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ABSTRACT # 11

A RANDOMIZED CONTROLLED TRIAL OF TRUS-ROBOT VS. URONAV BIOPSY IN THE DIAGNOSIS OF CLINICALLY SIGNIFICANT PROSTATE CANCER, PRELIMINARY RESULTS

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Introduction: Significant discrepancy exists between sextant template targets and the location of actual cores obtained by urologists during freehand systematic prostate biopsy (SB) [PMC3876458]. Despite the benefits of targeted biopsy (TB) using multiparametric MRI (mpMRI) [PMC26237632], SB still detects about 6-12% of clinically significant prostate cancers (csPCa) that may be MR-invisible [PCM35507051] or missed at TB. Transrectal ultrasound robotic-assisted (TRUS-Robot) biopsy is a novel method to diagnose prostate cancer by using a robotic ultrasound probe manipulator investigational device (Figure 1) [EUS2017 Abs.34, PMC4005376] and three-dimensional navigation software to optimize the location of biopsy cores. Prior research has shown that TRUS-Robot biopsy is feasible, safe, more uniformly samples the prostate gland, and may detect more csPCa's compared to freehand prostate biopsy [EUS2018 Abs.43, PMC6726124, EUS2022 Abs.36]. We hypothesized that TRUS-Robot would be superior to UroNav (Philips/Invivo) on SB, and noninferior to TB in the detection of csPCa.

Methods: A single-center, open-label, randomized-controlled trial of TRUS-Robot versus UroNav prostate biopsy in men ages 45 to 75 with an indication for prostate biopsy and mpMRI imaging. All men underwent 12-core SB. On the UroNav arm the SB plan followed the extended sextant biopsy template; On the Robot arm the SB plan was optimized for each patient [PMC27760001]. On both arms, if PI-RADS Ver.2 lesions scored 3-5 were identified on mpMRI, the lesions were targeted with the respective device and 3 cores were sampled per lesion. For comparison to TB a noninferiority margin of 9% was selected.

Results: To date, 41 men have enrolled and undergone prostate biopsy: 24 TRUS-Robot and 17 UroNav; PI-RADS Ver.2 scores 3-5 were identified in 16 and 15 patients, respectively. For SB, a greater proportion of men have been diagnosed with csPCa in the TRUS-Robot (25%) compared to the UroNav (18%) arm of the trial (p=0.25). For TB, the TRUS-Robot was noninferior to UroNav with a greater proportion of men diagnosed with csPCa in the TRUS-Robot (38%) compared to the UroNav (20%) (p=0.048). In this case, the upper 90% confidence limit for UroNav csCDR – Robot csCDR was 0.03, indicating the Robot may be at most 3% worse than UroNav, well within the noninferiority margin of 9%. Overall, based on SB or TB cores, more men have been diagnosed with csPCa in the TRUS-Robot (38%) compared to the UroNav (24%) arm (p=0.13). In PI-RADS 3-5 patients, based on the SB or TB cores, csPCa was detected in 56% vs 27% of patients for the Robot vs. UroNav (p=0.19). Statistical significance has yet to be achieved. Average biopsy sampling times were 9.2 and 9.0 minutes for the Robot and UroNav arms, respectively. No complications or adverse events were recorded on either arm of the study.

Conclusion: Preliminary results are encouraging and suggest superior detection of csPCa by TRUS-Robot compared to UroNav. The trial continues to accrue.

Disclosure: Under a license agreement between Eigen Health Services and the Johns Hopkins University, authors DS, DP, and the University are entitled to royalty distributions related to technology described in this article. This arrangement has been reviewed and approved by the Johns Hopkins University in accordance with its conflict-of-interest policies.

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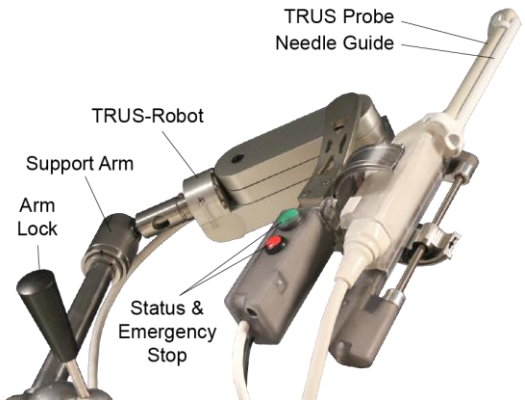

Figure 1: Robotic Ultrasound Probe Manipulator