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Introduction & Objectives: The reduction of unnecessary prostate biopsies is an important clinical goal in order to minimize patient stress and to reduce the risk of infection or overtreatment. The aim of the current study was to assess whether micro-ultrasound (mUS) can help to provide a sub-stratification of patients with an indeterminate (PIRADS 3) lesion at multiparametric MRI (mpMRI).

Materials & Methods: We retrospectively analyzed the records of 103 patients with suspicion of prostate cancer (PCa) who underwent a mpMRI showing at least one PIRADS 3 lesion, who were referred to our Institution for a prostate biopsy between October 2017 and April 2019. Before biopsy, all patients underwent a mUS examination. The PRI-MUS protocol was used identify targets within the prostate. Subsequently, patients were subjected both to MRI/US fusion biopsy and to mUS-targeted biopsies. Additionally, systematic randomized biopsies were also performed. The presence of overall PCa and of clinically significant PCa (csPCa) defined as Gleason score ≥ 7 was determined. Finally, multivariable logistic regression models were fitted to test the predictors of PCa.

Results: Median age was 63.0 years, median total PSA was 6.0 ng/mL and median prostate volume was 50.5 mL. Of the 103 patients, 23 (22.3%) did not show any lesion at mUS (PRIMUS 1-2) while in the remaining 80 (77.7%) patients at least one target was identified (PRI-MUS ≥ 3). Among patients without lesions at mUS, 18 (78.3%) did not harbor PCa, while 5 (21.7%) patients were diagnosed with a Gleason score 6 PCa. Among patients with at least one PRI-MUS ≥ 3 lesion, 43 (53.7%) had a negative biopsy while 37 (46.3%) harbored PCa and 21 (26.2%) harbored csPCa. MicroUS showed an extremely high sensitivity and negative predictive value (100%), while its specificity and positive predictive value were 28.1% and 26.2%, respectively. In multivariable logistic regression models, the PRI-MUS score emerged as the only independent predictor of PCa, with patients with at least one PRI-MUS ≥ 3 showing a 3.8-fold higher risk of harboring PCa as compared to their counterparts without any lesion at mUS ($p = 0.021$).

Conclusions: According to our results, mUS is capable of stratifying the presence of PCa in patients with an equivocal mpMRI. Further prospective studies are needed to determine whether mUS could be adopted as a supplementary diagnostic tool in patients with equivocal findings at mpMRI.