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Introduction & Objectives:

Multi-parametric MRI (mpMRI) of the prostate has consolidated its role in the diagnosis of prostate cancer for patient screening and targeting of suspicious lesions. High-resolution micro-ultrasound(micro-US) is a new US- based imaging modality enabling real-time targeted prostate biopsies. We examined the diagnostic accuracy of micro-US and mpMRI and compared their performance in guiding targeted and systematic prostate biopsies to diagnose clinically significant prostate cancer(defined as GS \geq 7; csPca).

Materials & Methods:

We enrolled 504 patients with clinical suspicion of PCa and available prostate mpMRI data in a prospective trial. The PRI-MUS protocol was applied to identify target lesions on micro-US. The urologist was blinded to mpMRI results until after the micro-US targeting was complete. All subjects received targeted biopsy (based on micro-US and mpMRI imaging) as well as systematic random biopsies. The detection rate of csPca was assessed and stratified according to biopsy strategy.

Results:

Mean age was 64.8(SD7.7)yr, median PSA was 7.0(IQR 5.0-9.5)ng/mL and median prostate volume was 50 (IQR 36-79)mL. Overall, 45.6% patients were in the repeat biopsy setting and 86(17.1%) were on active surveillance. Suspicious lesions were identified by micro-US and mpMRI in 402(79.8%) and 465(92.3%) patients, respectively. PCa was detection rate was 51.8%, with 184(36.5%) csPca diagnosed overall. CsPca detection rates significantly increased from 26.3% (15/57) to 36.4% (90/247) and 62.9% (61/97) in patients with PRI-MUS 3, 4 and 5 lesions, respectively (p<0.01). CsPca detection rates significantly increased from 20.8% (21/101) to 38.3% (108/282) and 62.2% (51/82) in patients with PI-RADS 3, 4 and 5 lesions, respectively (p<0.01). Micro-US target cores were positive for csPca in 137/184 (74.5%) patients, while combination of micro-US-guided targeted and randomized biopsies detected 176 (95.7%) csPca.

MpMRI-targeted cores were positive for csPca in 147 (78.6%) patients, while combination with randomized biopsies detected 178 (96.7%) csPca. Only 8 csPca were diagnosed by mpMRI-targeted cores alone, while 6 csPca patients were detected uniquely on micro-US-targeted cores. Micro-US imaging provided high sensitivity with 90.2% csPca patients (166/184) having at least one PRI-MUS score \geq 3 lesion. NPV was 82.5%, with 85/103 patients without target lesions receiving a benign or GS6 diagnosis. PPV and specificity were 41.4% and 26.6%, respectively. MpMRI sensitivity, specificity, PPV and NPV were 97.8%, 12.2%, 39.0% and 90.7%, respectively.

Conclusions:

Micro-US is a promising new imaging modality for targeted prostate biopsies, enabling high sensitivity to detect PCa. This work suggests that micro-US may provide additional information regarding the presence or absence of csPCa in patients with suspected PCa according to mpMRI and may further improve results over conventional MRI-US fusion biopsy.