

## P005 Micro-ultrasound target biopsies for the diagnosis of clinically significant prostate cancer: Results from a large single-center experience

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**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 (microUS) is a high-resolution new imaging modality for transrectal ultrasonography (TRUS). This study reports on our clinical experience after introducing microUS into our prostate biopsy clinic.

**Materials & Methods:** Data on 427 consecutive patients undergoing microUS-guided prostate biopsy due to clinical suspicion of PCa between 01/10/17 and 30/04/19 were prospectively collected. The PRI-MUS protocol was used to locate targets on microUS. Lesions with a PRI-MUS score  $\geq 3$  were targeted. Patients were also subjected to systematic prostatic biopsies. The presence of overall PCa and of clinically significant PCa (defined as a Gleason score  $\geq 7$ ; GS; csPCa) was determined and the diagnostic performance of microUS was assessed. Logistic regression models (LRMs) were fitted to test the predictors of csPCa.

**Results:** Median patient age was 66 (IQR 60-71) years, median total PSA was 7.1 (IQR 5.1-9.6) ng/mL and median prostate volume was 47.7 (IQR 35-70) mL. Overall, 184 (43.1%) patients were in the repeat biopsy setting. MicroUS detected prostate lesions with a PRI-MUS score of 3, 4 and 5 in respectively 53 (12.4%), 207 (48.5%) and 95 (22.2%) patients, while in 72 (16.9%) subjects no targets were identified. Overall PCa and csPCa detection rates were 52.9% (226/427) and 37.7% (161/427). MicroUS yielded a csPCa sensitivity of 91.3%, with 147/161 patients having at least one PRI-MUS score  $\geq 3$  lesion. Similarly, NPV was 80.6%, with 58/72 patients with negative TRUS receiving a benign or Pca GS=6 diagnosis after systematic biopsy. PPV and specificity were significantly lower (41.4% and 21.2%), likely due to over-targeting. In multivariable LRMs, patients with a PRI-MUS 4 or 5 lesion respectively showed a 2.3- and 5.4-fold higher risk of harbouring csPCa compared to those with a PRI-MUS  $< 3$  pattern ( $p \leq 0.035$ ). Also  $\log_{10}(\text{PSA})$  (OR: 3.8;  $p=0.01$ ), decade of age (OR: 2.0;  $p < 0.001$ ), abnormal DRE (OR: 2.2;  $p=0.009$ ), initial biopsy setting (OR: 2.7;  $p < 0.001$ ) and decreasing prostate volume (OR: 0.98;  $p < 0.001$ ) achieved the independent predictor status. The full model had an AUC of 0.77 in leave-one-out validation.

**Conclusions:** MicroUS is a promising new imaging modality showing high sensitivity in detecting 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.