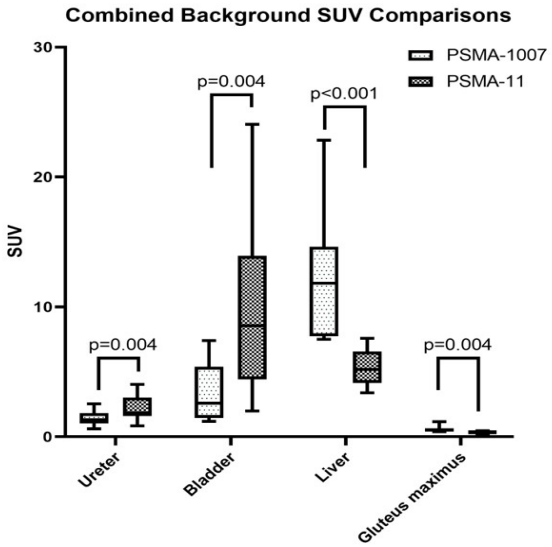

Figure 4: Comparison of background SUV readings between PSMA-1007 and PSMA-11 imaging for the ureter, bladder, liver, and gluteus maximus.

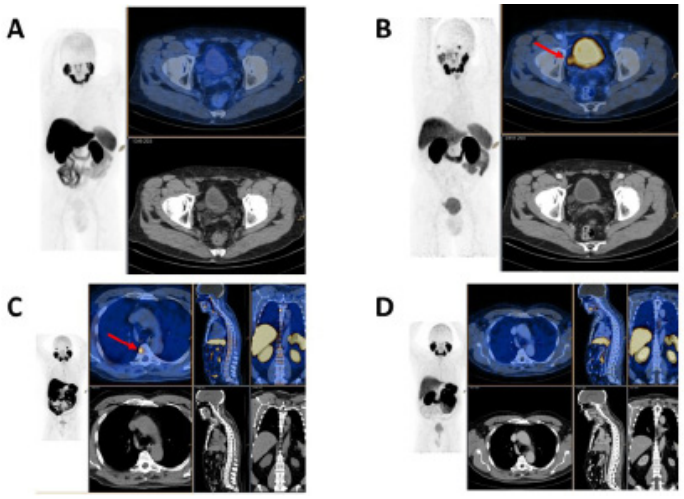

Figure 5: An example of discordance between the PSMA-1007 and PSMA-11 findings. The first patient had a lesion in the prostate bed (SUV max 2.2) which was not detected on PSMA-1007 **(A)** but was seen on PSMA-11 **(B)**. The second patient had a lesion detected (SUV max 5.1) in the T5 vertebral body on PSMA-1007 **(C)** but not PSMA-11 **(D)**.

Table 1: Baseline characteristics of the study population. (PSMA = prostate specific membrane antigen, PSA = prostate specific antigen).

Characteristic	Mean ± SD
n	14
Age at radical prostatectomy (years)	61.8 ± 7.1
Tumour stage • T2 • T3a • T3b	 6 6 2
Gleason score • 6/7 • 8/9	 7 7
Adjuvant treatment prior to PSMA PET • Nil • Radiotherapy	 12 2
Mean time between PSMA PET and RP (months)	61.6 ± 59.6
PSA at time of PSMA PET (ng/mL)	0.21± 0.15

Table 2: A summary of the lesions identified on either PSMA-1007 or PSMA-11 imaging modalities and treatment responses compared against the composite reference standard. (TBR= tumour-to-background ratio, PSA= prostate specific antigen).

Lesion	PSMA-11 SUV (TBR)	PSMA-1007 SUV (TBR)	Received adjuvant treatment?	>50% reduction in PSA	Composite reference standard outcome
Seminal vesicle bed	3.4 (9.19)	2.4 (4.36)	Yes	Yes	TP
Seminal vesicle bed	2.2 (9.17)	-	Yes	Yes	TP
Seminal vesicle bed	3.3 (8.05)	-	Yes	Yes	TP
Presacral node	3.4 (7.56)	-	Yes	Yes	TP
L5 vertebral body	5.8 (13.81)	7.3 (13.04)	Yes	Yes	TP
T5 vertebral body	-	5.1 (8.64)	No	No	FP
Liver segment II	29.9 (71.19)	20.2 (36.07)	Yes	Yes	TP
Right thigh lymph node	9.9 (24.15)	28.2 (56.4)	Yes	Yes	TP

Discussion

Diagnostic imaging targeting the PSMA receptor has been shown to change both management decisions and patient outcomes in the setting of biochemical recurrence following radical prostatectomy [7-9]. It has a high positive predictive value at low PSA levels, compared to conventional imaging or alternative PET agents [10,11].

It is now recommended that PSMA imaging be undertaken at a PSA ≥ 0.2ng/mL in men with BCR post-RP in both European and Australian guidelines [12]. However, up to a third of men will have negative scan results if imaged at a PSA level at which salvage fossa radiotherapy still has a good chance of cure [9]. These men with negative scans on PSMA-11 in prospective trials have been shown to respond well to salvage fossa radiotherapy, suggesting a significant number of false negative scans [13]. This is likely due to non-aggressive low PSMA expression disease which may be difficult to detect in the prostate fossa with adjacent high bladder counts. PSMA-1007, with a fluorine-18 radiotracer and limited renal excretion, has been considered as an alternative to PSMA-11 due to properties that may overcome these limitations. However, in this small pilot study, there was no improved detection of surgical fossa recurrences with PSMA-1007 compared to PSMA-11.

To date there has been no study comparing PSMA-11 and PSMA-1007 for the detection of lesions in patients with biochemical recurrence after radical prostatectomy. Technically PSMA-1007 has significant advantages over PSMA-11 for locoregional prostate cancer recurrence in this patient group. It has a high binding affinity for PSMA, its level of renal excretion is minimal, and its shorter positron deceleration distance improves the spatial resolution of the resultant images [4]. These characteristics make it potentially ideal for detecting low volume disease around the surgical fossa that previously went undetected on PSMA-11.

However, PSMA-1007 in our study detected only one lesion in the prostate fossa or pelvis, compared with a total of four detected by PSMA-11 (Figure 5). In a study by Giesel et al., 251 patients with BCR after RP underwent PSMA-1007 scanning (without PSMA-11 comparison) [14]. In their cohort, 81% of patients had positive scans, with 24.7% of patients having local recurrence and 40.6% of patients having pelvic lymph node recurrence. However, the median PSA level at imaging was higher in the Giesel study (1.2 ng/mL), in part explaining the higher locoregional detection rate. Our group has previously reported that PSMA-11 scanning was positive in the prostate fossa in 21% of men with a median PSA 0.28 ng/mL, similar to the PSA level in this study [9]. This pilot trial suggests that PSMA-1007 may not outperform PSMA-11 in detection of these lesions in this patient cohort, even with lower bladder and ureter background SUV measurements, particularly now that furosemide administration as a diuretic is now routine practice for improving pelvic lesion detection in PSMA-11 [15].

There was no difference in the SUV max of the identified lesions between the PSMA-1007 and PSMA-11 scans. This is similar to the comparative study by Giesel et al., who found similar intensities between DCFPYL and PSMA-1007 in a head on comparison of 12 men, and similar detection rates [16].

PSMA-1007 had greater inter-observer variability, and previous publications of PSMA-1007 have highlighted the high background activity in bone leading to a larger number of equivocal results [17,18]. This is interesting when also considering that of the patients with both scans negative for disease, the three men who received targeted salvage fossa radiotherapy all showed a PSA response, implying the presence of micro-metastatic disease that was unable to be detected by either modality. Taken together, this suggests that false-negative results with PSMA PET imaging are not so much due to the choice of PSMA ligand, but rather that these small volume local recurrences may be low-PSMA expressing and non-aggressive. Detection of these non-aggressive local recurrences may require an alternative ligand such as bombesin [19,20].

A further limitation of this study is the use of a composite reference standard endpoint rather than a biopsy for analysis. This is due to the obvious difficulties in biopsying low volume recurrences, but limits interpretation of the accuracy of findings. However, previous publications have confirmed the high specificity of PSMA imaging for prostate cancer and thus the high rate of true positives is not surprising. Additionally there is a small number of patients in this pilot trial, and larger studies would be beneficial.

Conclusion

PSMA-11 PET/CT detected more lesions than PSMA-1007 in patients with low PSA and BCR following RP. Despite low urinary

excretion, detection of local recurrences was not improved with PSMA-1007. PSMA-11 remains a suitable modality for imaging patients in this population.

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