

# P008 Micro-ultrasound guided prostate biopsies for clinically significant prostate cancer diagnosis in a cohort of biopsy-naive patients with mpMRI

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Maffei D.<sup>1</sup>, Avolio P.P.<sup>2</sup>, Paciotti M.<sup>2</sup>, Diana P.<sup>2</sup>, Frego N.<sup>2</sup>, Fasulo V.<sup>2</sup>, Regis F.<sup>2</sup>, Contieri R.<sup>2</sup>, Uleri A.<sup>2</sup>, Lazzeri M.<sup>2</sup>, Casale P.<sup>2</sup>, Saita A.R.<sup>2</sup>, Buffi N.M.<sup>1</sup>, Guazzoni G.F.<sup>1</sup>, Lughezzani G.<sup>1</sup>

<sup>1</sup>Humanitas University, Dept. of Biomedical Sciences, Pieve Emanuele, Italy, <sup>2</sup>Humanitas Clinical and Research Center - IRCCS, Dept. of Urology, Rozzano, Italy

## Introduction & Objectives:

Prostate mpMRI holds an early place in the EAU prostate cancer (PCa) diagnostic pathway, yet it is affected by drawbacks in terms of costs and availability while requires concomitant systematic biopsies. Micro-ultrasound (micro-US) has emerged as an alternative tool able to provide real-time identification and targeting of prostatic lesions. Our aims was to evaluate the diagnostic performance of micro-US in a biopsy-naïve population of patients with recent mpMRI and clinical suspicion of PCa.

## Materials & Methods:

Data on patients imaged with the Exact-Vu micro-US system during prostate biopsies at our centre between October 2017 and February 2020 were prospectively collected. 273 biopsy naïve patients with a clinical suspicion of PCa and prostate mpMRI were identified. PRI-MUS protocol was applied to identify suspicious lesions (PRIMUS score  $\geq 3$ ) which received 1-2 target biopsy cores. The procedure was completed with systematic biopsy and mpMRI-targeted biopsy of suspicious (i.e. PI-RADS  $\geq 3$ ) lesions. The detection rate of clinically significant PCa (defined as Gleason score  $\geq 7$  cancer; csPCa) was determined. The diagnostic performance of micro-US targeted, systematic, mpMRI-targeted biopsies and their combination was assessed.

## Results:

Mean patient age was 64.9 (SD8.1)yr, median total PSA was 6.5 (IQR 4.7-8.6) ng/mL and median prostate volume was 47 (IQR 35-68) mL. Suspicious lesions were identified by micro-US and mpMRI in 215 (78.8%) and 255 (93.4%) patients, respectively. Overall csPCa detection rate was 44.3% (121/273). CsPca rates significantly increased from 17.2% (5/29) to 44.9% (61/136) to 78.0% (39/50) in patients with PRI-MUS 3, 4 and 5 lesions, respectively ( $p < 0.01$ ). CsPCa detection rates significantly increased from 20.0% (10/50) to 45.7% (74/162) and 83.7% (34/43) in patients with PI-RADS 3, 4 and 5 lesions, respectively ( $p < 0.01$ ). Combination of micro-US targeted and randomized biopsies detected 119 (98.3%) patients, while combination of MRI-targeted and randomized biopsies also detected 119 (98.3%). 12 (9.9%) patients were identified only by random biopsy cores. Micro-US imaging provided high sensitivity, with 86.8% csPCa patients (105/121) having at least one PRI-MUS score  $\geq 3$  lesion. NPV was 72.4%, with 42/58 patients without target lesions receiving a benign or GS6 diagnosis. Conversely, PPV and specificity were lower (48.8% and 27.6%).

## Conclusions:

Micro-US may represent a valid tool in the initial diagnostic workup of patients suspected for PCa thanks to its high sensitivity and NPV as imaging test, as well as its ability to implement systematic biopsies with real-time identification and targeting of suspicious lesions. Randomised comparative trials with mpMRI are needed to establish its role in this patient population.