Assessing the diagnostic accuracy of micro-ultrasound for the detection of clinically significant prostate cancer: results from a single-institutional preliminary experience

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Background: Prostate cancer (PCa) is the most prevalent cancer among European men. While mpMRI has progressively gained an important role in the PCa diagnostic pathway, its widespread use in clinical practice is still limited by cost-effectiveness considerations. In addition, it has been shown that mpMRI may miss a significant proportion of cancers especially in the initial biopsy setting. Micro-ultrasound is a new ultrasound-based imaging modality with resolution down to 70 microns, a 300% improvement over conventional ultrasound. This study reports on our preliminary clinical after introducing micro-ultrasound into our prostate biopsy clinic.

Methods: Data on the first 42 patients at our institution imaged with the ExactVu micro-ultrasound system between October 17th and October 31st were prospectively collected. All patients were scheduled for prostate biopsy due to clinical suspicion of PCa (abnormal DRE or elevated PSA). The PRI-MUS protocol was used to locate targets on micro-ultrasound, and these targets were Compared to biopsy pathology results. Lesions with a PRI-MUS score ≥3 were targeted. The presence of clinically significant PCa (defined as a Gleason score ≥7 cancer; csPCa) was determined.

Results: Median age of patients was 64 years (range 50-78) and median total PSA was 6.7 ng/mL (range 2.2-19.0). Overall, 547 biopsy samples were taken from 42 patients. Micro-ultrasound detected prostate lesions with a PRI-MUS score of 3, 4 and 5 in respectively 2 (4.8%), 17 (40.4%) and 13 (309%) patients, while in 10 (23.8%) individuals micro-ultrasound did not identify any target. Overall PCa and csPCa detection rates were 47.6% (n=20) and 26.1% (n=11). Micro-ultrasound targets provided high sensitivity, with 90.9% of patients (10 out of 11) with csPCa having at least 1 positive target. Negative predictive value was also 90.9%, with 9 out of 10 patients with no micro-ultrasound targets receiving a benign diagnosis after systematic biopsy. Not surprisingly, in our preliminary experience, positive predictive value and specificity were lower (31.2% and 31.2%), likely due to over-targeting while we become more comfortable with the new tissue detail this modality offers. Retrospective analysis on the single false negative patient revealed a PRI-MUS 4 lesion missed during the case. Including this lesion as a target would bring both the sensitivity and NPV of micro-ultrasound up to 100%.

Conclusions: Micro-ultrasound is a promising new imaging modality showing high sensitivity to detect csPCa. In addition, the system appears to be capable of reliably excluding the presence of csPCa in the great majority of patients even in our initial experience. Future efforts aimed at outlining our learning curve and comparing the diagnostic accuracy of this technique to that of mpMRI are warranted.