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Prostate 3D transrectal ultrasound performance detecting clinically significant prostate cancer in patients with rising PSA level after previously negative prostate biopsy

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Introduction & Objectives: This is a prospective pair cohort validating study to assess the prostate 3D transrectal ultrasound (HistoScanning) performance detecting clinically significant prostate cancer in patients with rising PSA level after previously negative prostate biopsy.

Materials & Methods: Data was collected prospectively from 2016 April to 2018 September for 200 patients who had their serum PSA levels rising for at least 4 months after previous negative transrectal ultrasound-guided biopsy in a single center. All eligible men underwent prostate HistoScanning and transperineal template prostate mapping biopsy as our reference standard and additional single targeted biopsy, when prostate HistoScanning device tested positive with a suspicious lesion of ≥0.5 cm^3. Our primary goal was to obtain the results of PHS ability to detect clinically significant prostate cancer. Our secondary goal was to acquire data on prostate Histoscanning targeted biopsies.

Results: In our study 200 men were enrolled and the mean age was 62 (±5.9) years. Mean PSA concentration at consent was 5.63 (±2.86) ng/ml. Mean transrectal ultrasound prostate volume was 69.07 (±41.17). Mean number of previous biopsies was 1.51 (±0.65). Forty one (20.5%) patients had clinically significant prostate cancer on biopsy. One hundred four (52%) patients had prostate cancer of any significance on biopsy. Mean volume of PHS index lesion in any one prostate was 1.56 (±2.01) cm^3. One hundred forty eight underwent targeted biopsies to the largest suspicious lesion detected by prostate Histoscanning. One hundred sixteen (78.38%) were incorrectly classified as benign or malignant by prostate Histoscanning comparing to biopsy results. Thirty (73.17%) patients with clinically significant prostate cancer biopsy results were misclassified as benign by prostate Histoscanning. Two (4.88 %) patients were diagnosed with csPCa by targeted biopsies on prostate Histoscanning suspicious lesions, when on 20-core-TTPM biopsy csPCa was undetected. Sensitivity of prostate Histoscanning for detecting clinically significant prostate cancer was 61.9% (95% CI 45.64-76.43) with specificity 27.85% (95% CI 21-35.53). PPV and NPV for prostate HistoScanning were 18.57% (95% CI 15-22.76) and 73.33% (95% CI 63.45-81.33), respectively. Overall accuracy calculated by AUROC curve was 0.39 (95% CI 0.3-0.47).

Conclusions: Prostate 3D transrectal ultrasound performance results of our study on detecting clinically significant were insufficient to include this ultrasound-guided diagnostic test as standard diagnostic tool.