Impact of lesion visibility on transrectal ultrasound on the prediction of clinically significant prostate cancer (Gleason score ≥ 3+4) with TRUS-MRI fusion biopsy

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1 - OBJECTIVE

To estimate the impact of lesion visibility with transrectal ultrasound on the prediction of clinically significant prostate cancer with transrectal ultrasound-magnetic resonance imaging fusion biopsy.

2a – METHODS

IRB approved, HIPAA compliant, single institution, pragmatic retrospective study
UCSF Urological Oncological Database, PCa MRI Database and EMR from January 2013 to September 2016.

2b – INCLUSION CRITERIA

3T endorectal prostate MRI and TRUS-MRI fusion biopsy performed for suspected PCA (biopsy naïve or prior negative biopsies) or as a confirmatory procedure prior to pursuing active surveillance. 178 consecutive patients were included in the study.

2c – MRI

T2-weighted, high B-value diffusion-weighted and dynamically contrast enhanced images were acquired. MRI was considered positive when a PI-RADS v2 score 3 or greater was assigned.

2d – BIOPSY

Fusion biopsies were performed first using UroNav Fusion Biopsy System®. Ultrasound targeted biopsies were done next. Depending on the size of the lesion identified on MRI and/or ultrasound, 1 or 2 samples were taken from its center and 1 or 2 cores from its borders. These were were immediately followed by a 14-core extended sextant systematic biopsy, performed by the same urologist.

2e – TRUS-MRI CORRELATION

TRUS visible lesions were graphically represented using a sextant approach. MRI visible lesions were depicted on a 39 sector map using PI-RADS v2 guidelines. Concordance was defined as a lesion seen at the same location based on the comparison of these maps and on the description of the location in the reports. Also, TRUS reports described the concordance between a MRI target and a lesion seen on ultrasound.

2f – STATISTICAL ANALYSES

The unit of analysis was the location in the gland and the outcome of CS-PCA. If imaging findings occupied more than location, i.e. more than one 1 sextant, the combination of locations was considered a single unit. If no finding was visible, the individual sextant was the unit of analysis. To account for multiple lesions and locations in the gland, and multiple readers we used 3-level, mixed effects logistic regression to determine how concordance between MRI and TRUS predicted CS-PCA. The AUC ROC curves, and the sensitivity and specificity of MRI and TRUS were calculated. AUC ROCs were compared using the jackknife method. The 95% CIs were calculated and α <0.05 was considered statistically significant. STATA®, version 13.1 was used.

Table 1 - Patient characteristics

Number of patients	178
Mean age (years)*	64.7 (44-83)
Mean PSA (ng/ml)**	8.9 (6.0)
Clinical stage	152 (85)
T1c	23 (13)
T2a	2 (1)
T2b	2 (1)
Gland volume (g)**	55.0 (30.5)
# of men who had prior biopsies	119 (67)
Mean # days between MRI and TRUS **	66 (115)

Unless otherwise indicated, number in parenthesis represent percentages.
* range ** standard deviation

Table 2 – Imaging and Pathology Results

	No cancer	3+3	3+4	4+3	4+4	4+5	Total
No visible lesion	889	102	22	8	3	0	1024
Visible only on TRUS	29	6	7	2	0	0	44
Visible only on MRI	83	43	19	8	3	1	157
Visible on TRUS and MRI	36	32	21	15	1	1	106
Total	1037	183	69	33	7	2	1331

Numbers are number of locations within the gland

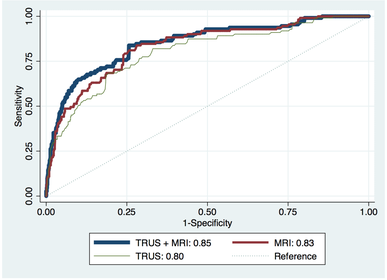
Table 3 - Univariate model

	OR	P	95% CI	
Comparison group: negative scans				
only TRUS +	11.72	< 0.001	4.19	32.79
only MRI +	11.88	< 0.001	6.17	22.88
both +	30.99	< 0.001	15.40	62.39

Multivariate model

	OR	P	95% CI	
Comparison group: negative scans				
age	1.11	< 0.001	1.05	1.16
PSA	1.04	0.08	1.00	1.09
gland volume	0.96	< 0.001	0.95	0.98
only TRUS +	14.78	< 0.001	5.23	41.78
only MRI +	12.31	< 0.001	6.41	23.66
both +	28.73	< 0.001	14.48	56.99
Comparison group: positive TRUS				
only MRI +	0.83	0.73	0.29	2.39
both +	1.94	0.22	0.67	5.63
Comparison group: positive MRI				
only TRUS +	1.20	0.73	0.42	3.45
both +	2.33	0.02	1.16	4.69

OR = odds ratio; P = probability; CI = confidence interval



3 - RESULTS

Tables 1-3 and figure 1 summarize the results of this study.

The proportion of lesions visible only on TRUS (9/44 or 20.5%, 95% CI 8.6–32.4) and only on MRI (31/157 or 19.7%, 95% CI 13.5–25.9) that were CS-PCA did not differ (p = 0.90). Furthermore, 33 of the 111 CS-PCAs (29.7%, 95% CI 27.2–32.2) were diagnosed in areas without visible lesions.

The AUC to detect CS-PCA using TRUS and MRI (0.85, 95% CI 0.81–0.89) was statistically larger than the AUC of TRUS alone (0.80, 95% CI 0.76–0.85, p = 0.001) and MRI alone (0.83, 95% CI 0.79–0.87, p = 0.04). TRUS and MRI alone did not differ (p = 0.09). The sensitivity and specificity of TRUS and MRI were 42.3% and 91.6%, and 62.2% and 84.1%, respectively.

A PI-RADS v2 score of 3, 4 and 5 was assigned to 44, 152 and 56 lesions, respectively, for a total of 252. The other 11 lesions were only identified as visible targets at TRUS-MRI fusion biopsy. PI-RADS v2 scores 3, 4 and 5 were CS-PCA in 6.8% (95% CI 1.4–18.7), 25% (95% CI 18.3–32.7) and 53.6% of cases (95% CI 39.7–67.0) that were visible only on MRI. When TRUS was also positive, the proportions increased to 9.1% (95% CI 2.3–41.3), 28.8% (95% CI 17.8–42.1) and 74.1% (95% CI 53.7–88.9), respectively.

4 - CONCLUSION

The probability of CS-PCA does not differ based on lesion visibility on MRI or TRUS. However, this probability is greater when the 2 examinations are positive, particularly when the PI-RADS score is higher.

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