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Preliminary results of 68Ga-PSMA PET/CT prospective study in prostate cancer occult recurrence patients: diagnostic performance and impact on therapeutic decision-making

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Introduction: The aim of this prospective study was to investigate the impact of 68Ga-PSMA-11 PET/CT on current management of prostate cancer patients with occult biochemical recurrence (BCR). Subjects & Methods: 130 hormone-naïve occult BCR (PSA) from 0.05 to 1.6 ng/mL) patients were enrolled in a prospective study (NCT03443609). All patients received a radical treatment (prostatectomy +/- radiotherapy) which allowed to an undetectable PSA level. Before PSMA PET/CT, patients were screened by conventional imaging as mpMRI and bone scan (+ trunk SPECT/ CT) and enrolled only if conventional imaging was doubtful or normal. PET images were recorded 1 and 2 hours after injection of 150 MBq of tracer and images interpreted by 2 nuclear physicians. Referring patient physician completed 2 questionnaires to assess PSMA PET imaging influence on therapeutic strategy: one prior and one after PSMA PET/CT indicating treatment plan without and with PSMA PET/CT information respectively. Six months after the end of treatment, a PSA assay was requested to evaluate therapeutic efficacy. **Results**: Currently, we have complete data analysis of the first 52 patients. After pre-screening, 7 patients were excluded due to positive MRI (5 pts) or bone scan (2 pts). The median time from radical prostatectomy or radiotherapy to BCR was 4.92y (0.6-15.46). Thirty-eight among the 52 patients (73%) had a positive PSMA PET/CT. Ninety-four lesions were detected, 53/94 in lymph nodes (56.4%) predominantly dispatched on pelvic area (75.5%), 25/94 in bone (26.6%) (mostly on axial skeleton) and 12/94 into prostate bed (12.7%). Detection rates were 56 %, 87 % and 74% for patients with PSA value ranging from 0.05 to 0.3, 0.3 to 0.6 and 0.6 to 1.6 ng/ml respectively. Thanks to PSMA PET/CT, therapeutic management changed in 35/52 patients (67.3%). PSMA-positive patients had undetectable PSA level after stereotaxic radiotherapy or focal surgery based on PSMA results in 30.7% (16/52). In this particular hormone naïve patient population, Rauscher's nomogram (1) was not validate, may be due a too small population. **Conclusion**: Preliminary results of this prospective study showed, in more than half of patients, a major impact of PSMA PET/CT on treatment management allowing them to benefit very early from focal therapy with the great result for 30% of them of PSA complete response. Reference: (1) Rauscher I., et al: doi:10.1016/j.eururo.2018.01.006