OBJECTIVE: To evaluate the diagnostic performance of \[^{68}\text{Ga} \]Ga-PSMA\textsuperscript{HBED-CC} conjugate 11 positron emission tomography (PSMA-PET) in the early detection of metastases in patients with biochemical recurrence (BCR) after radical prostatectomy (RP) for clinically non-metastatic prostate cancer, to compare it to CT/MRI alone and to assess its impact on further therapeutic decisions.

MATERIAL AND METHODS: We retrospectively assessed 117 consecutive hormone-naïve BCR patients who had \[^{68}\text{Ga} \]Ga-PSMA 11 PET/CT (n = 46) or PET/MRI (n = 71) between May 2014 and January 2017. BCR was defined as two PSA rises above 0.2 ng/ml. Two dedicated uro-oncological imaging experts (radiology/nuclear medicine) reviewed separately all images. All results were presented in a blinded sequential fashion to a multidisciplinary tumorboard in order to assess the influence of PSMA-PET imaging on decision-making.

RESULTS: The median time from RP to BCR was 36 months (IQR 16-72). Overall, 69 (59%) patients received postoperative radiotherapy. Median PSA level at the time of imaging was 1.04 ng/ml (IQR 0.58-1.87). PSMA-positive lesions were detected in 100 (85.5%) patients. Detection rates were 65% for a PSA value of 0.2 to <0.5 ng/ml, 85.7% for 0.5 to <1, 85.7% for 1 to <2 and 100% for ≥2. PSMA-positive lesions could be confirmed by either histology (16%), PSA decrease in metastasis-directed radiotherapy (45%) or additional information in diffusion-weighted imaging when PET/MRI was performed (18%) in 79% of patients. PSMA-PET detected lesions in 67 patients (57.3%) who had no suspicious correlates according to the RECIST 1.1 criteria on MRI or CT. PSMA-PET changed therapeutic decisions in 74.6% of these 67 patients (p < 0.001), with 86% of them being considered for metastases-directed therapies.

CONCLUSIONS: We confirm the high performance of PSMA-PET imaging for the detection of disease recurrence sites in patients with BCR after RP, even at relatively low PSA levels. Moreover, it adds significant information to standard CT/MRI, changing treatment strategies in a significant number of patients.

KEYWORDS: Biochemical recurrence; Hybrid imaging; PET/CT; PET/MRI; PSMA ligand; Prostate cancer

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