

Magnetic Resonance Imaging-Ultrasound Fusion Targeted Prostate Biopsy in a Consecutive Cohort of Men with No Previous Biopsy: Reduction of Over Detection through Improved Risk Stratification

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Purpose: MRF-TB (magnetic resonance imaging-ultrasound fusion targeted prostate biopsy) may improve the detection of prostate cancer in men presenting for prostate biopsy. We report clinical outcomes of 12-core systematic biopsy and MRF-TB in men who presented for primary biopsy and further describe pathological characteristics of cancers detected by systematic biopsy and not by MRF-TB.

Materials and Methods: Clinical outcomes of 452 consecutive men who underwent prebiopsy multiparametric magnetic resonance imaging followed by MRF-TB and systematic biopsy at our institution between June 2012 and June 2015 were captured in an institutional review board approved database. Clinical characteristics, biopsy results and magnetic resonance imaging suspicion scores were queried from the database.

Results: Prostate cancer was detected in 207 of 382 men (54.2%) with a mean $\pm$ SD age of 64 ± 8.5 years and mean $\pm$ SEM prostate specific antigen 6.8 ± 0.3 ng/ml who met study inclusion criteria. The cancer detection rate of systematic biopsy and MRF-TB was 49.2% and 43.5%, respectively ($p = 0.006$). MRF-TB detected more Gleason score 7 or greater cancers than systematic biopsy (117 of 132 or 88.6% vs 102 of 132 or 77.3%, $p = 0.037$). Of 41 cancers detected by systematic biopsy but not by MRF-TB 34 (82.9%) demonstrated Gleason 6 disease, and 26 (63.4%) and 34 (82.9%) were clinically insignificant by Epstein criteria and a UCSF CAPRA (University of California-San Francisco-Cancer of the Prostate Risk Assessment) score of 2 or less, respectively.

Conclusions: In men presenting for primary prostate biopsy MRF-TB detects more high grade cancers than systematic biopsy. Most cancers detected by systematic biopsy and not by MRF-TB are at clinically low risk. Prebiopsy magnetic resonance imaging followed by MRF-TB decreases the detection of low risk cancers while significantly improving the detection and risk stratification of high grade disease.

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

Abbreviations and Acronyms

CDR = cancer detection rate

GS = Gleason score

mpMRI = multiparametric MRI

MRGB = MRI guided targeted biopsy

MRI = magnetic resonance imaging

mSS = maximum MRI suspicion score

PCa = prostate cancer

PSA = prostate specific antigen

SB = systematic biopsy

US = ultrasound

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Study received institutional review board approval.

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PROSTATE cancer is the most common cancer diagnosed in men in the United States and the second most common cause of cancer death.¹ Traditional US guided prostate biopsy has been shown to have limited sensitivity for detecting PCa.^{2,3} Consequently an initial biopsy negative for PCa often does not reliably indicate absent disease.⁴ Additionally in light of the increasing number of prostate biopsies performed due to increased PSA⁵ the rate of over detection of clinically low risk disease varies from 2% to 67% of cancer diagnoses,⁶ leading to unnecessary morbidity associated with overtreatment and decreased quality of life.^{7,8}

Current evidence demonstrates improved sensitivity for detecting high grade PCa using mpMRI followed by MRI targeted biopsy than with standard 12-core systematic biopsy.^{9–12} We compared the outcomes of targeted prostate biopsy performed with automated MRI-US fusion and 12-core SB done with a computerized template in the population of men with increased PSA and no history of prostate biopsy. In light of recent evidence suggesting that MRI targeted biopsy selectively identifies high grade cancer compared to SB¹³ we further characterized cancers that were missed or mischaracterized as low grade by MRF-TB alone.

MATERIALS AND METHODS

Study Design and Population

Between June 2012 and June 2015, 675 consecutive men with no prior biopsy who presented to our institution for prostate biopsy were offered prebiopsy mpMRI. No abnormality was identified in 100 (14.2%) of these men. Of the remaining 575 men 452 (78.6%) proceeded to combined MRF-TB and SB. Clinical data mSS and biopsy results were recorded in an institutional review board approved database (fig. 1). Some men were excluded from analysis, including 20 who underwent MRI with a nonstandard prostate MRI protocol and 50 in whom the prebiopsy mpMRI was not read according to standardized trial reporting criteria.

Multiparametric MRI

mpMRI was performed using a 3 Tesla whole body system and a pelvic phased array coil. It included multiplanar turbo-spin echo T2-weighted images, axial single shot echo-planar imaging diffusion-weighted imaging with b-values of 50 and 1,000 seconds per mm², and dynamic contrast enhanced imaging MRI after intravenous administration of gadolinium chelate. Before biopsy MRI studies were reviewed by a single fellowship trained radiologist with 5 to 6 years of experience with prostate MRI at the time of this study to identify suspicious foci in the prostate. The probability of tumor was scored on a 5-point Likert scale, including mSS 2—low probability, 3—equivocal, 4—high probability and 5—very high probability as previously reported.^{10,14,15} Studies with no

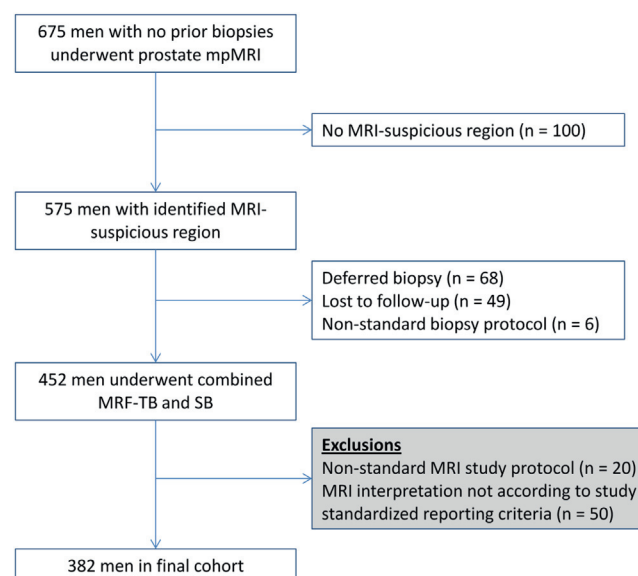


Figure 1. Patient enrollment

identified suspicious region received a score of 1 and were not candidates for MRI targeted biopsy.

MRI-US Fusion Targeted Biopsy

MRF-TB was done with the Artemis™ ProFuse co-registration system for mpMRI segmentation, co-registration of MRI to US images and 3-dimensional biopsy planning as described in our previous study.¹⁰ Briefly lesion boundaries were identified by the radiologist on T2-weighted images and transferred to the Artemis system for guidance during the biopsy procedure. Computer assisted co-registration of segmented MRI and US images of the prostate was performed by manual rigid translation followed by automated elastic deformation. With the patient in the left lateral decubitus position transrectal biopsies were obtained beginning with 4 biopsy cores targeted to each suspicious lesion identified on MRI and followed by 12-core computerized template biopsy with core locations designated by the Artemis generated template. Procedures were done using the Pro Focus™ or Noblus (Hitachi Aloka Medical America, Wallingford, Connecticut) US system, an end fire probe, a reusable biopsy gun, 18 gauge needles and local anesthesia with 1% lidocaine infiltration.

For each patient all systematic and targeted biopsies were performed by the same 1 of 4 faculty physicians with expertise in prostate biopsy. All biopsy cores were analyzed by specialized genitourinary pathologists at the same single institution.

Data Analysis and Statistics

Biopsy results were compared using the highest GS obtained by each technique. Determination of high grade cancer was based on GS 7 or greater. Clinically insignificant cancer was assessed using Epstein criteria¹⁶ and a UCSF CAPRA score of 2 or less.¹⁷ Other comparative data points included the number of biopsy cores demonstrating cancer, cancer core length per core and the percent of Gleason pattern 4 disease.

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