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Introduction & Objectives:

Active surveillance (AS) has been implemented as the standard of care for patients diagnosed with low-risk prostate cancer (PCa). However, identification of AS candidates remains challenging. Micro- ultrasound (microUS) is a new imaging modality for transrectal ultrasonography (TRUS) with a spatial 70µm resolution. In our study we explored the diagnostic effectiveness of microUS-guided prostate biopsies within a contemporary cohort of AS patients.

Materials & Methods:

Between October 2017 and March 2020 we prospectively enrolled 105 patients who were scheduled for reclassification biopsy at 1year from diagnosis of low-risk PCa as part of the AS protocol. TRUS was performed using the ExactVu microUS system; PRI-MUS protocol was applied to identify suspicious lesions (i.e. PRIMUS score ≥ 3). All patients were subjected to target biopsies of any identified microUS and mpMRI lesions if present and complemented by systematic prostate biopsies. The presence of overall and clinically significant PCa (defined as Gleason score(GS) ≥ 7 cancer; csPCa) was determined. The proportion of patients who were excluded from AS for upgrading to csPCa at reclassification biopsies was determined, and the diagnostic performance of microUS was evaluated.

Results:

Median patient age was 65 (IQR 60-71) years, median total PSA was 7.0 (4.9-9.1)ng/mL and median prostate volume was 50.0 (35.5-70.0) mL. Overall, 12 (11.4)% patients had a positive DRE. 72 (68.6%) out of 78 patients with available mpMRI images had a PI-RADS ≥ 3 lesion. MicroUS detected prostate lesions with a PRI-MUS score of 3, 4 and 5 in respectively 18 (17.1%), 58 (55.2%) and 11 (10.5%) patients, while in 18 (17.1%) individuals microUS did not identify any target. Prostate cancer detection rate was 64.8% (68/105). Patients upgrade to GS ≥ 7 cancer and thus excluded from AS were 32 (47.1%). Multivariable LRMs showed that a significant higher risk of harboring csPCa in patients with PRI-MUS 3 and 4 (OR 9.1, $p=0.04$) and PRI-MUS 5 (OR 42.2, $p<0.01$). The diagnostic performance of microUS for detecting individuals excluded from AS was the following: sensibility: 96.9%, specificity: 23.3%, negative predictive value: 94.4%, and positive predictive value: 35.6%.

Conclusions:

In our experience MicroUS may represent a promising imaging modality showing high sensitivity to detect csPCa. It may allow better identify those patients who may safely benefit from remaining under AS. However, large-scale efforts are still needed to provide further evidences supporting the adoption of microUS in patients enrolled in AS protocols.