

Avolio P.P., Persico F., Lazzeri M., Hurle R., Saita A., Frego N., Maffei D., Paciotti M., Diana P., Uleri A., Contieri R., Buffi N.M., Casale P., Guazzoni G.F., Lughezzani G.

Humanitas Clinical and Research, Dept. of Urology, Rozzano, Italy

**Introduction & Objectives:** While mpMRI has progressively gained an important role in the prostate cancer (PCa) diagnostic pathway, its widespread use in clinical practice is still limited by cost-effectiveness considerations. Micro-ultrasound (micro-US) is a new imaging modality with high resolution down to 70um. This study reports on our clinical experience after introducing micro-US into our prostate biopsy clinic.

**Materials & Methods:** Data on 709 consecutive patients imaged with the ExactVu micro-US system between October 2017 and July 2019 were prospectively collected. All patients were scheduled for prostate biopsy due to clinical suspicion of PCa. The PRI-MUS protocol was used to locate targets on micro-US. Lesions with a PRI-MUS score  $\geq 3$  were targeted. Patients were also subjected to systematic prostate biopsies. The presence of overall PCa and of clinically significant PCa (defined as a Gleason score  $\geq 7$ ; csPCa) was determined and the diagnostic performance of micro-US was assessed. Logistic regression models (LRMs) were fitted to test the predictors of csPCa.

**Results:** Median age was 66 (SD 7.8) yrs, median total PSA was 7 (IQR 5-9.5) ng/mL and median prostate volume was 50 (IQR 35 - 70) mL. Overall, 301 (42.4%) patients were in the repeat biopsy setting, with 119 (16.7%) patients on active surveillance. Micro-US detected prostate lesions with a PRI-MUS score of 3, 4 and 5 in respectively 89 (12.5%), 281 (39.6%) and 120 (16.9%) patients, while in 219 (30.9%) individuals micro-US did not identify any target. Overall PCa and csPCa detection rates were 51.9% (368/709) and 36.1% (256/709). Micro-US provided high sensitivity, with 93.8% csPCa patients having at least one PRI-MUS score  $\geq 3$  lesion. Similarly, NPV was 85.2 patients with no micro-US targets receiving a benign or GS=6 PCa diagnosis (after systematic and MRI-target biopsy). Conversely, PPV and specificity were lower (41.3% and 23.0%), likely due to over-targeting. At multivariable LRMs, after adjusting for several confounders, patients with a PRI-MUS 4 or 5 lesion had respectively a 2.85 and 8.35 higher risk of harboring csPCa compared to those with a micro-US PRIMUS <3 pattern ( $p < 0.01$ ). Besides increasing PRI-MUS score, age (OR 1.056;  $p < 0.001$ ), initial biopsy setting (OR 2.45;  $p < 0.001$ ) and increasing prostate volume (OR: 1.006;  $p < 0.001$ ) achieved the independent predictor status.

**Conclusions:** Micro-US 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. Multi-institutional efforts are still needed to further support the adoption of this tool in the diagnostic pathway of patients with suspected PCa.