19-3118

Prospective Evaluation of a Novel Transperineal Electromagnetically-Tracked MR/US Fusion Biopsy System

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INTRODUCTION AND OBJECTIVES: Transrectal fusion biopsy (TRFBx) has become ubiquitous with multiple published series establishing its utility. Validation of transperineal fusion biopsy (TPFBx) is limited to a small single series. We aim to evaluate cancer detection rate (CDR; overall and high-grade) and 30-day complications of TRFBx vs TPFBx in the largest series to date.

METHODS: A review of the Michigan Urologic Surgery Improvement Collaborative (MUSIC) prospective registry of all patients undergoing TRFBx and TPFBx at a single practice was performed. TPFBx was performed under sedation using a electromagnetically tracked stepper and fusion platform for MR targets in addition to the Modified Barzell 12-core template. Patient, MRI, pathology characteristics, and 30-day complications were prospectively collected and analyzed. Multivariable analysis was performed to control for individual risk and PIRADS score. High grade CDR (hgCDR) was defined as GS $\geq$ 7.

RESULTS: A total of 398 TRFBx and 60 TPFBx were performed. The overall CDR was 73.4% (292/398) for TRFBx and 68.3% (41/60) for TPFBx (p=0.42). HgCDR was similar for TRFBx and TPFBx for PIRADS 3 (11.0% vs. 6.3%, p=0.56), 4 (35.3% vs. 27.3%, p=0.45), and 5 (67.2% vs. 59.1%, p=0.46) lesions, respectively. Controlling for patient characteristics, there was no statistically significant difference in overall CDR, targeted-core CDR, standard CDR, hgCDR, or pathological upgrading (Table 1a). There were no infection-related hospitalizations, sepsis episodes, UTI, fever, or episodes of retention after TPFbx at 30-days follow-up (Table 1b). Infectious complications did occur after TRFbx, but were rare.

CONCLUSIONS: In our cohort, TPFBx was similar to TRFBx for cancer detection and pathologic upgrading. Early outcomes in a limited series of TPFbx demonstrated zero infectious complications within 30 days. Larger series with longer-term outcomes are needed.

Source of Funding: Blue Cross and Blue Shield

Figure 1: Transperineal fusion of a lesion with US (top left) and MR (bottom left) co-display in the sagittal view demonstrating precise co-registration and accurate targeting.

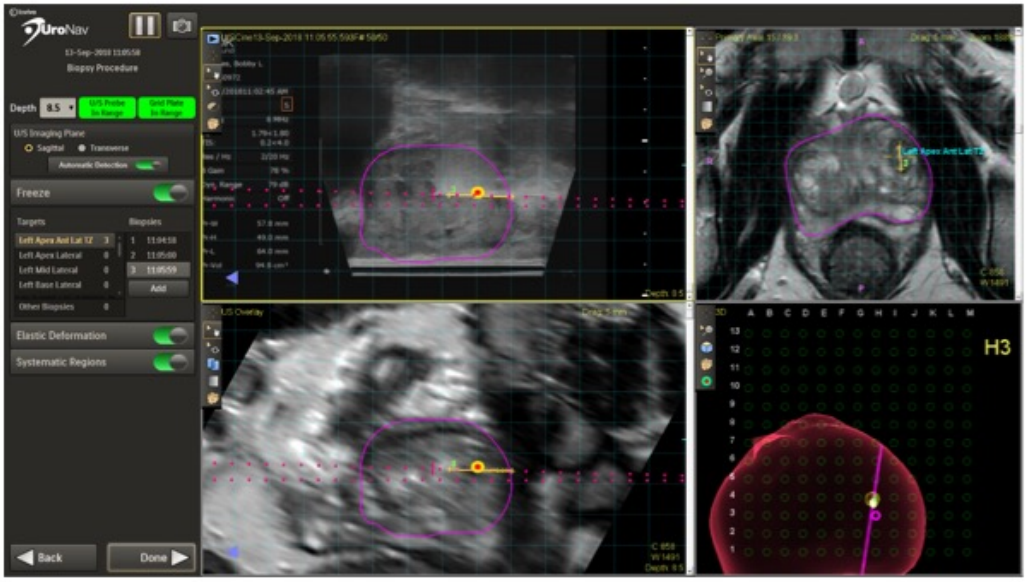

Table 1a. Factors associated with overall cancer detection rate, high grade cancer detection rate, and pathological upgrading, separated by targeted and standard cores.

Variable	Adjusted OR (TPFBx vs. TRFBx)	95% CI	*p*
Overall CDR	0.93	(0.30, 2.89)	0.90
Targeted Biopsy CDR	1.71	(0.62, 4.66)	0.30
Standard Biopsy CDR	1.48	(0.53, 4.16)	0.45
Targeted Biopsy High Grade CDR	0.63	(0.23, 1.69)	0.36
Upgrading by Targeted Biopsy	0.82	(0.29, 2.34)	0.72
Upgrading by Standard Biopsy	0.57	(0.20, 1.59)	0.28
Upgrading to High Grade by Targeted Biopsy	0.76	(0.20, 2.93)	0.69
Upgrading to High Grade by Standard Biopsy	0.39	(0.08, 2.02)	0.26

Table 1b. Rates of post-biopsy complications: Transrectal Fusion Biopsy vs. Transperineal Fusion Biopsy

	TRFbx	TPFbx	*p*
No. bx	398	60	
Infectious hospitalization	10 (2.51%)	0 (0%)	0.37
Sepsis	6 (1.51%)	0 (0%)	>.99
UTI	6 (1.51%)	0 (0%)	>.99
Fever	9 (2.26%)	0 (0%)	0.61
Urinary Retention	1 (0.25%)	0 (0%)	>.99