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Relationship of Pre-biopsy Multiparametric MRI and Biopsy Indication with MRI-US Fusion-Targeted Prostate Biopsy Outcomes

Xiaosong Meng, MD, PhD[1], **Andrew B. Rosenkrantz, MD**[2], **Neil Mendhiratta, BA**[3], **Michael Fenstermaker, BS**[3], **Richard Huang, BS**[1], **James S. Wysock, MD**[4], **Marc Bjurlin, DO**[5], **Susan Marshall, MD**[1], **Fang-Ming Deng, MD, PhD**[6], **Ming Zhou, MD, PhD**[6], **Jonathan Melamed, MD**[6], **William C. Huang, MD**[1], **Herbert Lepor, MD**[1], and **Samir S. Taneja, MD**[1,2]

[1]Department of Urology, NYU Langone Medical Center, New York, NY

[2]Department of Radiology, NYU Langone Medical Center, New York, NY

[3]School of Medicine, NYU Langone Medical Center, New York, NY

[4]Department of Urology, New York Hospital Queens, Flushing, NY

[5]Department of Urology, St. Barnabas Hospital, Bronx, NY

[6]Department of Pathology, NYU Langone Medical Center, New York, NY

Abstract

BACKGROUND—Increasing evidence supports the use of MRI-ultrasound fusion-targeted prostate biopsy (MRF-TB) to improve the detection of clinically significant prostate cancer (PCa) while limiting detection of indolent disease compared to systematic 12-core biopsy (SB).

OBJECTIVE—We report results of MRF-TB and SB and the relationship between biopsy outcomes and pre-biopsy MRI in 601 men presenting to our center.

DESIGN/SETTING/PARTICIPANTS—Retrospective analysis of a prospectively acquired cohort of men presenting for prostate biopsy over a 26-month period. A total of 601 of 803 consecutively eligible men were included.

INTERVENTIONS—All men were offered pre-biopsy MRI and assigned a maximum MRI suspicion score (mSS). Men with an MRI abnormality underwent combined MRF-TB and SB.

OUTCOMES—Detection rate of all PCa and high-grade PCa (Gleason score (GS)≥7) were compared by McNemar's test.

RESULTS—MRF-TB detected fewer GS6 PCa (75 vs 121, $p<0.001$) and more GS≥7 PCa (158 vs 117, $p<0.001$) than SB. Increasing mSS was associated with increasing detection of GS≥7 PCa ($p<0.001$), but had no relationship to the detection of GS6 PCa. The prediction of GS≥7 disease by mSS varied according to biopsy history. Compared to SB, MRF-TB identified more GS≥7 cancer in men with no prior biopsy (88 vs 72, $p=0.012$), with prior negative biopsy (28 vs 16, $p=0.010$),

Corresponding Author: Samir S. Taneja, M.D., Department of Urology and Radiology, NYU Langone Medical Center, New York, NY 10016, samir.taneja@nyumc.org, phone: 646-825-6321.

and with prior cancer diagnosis (42 vs 29, p=0.043). MRF-TB detected fewer GS6 cancers in men with no prior biopsy (32 vs 60, p<.001) and prior cancer (30 vs 46, p=0.034). Limitations include retrospective design and potential for selection bias given a referral population.

CONCLUSIONS—MRI-US fusion-targeted biopsy detects more high-grade cancer than systematic biopsy while limiting detection of GS6 cancer in men presenting for prostate biopsy. These findings suggest that pre-biopsy mpMRI and MRF-TB should be considered in all men undergoing prostate biopsy and, in conjunction with biopsy indication, mSS may ultimately help identify a select group of men at low risk of high-grade cancer in whom prostate biopsy may not be warranted.

Introduction

Increasing evidence supports the use of pre-biopsy multiparametric (mp) MRI for disease localization in order to address many of the limitations of systematic biopsy, most importantly by improving the detection of clinically significant prostate cancer while potentially limiting the detection of indolent disease[1–4]. MRI-targeted biopsy, using cognitive or software-based fusion of prostate MRI and real-time ultrasound images, has shown increased detection of clinically significant prostate cancer using fewer cores than systematic biopsy[2,5], while potentially reducing the detection of low grade cancers which are unlikely to affect a man's longevity. Pre-biopsy mpMRI not only yields accurate tumor localization[6], but grading of suspicion of cancer, through application of MRI suspicion scores (mSS), allows for accurate prediction of the likelihood of PCa on prostate biopsy[7] which correlates with the aggressiveness of cancer[8] prior to biopsy.

In this study we report outcomes of MRI-targeted prostate biopsy using MRI-US fusion (MRF-TB) as compared to 12-core systematic biopsy (SB) among all men consecutively presenting to our institution for prostate biopsy over a 26 month period. We explore the relationship of pre-biopsy MRI findings and clinical biopsy indication to outcomes of MRF-TB and SB in hopes of optimizing the current prostate cancer diagnostic pathway by identifying men, prior to biopsy, in whom prostate biopsy has low diagnostic yield.

Materials/Methods

Study design and population

Between June 2012 and August 2014, all men presenting to our institution for prostate biopsy were recommended to undergo pre-biopsy multiparametric MRI (mpMRI) to identify areas within the prostate suspicious for cancer, unless medically contra-indicated. A total of 803 men underwent mpMRI followed by prostate biopsy, and outcomes were recorded in an IRB-approved database. Prior to biopsy, MRIs of all patients were reviewed by a single fellowship-trained radiologist with expertise in prostate imaging to identify and score suspicious regions within the prostate on a 5-point Likert scale of cancer suspicion, as previously described[6,9]. For each patient, systematic and targeted biopsies were performed by one of four faculty urologic oncologists experienced in prostate biopsy. Biopsy cores were interpreted by one of three specialized genitourinary pathologists.

We queried clinical characteristics, biopsy history, biopsy indication, PSA, mSS, and histopathologic results of SB and MRF-TB biopsy from all men who underwent biopsy in the study period. Men were excluded from analysis if they had a MRI study not performed at our institution (n=47), had a repeat MRF-TB biopsy for a patient already included within this cohort (n = 49), had prior treatment for prostate cancer (n = 15), or other exclusion due to non-standard MRI protocol, 1.5T MRI studies, artifact from hip hardware, or missing data element (n = 91) (Figure 1). Among 125 men in the cohort included within the PROFUS trial (ref) comparing 2 co-registration guided and 2 cognitively directed cores, all 4 cores were grouped as MRI-targeted. In total, 601 patients were included in the final cohort analysis.

Multiparametric MRI

MRI was performed using a 3T clinical MRI and an external phased-array coil and included multiplanar T2-weighted images (T2WI), axial diffusion-weighted imaging (DWI) using b-values of 50 and 1,000 sec/mm^2, and dynamic contrast-enhanced imaging (DCE) MRI following the intravenous administration of gadolinium-chelate. Lesions identified on MRI were scored as 2 (low probability), 3 (equivocal), 4 (high probability), or 5 (very high probability), as previously described[5,9,10]. Men with mSS 1 (no findings suspicious for cancer) were not candidates for targeted biopsy and thus were not included in this analysis. For men with multiple lesions with differing mSS, the highest mSS of any individual lesion was recorded as representing the overall mSS for the patient.

MRI-US fusion targeted biopsy

MRF-TB using the Artemis prostate biopsy system was accomplished using ProFuse™ (Eigen, Grass Valley, CA) software for mpMRI segmentation, coregistration of MRI to US images, and 3D biopsy planning, as described in our previous work[5]. T2-weighted MRI sequences in which the suspicious lesions were outlined were loaded onto the Artemis biopsy device. Computer-assisted co-registration of segmented MRI and ultrasound images of the prostate was performed using manual rigid translation followed by automated elastic deformation. Transrectal biopsies were obtained with the patient in left lateral decubitus position, beginning with four biopsy cores targeted to each suspicious lesion identified on mpMRI followed by 12 software-populated, spatially distributed cores. Sites for 12 core sampling were selected by the Artemis device, not the operating surgeon. The procedures were performed using the Pro Focus (BK Medical, Peabody, MA, USA) or Noblus ultrasound systems (Hitachi Aloka Medical America, Wallingford, CT, USA), endfire probe, reusable biopsy gun, 18G biopsy needles, and local anesthesia with 1% lidocaine infiltration.

Statistical analysis

Univariable categorical variable comparisons were performed using the chi-square test and continuous variables were evaluated with the Student t test after evaluating normality of the data using a one-sample Kolmogorov-Smirnov test. The McNemar test was used to evaluate differences in cancer detection rates between MRF-TB and SB. One way ANOVA was used for comparison of continuous variables between groups unless the data were not normally distributed, in which case the Kruskal-Wallis test was used. The Cochran-Armitage Trend Test was used to calculate the relationship between mSS and CDR. For each test result, a

corresponding two-tailed p-value <.05 was considered a statistically significant finding. All analysis was carried out in SPSS v.21.0 software (IBM Corp., Armonk, NY, USA).

Results

Study population

Among 601 men, 292 (48%) men had no prior prostate biopsy (no prior biopsy group), 172 (29%) men had prior negative prostate biopsy (prior negative biopsy group) and 137 (23%) men had been previously diagnosed on SB with low volume Gleason 6 cancer and were under consideration for active surveillance after risk stratification biopsy (prior cancer diagnosis group) (Table 1). MRI suspicion scores within the cohort included mSS2 in 171 (29%), mSS3 in 196 (33%), mSS4 in 144 (24%), and mSS5 in 90 (15%) men. The distribution of mSS did not differ among the three groups [p = 0.123].

Targeted versus systematic cancer detection rate (CDR) for the whole cohort

For detection of all PCa, MRF-TB was similar to SB [p=0.731]. However, MRF-TB detected significantly less Gleason 6 (GS6) PCa [p<0.001] and significantly more Gleason ≥7 (GS≥7) PCa compared to SB [p<0.001]. MRF-TB also detected significantly more Gleason dominant pattern 4 PCa as compared to SB [p=0.025]. Table 2 describes the differences in high-grade (blue and grey shading) and low-grade (yellow shading) cancer detection. In the 61 men with GS6 on SB and no cancer detected on MRF-TB, only 2 men had >3 cores and only 4 men had more than >50%/core (eTable 1).

Targeted versus systematic CDR stratified by biopsy indication

To assess the effect of biopsy indication on CDR, men were evaluated separately by groups (Figure 2). MRF-TB detected more GS≥7 PCa in all three groups. In the no prior biopsy group, while MRF-TB detected significantly more GS≥7 than SB [p=0.012], the overall lower CDR of MRF-TB was due to the significant decrease in detection of GS6 PCa (32 vs 60 men) [p<0.001]. In the prior negative biopsy group, MRF-TB significantly increased detection of GS≥7 PCa compared to SB (28 vs 16 men) [p=0.010], but was not different in the detection of GS6 PCa [p=0.838]. In the prior cancer diagnosis group, while overall PCa detection was similar between MRF-TB and SB, MRF-TB detected significantly more GS≥7 PCa [p=0.043] and significantly fewer GS6 PCa [p=0.034] compared to SB (eTable 2). Of all cancers detected by MRF-TB alone, 9/21 (43%), 11/22 (50%), and 10/22 (45%) were located in the anterior prostate in men with no prior biopsies, prior negative biopsies, and prior cancer, respectively.

Relationship of mSS with CDR

There was a significant trend in increased detection of GS≥7 PCa with increasing mSS with both SB [p<0.001] and MRF-TB [p<0.001]. This finding was not seen in GS6 PCa detection with either SB [p = 0.752] or MRF-TB [p = 0.896] (Figure 3). Overall CDR in men with mSS2 and mSS5 were similar between groups, though among men with mSS 3 or 4, CDR varied significantly by biopsy indication [p < 0.001] (Table 3).

Targeted versus systematic CDR stratified by mSS

To evaluate CDR by mSS men were split into two groups consisting of men with low or equivocal suspicion (mSS 2 or 3) and those with high or very high suspicion (mSS 4 or 5). SB detected more GS6 cancer than MRF-TB in both groups [$p < 0.001$]. In 370 men with mSS 2 or 3, MRF-TB detected significantly less PCa overall compared to SB [p=0.001] but was similar to detection of GS≥7 PCa [p=0.230]. In 234 men with mSS 4 or 5 lesions, MRF-TB detected significantly more PCa overall [p=0.005] and significantly more GS≥7 PCa [p<0.001] than SB (eTable 3).

When evaluating the cohort by biopsy indication, in men with mSS 2 or 3 lesions MRF-TB detected significantly less GS6 PCa than SB only in men with no prior biopsy [p=0.021]. There was no significant difference in detection of GS6 or GS≥7 PCa with either MRF-TB or SB in men with prior negative prostate biopsy or prior cancer diagnosis. In men with mSS 4 or 5 lesions, MRF-TB detected significantly less GS6 PCa than SB only in men with no prior biopsy [p=0.002], but was similar to SB in men with prior negative PB [p=1.0] or prior cancer diagnosis [p=0.055]. However, MRF-TB detected more GS≥7 PCa compared to SB in all three groups.

Discussion

Many recent studies have evaluated the outcome of MRF-TB compared to SB[11–14]. Although the detection rate has varied between studies, the use of MRF-TB consistently detected more clinically significant cancers (median difference of 6.8%) compared to SB, and found cancers (median 9.1%) missed by SB alone[15]. Our study findings compare favorably with previous series evaluating the relative performance of MRF-TB and SB in men with mixed indications for biopsy[13,14,16]. In the largest study Siddiqui et al.[14] recently reported greater detection of GS≥4+3 PCa using a transrectal fusion system compared to SB (17.2% vs 12.2%) in a cohort of 1003 men, largely comprised of those with history of previous biopsy. Although our analysis was designed to answer questions similar to those addressed in previous studies, our study is distinct in that our cohort does not reflect a group of men referred for MR based risk assessment and biopsy, but rather reflect a consecutive cohort of men presenting for prostate biopsy based upon clinical indications. All men were subjected to pre-biopsy MRI and, if abnormal, targeted sampling. The primary effect of this distinction is that a much larger proportion of our cohort are men who have never previously been biopsied (49% vs 20%) compared to Siddiqui et al.[14]

Additionally, rather than focusing upon the general outcomes of targeted biopsy, in this study we chose to investigate the relationship of pre-biopsy MRI findings and biopsy indication to biopsy outcome. Because the performance characteristics of MRF-TB would likely vary with the prevalence of disease in the tested cohort, such an evaluation may allow insight into the optimal utilization of MR-targeted biopsy in clinical practice. In men with no prior biopsy, MRF-TB identifies more GS≥7 cancers, while identifying fewer GS6 cancers. This is likely due to both identification of missed cancers and more accurate risk stratification. In men with prior negative biopsy, MRF-TB identifies more GS≥7 cancers than SB, but overall detection of GS6 cancers is relatively low with either technique, likely owing to the previous sampling.

The relative contribution of SB to high grade cancer detection varies by biopsy indication as well. Among men with no prior biopsy, 10/98 (10.2%) men with GS≥7 cancer were diagnosed solely by SB. Similarly, among men with previous biopsy positive for GS6 cancer, upgrading to GS≥7 on SB alone was noted in 11/53 (20.8%) men. These findings may be, in part, reflective of the relative prevalence of GS≥7 cancers in each group, errors in biopsy targeting, or qualitative differences (such as tumor volume and relative high grade component) in the cancers missed by MRF-TB as compared to those found. Regardless of the reason, the greatest potential to reduce over-detection of indolent disease would be through avoidance of SB, particularly in men with no previous biopsy, but this may come at the cost of missing some high grade cancers. In contrast, among men with previous negative biopsy, SB did not uniquely identify any men with GS≥7cancer in whom no cancer was found on MRF-TB. In these men, avoidance of SB would seem prudent, but given the small number of low grade cancers found, its impact on reducing over-detection may be relatively small.

In evaluating the outcomes of men undergoing MRF-TB following pre-biopsy mpMRI, several important observations regarding the relationship of mSS to biopsy findings can be made. First, there is a positive trend between increasing mSS and detection of high grade (GS≥7 PCa) disease, but not with detection of GS6 disease on MRF-TB or SB. This demonstrates the selective nature of pre-biopsy mpMRI in identifying high grade disease, and the potential for its use in selecting men who would most benefit from MRF-TB. Additionally, a low mSS may be useful in predicting a low likelihood of high grade PCa, potentially allowing for avoidance of biopsy. For example, if none of the 171 men with mSS 2 in our series were biopsied, only 8 cancers with GS 3+4 and none with GS≥4+3 would have been missed, while detection of 31 GS 3+3 cancers would have been avoided. Finally, the likelihood of cancer detection for each mSS stratile varies by biopsy indication, likely owing to the prevalence of disease in each group. This has been previously demonstrated for men undergoing MR-guided biopsy[17], and our data suggests that cancer detection varies by biopsy indication the most among men with intermediate mSS (3 or 4) (Table 3).

Collectively these findings suggest that combining mSS and patient biopsy indication may ultimately help identify a population of men in whom prostate biopsy is unlikely to detect significant disease. The reduction of biopsy utilization, and limitation of indolent cancer detection, offers the potential to partially offset costs incurred through the addition of pre-biopsy mpMRI, through reduction of costs incurred from biopsy, treatment, and secondary complications. Such an assertion relies upon future standardization of MR interpretation and MR-acquisition protocols. In addition, in our prior cancer group, our initial risk stratification biopsy upgrade rate of 39% using a combination of MRF-TB and SB is higher than traditionally published upgrade rates of around 15–30% on confirmatory or first surveillance prostate biopsy[18–20]. Using a single biopsy, we achieved similar GS upgrade rates as those published for men on active surveillance undergoing serial biopsies over many years[19,21]. Given the more accurate risk stratification of MRF-TB, this may potentially save patients from undergoing multiple rounds of repeat risk stratification biopsy without significant numbers of missed high grade cancers.

Our study is limited by the fact that it is retrospective in nature, and, therefore, suffers from potential for selection biases related to the nature of our institutional referral practice. In addition, our reference standard remains the biopsy, rather than final prostatectomy specimen, thereby providing inability to validate our scoring accuracy and determine actual significance of a negative biopsy. As our analysis excludes men without visible lesions on mpMRI, we are also unable to assess the rate of significant cancer in those men. In addition, we did not correct for multiple comparisons. Finally, clinical recommendations derived from our data must be predicated upon our considerable experience with mpMRI of the prostate, its interpretation, and MR-targeted biopsy techniques. Whether such observation could be duplicated in other centers remains to be determined through additional studies.

Despite the limitations, our study has several strengths, including the fact that all men presenting to our center during the reported analysis underwent pre-biopsy mpMRI, when medically feasible, thereby reducing the likelihood of selection bias to some extent. While the PROFUS study[5], conducted at our institution, demonstrated no difference in co-registration guided and cognitive directed MRI targeting, we have adopted MRI-US fusion as our standard biopsy approach since March, 2013 (end of PROFUS accrual) given the ability to standardize biopsy approach, reduce operator learning curve, reduce intra-operator variability, and provide standard methods for computer-directed 12 core biopsy. As men were subjected to standardized MRI interpretation and biopsy protocols using an automated system, operator variability in biopsy technique is also reduced. While our reference standard remains biopsy, the analysis does offer the opportunity to allow a comparison of biopsy techniques and outcomes that ultimately drive clinical management. Our findings offer the potential to inform the design of future prospective studies of MR-based risk stratification.

Conclusion

MRI-US fusion targeted biopsy detects more GS≥7 cancer compared to systematic biopsy while limiting detection of indolent disease in all men presenting for prostate biopsy. Increasing MRI suspicion score correlates strongly with a higher likelihood of GS≥7 cancer in all men, regardless of biopsy indication. The role of pre-biopsy mpMRI, the prediction of cancer risk, the need for SB, and the performance characteristics of MRF-TB all vary greatly by biopsy indication and mSS. While the clinical impact and benefit of MRF-TB varies by biopsy indication, it does seem to offer clear clinical benefit in all groups. Our data will not only provide a framework for further trial design in the evaluation of MR-targeted biopsy, but strongly suggest that pre-biopsy mpMRI and MRF-TB should be considered in all men undergoing prostate biopsy.

Acknowledgments

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PATIENT SUMMARY

In this study, we examined how MRI-targeted prostate biopsy compared to traditional systematic biopsy in detecting prostate cancer among men with suspicion of prostate cancer. We found that MRI-targeted biopsy detected more high-grade cancers than systematic biopsy, and that the MRI performed prior to biopsy was able to predict the risk of high-grade cancer.

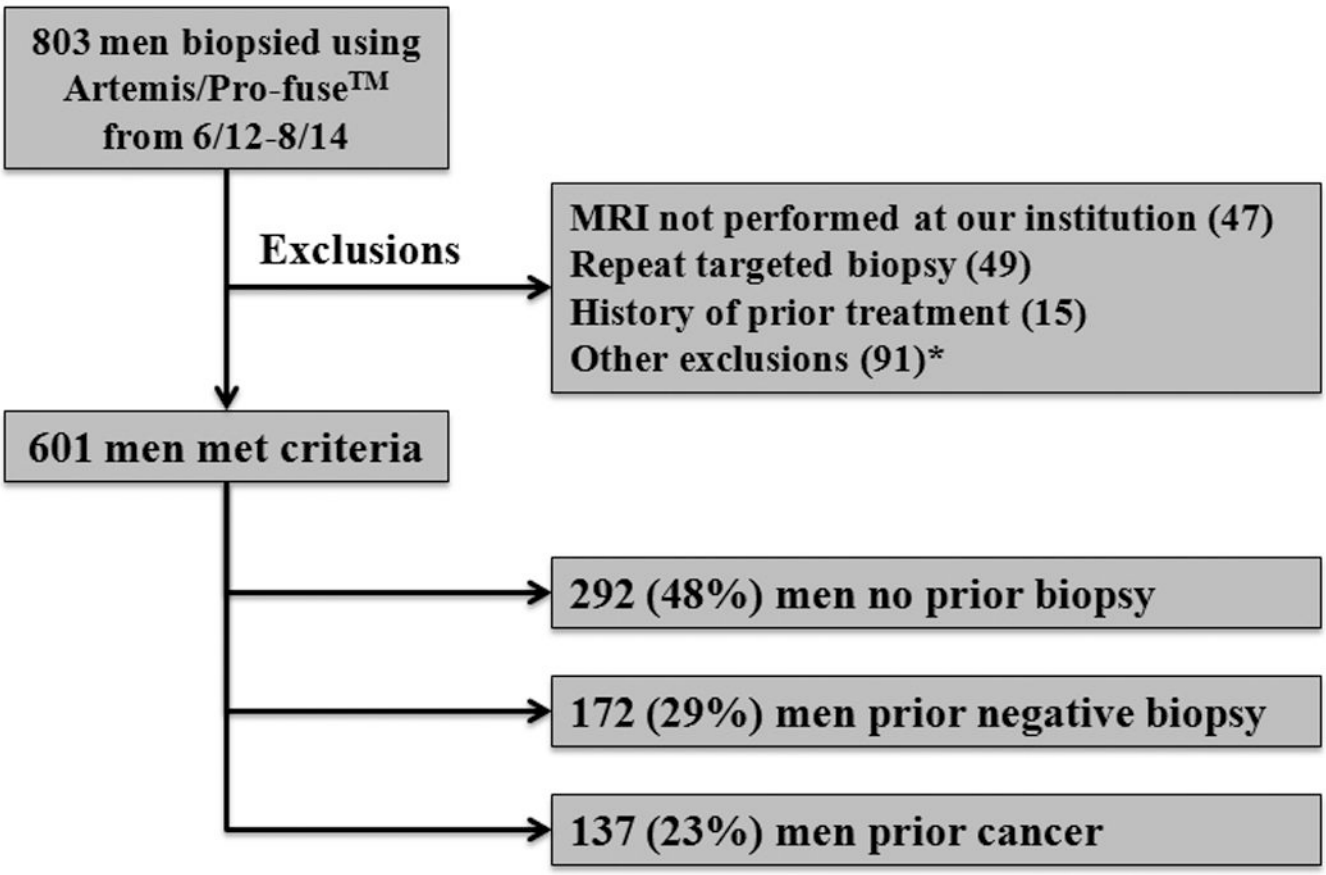

Figure 1.
Study flow diagram
MRI = magnetic resonance imaging
* See text for list of exclusions

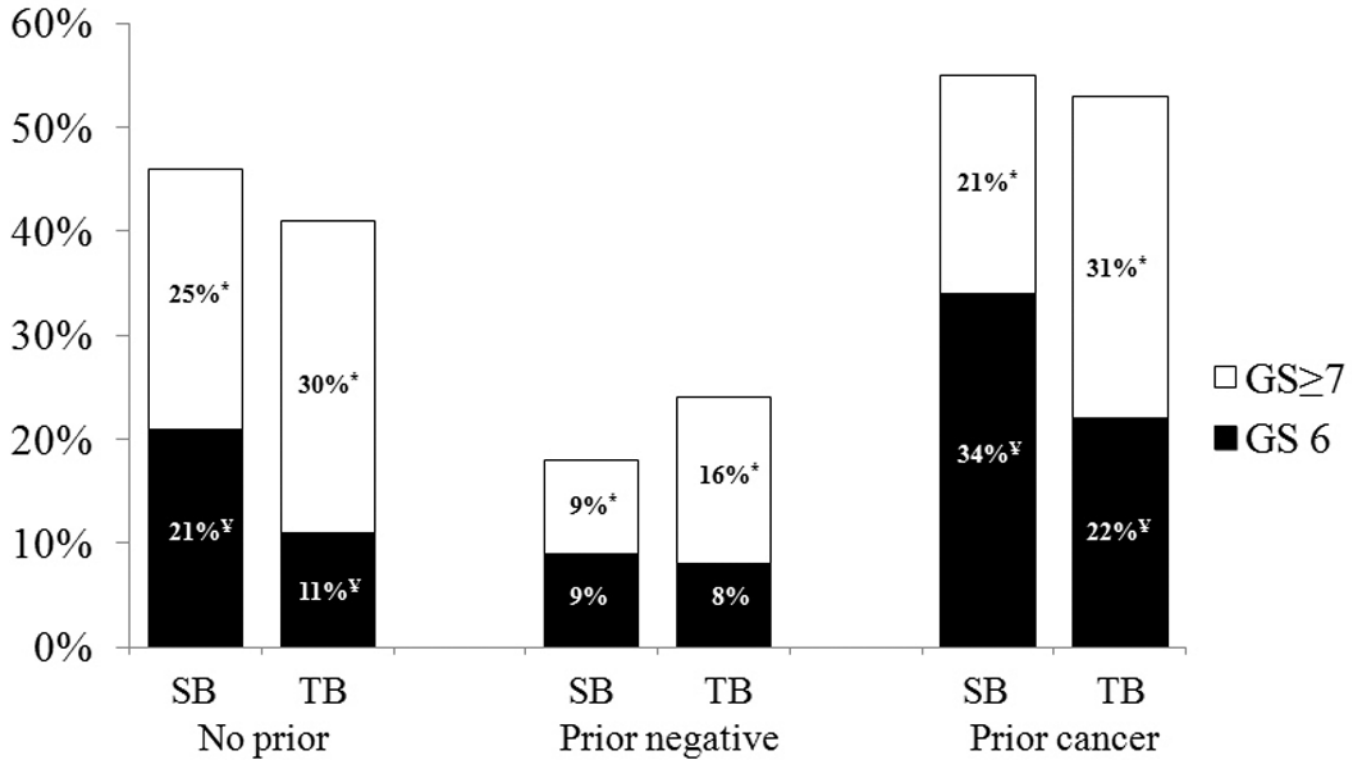

Figure 2.

Comparison of GS≥7 and GS6 cancer detection between systematic and MRI-fusion biopsy stratified by biopsy indication.

* $p < 0.05$, SB vs MRF-TB for GS≥7

¥ $p < 0.05$, SB vs MRF-TB for GS 6

SB = systematic biopsy

TB = MRI-US Fusion Targeted Biopsy

GS = Gleason score

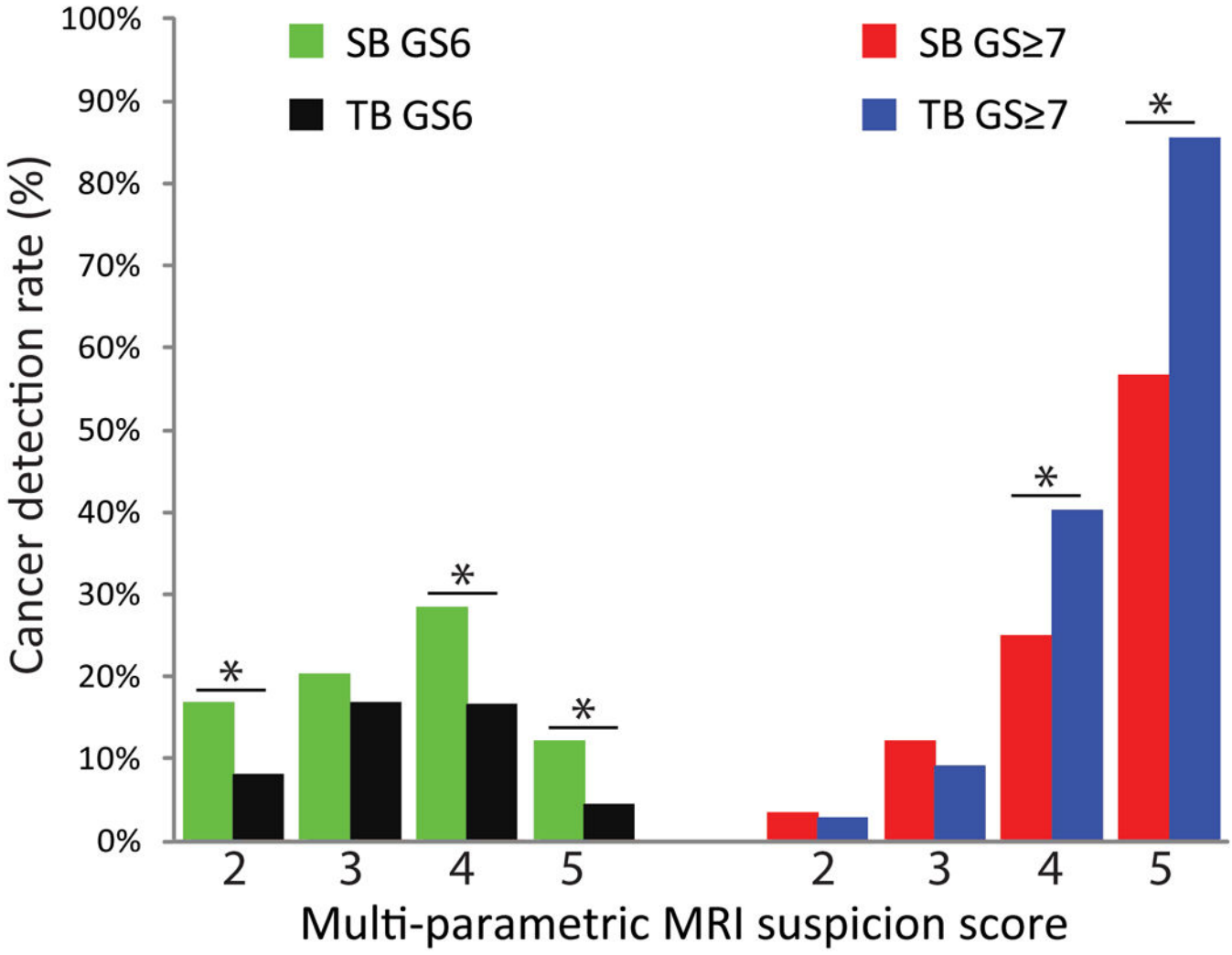

Figure 3.

Cancer detection rate for systematic compared to MRI-fusion biopsy for GS6 and GS≥7 prostate cancer stratified by MRI suspicion score.

* $p < 0.05$

SB = systematic biopsy

TB = MRI-US Fusion Targeted Biopsy

GS = Gleason score

Table 1

Patient characteristics

	Total n=601	No Prior n=292	Prior Negative n=172	Prior Cancer n=137	p value
Age, mean (SD)	65.2 (8.0)	64.4 (8.4)	65.9 (7.5)	66.3 (7.7)	0.033
PSA, mean (SEM)	6.7 (.3)	6.2 (.4)	8.9 (0.7)	5.4 (0.4)	<0.001
BMI, mean (SD)	27.1 (4.3)	27.1 (4.4)	27.0 (3.4)	27.1 (4.8)	0.963
Prostate volume, mean (SD)	59.9 (38.2)	53.1 (27.2)	76.9 (44.4)	53.4 (42.2)	<0.001
# MRI suspicious regions, mean (SD)	1.58 (0.66)	1.63 (0.66)	1.56 (0.65)	1.51 (0.64)	0.213
Maximum MRI suspicion score, mean (SD)	3.3 (1.0)	3.3 (1.1)	3.1 (1.0)	3.3 (1.0)	0.144

Table 2

Comparison of cancer detection rate between targeted biopsy and systematic biopsy in all patients

Systematic biopsy CDR n(%)		Targeted biopsy CDR n(%)				
		Gleason ≥4+3	**Gleason 3+4**	**Gleason 6**	**No Cancer**	**Total**
	Gleason ≥4+3	42 7%	8 1%	2 0%	2 0%	**54 *** **9%**
	Gleason 3+4	4 1%	39 6%	13 2%	7 1%	**63 †** **10%**
	Gleason 6	3 0%	20 3%	37 6%	61 10%	**121 ‡** **20%**
	No Cancer	20 3%	22 4%	23 4%	298 50%	363 60%
	Total	**69 *** **11%**	**89 †** **12%**	**75 ‡** **12%**	368 61%	601 100%

* $p < 0.05$, Systemic biopsy vs MRI-US fusion targeted biopsy for GS≥7 (4+3) prostate cancer

† $p < 0.05$, Systemic biopsy vs MRI-US fusion targeted biopsy for GS 7 (3+4) prostate cancer

‡ $p < 0.05$, Systemic biopsy vs MRI-US fusion targeted biopsy for GS 6 prostate cancer

Table 3

Cancer detection rate by MRI suspicion score within each group

	Number of Men				All Cancer			
mSS	**No prior (n = 292)**	**Prior negative (n = 172)**	**Prior cancer (n = 137)**	**p-value**	**No prior**	**Prior negative**	**Prior cancer**	**p-value**
2	82 (28%)	54 (31%)	35 (26%)	-	23.2%	18.5%	31.4%	0.372
3	92 (32%)	60 (35%)	44 (32%)	-	39.1%	16.7%	75.0%	**<0.001**
4	63 (22%)	40 (23%)	41 (30%)	-	74.6%	42.5%	87.8%	**<0.001**
5	55 (19%)	18 (10%)	17 (12%)	-	92.7%	88.9%	100.0%	0.403
	Gleason ≥ 7				**Gleason 6**			
mSS	No prior	Prior negative	Prior cancer	p-value	No prior	Prior negative	Prior cancer	p-value
2	3.7%	5.6%	5.7%	0.832	19.5%	13.0%	25.7%	0.311
3	16.3%	5.0%	29.5%	**0.003**	22.8%	11.7%	45.5%	**<0.001**
4	50.8%	25.0%	53.7%	**0.014**	23.8%	17.5%	34.1%	0.215
5	87.3%	83.3%	94.1%	0.612	5.5%	5.6%	5.9%	0.998

mSS = MRI suspicion score