Comparison of Systematic and MRI-Ultrasound Fusion Targeted Prostate Biopsies in Men With No Prior Biopsies

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Target Audience: Uroradiologists, urologists, oncologists, bioengineers

<u>Purpose:</u> Compare the performance of MRI-transrectal ultrasound (TRUS) fusion targeted biopsy versus standard systematic 10-point sextant prostate biopsy for detection of significant disease.

Methods: A NIH-funded, HIPAA-compliant, IRB-approved prospective trial enrolled men for image fusion prostate biopsy. Those men who had never undergone prostate biopsy and successfully underwent multiparametric MRI (mpMRI) on a Siemens Somatom TrioTim or Skyra 3.0 T platform with high performance gradients using a multichannel external phased array coil were included in the analysis. Imaging included multiplanar 2-dimensional and 3-dimensional turbo spin-echo (TSE) T2-weighted imaging (T2WI: Siemens SPACE, TR/TE 3800-5040/101 ETL 13, 14 cm FOV, 256 x 256 matrix, 1.5 mm contiguous slices), echo-planar diffusion-weighted imaging (DWI: echoplanar, TR/TE 3900/60, 21 x 26 cm FOV, 130 x 160 matrix, 3.6 mm slices, 4 NEX, b-values 0, 100, 400, 800 s/mm²) with apparent diffusion coefficient (ADC) map generated from all b-values used, and dynamic contrast-enhanced (DCE: Siemens TWIST, TR./TE 3.9/1.4 ms, 12° flip angle, 26 x 26 cm FOV, 160 x 160 matrix, 3.6 mm slices, 4.75 s/acquisition over 6 minutes with 15 s injection delay, image analysis using iCAD Versavue) perfusion. Each scan was evaluated by a radiologist with 8 years' experience in prostate MRI. All biopsies were performed with image fusion (Artemis, Eigen Inc.) in addition to systematic biopsies. Four "significance levels" were used for analysis. The two definitions established at the University College London, denoted U1 (at least 6 mm of any GS or at least GS 4+3) and U2 (at least 4 mm of any GS or at least GS 3+4). The third level, denoted "Any4" was for any core GS > 6 and the fourth, "Dom4" was any GS > 3+4.

Results: Of 162 subjects who met the inclusion criteria, with an average PSA of 8.1 ng/mL, 153 (94%) had at least one target. For none of the definitions did χ^2 analysis meet significance – mismatches occurred for both systematics and targets for all definitions as presented in the table, where "T" denotes targets and "S" systematic assessment. The average number of systematic cores per subject was 11.6. The average number of targets per subject was 1.8 with an average of 3.6 cores per target or 6.4 targeted cores per subject.

U1	T(-)	T(+)	Tot	U2	T(-)	T(+)	tot
S(-)	125	9	134	S(-)	98	10	108
S(+)	9	19	28	S(+)	19	35	54
tot	134	28	162	tot	117	45	162
Any4	T(-)	T(+)	tot	Dom4	T(-)	T(+)	tot
Any4 S(-)	T(-) 108	T(+)	tot 121	Dom4 S(-)	T(-) 144	T(+)	tot 149
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Discussion: Although this study of biopsy-naïve men shows that targeted biopsy does not outperform systematic cores, and that image fusion targeted biopsy misses some significant disease for all definitions, it also shows that the rate of detection for significant disease is nearly identical between targeted and systematic biopsies despite nearly twice as many systematic cores per subject compared with targeted cores. This suggests that one could reduce the number of biopsy cores by approximately half with no decrease in detection rate for significant disease. It also suggests that there is room for improvement of the image fusion targeting system in terms of MRI technique, image fusion software, and targeting guidance.

<u>Conclusion:</u> Targeted biopsies find significant disease at an identical rate to systematic biopsies in men who have never undergone prostate biopsy with an elevated PSA, but miss some significant disease for all definitions.

References:

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- 2. Natarajan S, Marks LS, Margolis DJ, et al. Clinical application of a 3D ultrasound-guided prostate biopsy system. Urol Oncol. 2011;29(3):334-42