Prospective head-to-head comparison of 68Ga-PSMA-11 and 18F-Fluciclovine PET/CT in 50 patients with prostate cancer biochemical recurrence after primary prostatectomy: A preliminary analysis

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Background: 18F-Fluciclovine PET/CT (AXUMIN) is FDA approved and CMS reimbursed for localization of prostate cancer (PCa) biochemical recurrence (BCR) after definitive therapy.
68Ga-PSMA-11 PET/CT (PSMA) detects PCa BCR even at low prostate-specific antigen (PSA) levels (<2.0 ng/mL) and is thus used in US clinical trials and in clinical routine practice worldwide. Here we present a prospective head-to-head comparison of these 2 PET/CT imaging tracers for localizing PCa BCR after radical prostatectomy (RP) in patients with PSA < 2.0 ng/ml.

Methods: This was a prospective single-center head-to-head comparison (NCT03515577, UCLA IRB#17-001885). Patients with PCa BCR and PSA levels ranging from ≥0.2 to ≤2.0 ng/mL without any prior salvage therapy were eligible. All patients underwent AXUMIN and PSMA scans within ≤15 days. Images analysis was performed a) by on-site clinical reading and b) by 3 blinded international expert readers for each modality. Detection rates on per-patient and per-region based analysis served as primary study endpoint. Detection rates stratified by PSA, sensitivity and positive predictive value verified by histopathology and/or clinical and conventional imaging follow-up as reference standard, served as secondary endpoints. Based on literature data we hypothesized a detection rate difference of 22% in favor of PSMA. A power analysis determined a sample size of 50 patients.

Results: Enrollment of the 50 patients was completed from March to September 2018. Median PSA level was 0.50 ng/ml (mean 0.63; range 0.2-2.0 ng/ml). Median time interval between the 2 scans was 6 days (range 1-15). We present here the preliminary results from the non-blinded clinical reads. Detection rate on a per-patient basis was 69% for PSMA and 34% for AXUMIN. Concordant findings were observed in 30/49 patients (61%): 16/49 (32%) had concordantly positive scans while 14/49 (29%) had concordantly negative scans. Discordant findings were observed in 19/49 patients (39%): 18/49 (37%) had a positive PSMA but a negative AXUMIN scan while 1/49 (2%) had a positive AXUMIN with a negative PSMA (local recurrence). Detection rates were consistently lower for AXUMIN than for PSMA for all examined regions (Prostate bed (12% vs 20%), pelvic nodes (14% vs 37%), extra-pelvic nodes (2% vs 8%), skeleton (2% vs 8%) and visceral organs (2% vs 6%).

Conclusion: This preliminary analysis demonstrates prospectively that PSMA detection rate is more than double the AXUMIN detection rate in patients with PCa BCR after RP and with PSA < 2.0 ng/ml. Detection rates were superior on per-patient and per-region based analysis. Final results will include the blinded reads of the 3 international expert readers for each modality, patient follow-up as well as lesion verification (histopathology, imaging follow-up, PSA after focal therapy).

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Conflict of Interest

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