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A Phase 2/3 Prospective Multicenter Study of the Diagnostic Accuracy of Prostate Specific Membrane Antigen PET/CT with ^{18}F-DCFPyL in Prostate Cancer Patients (OSPREY)

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Abstract

Purpose: Prostate specific membrane antigen-targeted positron emission tomography/computerized tomography has the potential to improve the detection and localization of prostate cancer. OSPREY was a prospective trial designed to determine the diagnostic performance of ^{18}F-DCFPyL-positron emission tomography/computerized tomography for detecting sites of metastatic prostate cancer.

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Materials and Methods: Two patient populations underwent ^{18}F-DCFPyL-positron emission tomography/computerized tomography. Cohort A enrolled men with high-risk prostate cancer undergoing radical prostatectomy with pelvic lymphadenectomy. Cohort B enrolled patients with suspected recurrent/metastatic prostate cancer on conventional imaging. Three blinded central readers evaluated the ^{18}F-DCFPyL-positron emission tomography/computerized tomography. Diagnostic performance of ^{18}F-DCFPyL-positron emission tomography/computerized tomography was based on imaging results compared to histopathology. In cohort A, detection of pelvic nodal disease (with specificity and sensitivity as co-primary end points) and of extrapelvic metastases were evaluated. In cohort B, sensitivity and positive predictive value for prostate cancer within biopsied lesions were evaluated.

Results: A total of 385 patients were enrolled. In cohort A (252 evaluable patients), ^{18}F-DCFPyL-positron emission tomography/computerized tomography had median specificity of 97.9% (95% CI: 94.5%—99.4%) and median sensitivity of 40.3% (28.1%—52.5%, not meeting prespecified end point) among 3 readers for pelvic nodal involvement; median positive predictive value and negative predictive value were 86.7% (69.7%—95.3%) and 83.2% (78.2%—88.1%), respectively. In cohort B (93 evaluable patients, median prostate specific antigen 11.3 ng/ml), median sensitivity and positive predictive value for extraprostatic lesions were 95.8% (87.8%—99.0%) and 81.9% (73.7%—90.2%), respectively.

Conclusions: The primary end point for specificity was met while the primary end point for sensitivity was not. The high positive predictive value observed in both cohorts indicates that ^{18}F-DCFPyL-positive lesions are likely to represent disease, supporting the potential utility of ^{18}F-DCFPyL-positron emission tomography/computerized tomography to stage men with high-risk prostate cancer for nodal or distant metastases, and reliably detect sites of disease in men with suspected metastatic prostate cancer.

Keywords

prostatic neoplasms; neoplasm staging; neoplasm metastasis; molecular imaging

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Current conventional imaging modalities, including contrast-enhanced computerized tomography, magnetic resonance imaging and ^{99m}Tc-methylene diphosphonate bone scintigraphy, are suboptimal for detecting sites of metastatic prostate cancer across the various states of the disease.[1–6] Although ^{11}C-choline and ^{18}F-fluciclovine are FDA-approved radiopharmaceuticals for positron emission tomography in men with suspected recurrent disease, their diagnostic performance declines in patients with low prostate specific antigen (<2.0 ng/ml),[7] and neither agent is approved in the United States for initial staging of newly diagnosed PCa. The FDA recently approved ^{68}Ga-PSMA-11 at limited sites for patients with suspected PCa metastasis who are potentially curable by surgery or radiation therapy, as well as for patients with suspected PCa recurrence based on elevated serum PSA levels.[8] A widely available PCa-targeted agent with improved diagnostic performance to detect pelvic nodal and extrapelvic metastases is needed to better guide the staging and treatment planning of PCa patients.

^{18}F-DCFPyL is a PET ligand that targets the extracellular domain of prostate specific membrane antigen with high affinity, enabling its use in diagnostic and therapeutic

applications.[9–17] The objective of the OSPREY trial was to evaluate the diagnostic performance of ^{18}F-DCFPyL-PET/CT validated against a histopathology truth standard in men with either newly diagnosed PCa or known metastatic disease.

METHODS

Trial Design

OSPREY was a prospective, multicenter, multi-reader, open-label, phase 2/3 study (NCT02981368) in 2 patient populations: cohort A enrolled men with newly diagnosed high-risk PCa planned for radical prostatectomy with pelvic lymph node dissection, and cohort B enrolled men with presumptive radiological evidence of recurrent or metastatic PCa on conventional imaging and considered feasible for biopsy. The Standards for Reporting of Diagnostic Accuracy flow diagrams for the trial are shown in figures 1 and 2. The study was conducted in accordance with the Declaration of Helsinki and the International Council for Harmonization Guidelines for Good Clinical Practice. It was approved by the Institutional Review Board at each participating institution. Written informed consent was obtained from all patients.

Study Population

Men ≥18 years of age with histologically confirmed prostate adenocarcinoma were eligible. Cohort A included patients with high-risk PCa (clinical stage ≥T3a or PSA >20 ng/ml or Gleason score ≥8) who were planned for RP with PLND.[18] Patients with prior androgen deprivation therapy were excluded. Cohort B included patients with radiological evidence of local recurrence or metastatic disease on anatomical imaging (CT, MRI) or whole-body bone scintigraphy and in whom lesion(s) were amenable to biopsy.

Interventions

Baseline conventional imaging.—Whole-body bone imaging and contrast-enhanced CT of the chest, abdomen and pelvis (or noncontrast CT chest and gadolinium-enhanced MRI of the abdomen and pelvis) were obtained 4 to 6 weeks prior to ^{18}F-DCFPyL-PET/CT. All baseline conventional images were submitted to a central imaging core laboratory for assessment.

^{18}F-DCFPyL dosing and PET/CT.—Both cohorts received a single dose of 9 mCi (333 MBq) ^{18}F-DCFPyL (supplementary Appendix, table 8, https://www.jurology.com) via intravenous injection, followed by PET/CT 1 to 2 hours thereafter. Patients voided prior to imaging, and PET and noncontrast low-dose CT images were acquired from the mid thigh through the skull vertex. All ^{18}F-DCFPyL-PET/CT scans were also submitted to the central imaging core laboratory.

Central imaging review.—Three independent board-certified nuclear medicine physicians blinded to all clinical information and other radiographic assessments evaluated the ^{18}F-DCFPyL-PET/CT scans and biopsy images (for cohort B patients). A separate blinded board-certified radiologist evaluated all baseline conventional images. Truth table

classifications for all central ^{18}F-DCFPyL-PET/CT results vs. local histopathology for all patients are shown in the supplementary Appendix, table 1 (https://www.jurology.com).

Histopathology truth standard.—Pathology specimens were evaluated locally by pathologists who were blinded to the imaging results. For cohort A, nodal packets collected at PLND were specifically analyzed. All patients underwent PLND using an extended template dissection (external iliac vein, obturator fossa and internal iliac vessels). The number of positive pelvic lymph nodes and size(s) of the largest metastatic foci of the positive node(s) were recorded. For cohort B, biopsied tissue of at least 1 lesion identified on conventional imaging before ^{18}F-DCFPyL-PET/CT was obtained using standard methods and evaluated for the presence or absence of PCa, other neoplasm or deemed unevaluable.

Safety Outcomes

Safety assessments included monitoring of adverse events and serious adverse events, occurring after ^{18}F-DCFPyL administration through the date of surgery or biopsy, and within 21±7 days after the protocol-mandated biopsy. AEs were graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events version 4.03.

Efficacy Outcomes

In men with high-risk PCa planned for surgery (cohort A), the clinical utility of ^{18}F-DCFPyL-PET/CT was based on the diagnostic performance to determine pelvic lymph node metastases, with specificity and sensitivity at the patient level as co-primary end points. Positive and negative predictive values, detection of extrapelvic (M1) disease and detection of the primary tumor within the prostate were secondary end points. No minimum size or standard uptake value criterion was used as a threshold for considering a node positive by PET/CT, while any disease confirmed microscopically was considered positive histopathology.

In men with suspected recurrent or metastatic PCa with at least 1 lesion on conventional imaging accessible for biopsy (cohort B), the sensitivity and PPV of ^{18}F-DCFPyL-PET/CT for extraprostatic lesions were calculated, including analyses by region and PSA level. In cohort B, since only presumptive PCa lesions were targeted for biopsy, specificity and NPV were not evaluated because of the high prevalence of disease in this cohort.

Statistical Methods

Patients in cohort A who did not undergo RP with PLND were excluded from the primary analysis. Patients in cohort B who did not undergo biopsy, who had no pathology or imaging results, or in whom the biopsied lesion was a second primary tumor were also excluded. Determination of sample size is described in the study protocol (supplementary Appendix, https://www.jurology.com). Summaries were created using SAS® version 9.4. Cohort A provided 80% power to test the null hypotheses for specificity at 80% and for sensitivity at 40% (the co-primary end points). Formal hypothesis testing was not employed for cohort B end points. Point estimates and 2-sided 95% confidence intervals were provided for all diagnostic performance parameters. Interreader and intrareader agreement also were assessed (supplementary Appendix, table 2, https://www.jurology.com).

RESULTS

Patients were enrolled between November 2016 and July 2018 across 8 sites in the United States and 2 sites in Canada. A total of 462 patients were screened; 77 were screen failures and 385 men were enrolled (268 in cohort A and 117 in cohort B; supplementary Appendix, figure, https://www.jurology.com). Baseline demographic and clinical characteristics for each cohort prior to PET imaging and PET imaging details are described in the table.

Safety

^{18}F-DCFPyL was safe and well-tolerated. Of 385 patients 51 (13.2%) experienced at least 1 adverse event; the most frequent were dysgeusia (2.6%), headache (2.3%), and fatigue (1.3%). Seven patients (1.8%) experienced a serious adverse event; none was considered related to ^{18}F-DCFPyL.

Cohort A

Of the 268 men with high-risk PCa imaged with ^{18}F-DCFPyL-PET/CT, 252 had evaluable histopathology for determining the diagnostic performance of ^{18}F-DCFPyL-PET in identifying pelvic nodal metastases. The specificity co-primary end point was met, as the lower limits of the 95% CIs for all readers exceeded the prespecified 80% success threshold (fig. 3 and supplementary Appendix, table 3, https://www.jurology.com). Of the 190 (75.4%) men with pathologically negative pelvic lymph nodes, specificity across all 3 readers ranged from 96.3% to 98.9% (lower limits of the 95% CI: 93.6%—96.0%). The sensitivity end point was not met, as the lower bounds of the 95% CI (19.2%—29.7%) did not reach the success threshold of 40%. Of the 62 men (24.6%) with at least 1 pathologically proven pelvic nodal metastasis, sensitivity for the 3 readers ranged from 30.6% to 41.9%. Results for PPV and NPV were 78.1%—90.5% (lower bounds of 95% CI: 63.8—69.9) and 81.4%—83.8% (lower bounds of 95% CI: 76.4%—78.9%), respectively. Primary tumor in the prostate gland was identified on ^{18}F-DCFPyL-PET/CT by the blinded readers in 95.2%—99.3% of cases. Reader agreement results are summarized in the supplementary Appendix, table 2 (https://www.jurology.com).

In a post hoc sensitivity analysis, we evaluated PET/CT for detection of nodal metastases >5 mm in diameter based on the assumption that smaller tumor deposits are below PET detection limits.[19] After exclusion of the 27 patients whose largest nodal metastasis was ≤5 mm, sensitivity and specificity both met the success criteria, and high PPV and NPV results were preserved (fig. 3 and supplementary Appendix, table 3, https://www.jurology.com).

The median results of the 3 ^{18}F-DCFPyL-PET/CT readers for detecting pelvic lymph node metastases were compared with CT or MRI; ^{18}F-DCFPyL-PET/CT demonstrated threefold higher PPV (86.7% vs. 28.3%), higher specificity (97.9% vs. 65.1%) and slightly higher NPV (83.2% vs. 77.8%), and similar sensitivity (40.3% vs. 42.6%; supplementary Appendix, table 4, https://www.jurology.com). At least 1 reader detected extrapelvic lesions by ^{18}F-DCFPyL-PET/CT in 12.3% (33/268) of high-risk patients, potentially up staging them from clinical M0 to M1 disease. Figure 4 provides an example of this up staging, with complete reader agreement.

Cohort B

A total of 117 men were enrolled in cohort B, of whom 37% (43/117) were hormone-therapy naïve. At the time of study entry, conventional imaging showed findings suggesting only locoregional disease in 28% of patients (33/117) and suggesting distant disease in the remainder. Of the patients 27.4% (32/117) presented with PSA levels <2 ng/ml.

Sensitivity and PPV of ^{18}F-DCFPyL-PET/CT for detecting sites of PCa metastasis or locoregional recurrence were evaluated (93 patients). Median sensitivity was 95.8% (95% CI: 87.8%—99.0%) and median PPV was 81.9% (95% CI: 73.7%—90.2%; fig. 5 and supplementary Appendix, table 5, https://www.jurology.com). Across the readers, false-negative results ranged from 1.4%—7.1% and false-positive results from 12.2%—18.8%. Although the cohort included lesions that presumptively represented recurrent or metastatic disease on conventional imaging, 23.9% of patients (22/92) had negative histopathology for PCa on biopsy (supplementary Appendix, table 5, https://www.jurology.com).

Sensitivities and PPVs for detection of PCa within different anatomical regions were also determined. All 93 evaluable patients underwent extraprostatic biopsy: 20 (21.5%) had pelvic lymph nodes, 19 (20.4%) had extrapelvic lymph nodes, 44 (47.3%) had osseous lesions and 10 (10.8%) had distant visceral/soft tissue lesions (fig. 5, A and B, and supplementary Appendix, table 6, https://www.jurology.com). ^{18}F-DCFPyL-PET/CT demonstrated >88% sensitivity and ≥75% PPV in confirming PCa within all sites of disease and extent of disease spread (eg pelvic and extrapelvic lymph nodes [N1 and M1a], bone [M1b] and distant visceral/soft tissue lesions [M1c]) at the region level. Reader agreement results are summarized in the supplementary Appendix, table 2 (https://www.jurology.com).

Sensitivities and PPVs of ^{18}F-DCFPyL-PET/CT across different baseline PSA levels were also evaluated (fig. 5, C and supplementary Appendix, table 7, https://www.jurology.com). In men with low PSA (<2 ng/ml), sensitivity ranged from 88.9%—100% and PPV ranged from 61.5%—88.9%. Relative to conventional imaging (CT/MRI, bone scintigraphy) findings, ^{18}F-DCFPyL-PET/CT indicated that distant metastasis was likely in 19/33 patients (57.6%) and unlikely in 18/82 patients (22.0%).

DISCUSSION

The OSPREY study was designed to evaluate the diagnostic performance of ^{18}F-DCFPyL-PET/CT in staging men with high-risk PCa and for detecting metastases against histopathology from pelvic lymphadenectomy or biopsy. In cohort A, ^{18}F-DCFPyL-PET/CT demonstrated improved diagnostic performance over conventional imaging modalities with comparable sensitivity (~40%), but threefold higher PPV for detecting pelvic nodal metastasis. The performance characteristics of conventional imaging were comparable to those reported in a large meta-analysis of CT and MRI by Hövels et al.[5]

The sensitivity of ^{18}F-DCFPyL-PET/CT did not meet its prespecified end point in cohort A. One explanation is that no size threshold was set for defining a positive lesion considered detectable by PET, while any lesion was considered positive by microscopy on pathology regardless of size. Hence, the design of the cohort A analysis yielded false-negative

results due to PET being less sensitive than histopathology. Because of the inherent spatial resolution limitations of PET,[19] this difference in sensitivity for small lesions is not surprising. Nonetheless, clinicians can be confident that a ^{18}F-DCFPyL-avid node, even if it is nonenlarged on conventional imaging, likely does represent disease, and thus ^{18}F-DCFPyL-PET/CT provides clinically meaningful improvements compared to currently available imaging modalities.

Cohort B included patients with more advanced PCa who had suspected recurrent and/or metastatic disease.[20] The clinical utility of ^{18}F-DCFPyL-PET/CT was confirmed across multiple subcategories of recurrent and metastatic PCa. Notably, ^{18}F-DCFPyL-PET/CT detected presumptive metastatic disease in 57.6% of cohort B patients (19/33) who had no evidence of distant disease on conventional imaging. The demonstration that these patients had distant disease is important clinical information that can directly impact the strategy for disease management.[21] Furthermore, the high sensitivity and PPV of ^{18}F-DCFPyL-PET/CT based on biopsied lesions, spanned across all sites of metastases, including nodal, osseous and visceral/soft tissue. Indeed, the true-positive rate might even be higher than demonstrated, given that biopsies of small metastatic lesions, especially in bone, are notoriously difficult and often do not yield tumor.

Suboptimal diagnostic performance of conventional imaging in patients with PCa may lead to ineffective undertreatment or unnecessary overtreatment. The proper selection of therapies is contingent on accurate staging to define the patient's "true" extent, location and burden of disease.[22,23] Molecular imaging, such as PSMA-targeted PET, may help guide clinicians by more accurately demonstrating disease burden and distribution than is currently done by conventional imaging and by providing useful information on tumor biology.[10,24–26] New imaging agents that can reliably detect and localize both nodal and distant metastatic lesions, especially early, at low PSA values, are desirable. Such early detection opens the door to reexamining current treatment paradigms, risk assessments and the need to prospectively re-test the application of therapies using molecular imaging rather than standard imaging modalities. In this study, ^{18}F-DCFPyL-PET/CT exhibited the ability to detect PCa lesions, both at initial diagnosis and recurrence after treatment failure, and could enable improved disease management for patients with PCa.

While the advantages of PSMA-PET/CT over conventional imaging for initial staging of high-risk PCa have been recently published by Hofman et al,[27] the use of a histopathological truth standard for all patients and a blinded, independent reader paradigm in OSPREY is a distinct feature of this study in establishing diagnostic performance when compared to that study, which used a composite panel of histopathological, imaging, biochemical and clinical data to serve as evidence of truth. The OSPREY sensitivity and specificity results also are comparable to those from the similarly designed pivotal trial for ^{68}Ga-PSMA-11.[28]

Limitations of this study are several-fold. Chief among them is intrinsic to any diagnostic study in which the gold standard is histopathology. As mentioned above, ^{18}F-DCFPyL-PET/CT is much less sensitive than microscopy, and therefore the false-negative rate will rise with diminishing lesion size as seen in cohort A. For the clinician caring for a high-risk patient before surgery, this means that a positive result is likely a true-positive, but a negative

one neither excludes disease nor obviates nodal dissection. False-positives would also be possible in cohort A if nodes identified on PET were not part of the nodal dissection at surgery, although these were seemingly rare. By the same token, false-positives could occur in cohort B, given that PET can demonstrate lesions that are difficult to localize and may be embedded within sclerotic bone. Furthermore, because of practical and ethical concerns about performing multiple research biopsies on patients, cohort B only required 1 biopsy per patient, regardless of the PET findings, and so there are no data on unbiopsied lesions. Additionally, the impact of ^{18}F-DCFPyL-PET/CT on patient management was not prospectively evaluated in either cohort. Lastly, whether use of ^{18}F-DCFPyL-PET/CT will impact survival or other outcomes remains to be determined.

CONCLUSIONS

^{18}F-DCFPyL-PET/CT demonstrated high PPV, NPV and specificity for pelvic lymph node involvement in men with newly diagnosed high-risk PCa, despite low sensitivity compared with histopathology. Additionally, in men post-therapy with suspected recurrent or metastatic disease, ^{18}F-DCFPyL-PET/CT demonstrated high sensitivity and PPV in all sites of disease and across all PSA ranges. In both clinical settings, ^{18}F-DCFPyL-PET/CT provides reliable information to help improve staging of PCa, compared to conventional imaging.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations and Acronyms

AJCC	American Joint Committee on Cancer
CT	computerized tomography
FDA	U.S. Food and Drug Administration
MRI	magnetic resonance imaging
NPV	negative predictive value
PCa	prostate cancer
PET	positron emission tomography
PLND	pelvic lymph node dissection
PPV	positive predictive value

PSA	prostate specific antigen
PSMA	prostate specific membrane antigen
RP	radical prostatectomy

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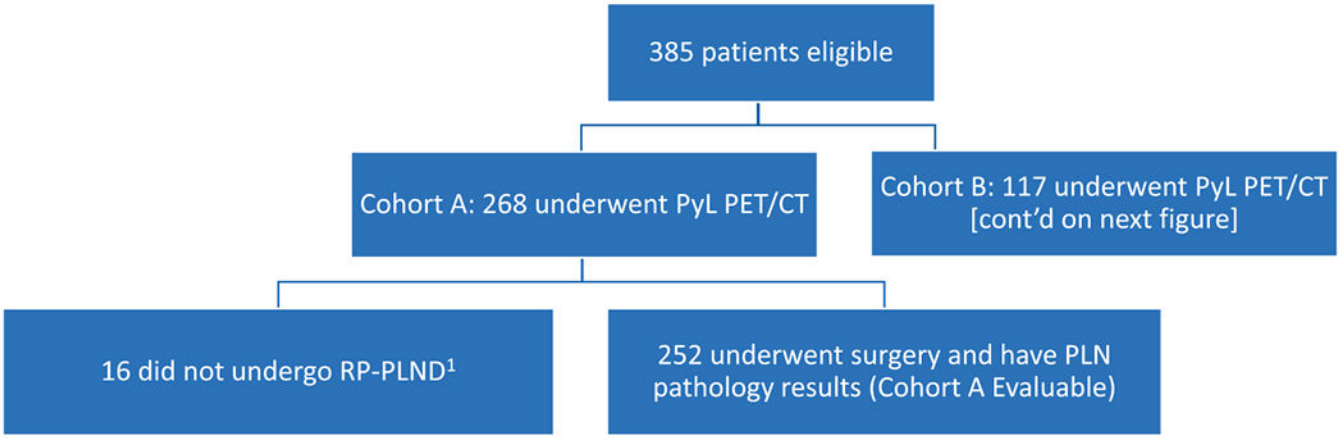

Figure 1.

Standards for Reporting of Diagnostic Accuracy flow diagram, cohort A (see supplementary Appendix figure for details, https://www.jurology.com). *PLN*, pelvic lymph node. *PyL*, ^{18}F-DCFPyL.

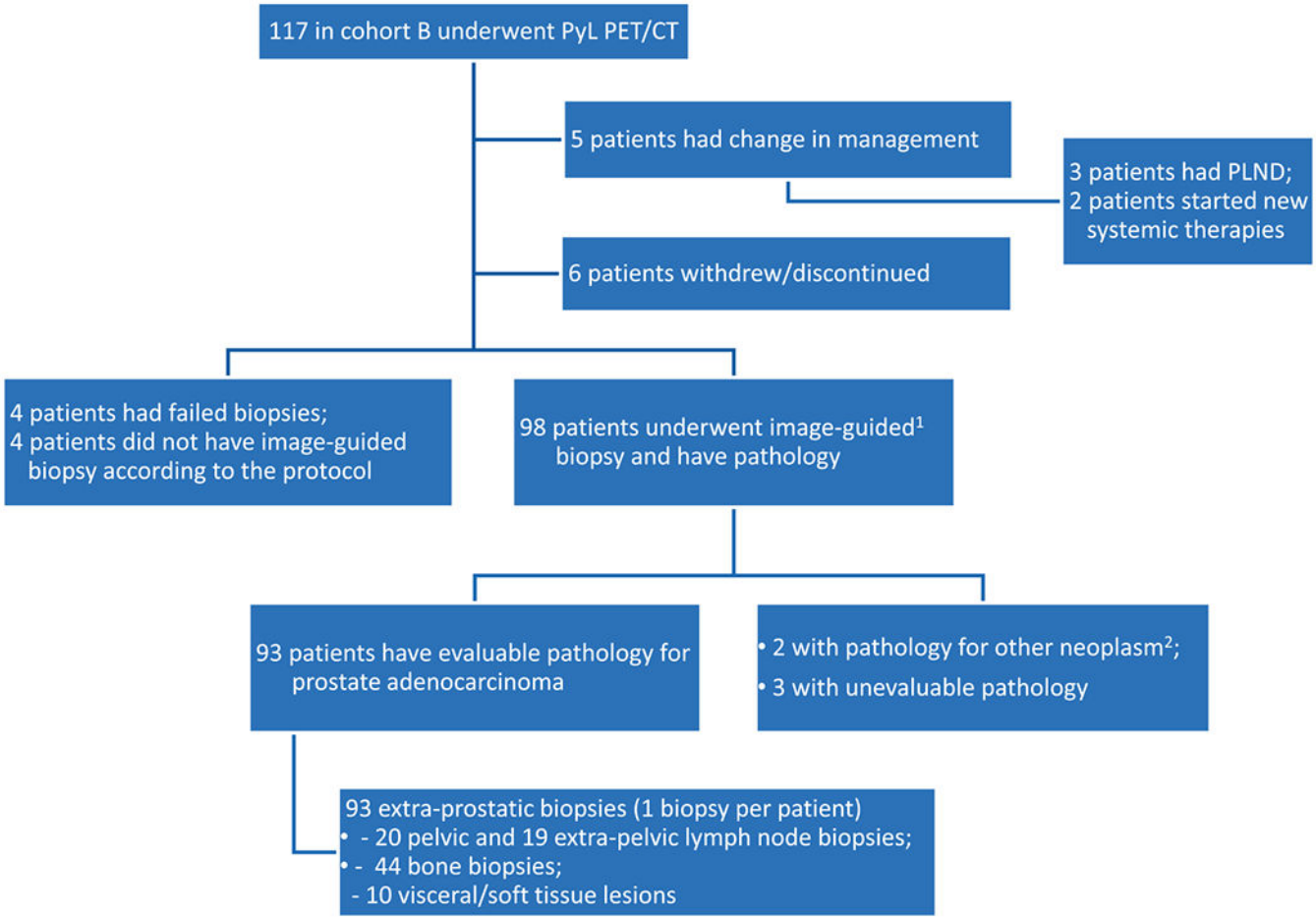

Figure 2.

Standards for Reporting of Diagnostic Accuracy flow diagram, cohort B.[1] Image-guided biopsy as specified by protocol included CT/MRI or ultrasound-guided biopsy.[2] While negative for prostate cancer, ^{18}F-DCFPyL (*PyL*) scan correctly identified malignancy, and therefore these rare cases were neither considered to be false-positive for prostate cancer nor true-positive for cancer, but rather as nonevaluable.

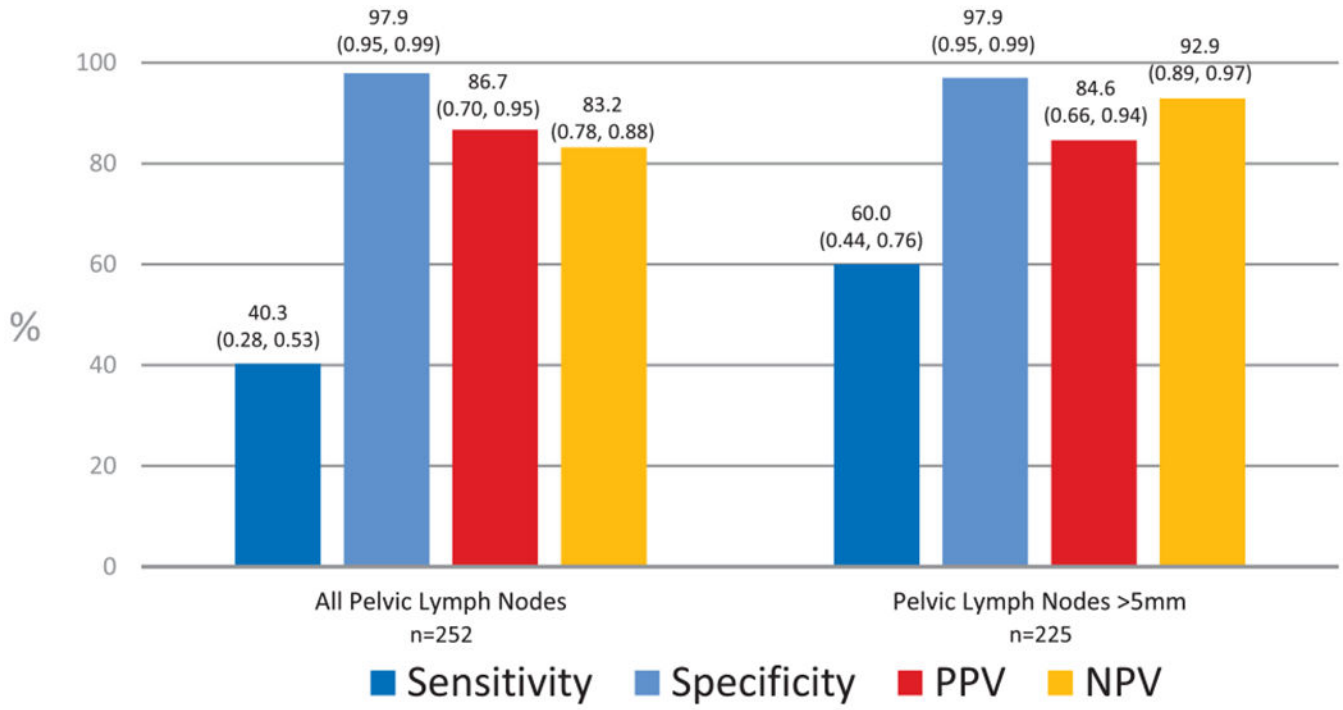

Figure 3.

^{18}F-DCFPyL-PET/CT diagnostic performance (median of 3 independent readers) in high-risk prostate cancer in cohort A.

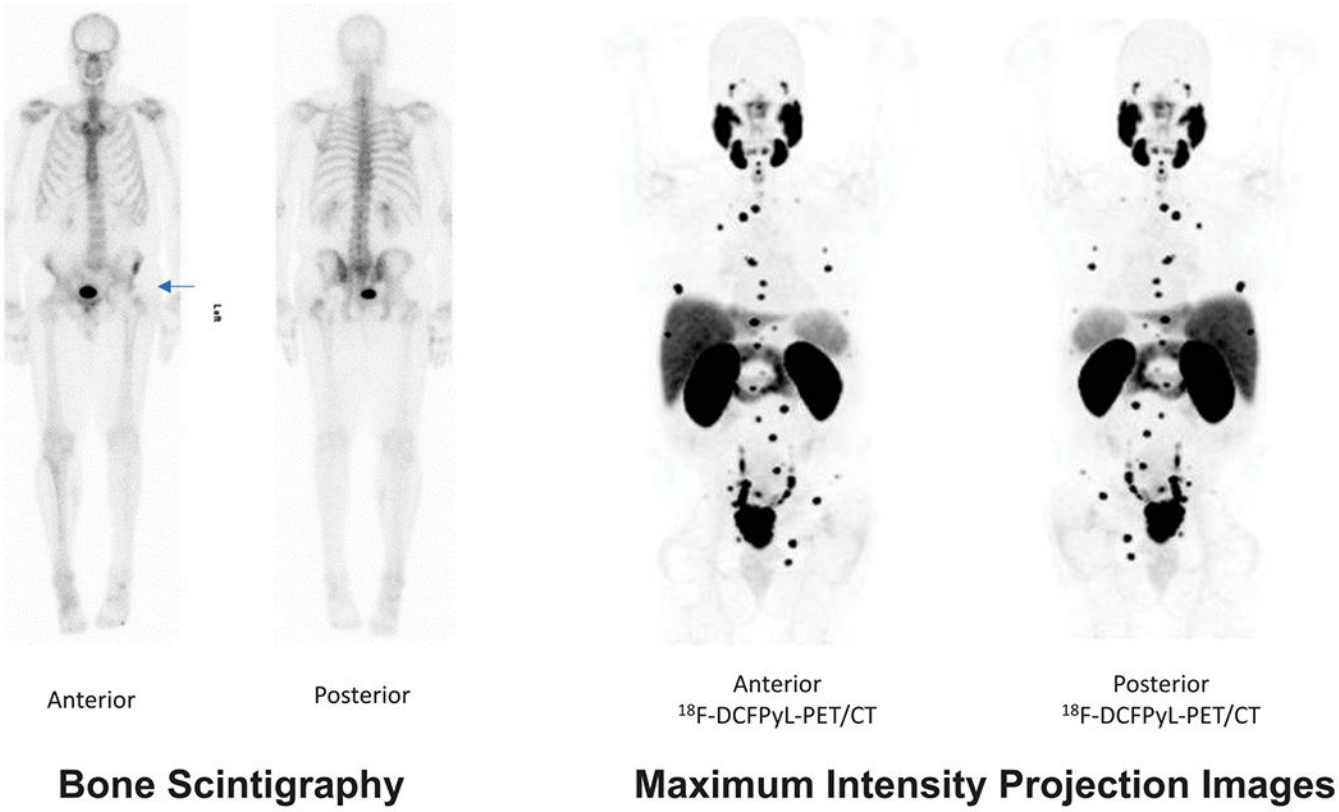

Figure 4.

^{18}F-DCFPyL-PET/CT up staged patient with high-risk prostate cancer. This cohort A patient was staged at baseline as T1cN0M0; his PSA was 13.68 ng/ml and his biopsy Gleason score was 4+5. CT (not shown) demonstrated no evidence of metastatic disease. Anterior and posterior bone scintigraphy showed changes of left hip arthroplasty and increased tracer uptake in anterior superior iliac spine (arrow) of uncertain significance, butwas otherwise normal. ^{18}F-DCFPyL-PET/CT showed multifocal osseous lesions involving spine, ribs, pelvis and right clavicle. On subsequent biopsy of transverse process of L3, osseous metastatic (M1b) disease was confirmed.

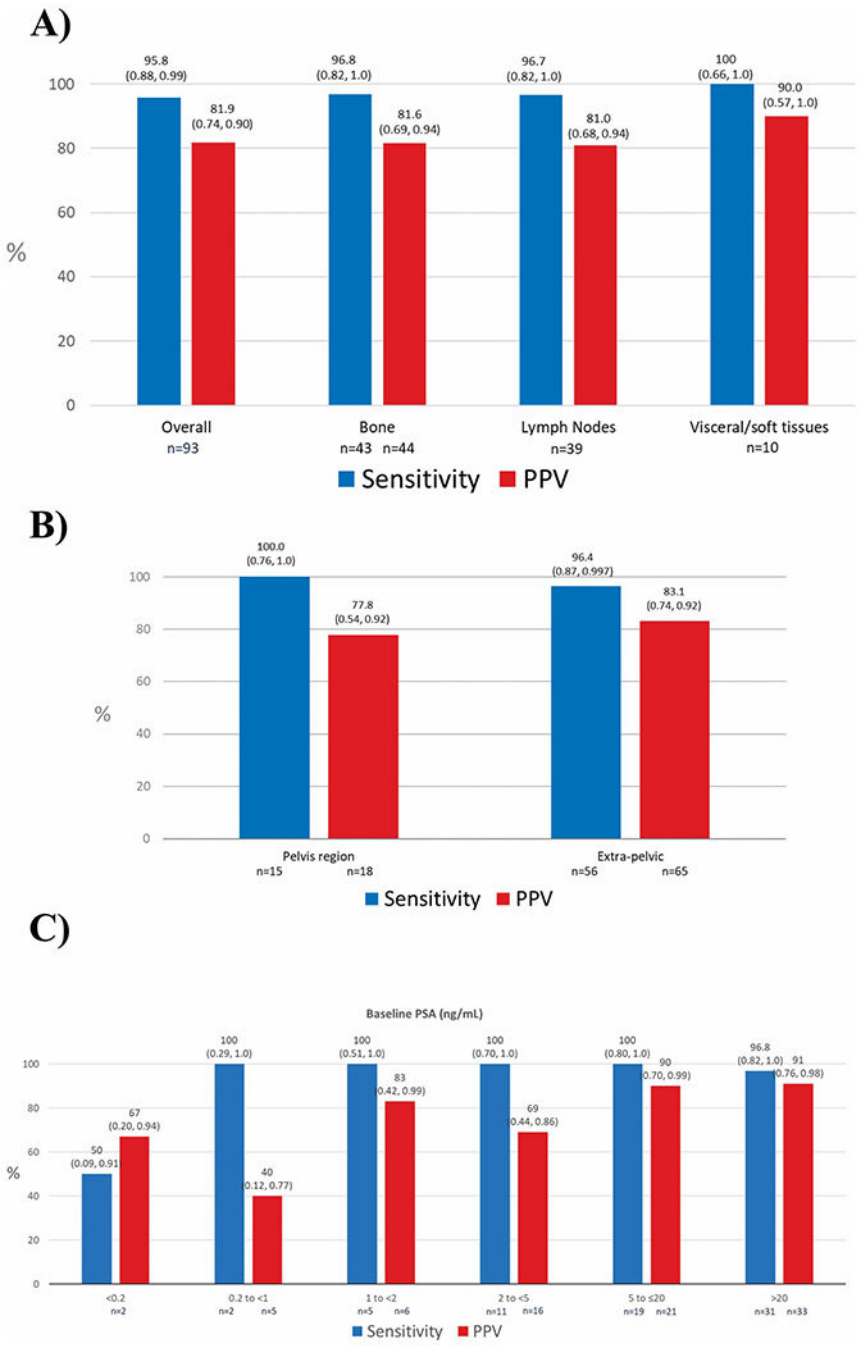

Figure 5.

Sensitivity and PPV (median of 3 independent readers, relative to histopathology truth standard) of ^{18}F-DCFPyL-PET/CT in metastatic disease sites (*A*), by anatomical region (*B*) and across all PSA ranges in men with recurrent or metastatic prostate cancer (*C*) in cohort B.

Table.

Demographic, baseline characteristics and ^{18}F-DCFPyL dosing/uptake time

	High-Risk Disease (cohort A)		Recurrent/Metastatic Disease (cohort B)	
No. pts	268		117	
Median yrs age at informed consent (range)	65	(46-84)	68	(45-86)
No. ethnicity (%):				
Hispanic/Latino	11	(4.1)	5	(4.3)
Not Hispanic or Latino	256	(95.5)	105	(89.7)
Missing	1	(0.4)	7	(6.0)
No. race (%):				
White	233	(86.9)	101	(86.3)
Black or African American	23	(8.6)	6	(5.1)
Asian	7	(2.6)	4	(3.4)
Other	2	(0.7)	3	(2.6)
Unknown/denied	3	(1.1)	3	(2.6)
Mos since last prostate Ca staging evaluation:				
No. available	267		112	
Median (range)	1.7	(−2.2 *−66.2)	31.1	(0—321)
No. AJCC primary tumor (T) stage (%): †				
No. available	268	(100)	112	(95.7)
TX	8	(3.0)	12	(10.3)
T1a	1	(0.4)	0	
T1b	2	(0.7)	1	(0.9)
T1c	87	(32.5)	16	(13.7)
T2	7	(2.6)	3	(2.6)
T2a	45	(16.8)	10	(8.5)
T2b	30	(11.2)	7	(6.0)
T2c	14	(5.2)	10	(8.5)
T3	3	(1.1)	3	(2.6)
T3a	56	(20.9)	24	(20.5)
T3b	14	(5.2)	17	(14.5)

	High-Risk Disease (cohort A)		Recurrent/Metastatic Disease (cohort B)	
T4	1	(0.4)	9	(7.7)
Missing	0		5	(4.3)
No. AJCC regional lymph node (N) stage (%): †				
No. available	268	(100)	112	(95.7)
NX	103	(38.4)	39	(33.3)
N0	156	(58.2)	46	(39.3)
N1	9	(3.4)	27	(23.1)
Missing	0		5	(4.3)
No. AJCC distant metastases (M) stage (%): †				
No. available	266	(99.3)	112	(95.7)
MX	48	(17.9)	1	(0.9)
M0	216	(80.6)	68	(58.1)
M1:	1	(0.4)	33	(28.2)
M1a	0		6	(5.1)
M1b	1	(0.4)	4	(3.4)
M1c	0		0	
No. total Gleason grade (%):				
No. available	268	(100)	113	(96.6)
6	3	(1.1)	4	(3.4)
7	49	(18.3)	39	(33.3)
8	120	(44.8)	32	(27.3)
9	92	(34.3)	37	(31.6)
10	4	(1.5)	1	(0.9)
Missing	0		4	(3.4)
PSA:				
No. available	267		117	
Median ng/ml (range)	9.7	(1.2—125.3)	7.1	(0.03—596.9)
No. prior prostatectomy (%)	0		55	(47.1)
No. prior prostate radiation therapy (%)	1	(0.4)	68	(58.1)
No. prior systemic therapy (%)	4	(1.5)	74	(63.2)
^{18}F-DCFPyL dosing and uptake time:				

	High-Risk Disease (cohort A)	Recurrent/Metastatic Disease (cohort B)
Median mCi/MBq administered (range)	9.14 (6.4—10.5)/338 (237—389)	
Median mins from injection to imaging (range)	74 (25—194)	

*One patient had staging recorded at 2 months following dosing and prostatectomy.

†Stage at time of study entry or most recent prior to entry.