Impact of Lesion Visibility on Transrectal Ultrasound on the Prediction of Clinically Significant Prostate Cancer (Gleason Score 3 + 4 or Greater) with Transrectal Ultrasound-Magnetic Resonance Imaging Fusion Biopsy

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Purpose: The purpose of this study was 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.

Materials and Methods: This HIPAA (Health Insurance Portability and Accountability Act) compliant, institutional review board approved, retrospective study was performed in 178 men who were 64.7 years old with prostate specific antigen 8.9 ng/ml. They underwent transrectal ultrasound-magnetic resonance imaging fusion biopsy from January 2013 to September 2016. Visible lesions on magnetic resonance imaging were assigned a PI-RADS™ (Prostate Imaging Reporting and Data System), version 2 score of 3 or greater. Transrectal ultrasound was positive when a hypoechoic lesion was identified. We used a 3-level, mixed effects logistic regression model to determine how transrectal ultrasound-magnetic resonance imaging concordance predicted the presence of clinically significant prostate cancer. The diagnostic performance of the 2 methods was estimated using ROC curves.

Results: A total of 1,331 sextants were targeted by transrectal ultrasound-magnetic resonance imaging fusion or systematic biopsies, of which 1,037 were negative, 183 were Gleason score 3 + 3 and 111 were Gleason score 3 + 4 or greater. Clinically significant prostate cancer was diagnosed by transrectal ultrasound and magnetic resonance imaging alone at 20.5% and 19.7% of these locations, respectively. Men with positive imaging had higher odds of clinically significant prostate cancer than men without visible lesions regardless of modality (transrectal ultrasound OR 14.75, 95% CI 5.22–41.69, magnetic resonance imaging OR 12.27, 95% CI 6.39–23.58 and the 2 modalities OR 28.68, 95% CI 14.45–56.89, all $p < 0.001$). The ROC AUC to detect clinically significant prostate cancer using the 2 methods (0.85, 95% CI 0.81–0.89) was statistically greater than that of transrectal ultrasound alone (0.80, 95% CI 0.76–0.85, $p = 0.001$) and magnetic resonance imaging alone (0.83, 95% CI 0.79–0.87, $p = 0.04$). The sensitivity and specificity of transrectal ultrasound were 42.3% and 91.6%, and the sensitivity and specificity of magnetic resonance imaging were 62.2% and 84.1%, respectively.

Conclusions: Lesion visibility on magnetic resonance imaging or transrectal ultrasound denotes a similar probability of clinically significant prostate cancer. This probability is greater when each examination is positive.

Key Words: prostatic neoplasms, magnetic resonance imaging, ultrasonography, biopsy, diagnostic imaging

Abbreviations and Acronyms

CS-PCA = clinically significant PCA

MRI = magnetic resonance imaging

PCA = prostate cancer

PI-RADS™ v2 = Prostate Imaging Reporting and Data System, version 2

PROMIS = Prostate MRI Imaging Study

PSA = prostate specific antigen

PZ = peripheral zone

TRUS = transrectal ultrasound

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TRANSRECTAL ultrasound and MRI are the 2 techniques used to identify CS-PCA. Studies suggest that men with nonvisible PCA have better outcomes than men with TRUS visible lesions[1,2] and positive MRI findings have been shown to predict CS-PCA.[3]

Recently TRUS-MRI fusion biopsy has been added to the assessment of men with known or suspected PCA. Studies have revealed that using MRI to target biopsies may reduce sampling error and improve risk stratification.[3–7] PROMIS, a large, prospective, multicenter study of 576 men, concluded that TRUS performs poorly compared to MRI.[7] MRI missed 6% to 17% of CS-PCAs. Other studies support the combination of targeted and systematic biopsies but the impact of a visible lesion on TRUS at TRUS-MRI fusion biopsy remains unclear. In PROMIS MRI was compared to a true systematic TRUS biopsy, ie not considering or at least not reporting positive findings on TRUS. The purpose of our study was to estimate the impact of lesion visibility at TRUS on the prediction of CS-PCA with TRUS-MRI fusion biopsy.

MATERIALS AND METHODS

This institutional review board approved, HIPAA (Health Insurance Portability and Accountability Act) compliant, single institution, pragmatic retrospective study included subjects from our Urological Oncological Database, Prostate Magnetic Resonance Imaging Database and electronic medical records from January 2013 to September 2016.

Study Inclusion and Exclusion Criteria

Inclusion criteria were 3 Tesla endorectal prostate MRI as well as TRUS-MRI fusion biopsy performed for suspected PCA (biopsy naïve patient with prior negative biopsies) or as a confirmatory procedure prior to pursuing active surveillance, ie after the initial diagnosis. Exclusion criteria were nonretrievable MRI, TRUS-MRI fusion biopsy or pathological results. A total of 178 consecutive patients met study inclusion criteria.

Magnetic Resonance Imaging Technique and Interpretation

T2-weighted, high B-value, diffusion-weighted and dynamically contrast enhanced magnetic resonance images were acquired on a 3 Tesla scanner (GE Healthcare, Waukesha, Wisconsin) using an eCoil endorectal coil (Medrad®). Table 1 lists protocol details.

Scans were interpreted as part of clinical care by 1 of 16 subspecialized abdominal imaging radiologists with varying degrees of experience with prostate imaging. Notably 79.2% of the studies were interpreted by 5 of these radiologists who had 3 to 20 years of experience with prostate MRI, including 3 of us with 13, 13 and 20 years of experience, respectively. Suspicious findings were classified according to PI-RADS v2.[8] MRI was considered positive when the PI-RADS v2 score was 3 or greater. Up to 4 lesions were identified per case. Data in our Urological Oncological Database are regularly updated and cases acquired before the release of PI-RADS v2 had been reinterpreted to adhere to those guidelines. For the fusion biopsy the prostate was segmented and lesions were identified in DynaCAD® for Prostate.

Magnetic Resonance Imaging-Ultrasound Fusion Biopsies

Four urologists performed all MRI-ultrasound fusion biopsies as part of clinical care. Two of them with 32 and 4 years of overall and fusion biopsy experience, respectively, did 97.7% of cases (79.6%) and the other 2 with 2 years of experience each did 18.1% of cases. Scans were systematically performed with real-time cine. Still images were obtained in 2 planes using high resolution B-mode ultrasound with a 6 to 9 Hz TRUS probe (Philips Healthcare, Amsterdam, The Netherlands). A focus with lower echogenicity than adjacent tissue was considered a positive finding. Color Doppler was used but increased vascularity was not mandatory to proceed with biopsy. Urologists used the UroNav Fusion Biopsy System (InVivo, Gainesville, Florida) and 18 gauge needles.

Depending on the size of the lesion identified on MRI and/or ultrasound and at the discretion of the urologist 1 or 2 samples were taken from the center of the lesion and 1 or 2 additional cores were obtained from the lesion borders. These cores were followed by 14-core extended sextant systematic biopsy of the right and left anterior

Table 1. *Acquisition parameters of multiparametric endorectal MRI of prostate*

Series	Pulse Sequence Definition	Scan/Plane	Repetition/Echo Time (millisecs)	Slice/Gap (mm)	Field of View (mm)	Acquisition Matrix	No. Excitations	Sequence or Comments
Scout	Fast spin-echo	—/3-Plane	867/83	5/1.5	400 × 400	256 × 192	1	
T1-weighted	Fast gradient echo	—/Axial	5.06/2.46	4.2/0	240 × 240	192 × 128	1	3-Dimensional
T2-weighted	Fast spin-echo	Oblique/axial	5,600—7,400/96—114	3/0	180 × 180	512 × 512	1	2-Dimensional
T2-weighted	Fast spin-echo cube	Oblique/axial	2,400/142.4	1.6/0	180 × 180	512 × 512	2	3-Dimensional
Diffusion weighted imaging:	Steady state-echo planar imaging							
Mid		Oblique/axial	4,725/Min	3/0	180 × 180	128 × 64	6	B = 600 s/mm^2
High		Oblique/axial	4,725/Min	6/0	260 × 260	128 × 64	7	B = 1,350 s/mm^2
Dynamic contrast enhanced	3-Dimensional spoiled gradient recalled acquisition in steady state	Oblique/axial	Min/Min	3/0	260 × 260	192 × 128	1	Temporal resolution 10.4 msec*

* Injection of gadopentetate dimeglumine 0.1 mmol/kg body weight at 3 cc per second using power injector followed by 20 cc saline bolus at same rate with 5-minute acquisition.