P004 Assessing the diagnostic accuracy of micro-ultrasound for the detection of clinically significant prostate in the initial biopsy setting

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Introduction & Objectives: Prostate cancer (PCa) is the most prevalent cancer among European men. Current EAU guidelines have included MRI in the PCa diagnostic pathway for biopsy-naive subjects, yet it has significant drawbacks in terms of costs and availability. Micro-ultrasound(microUS) has recently emerged as an alternative diagnostic strategy capable of providing real-time targeting of prostatic lesions. Our aim was to evaluate the diagnostic accuracy of micro-US in a naïve population of patients with clinical suspicion of PCa.

Materials & Methods: Data on 243 subjects undergoing transrectal ultrasonography (TRUS) with the ExactVu microUS system between 01.10.2017 and 30.04.19 were prospectively collected. All subjects were scheduled for prostate biopsy due to clinical suspicion of PCa; none had previously undergone prostate biopsy. The PRI-MUS protocol was used to locate targets on microUS. Lesions with a PRI-MUS score ≥3 were targeted; complementary systematic random prostate biopsies were obtained. The presence of overall PCa and of clinically significant PCa (defined as Gleason Score ≥7 cancer; GS; csPCa) was determined. The diagnostic accuracy of microUS was determined.

Results: Median patient age was 65(IQR 60-71) years, median total PSA was 6.7 (IQR 4.7-9.0) ng/mL and median prostate volume was 42 (IQR 32-60). 83 (34%) patients had a positive digital rectal examination. Micro-US detected prostate lesions with a PRI-MUS score of 3, 4 and 5 in respectively 31(12.8%), 116 (47.7%) and 59 (24.3%) subjects, while in 37 (15.2%) patients microUS did not identify any target. Overall PCa and csPCa detection rates were 57.2% (n=139) and 46.9% (n=114). CsPCa rates significantly increased from 27.0% in patients without micro-US lesions to 25.8%, 44.8% and 74.6% in patients with PRI-MUS 3, 4 and 5 lesions, respectively (p<0.001). MicroUS provided high sensitivity, with 91.2% (104/114) of patients with csPCa having at least one PRI-MUS score ≥3 lesion. The negative predictive value was 73.0%, with 27/37 patients with no microUS targets receiving a benign or GS=6 diagnosis after systematic biopsy. Conversely, positive predictive value and specificity were significantly lower (50.5% and 20.9%), likely due to over-targeting. Negative predictive value increased to 94.6% to rule out high grade cancer with only 2/37 patients with negative micro-US having GS≥4+3.

Conclusions: MicroUS could represent a notable upgrade in the initial diagnostic workup of patients with suspected PCa. Given its high sensitivity and NPV, this approach can be used to provide a real-time targeting of any suspicious lesion, while limiting the number of systematic cores when microUS is negative. Despite our promising results, multi-institutional efforts are still needed to further support the adoption of this tool in the initial diagnostic pathway of patients with suspected PCa.