**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

This is an investigator-initiated trial with institutional funding. Study is funded by the Ahmanson Translational Theranostics Division (UCLA). Amar Kishan received honoraria from Varian Medical Systems. Johannes Czernin is founder and board member of Sofie Biosciences and a Founder of Trethera Therapeutics. No other potential conflict of interest relevant to this article was reported.