

Verification of ¹⁸F-Prostate-Specific Membrane Antigen PET/CT detected lesions - A systematic assessment of the positive predictive value in patients with biochemically recurrent prostate cancer

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Introduction & Objectives: Prostate-Specific Membrane Antigen (PSMA) PET/CT is a new imaging modality with high sensitivity for prostate cancer (PCa) metastases. Despite its widespread use in patients with biochemically recurrent prostate cancer (BCR), the malignant nature of PSMA-avid lesions is seldom confirmed, which bears important clinical consequences. Therefore, the aim of this study was to assess the positive predictive value (PPV) of PSMA PET/CT in patients with BCR.

Materials & Methods: All patients with BCR scanned with ¹⁸Fluorine (¹⁸F)-PSMA (i.e. ¹⁸F-DCFPyL) PET/CT between November 2016 and March 2019 in two Dutch hospitals were retrospectively analyzed and their follow-up was collected. The PPV was calculated for PSMA PET detected metastases that could be verified through either (1) histopathological examination (lymph node dissection; CT-guided biopsy; transrectal prostate biopsy); (2) additional imaging studies (e.g. MRI, CT); (3) a $\geq 50\%$ prostate-specific antigen (PSA)-response following stereotactic or salvage radiotherapy; (4) characteristic abnormalities on the concomitant CT scan (lymph nodes $>6\text{mm}$; bone lesions suspected for metastases).

Results: A total of 262 patients was included, of whom 226 patients (86.3%) had a positive ¹⁸F-PSMA PET/CT scan (95% CI 82.1-90.5%). In 150 out of 262 scans (57.3%), verification of the PET-detected lesions had been performed. The PPV of PSMA-avid lesions was 96.1% (95% CI 94.2-97.9%). In patients with a PSA $<2.0\text{ng/mL}$ ¹⁸F-DCFPyL PET/CT showed a PPV of 86.7%, compared to a PPV of 98.3% ($P < 0.001$) in patients with a PSA $\geq 2.0\text{ng/mL}$.

	Histopathology	Additional imaging	PSA-response $\geq 50\%$	CT correlation	Total
Confirmed lesions	24	25	28	337	414
Falsified lesions	7	2	8	0	17
PPV	77.4%	92.6%	77.8%	100.0%	96.1%

Conclusions: This is the first thorough evaluation of ¹⁸F-PSMA PET positive lesions in patients with BCR. High PPV was observed, even at PSA levels $<2.0\text{ng/mL}$. Combined with a high detection rate, PSMA PET appears both a sensitive and valid instrument to guide further treatment in patients with BCR.