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Role of PSMA PET/CT in evaluation of therapy response in patients with metastatic prostate cancer

Ahmed Badawy[1], Sherif El Refaei[1], Maha Abd El-Kareem[1], Marwa Abdallah Hassan[1], Mohamed Houseni[2]

[1] Clinical Oncology and Nuclear Medicine Department, Faculty of Medicine, Cairo University, Egypt
[2] Department of Radiology, National Liver Institute, Egypt

ABSTRACT

Background: Even though PSMA PET/CT is the imaging technique for prostate cancer that is growing at the quickest pace, its widespread utilization must be supported by clear guidelines for when and how to deploy it. This is because PSMA PET/CT is the imaging tool that is increasing at the fastest rate. PSMA PET/CT has shown promise as a diagnostic tool that could be utilized in a diverse range of therapeutic settings.

Aim: To determine the extent to which PSMA PET/CT may be used to predict how well individuals who have metastatic prostate cancer will respond to treatment based on the criteria established by Positron Emission tomography Response Criteria In Solid Tumors (PERCIST).

Methods: In this study, there were a total of 53 male participants, all of whom had pathologically established instances of metastatic prostatic adenocarcinoma and participated in both the initial PSMA-PET/CT study and the post-therapy PSMA-PET/CT study. The medical histories of every individual were examined in great detail. The collection of data comprised the patient's medical history, histology, age, weight, height, the type of therapy that was administered, pre-and post-treatment PSA levels (biochemical response), and serum creatinine levels that were completed no more than 2 weeks before the study (in individuals who had received IV contrast).

Results: Regarding post-therapy response by PET/CT (PERCIST criteria); 38 patients out of 53 (71.7%) were responders to therapy including patients with partial response, stable disease, and complete response. 15 patients out of 53 (28.3%) were non-responders to treatment including patients with progressive disease. Regarding post-therapy response by CT study (RECIST criteria); 30 cases out of 41 (73.2%) were responders to therapy including patients with partial response, stable disease, and complete response and 11 cases out of 41 (26.8%) were non-responders to treatment including progressive disease. There is good agreement among PERCIST and RECIST criteria with Kappa value=0.75 mostly seen in the cases with partial response with 16 cases (42.1%). The agreement between biochemical response and post-therapy PSMA-PET study was assessed on 53 patients and found that there is a moderate agreement with Kappa value=0.57 mostly seen in the patients with partial response with 25 patients (47.2%).

Conclusion: there was moderate agreement among post-therapy biochemical response and PERCIST as well as RECIST criteria. There was a good agreement among PERCIST and RECIST criteria.

Keywords: PSMA PET/CT, prostate cancer, Positron Emission tomography Response Criteria In Solid Tumors (PERCIST)

Address for correspondence:
Marwa Abdallah Hassan, Clinical Oncology and Nuclear Medicine Department, Faculty of Medicine, Cairo University, Egypt

E-mail: marwa.abdallah0713@gmail.com

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INTRODUCTION

The clinical management decisions for patients with prostate cancer are based on risk stratification and TNM staging. Prostate Specific Membrane Antigen (PSMA) has the potential to overcome numerous well-known difficulties in assessing metastatic prostate cancer in response to different therapies. PSMA PET is expressed in prostatic cancer 100-1000 times more than in benign prostatic cells and other tissues, it is one of the most promising targets for imaging and therapy in nuclear medicine [1].

PET studies, in addition to morphological imaging in prostate cancer, have been shown to provide information on the molecular process [2-4]. Antigen for the prostatic membrane expressed in gallium 68 (Ga68-PSMA). New molecular imaging techniques like PET-CT are showing promise in the staging and recurrence detection of prostate cancer [5, 6].

Clinical parameters, biochemical response as measured by the change in serum Prostate Specific Antigen (PSA) levels, and morphological assessment on Computerized Tomography (CT) imaging using the Response Evaluation Criteria in Solid Tumors (RECIST) are used to evaluate treatment response in prostate cancer patients [7-9].

In this study, we intended to determine if PSMA PET/CT is useful for evaluating the response to therapy in cases with metastatic prostatic cancer using the PERCIST criteria.

PATIENTS AND METHODS

From March 2020 and March 2022, a total of 53 male patients with pathologically confirmed metastatic prostatic adenocarcinoma were referred to our center for both an initial PSMA-PET/CT study and a PSMA-PET/CT study after treatment had concluded. After receiving approval from the hospital's and university's ethical review boards, the study was conducted in the Nuclear Medicine and Radiation Oncology department at Kasr El-Ainy Hospital.

Cases who had received systemic therapy before the first PSMA-PET/CT trial were also disqualified from inclusion.

The medical histories of all cases were carefully examined. Patients who received IV contrast up to 2 weeks before the trial had their medical history, histology, age, weight, height, type of treatment, pre-and post-treatment PSA level (biochemical response), and

serum creatinine level collected. All participants agreed in writing to the dissemination of their data for scientific investigation.

Study protocol

A Philips Gemini TF camera equipped with 64 slices of Time of Flight (TOF) CT was used to acquire the PSMA PET/CT images.

In the pre-and post-treatment examinations, cases were radioactively traced with a PSMA ligand. The amount of tracer administered was calculated based on body mass index (MBq/kg). The original trial involved the injection of 68Ga-PSMA into 9 patients (mean of injected doses: 159 MBq, range: 114.7 MBq-203.5 MBq) and 18F-PSMA-1007 into 44 patients (mean of injected doses: 318.2 MBq, range: 236.8 MBq-399.6 MBq). In the follow-up study, 68Ga-PSMA (mean injected dose: 159 MBq, range: 129.5 MBq-188.7 MBq) and 18F-PSMA-1007 (mean injected dose: 307 MBq, range: 247.9 MBq-366.3 MBq) were injected into 12 and 41 individuals, respectively.

Before the trial began, subjects were asked to use the restroom, and PET collection commenced after an uptake time of 45 minutes to 90 minutes post-PSMA ligands injection, using 23-minute frames spanning 12 frames to 14 frames. Attenuation was corrected and anatomical landmarks were mapped using low-dose CT scans. Diagnostic CT with intravenous contrast (dosage 70 ml) was also performed in individuals who were suitable for contrast injection to better delineate metastatic lesions. In the preliminary study, 47 patients and 45 persons received intravenous contrast.

The entire body was scanned using PET/CT technology, from the knees to the skull.

Image analysis

The PET/CT scan is analyzed by two seasoned nuclear medicine doctors and two radiologists, who then determine whether or not the scan is positive. OsiriX Software was used to analyze the images.

PSMA-PET/CT analysis of therapeutic response according to PERCIST criteria.

Imaging response was classified as advancing disease, improved disease (full or partial response), or stable disease based on a comparison of pre-and post-treatment PET/CT findings using the following criteria:

- New lesions or an increase of 30% in pathologic uptake intensity or size were considered to be indicative of progressive illness.
- Partial response was defined as a 30% reduction in the intensity and extent of pathologic uptake, while a complete imaging response was defined as the elimination of lesions.
- Stable disease was defined as a Change in-between partial response and progressive disease (≤ 30% and ± 30%) in PET/CT findings.

Interpretation of biochemical response as determined by serum PSA level (ng/mL) dynamics between pre and post-treatment values, as follows:

- Progressive disease was defined as a rise of ≥ 25% in PSA.
- Partial response was defined as a decrease of ≥ 50% in PSA.
- Any fluctuation in PSA between the aforementioned ranges was considered to indicate stable illness.

True positive PET/CT results

- Post-therapy PET/CT and high level of serum PSA have been agreed upon.
- New lesions have been detected on the PET/CT scan performed as a follow-up.

False positive PET/CT results

On follow-up PET/CT, lesions seemed to progress after Anti Androgen Treatment (ADT), although there is improvement in the clinical follow-up and good biochemical response.

True negative

PET/CT scan was termed true negative if the following conditions were met:

- No new events were found during clinical follow-up, and all tumor markers were within normal range, therefore the negative PET/CT results made sense.
- No obvious morphological changes were seen on CT scans.

Semi-quantitative assessment

For each scenario, the maximum number of SUVs was calculated. Standardized Uptake Values (SUVmax) for lesions with focally enhanced uptake are obtained by manually drawing zones of interest on attenuation-corrected emission pictures along all axial planes.

The following formula is used to calculate the maximal Standardized Uptake values (SUVmax):

$$SUV_{\max} = \frac{Maximum\ activity\ concentration\ in\ the\ neoplasm\ (kBq\ /\ ml)}{Injected\ dose\ (MBq)\ /\ body\ waight\ (Kg)}$$

Validation

Initial and post-therapy follow-up PSMA-PET/CT studies were available for all cases and were used as an outcome standard. Serum PSA level was available during follow-up.

Statistical methods

For data administration and analysis, version 28 of the Statistical Package for the Social Sciences was utilized. To provide a concise interpretation of the numerical information, we utilized measures of central tendency such as means and standard deviations, medians, and/or ranges. To provide a numerical and graphical representation of the category data, we used numbers and percentages. We were able to generate educated assumptions about the frequency by using the data and the percentages. To determine whether or not the numerical data adhere to a normal distribution, the Kolmogorov-Smirnov and Shapiro-Wilk tests were carried out. When comparing two or more groups based on categorical data, we used either the Chi-square test or the Fisher's test, depending on which one was more appropriate. The level of concordance across different groups that were characterized by

distinct categories was analyzed using kappa statistics, which can take on values from zero to one, with 0 being the most discordant. To compare two groups whose data were not regularly distributed, the Wilcoxon test was carried out. Spearman's correlation coefficients (r is the correlation coefficient, and it ranges from -1 to +1) were computed to assess the degree of relationship between the non-normally distributed measures. Each exam consisted of two legs, and Probability (p-value) ≤ 0.05 is considered significant [10].

RESULTS

Out of 53 cases, we found that 33 (62.3% of the total) had bone metastases, 39 (73.6% of the total) had lymph node lesions, and 5 (9.4% of the total) had visceral deposits (2 patients had lung metastases, 1 had hepatic deposits, 1 had pleural deposits, and 1 had metastatic peritoneal disease (Table 1).

Tab. 1. Sites of metastases data

	n=53 (%)
Bone marrow	
Yes	33 (62.3)
No	20 (37.7)
Visceral	
Yes	5 (9.4)
No	48 (90.6)
Lymph node	
Yes	39 (73.6)
No	14 (26.4)
Site of nodal metastasis	
Pelvic	
Yes	37 (69.8)
No	16 (30.2)
Inguinal	
Yes	5 (9.4)
No	48 (90.6)
Retroperitoneal	
Yes	12 (22.6)
No	41 (77.4)
Supra-diaphragmatic	
Yes	6 (11.3)
No	47 (88.7)

Post-treatment response was evaluated by PSMA PET before and after treatment based on responder and non-responder criteria, as well as PERCIST criteria. Partially responding, stable, or responding completely to treatment accounted for 38 cases of 53 cases (71.7%). Fifteen of the 53 cases (28.3%), including several with progressing disease, did not show any signs of improvement while receiving treatment (Table 2).

Tab. 2. Follow-up PSMA PET response (PERCIST)

	n=53 (%)
Responders	38 (71.7)
Nonresponders	15 (28.3)
Follow-up PSMA PET response (PERCIST)	
Complete response	2 (3.8)
Partial response	27 (50.9)
Stable disease	9 (17)
Progression	15 (28.3)
New lesion	
Yes	11 (20.8)
No	42 (79.2)

Thirty out of the forty-one cases (73.2%; including those with partial response, stable disease, and complete response) responded to therapy based on a CT study (RECIST criteria), while eleven out of the forty-one cases (26.8%; including those with progressive disease) did not (Table 3).

Tab. 3. Post-therapy response by CT study (RECIST criteria)

	n (%)
RECIST response	
Responders	30 (73.2)
Nonresponders	11 (26.8)
RECIST response	
Complete response	2 (4.9)
Partial response	16 (39)
Stable disease	12 (29.3)
Progression	11 (26.8)
RECIST (new lesion)	
Yes	9 (22)
No	32 (78)

Results from research comparing PSMA PET and CT scans in 41 cases of 53 cases showed good agreement among PERCIST and RECIST criteria, with a Kappa value of 0.75. This was most evident in the 16 cases (42.10%) who had a partial response. According to responders and non-responders criteria, Kappa value =0.88 is detected among PET-PSMA and CT measurements study (Table 4).

Tab. 4. Agreement among PSMA PET response (PERCIST) and RECIST response

Follow-up PSMA PET response (PERCIST)							
	Complete response n (%)*	**Partial response n (%)***	**Stable disease n (%)***	**Progression n (%)***	**Kappa value**	**p-value**	**Interpretation**
RECIST (response)							
Complete response	2 (5.2)	0 (0)	0 (0)	0 (0)	0.75	<0.001	Good agreement
Partial response	0 (0)	16 (42.1)	0 (0)	0 (0)	-	-	
Stable disease	0 (0)	0 (0)	9 (23.7)	0 (0)	-	-	
Progression	0 (0)	0 (0)	0 (0)	11 (28.9)	-	-	

(PERCIST)						
		Responders n (%)*	**Non responders n (%)***	**Kappa Value**	**P value**	**Interpretation**
RECIST response	Responders	30 (73.17)	0 (0)	0.88	<0.001	Good agreement
	Nonresponders	0 (0)	11 (26.8)	-	-	-

(PERCIST) (new lesion)						
		Yes n (%)*	**No n (%)***	**Kappa Value**	**p-value**	**Interpretation**
RECIST (new lesion)	Yes	9 (17)	0 (0)	0.87	<0.001	Good agreement
	No	0 (0)	44 (83)	-	-	-

*Percentages were calculated from the table total, p-value <0.05 is considered significant

Kappa value=0.57 indicates reasonable agreement among biochemical response and post-therapy CT study in a sample of 41 patients, with this agreement being most pronounced among those who showed just a partial response, of whom there were 16 (39%) (Table 5).

Tab. 5. Agreement between F/U PSA response and RECIST response

F/U PSA response							
	Complete response n (%)*	Partial response n (%)*	Stable disease n (%)*	Progression n (%)*	Kappa value	p-value	Interpretation
RECIST (response)							
Complete response	2 (4.8)	0 (0)	0 (0)	0 (0)	0.57	<0.001	Moderate agreement
Partial response	0 (0)	16 (39)	0 (0)	0 (0)	-	-	-
Stable disease	0 (0)	0 (0)	12(29.2)	0 (0)	-	-	-
Progression	0 (0)	0 (0)	0 (0)	11 (26.8)	-	-	-

PSA: Prostatic specific antigen,
*Percentages were calculated from table total, p-value <0.05 is considered significant

Kappa value=0.57 indicates moderate agreement between biochemical response and post-therapy PSMA-PET studies in an analysis of 53 patients, with the highest proportion of partial-responders (25/53, or 47.2%) (Table 6).

Tab. 6. Agreement among F/U PSA response and F/U PSMA PET response (PERCIST)

F/U PSA response							
	Complete response n (%)*	Partial response n (%)*	Stable disease n (%)*	Progression n (%)*	Kappa value	p-value	Interpretation
F/U PSMA PET response (PERCIST)							
Complete response	2 (3.7)	0 (0)	0 (0)	0 (0)	0.57	<0.001	Moderate agreement
Partial response	0 (0)	25 (47.2)	0 (0)	0 (0)	-	-	-
Stable disease	0 (0)	0 (0)	9 (17)	0 (0)	-	-	-
Progression	0 (0)	0 (0)	0 (0)	12 (22.6)	-	-	-

DISCUSSION

PSMA PET/CT is increasingly used for staging Prostate Cancer (PCa) and locating disease recurrence. European Association of Urology (EAU) and other international guidelines now include PSMA PET/CT testing. For men whose PSA levels have been rising after undergoing radical treatment for prostate cancer, this imaging technique is the gold standard [11].

PSMA PET/CT is also recommended in other therapeutic settings, such as when PSA persists after radical treatment has been administered. Although PSMA PET/CT's definitive role is still being debated, it is currently employed in the first stage of high-risk patients' treatment. The findings of recent prospective trials are quite promising [12].

The utility of (68Ga)-PSMA-PET/CT for primary staging and biochemical recurrence has been studied in depth with large patient series, and it is superior to conventional imaging modalities, with a diagnostic rate of up to 90%, even in the presence of low serum PSA values [13].

Regrettably, not enough research has been done on the role of PSMA PET/CT in determining how effectively a case of prostate cancer is responding to systemic treatment. This is a limitation of the current state of the field. In the year 2020, the European Association of Neuro-Oncology and the European Association of Urology (EANM and EAU) hosted a roundtable discussion in the Netherlands with the participation of an international panel of cancer experts specializing in prostate cancer. In the end, the panel concluded that PERCIST 1.0 should be considered the gold standard when assessing the effectiveness of therapeutic interventions [14].

This study aimed to evaluate whether or not PSMA PET/CT is useful for evaluating the success of treatment in male patients who have metastatic prostate cancer.

The PERCIST and responders/nonresponders criteria were applied to 53 cases that were enrolled in our study and given a PSMA PET before and after therapy to evaluate the effectiveness of the treatment. A positive response to treatment was seen in 71% of instances (38/53) with variable degrees of improvement across the board. Treatment was unsuccessful for fifteen (53.3%) of the patients, including several patients whose conditions were deteriorating.

The findings of Stefano Fanti and his colleagues are corroborated by the statements of a consensus group that used a modified nominal group technique to get to an agreement on evaluation criteria for PSMA PET/CT responses [15-17]. In patients with metastatic disease, PSMA PET/CT can be utilized both before and after the administration of any systemic or regional medication to evaluate the patient's response to treatment. PSMA PET/CT imaging criteria should ideally be used to differentiate between responders (also known as "patients with stable disease, partial response, and complete response") and non-responders (also known as "cases with progressive disease"). According to the findings of

the study, PSMA PET/CT criteria ought to be utilized to classify instances as either responders or non-responders [15]. This is because PSMA PET/CT is at its most efficient when it is utilized for a specific goal and by a predetermined set of parameters.

Our study included 53 individuals with metastatic lesions, 41 of whom were suitable for CT measurement (due to lymph node and visceral disease) and 12 of whom were excluded (due to solely hav-ing bone metastases). Metastatic lymph node and visceral lesion sizes were assessed in both the initial and repeat PSMA-PET/CT scans. Biopsies collected from lymph nodes following treatment showed a significant enhancement. The post-treatment study showed that visceral deposits were not considerably decreased.

Similar to our results, Meijer et al. conducted a retrospective study using (18F) DCFPyL PET/CT or (68Ga)-PSMA-11 PET/CT to stage 150 patients with biochemical persistence following robot-assisted radical prostatectomy. There were 101 people with increased PSMA-expressing lesions that could be detected; 26 had lesions just in the pelvic region, 13 had lesions elsewhere, and 62 had lesions in the pelvic region and elsewhere. PSMA-avid regions were seen in 89 cases outside of the prostatic fossa, and 39 cases had distant metastatic disease. Since PSMA PET/CT reveals signs of extra-pelvic illness or distant metastases in a substantial proportion of these people, the results of this study suggest that it is effective for selecting the optimal treatment for cases with biochemical persistence [18].

Positive predictive value for localizing prostate cancer using [68Ga] PSMA-11 PET/CT was 91% in a retrospective research involving 130 of 191 cases with high-risk prostate cancer by Farolfi et al. Most cases included the obturator and presacral/mesorectal lymph nodes. Lymph node metastasis must be precisely located for subsequent treatment planning and radiation field optimization [19]. Because standard imaging has a low diagnostic accuracy for lymph nodes smaller than 10 mm in diameter, the mesorectum may be missed in the standard workup of prostate cancer.

Serum total PSA levels were measured before and after treatment in 53 patients to assess the biochemical response to therapy. According to the study, "25 cases out of 53 (47.2%)" had a moderate reaction. A Kappa value of 0.57 was found to indicate reasonable agreement among post-therapy serum PSA level and RECIST criteria based on an examination of 41 cases, with the highest level of agreement shown in the 16 cases that obtained a partial response (39%).

Serum PSA levels were correlated with PERCIST criteria before and after therapy, and the Kappa value was 0.57, indicating moderate agreement. Twenty-five individuals (47.2% of the total) exhibited this, the majority of whom had a partial response.
Although the sensitivity of conventional imaging is low in patients with a PSA 2 ng/mL, PSMA PET/CT can increase detection rates for further treatment planning (e.g., salvage RT, metastasis-directed therapy, or systemic therapy), and there is only moderate agreement among the PERCIST and RECIST criteria and the post-therapy response of serum PSA level. From 33% in men with post-therapy PSA among 0-0.19 ng/mL to 97% in men with PSA >2 ng/mL, the positivity rates of PSMA PET/CT correspond with the PSA level [20]. Biochemical persistence was observed in 52% of 129 cases who had received radiation therapy based on PSMA PET/CT. cases who experienced a biochemical recurrence or biochemical persistence had a significant PSA response to this therapy [21].

Previously, we mentioned that our study found only modest concordance between PERCIST and RECIST and biochemical reactions. Supporting these results is a retrospective study by Jonathan Kuten et al. in which 52 cases with metastatic prostate cancer were imaged with 68Ga-PSMA-11 PET/CT and their serum PSA levels were measured before and during treatment of these cases, 34 (65.4%) had a response that was compatible biochemically and imaging-based [22]. PET/CT showed worsening sickness in 5/52 (9.6%) and improvement/stable disease in 13/52 (25%), although in 18/52 cases (34.6%), there was a difference among imaging and biochemical responses. The data demonstrated a high correlation between 68Ga-PSMA-PET/CT and biochemical response.

CONCLUSION

PSMA PET/CT can be used both before and after treatment to assess patients who have metastatic disease to see how well they are responding to either local or systemic treatment. Responders are defined as those who have achieved disease stabilization, partial response, or complete response by the PSMA PET/CT criteria. Non-responders, on the other hand, are defined as those who have not responded to treatment in any way. In the framework of clinical research, PSMA PET/CT response assessment can be implemented and evaluated most effectively.

We also discovered that there was only a weak link between the biochemical response and the RECIST criteria. There was a moderate association between the characteristics of the PSMA PET/CT scan and the blood PSA response after treatment. Both the PERCIST and RECIST criteria were found to have high degrees of agreement with one another.

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