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A multicentre prospective clinical trial of ⁶⁸Gallium PSMA HBED-CC PET-CT restaging in biochemically relapsed prostate carcinoma: Oligometastatic rate and distribution, compared to standard imaging.

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AIM: This study is to assess the utility of ⁶⁸Gallium PSMA HBED-CC PET/CT (PSMA-HBED), compared to standard imaging, in the detection of recurrent prostate carcinoma in patients with biochemical relapse, to determine the prevalence of oligometastatic disease recurrence and its distribution.

METHOD: This is a prospective, multicentre clinical trial of PSMA-HBED PET/CT imaging in patients with early biochemical relapse of prostate carcinoma (PCa) (median PSA 2.55ng/ml) following definitive prostatectomy (152 patients) or radiotherapy (86 patients) with either no lesions or oligometastatic disease on abdominopelvic CT (CT) and bone scan (BS). PSMA-HBED PET/CT scan was performed within 8 weeks of restaging imaging, all sites of abnormal PSMA-HBED binding determined as probable or definite for prostate carcinoma were included in the analysis. PSMA positivity was assessed for correlation with Gleason Score, PSA level and PSA doubling time (PSAdt).

RESULTS: 238 patients underwent PSMA-HBED PET/CT imaging. In 199 patients with no lesions

on restaging CT and BS, 148 (74%) demonstrated PSMA positive lesions, with 113 (57%) being oligometastatic. In 39 patients with oligometastatic lesions on restaging CT and BS, 19 (49%) were confirmed as oligometastatic on PSMA PET/CT and 16 patients (41%) were upstaged to polymetastatic. The 4 remaining patients (10%) with sites of possible metastatic disease were not confirmed as prostate carcinoma. Combining the overall group, there were 183 patients (77%) with PSMA-HBED positive lesions (682 lesions) suggesting prostate carcinoma, of which 132 patients (55%) were oligometastatic. In the oligometastatic group, PSMA positivity was limited to the pelvis in 65% of patients, involving either the prostate or nodes (AJCC N1). This study found a positive correlation between PSMA-HBED positivity and PSA levels, no other factors were statistically significant.

CONCLUSION: For patients with biochemical relapse with BS and CT demonstrating either no disease or low volume disease, there is a high overall prevalence of PSMA PET/CT positive disease. More than half of the patients were oligometastatic and of those, disease was confined to the pelvis in nearly two thirds of patients. This confirms that PSMA PET/CT is significantly more sensitive than standard restaging imaging and may be useful in identifying patients for subsequent targeted therapy.

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KEYWORDS: Biochemical relapse; HBED-CC; PSMA; Prostate cancer; Prostate specific membrane antigen; oligometastasis

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