Original Article

Can ^{18}F-PSMA-7Q PET/CT replace prostate biopsy for the diagnosis of prostate cancer?—A single-center retrospective study

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Background: Of the currently available prostate-specific membrane antigen (PSMA) positron emission tomography (PET) tracers, although ^{68}Ga-PSMA-11 and ^{18}F-DCFPyL have been approved by the US Food and Drug Administration (FDA), both tracers are excreted rapidly through the urinary tract, resulting in strong accumulation in the bladder and blurring the prostate.^{18}F-PSMA-7Q is a novel quinoline-containing PSMA PET tracer developed by our team, which is primarily excreted through the liver. It can reduce the incidence of urine-induced false-positives in the prostate. We aimed to explore the diagnostic efficacy of ^{18}F-PSMA-7Q PET/computed tomography (CT), and when ^{18}F-PSMA-7Q PET/CT can be used instead of prostate biopsy to diagnose prostate cancer.

Methods: Patients who underwent ^{18}F-PSMA-7Q PET/CT for prostate cancer staging or prostate biopsy guidance at our institution between July 2020 and December 2021 were retrospectively enrolled. Molecular imaging PSMA (miPSMA) scores were assigned for intra-prostatic lesions according to the Prostate Cancer Molecular Imaging Standardized Evaluation (PROMISE) criteria, and the diagnostic efficacy of ^{18}F-PSMA-7Q PET/CT for different miPSMA scores was evaluated using pathological diagnosis as the gold standard.

Results: Of the 125 enrolled patients, 101 had prostate cancer, and 24 had prostatic hyperplasia or prostatitis. miPSMA ≥2 was the optimal diagnostic threshold, and area under curve (AUC) was 0.948, the sensitivity and specificity were 91.1% and 83.0%. The prostate cancer detection rates of ^{18}F-PSMA-7Q PET/CT were 14.3% (3/21), 60.0% (6/10), 96.7% (58/60), and 100% (34/34) for patients with miPSMA scores of 0, 1, 2, and 3, respectively. There was no significant difference in the detection rate of prostate cancer between groups with miPSMA scores of 2 and 3, but there were significant differences between any other 2 groups.

Conclusions: The prostate cancer detection rate of ^{18}F-PSMA-7Q PET/CT was high for lesions with greater miPSMA scores of 2 and 3. For patients with a high miPSMA score, particularly those with a miPSMA score of 3, prostate biopsy can be omitted and prostate cancer-related treatment can be considered.

Keywords: Prostate cancer; prostate-specific membrane antigen (PSMA); positron emission tomography/computed tomography (PET/CT); biopsy

Introduction

Prostate cancer is one of the most common malignancies in older men (1). The current gold standard for diagnosing prostate cancer relies on a transrectal ultrasound-guided, systematic twelve-core random biopsy that is blind to the cancer location, and thus, can lead to false-negative prostate cancer diagnoses (2). Moreover, prostate biopsies often underestimate the final prostate cancer Gleason score compared to histologic examination after radical prostatectomy (3). Repeated biopsy is permitted for patients whose initial biopsy is negative but is still highly suspicious for prostate cancer. However, repeated biopsies are challenging for patients.

In contrast to needle biopsy, imaging is non-invasive. Therefore, accurately identifying men with prostate cancer using imaging rather than (repeat) systematic prostate biopsies is appealing. However, the imaging tools must be accurate (4). Presently, the primary reason that conventional imaging examinations [such as ultrasound, computed tomography (CT), and magnetic resonance imaging (MRI)] have not replaced needle biopsy is that their diagnostic accuracy is too low.

Prostate-specific membrane antigen (PSMA) is a cell-surface glycoprotein with an increased expression in prostate cancer cells (5). Due to this unique characteristic,

PSMA is an excellent target for binding radiolabeled ligands. As a result, PSMA positron emission tomography (PET) imaging is superior to conventional imaging methods and shows high accuracy about 91% in the diagnosis and staging of prostate cancer (6-8). Of the currently available PSMA PET tracers, only ^{68}Ga-PSMA-11 and ^{18}F-DCFPyL are approved by US Food and Drug Administration (FDA) for PET imaging of prostate cancer. However, both tracers are excreted rapidly through the urinary tract, resulting in strong accumulation in the bladder and blurring the prostate. ^{18}F-PSMA-7Q is a novel quinoline-containing PSMA PET tracer developed by our team, which is mainly excreted through the liver (9). Since ^{18}F-PMA-7Q is rarely excreted in the urine, the incidence of false positives in the prostate may be reduced. However, it remains unknown whether ^{18}F-PMA-7Q PET can replace prostate biopsies in the diagnosis of prostate cancer. This study is a retrospective analysis to determine whether ^{18}F-PSMA-7Q PET/CT can replace prostate biopsy for the diagnosis of prostate cancer, and under which circumstances this can be used. We present the following article in accordance with the STARD reporting checklist (available at https://tau.amegroups.com/article/view/10.21037/tau-22-813/rc).

Methods

Study design and patient population

A total of 125 patients, with a median age of 68 years (range, 48–88 years), were included in this retrospective study. The Ethics Committee of the Chinese PLA General Hospital approved this study (No. S2020-324–01) and written informed consent was obtained from all patients. The serum prostate-specific antigen (PSA) levels at the time of the PET/CT scan were available for all patients. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013).

All patients who performed an ^{18}F-PSMA-7Q PET/CT scan for newly diagnosed and suspected prostate cancer between June 2020 and December 2021 were identified from the databases. Only the newly diagnosed prostate cancer patients and the suspected prostate cancer patients with biopsy-naïve who underwent prostate biopsy (at least with transrectal ultrasound-guided systematic twelve-core biopsy and a combination of ^{18}F-PSMA-7Q PET/CT-ultrasound cognitive fusion-guided 2–4 core targeted biopsy for PET-positive lesions) or radical prostatectomy

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**Highlight box**

Key findings

• For patients with a high miPSMA score, particularly those with a miPSMA score of 3 on ^{18}F-PSMA-7Q PET/CT, prostate biopsy can be omitted and prostate cancer-related treatment can be considered.

What is known and what is new?

• PSMA PET/CT plays an important role in the diagnosis and staging of prostate cancer. The detection rate of prostate cancer for standard prostate biopsy is low, and some patients have to undergo repeated biopsies until prostate cancer is found.

• The ^{18}F-PSMA-7Q we used is a novel quinoline-containing PSMA PET tracer, which has the advantage of being excreted mainly through the liver and almost no excretion through urine. We used miPSMA score to evaluate the suspected lesions in the prostate found by ^{18}F-PSMA-7Q PET/CT.

What is the implication, and what should change now?

• Further prospective multicenter studies are warranted to validate these findings.
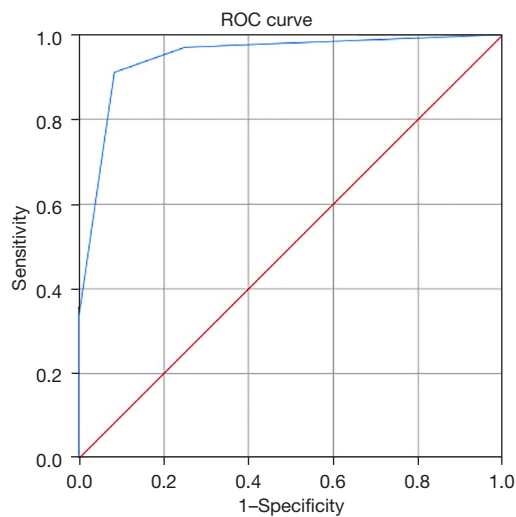
Figure 1 ROC curve of miPSMA score for benign and malignant prostate diseases. ROC, receiver operating characteristic; miPSMA, molecular imaging prostate-specific membrane antigen.

within three months after the PET/CT scan were selected. Patients with androgen deprivation therapy, chemotherapy, or radionuclide therapy were excluded from the analysis.

^{18}F-PSMA-7Q PET/CT scan and image analysis

^{18}F-PSMA-7Q was synthesized as described previously (10). The PET/CT (Siemens Biograph 64) scans were performed one hour after the ^{18}F-PSMA-7Q (5.55 MBq per kilogram of body weight) injection. The ^{18}F-PSMA-7Q PET/CT images were evaluated by two nuclear medicine physicians with more than five years of experience in PSMA PET/CT and PET/MR interpretation, and the lesions were assigned molecular imaging PSMA (miPSMA) scores according to the Prostate Cancer Molecular Imaging Standardized Evaluation (PROMISE) criteria (11). Finally, pathological diagnosis with prostate biopsy or radical prostatectomy was used as the gold standard to evaluate the diagnostic efficacy of ^{18}F-PSMA-7Q PET/CT. And the prostate cancer detection rate in lesions with different miPSMA scores on ^{18}F-PSMA-7Q PET/CT were analyzed.

Clinically significant prostate cancer was defined as International Society of Urological Pathology (ISUP) grade ≥3 and/or cancer core length ≥6 mm (12). For patients who underwent both prostate biopsy and radical prostatectomy, the final pathological result used was the one with a higher ISUP grade.

Statistical analysis

SPSS26.0 statistical software was used to process the data, the measurement data were described by median or average (range), and the counting data were described by examples or percentage. Receiver operating characteristic curve (ROC) was plotted and area under (AUC) curve was calculated to obtain the optimal diagnostic threshold of miPSMA score. The nonparametric McNemar test was used to compare the prostate cancer detection rate of different miPSMA score lesions.

Results

Histopathological diagnoses

Of the 125 enrolled patients, 101 had prostate cancer (Gleason Score 3+3: n=8; Gleason Score 3+4: n=17; Gleason Score 3+5: n=1; Gleason Score 4+3: n=36; Gleason Score 4+4: n=14; Gleason Score 4+5: n=18; Gleason Score 5+3: n=1; Gleason Score 5+4: n=4; and Gleason Score 5+5: n=2) and 24 had prostatic hyperplasia or prostatitis.

Diagnostic efficiency of ^{18}F-PSMA-7Q PET/CT

miPSMA ≥2 was the optimal diagnostic threshold, and AUC was 0.948. Under this threshold, the sensitivity and specificity were 91.1% and 83.0%. ROC curve is shown in *Figure 1*.

### The prostate cancer detection rate for different miPSMA scores on ^{18}F-PSMA-7Q PET/CT

Among the 125 patients, there are 21 with a miPSMA score of 0, 10 with a miPSMA score of 1, 60 with a miPSMA score of 2, and 34 with a miPSMA score of 3.

Two patients with a miPSMA score of 2 on ^{18}F-PSMA-7Q PET/CT were diagnosed with prostatic hyperplasia or prostatitis after the first prostate biopsy. However, both were found to have prostate cancer after the second prostate biopsy (1 of the cases is shown in *Figure 2*).

The detection rates of prostate cancer and clinically significant prostate cancer for different miPSMA scores are shown in *Table 1*.

Comparison of prostate cancer rate among the different miPSMA score lesions

There was no significant difference in the prostate cancer
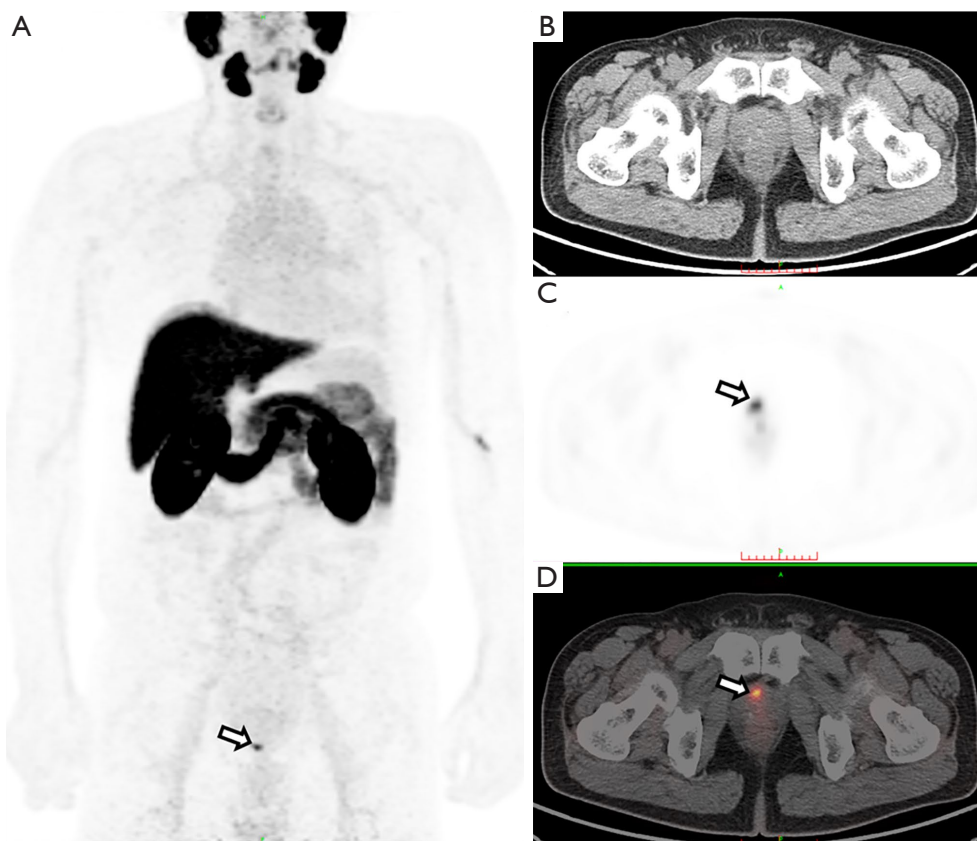
Figure 2 A 65-year-old male, with a total PSA of 8.6 ng/mL underwent ¹⁸F-PSMA-7Q PET/CT (A, MIP image; B, CT image; C, PET image; D, fused PET/CT image). The image shows an intraprostatic lesion (arrows) with a miPSMA score of 2. The subsequent biopsy showed benign prostatic hyperplasia and prostatitis. However, the second biopsy 3 months later revealed prostate cancer with a Gleason score of 4+3. PSA, prostate-specific antigen; MIP, maximum intensity projection; CT, computed tomography; PET, positron emission tomography; PSMA, prostate-specific membrane antigen; miPSMA, molecular imaging PSMA.

Table 1 The detection rates of prostate cancer and clinically significant prostate cancer for different miPSMA scores

miPSMA	Total (n)	Prostate cancer rate	Clinically significant prostate cancer rate
0	21	14.3% (3/21)	4.8% (1/21)
1	10	60.0% (6/10)	0.0% (0/10)
2	60	96.7% (58/60)	76.7% (46/60)
3	34	100% (34/34)	85.3% (29/34)

miPSMA, molecular imaging prostate-specific membrane antigen.

detection rate between groups with a miPSMA score of 2 and 3, but there were significant differences between any other 2 groups (*Table 2*).

Discussion

This retrospective study explored whether ¹⁸F-PSMA-7Q PET/CT could replace prostate biopsy for the diagnosis of prostate cancer. The results showed that using a pathological diagnosis as the gold standard, the prostate cancer detection rates for miPSMA scores of 2 and 3 on ¹⁸F-PSMA-7Q PET/CT were as high as 96.7% and 100%, respectively. Notably, the detection rates were underestimated because there is a specific false-negative rate

Table 2 Statistical differences in prostate cancer detection rates among different miPSMA score groups

miPSMA score group	miPSMA score group	P value
0	1	0.004
0	2	<0.001
0	3	<0.001
1	2	0.019
1	3	0.009
2	3	0.533

miPSMA, molecular imaging prostate-specific membrane antigen.

for prostate biopsies. Therefore, for these cases, particularly patients with a miPSMA score of 3, clinicians could forego the prostate biopsy and directly commence prostate cancer treatment.

It remains unclear whether patients with highly suspected prostate cancer can forego needle biopsy and go directly to radical prostatectomy. This decision primarily depends on the accuracy of the imaging diagnosis. Although MRI is increasingly used to diagnose or monitor prostate cancer, it cannot replace prostate biopsy because of its relatively low specificity (13,14). PSMA PET imaging has high accuracy in detecting prostate cancer. Of the currently available PSMA PET tracers, ^{68}Ga-PSMA-11 and ^{18}F-DCFPyL are approved by the FDA (15,16). ^{68}Ga-PSMA PET/MRI improves specificity for clinically significant prostate cancer compared with multiparametric MRI (mpMRI), particularly in Prostate Imaging Reporting and Data System grade 3 lesions (17,18). In 1 study, 42 patients underwent ^{68}Ga-PSMA-11 PET/MRI-guided biopsy, and the sensitivity, specificity, negative and positive predictive value, and accuracy for clinically significant prostate cancer were 96%, 81%, 93%, 89%, and 90%, respectively (12).

In our previous study (19), we performed ^{18}F-DCFPyL PET/CT ultrasound (PET/CT-US) or PET/MRI ultrasound (PET/MRI-US) software fusion-targeted biopsy for intra-prostatic PET-positive lesions (2–4 cores/lesion), and 92.7% patients were pathologically confirmed as having prostate cancer. However, since ^{68}Ga-PSMA-11 and ^{18}F-DCFPyL are primarily excreted through the urinary system, the retention of radioactive urine in the prostate may interfere with the accurate diagnosis of prostate lesions (20).

In contrast to ^{68}Ga-PSMA-11 and ^{18}F-DCFPyL, ^{18}F-PSMA-7Q used in this study is a novel quinoline-containing PSMA PET tracer that is mainly excreted through the liver. The diagnostic performance of ^{18}F-PSMA-7Q PET/CT in patients with newly diagnosed prostate cancer is not inferior to that of ^{18}F-DCFPyL PET/CT (9). Furthermore, since ^{18}F-PMA-7Q is rarely excreted through the urine, it may reduce the incidence of false-positives in the prostate to some extent.

The miPSMA scoring system enables standardized reporting of PSMA PET imaging based on visual scores of PSMA expression (11). In our study, the miPSMA score system was used to classify the intra-prostatic lesions. The prostate cancer detection rate was high for patients with high miPSMA scores of 2 and 3. Repeated prostate biopsies often burden patients who have suspicious (particularly highly suspicious) prostate cancer, but a negative initial biopsy.

In our study, 2 patients with a miPSMA score of 2 on ^{18}F-PSMA-7Q PET/CT were found to have prostatic hyperplasia or prostatitis on the first prostate biopsy. However, both were diagnosed with prostate cancer on the second prostate biopsy.

It remains unclear whether to recommend a prostate biopsy for patients with low miPSMA scores (miPSMA scores of 0 and 1). In our study, 14.3% and 60.0% of patients with miPSMA scores of 0 and 1, respectively, had prostate cancer. Therefore, prostate biopsy should not be omitted for these patients. However, the clinical significance of prostate cancer was only 4.8% and 0.0% for the patients with miPSMA scores of 0 and 1, respectively. Clinically insignificant prostate cancer is associated with a high rate of overdiagnosis and overtreatment. Therefore, it is not easy to judge whether a prostate biopsy should be recommended by relying solely on low miPSMA scores (miPSMA score 0 or 1).

There are some limitations to this investigation. First, this was a retrospective, single-center study in which the number of patients is relatively small, so it is statistically insufficient and therefore was statistically underpowered, for example, the proportion of patients with prostate cancer is higher in this study. Further prospective multicenter studies are warranted to validate these results. Second, the reference standard for prostate cancer in some patients is based on biopsy specimens, which underestimates the clinical value of PSMA PET imaging to some extent because of inevitable missed diagnoses through biopsy. Finally, the object of our study was PSMA PET/CT rather than PSMA PET/MRI. The use of PSMA PET improves the management of prostate cancer patients as it outperforms mpMRI (21).

In addition, PSMA PET/MRI was found to have a higher clinical diagnostic accuracy in prostate cancer than PSMA PET or mpMRI (22-24).

Conclusions

In this study, the prostate cancer detection rate of ¹⁸F-PSMA-7Q PET/CT was elevated for lesions with high miPSMA scores of 2 and 3. Therefore, the diagnosis of prostate cancer in patients with a high miPSMA score, particularly those with a miPSMA score of 3, could involve foregoing prostate biopsy and directly commencing treatment. Further research is warranted to verify these findings.

Acknowledgments

Footnote

Reporting Checklist: The authors have completed the STARD reporting checklist. Available at https://tau.amegroups.com/article/view/10.21037/tau-22-813/rc

Data Sharing Statement: Available at https://tau.amegroups.com/article/view/10.21037/tau-22-813/dss

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://tau.amegroups.com/article/view/10.21037/tau-22-813/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The Ethics Committee of the Chinese PLA General Hospital approved this study (No. S2020-324–01) and written informed consent was obtained from all patients.

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