

⁶⁸Ga-PSMA PET/CT and Prostate Cancer Diagnosis: Which SUVmax Value?

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Abstract. *Background/Aim:* To evaluate the diagnostic accuracy of ⁶⁸Ga-prostate-specific membrane antigen (PSMA) positron emission tomography/computed tomography (PET/CT) in the diagnosis and staging of prostate cancer (PCa). *Patients and Methods:* From January 2021 to December 2022, 160 men (median age: 66 years) with PCa (median PSA of 11.7 ng/ml) before prostate biopsy underwent ⁶⁸Ga-PET/CT imaging examinations (Biograph 6; Siemens, Knoxville, TN, USA). The location of focal uptake on ⁶⁸Ga-PSMA PET/CT and standardized uptake values (SUVmax) were reported on a per-lesion basis for each International Society of Urological Pathology (ISUP) grade group (GG) PCa. *Results:* Overall, the median intraprostatic ⁶⁸Ga-PSMA SUVmax was 26.1 (range=2.7-164); in the 15 men with not clinically significant PCa (ISUP grade group 1) median SUVmax was 7.5 (range=2.7-12.5). In the 145 men with csPCa (ISUP GG≥2) median SUVmax was 33 (range=7.8-164). A SUVmax cut-off of 8 demonstrated a diagnostic accuracy in the diagnosis of PCa equal to 87.7% vs. 89.3% vs. 100% in the presence of a GG1 vs. GG2 vs. GG≥3 PCa, respectively. In addition, median SUVmax in the bone and node metastases was 52.7 (range=25.3-92.8) and 47 (range=24.5-65), respectively. *Conclusion:* ⁶⁸GaPSMA PET/CT with a SUVmax cut-off of 8 demonstrated a good accuracy in the diagnosis of csPCa (100% in the presence of GG≥3) showing a good cost-benefit ratio as a single procedure for the diagnosis and staging of high-risk PCa.

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Prostate-specific membrane antigen (PSMA) is expressed in primitive and metastatic prostate cancer (PCa) (1, 2), and PSMA inhibitors conjugated with the radionuclides Gallium 68 (⁶⁸Ga) and fluoride 18 (¹⁸F) are currently used for the diagnosis and staging of PCa (3-8); in fact, ⁶⁸Ga-PSMA positron emission tomography/computed tomography (PET/CT) has been demonstrated to be sensitive for the detection of primary prostatic lesions, regional lymphadenopathy (9) and clinical metastases (10). Recently, tumor uptake, which represents PSMA expression, has been highly correlated with the aggressiveness of the primary prostatic tumor (7, 8), allowing with a single procedure the diagnosis and staging of high-risk PCa.

This study prospectively evaluated the accuracy of ⁶⁸Ga-PSMA PET/CT in the diagnosis and staging of PCa.

Patients and Methods

From January 2021 to December 2022, 160 men (median age: 66 years; range=49-84 years) with PCa were evaluated by ⁶⁸Ga-PSMA PET/CT; 63 vs. 97 men were previously submitted to initial vs. repeated biopsy and 25 of them were enrolled in an Active Surveillance (AS) protocol (4). Median PSA was 11.7 ng/ml (range=4.5-160 ng/ml) and 42/160 (26.2%) had abnormal digital rectal examination (DRE); all clinical parameters of men with PCa are listed in Table I. The study was approved by the Ethics Committee of our Hospital. All patients, before prostate biopsy, underwent mpMRI (11, 12) and ⁶⁸Ga-PET/CT imaging examinations (1) (Biograph 6; Siemens, Knoxville, TN, USA). ⁶⁸Ga-PSMA was prepared with a fully automated radiopharmaceutical synthesis device (Eckert & Ziegler Eurotope, Berlin, Germany); ⁶⁸Ga-PSMA-11 was administered to patients via an intravenous bolus and scans were acquired in 3-dimensional mode with an acquisition time of 3 min per bed position. Images were processed to obtain PET, CT, and PET-CT fusion sections in the axial, coronal, and sagittal planes with a thickness of approximately 0.5 ~ cm. The location of focal uptake on ⁶⁸Ga-PSMA PET/CT (Figure 1), three-dimensional size, and standardized uptake value (SUVmax) values were reported on a per-lesion basis with a sextant scheme (apex, midgland, and base, each split into left and right) (11). The diagnosis of PCa was previously performed by



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Table I. Clinical, histological, and ⁶⁸Ga-prostate specific membrane antigen (PSMA) positron emission tomography/computed tomography (PET/CT) parameters in 160 men with prostate cancer.

Clinical and biopsy findings (number of patients)	GG1	GG2	GG3	GG4	GG5
Initial biopsy	9	6	5	8	35
Repeated biopsy	41	19	10	12	15
Median PSA (range=4.5-160 ng/ml)	5.3	6.5	7.2	30	31
Abnormal DRE	0	2 (8%)	3 (20%)	7 (31.8%)	30 (60%)
Median GPC	30%	45%	70%	85%	90%
Median number of positive cores	3	8	10	12	13
mpMRI PI-RADS score ≥3	12 (24%)	10 (40%)	9 (60%)	16 (80%)	45 (90%)
⁶⁸ Ga-PSMA PET/TC	11	14.7	20.8	40.6	42.8
Median SUVmax value (range)	(2.7-20)	(7.8-20)	(12.8-22.9)	(13.6-94.2)	(20-164)

ISUP GG: International Society of Urological Pathology Grade Group; mpMRI: multiparametric magnetic resonance imaging; PSA: prostate specific antigen; GPC: greatest percentage of cancer; DRE: digital rectal examination; PI-RADS: Prostate imaging reporting and data system; SUVmax: standardized uptake value.

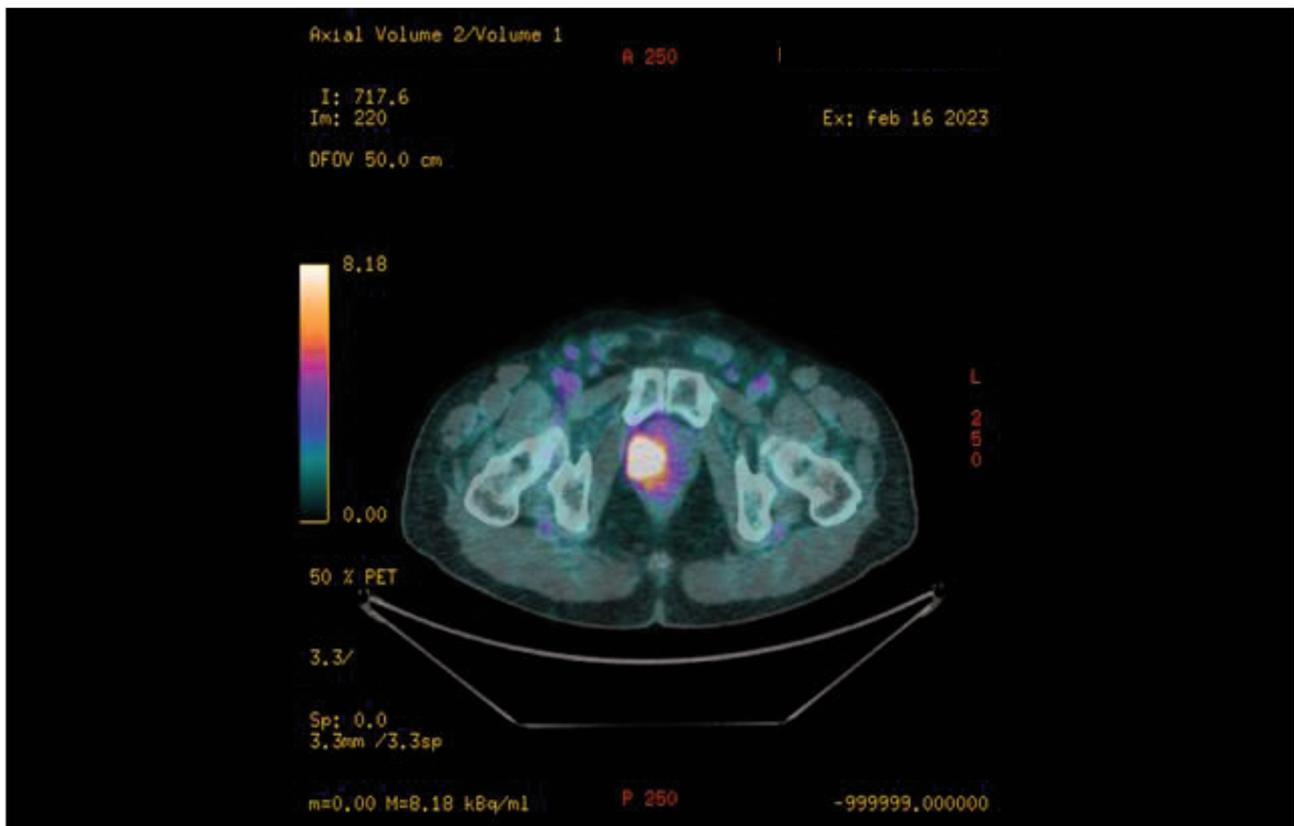


Figure 1. ⁶⁸Ga-prostate-specific membrane antigen (PSMA) positron emission tomography/computed tomography: presence of ISUP grade group 5 prostate cancer (SUVmax 18) in the right lobe of the gland (axial evaluation).

extended systematic prostate biopsy (median 18 cores) (13,14) combined with four targeted cores in the presence of mpMRI (Prostate Imaging Reporting and Data System “PI-RADS version 2”≥3) and ⁶⁸GaPSMA-PET/CT lesions suspicious for PCa (1,12). The procedure was performed transperineally using a tru-cut 18-

gauge needle (Bard, Covington, GA, USA) under sedation and antibiotic prophylaxis. Prostate-targeted cores were obtained using a Hitachi 70 Arietta ecograph (Chiba, Japan) supplied by a bi-planar transrectal probe by one urologist with 10 years of experience in cognitive targeted biopsy. Data were collected following START

criteria (15). None of the patients had clinical complications following prostate biopsy (Dindo-Clavien grade1) (16). The intraprostatic SUVmax value was evaluated for each International Society of Urological Pathology (ISUP) grade group (GG) PCa. In addition, the SUVmax value of the metastatic lesions was reported. For the statistical analysis, we used the Student's *t*-test with a *p*-value < 0.05 considered as statistically significant.

Results

Among the 160 men with Pca, 50 (31.2%) were ISUP GG1, 25 (15.6%) ISUP GG 2, 15 (9.5%) ISUP GG3, 20 (12.5%) ISUP GG4, and 50 (31.2%) ISUP GG 5, respectively. In detail, 145/160 (90.7%) were csPCa (ISUP GG \geq 2): 119/160 (74.3%) and 41 (25.7%) were located in the peripheral and anterior zones of the gland, respectively. Clinical and histological biopsy parameters of men with PCa are reported in Table I. In the 160 men with PCa, the median intraprostatic ⁶⁸Ga-PSMA SUVmax was 26.1 (range=2.7-164); in the 15 men with not clinically significant PCa (ISUP GG1) median SUVmax was 7.5 (range=2.7-12.5); only 1/25 (4%) of patients enrolled in the AS protocol was reclassified. In the 145 men with csPCa, median SUVmax was 33 (range=7.8-164) and significantly correlated with PCa grade group: ISUP GG3 (SUVmax 20.8) vs. ISUP GG4 (SUVmax 40.6) and GG5 (SUVmax 42.8), (*p*=0.01), respectively (Table I). Median SUVmax in the bone and node metastases was 52.7 (range=25.3-92.8) and 47 (range=24.5-65), respectively.

A SUVmax cut-off equal to 8 demonstrated a diagnostic accuracy in the diagnosis of csPCa equal to 87.7% vs. 89.3% vs. 100% in the presence of a GG1 PCa vs. GG2 PCa vs. GG \geq 3 PCa, respectively.

Discussion

⁶⁸Ga-PSMA-PET/CT is recommended to improve the clinical staging of high-risk PCa and disease recurrence (1, 10, 17); at the same time, PSMA PET/CT has been proposed for the diagnosis of primary intraprostatic cancer because a positive PET/CT scan results from a combination of factors, such as homogeneity and intensity of PSMA expression, tumor volume, and grade. The presence of focal uptake on PSMA-PET/CT, SUVmax, and the maximal dimensions of PET-avid lesions have been correlated with the presence of csPCa (18-21). There is a range of proposed cutoffs to detect csPCa from SUVmax 3.15 to SUVmax 9.1 (22-26). Kalapara *et al.* (27) compared the accuracy of ⁶⁸Ga-PSMA PET/CT with mpMRI in 205 men who underwent radical prostatectomy and showed an accuracy of 96% vs. 91% for the detection of csPCa. Demirci *et al.* (22) in 141 patients submitted to radical prostatectomy showed that the SUVmax values were significantly higher in high-risk patients compared those in low-risk patients (18.9 \pm 12.1 vs. 7.16 \pm 6.2).

Recently, the PRIMARY study (28) evaluated the clinical significance of intraprostatic patterns of PSMA activity, proposing a 5-point PRIMARY score to optimize the accuracy of ⁶⁸Ga-PSMA PET/CT for csPCa; ⁶⁸Ga-PSMA PET/CT was centrally read for pattern [diffuse transition zone (TZ), symmetric central zone (CZ), focal TZ, or focal peripheral zone (PZ) and intensity (SUVmax)]. In this post hoc analysis, a 5-level PRIMARY score was assigned on the basis of analysis of the central read: no pattern (score of 1), diffuse TZ or CZ (not focal) (score of 2), focal TZ (score of 3), focal PZ (score of 4), or an SUVmax of at least 12 (score of 5). Sensitivity, specificity, positive predictive value, and negative predictive value for a PRIMARY score \geq 3 (high-risk patterns) were 88%, 64%, 76%, and 81%, respectively.

In definitive, in the last years, ⁶⁸Ga-PSMA PET/CT evaluation has been proposed in men with clinically suspicious high risk PCa and/or when mpMRI cannot be performed (claustrophobia, cardiac pacemaker, and severe obesity) (1, 29, 30-32).

In our series, among the 160 men, ⁶⁸Ga-PSMA was correlated with the aggressiveness of PCa; in detail, a SUVmax of 8 demonstrated the presence of a csPCa in 142/145 (98%) with a false positive rate of 4.8% (7 cases). On the contrary, only 3/25 (12%) men with a ISUP GG2 had a SUVmax below 8. In addition, median SUVmax in the bone and node metastases was 52.7 (range=25.3-92.8) and 47 (range=24.5-65), respectively.

Our study has some limitations. First, a greater number of patients should be evaluated; second, the results should be evaluated in the entire prostate specimen and not in biopsy histology. Finally, the true accuracy of ⁶⁸Ga-PSMA PET/CT in the diagnosis of PCa should be evaluated also based on the biopsy specimen with a benign pathology.

Conclusion

⁶⁸GaPSMA PET/CT with a SUVmax cut-off of 8 demonstrated a good accuracy in the diagnosis of csPCa (100% in the presence of GG \geq 3) and metastases and has a good cost-benefit ratio as a single procedure for the diagnosis and staging of high-risk PCa.

Conflicts of Interest

The Authors declare no conflicts of interest in regard to this study.

Authors' Contributions

Pepe Pietro designed, interpreted clinical data, and wrote the manuscript. Pepe Ludovica, Tamburo Maria, Marletta Giulia, Savoca Francesco, Pennisi Michele, and Frassetto Filippo analyzed and interpreted the clinical data. All Authors revised the manuscript critically for important intellectual content and approved its final version.

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