Detection Rate of Clinically Significant Prostate Cancer by 3-Tesla In-bore MR-Guided Biopsy: Diagnostic Performance Based on PIRADSv2.1

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Introduction: Transrectal ultrasound-guided biopsy (TRUS-GB) is considered the diagnostic method of choice in individuals with suspicion of prostate cancer (PCa), however it leads to over-diagnosis of clinically insignificant PCa and underestimation of disease grade in clinically significant PCa (csPCa). Multiparametric MRI (mpMRI) followed by MR-targeted biopsy of suspicious lesions is shown to be accurate with high diagnostic yield and negative predictive value.

Objective and Specific Aims: To evaluate the diagnostic yield of 3 Tesla in-bore trans-rectal magnetic-resonance-guided biopsy (3T-MRGB) for PCa detection based on Prostate Imaging Reporting and Data System version 2.1 (PIRADSv2.1) in patients with either suspected PCa or under active surveillance (AS).

Rationale and background: There is no consensus on indications of in-bore MRGB of prostate and the accuracy of recently updated PIRADSv2.1 has not been assessed yet.

Methods and materials: This retrospective, IRB-approved, HIPAA-compliant, single-institution study included individuals who underwent 3T mpMRI and subsequent in-bore 3T-MRGB between February 2012 and March 2019. Three subcohorts included biopsy-naïve patients, those with history of recent negative TRUS-GB and those under AS. Clinically significant PCa was defined as Gleason score (GS) $\geq$ 3+4.

Results: Overall, 475 targets were sampled in 379 individuals (median age: 68 years). The rate of urosepsis was 1% (4 patients). MRGB detected PCa in 69.1% (262/379) of individuals, of whom 73.7% (193/262) had csPCa. The detection rate of PCa was 64.2% (305/475) per target with 68.2% (208/305) being clinically significant. The core positivity percentage was 46.2%. csPCa was detected in 36.8% (39/106) and 52.8% (65/123) of negative TRUS-GB and biopsy-naïve subcohorts, respectively. In AS subcohort, MRGB upgraded GS in 50.7% (76/150) of patients compared to GS from prior TRUS-GB. Higher PIRADSv2.1 category was significantly associated with overall PCa (OR: 3.97, 95%CI: 2.98-5.28) and csPCa (OR: 1.41, 95%CI: 1.03-1.94) detection. Overall, PIRADSv2.1 in comparison with PIRADSv2, allowed a downgrade to PIRADSv2.1 category 2 in 19% (26/137) of lesions with PIRADSv2 category 3.

Discussion and Conclusion: 3T-MRGB was safe and resulted in the detection of csPCa in 50.9% of individuals. Our detection rate was higher than the reported detection rates of MR-ultrasound fusion studies. 3T-MRGB had a high diagnostic yield in individuals with history of negative TRUS-GB and those under active surveillance. PIRADSv2.1 category

was a strong predictor of PCa and csPCa detection. We recommend performing prostate mpMRI, followed by in-bore MRGB of positive lesions in individuals with high suspicion of csPCa despite a negative systematic biopsy and in those who are qualified for AS.