“In-bore” MRI-guided Prostate Biopsy Using an Endorectal Nonmagnetic Device: A Prospective Study of 70 Consecutive Patients

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Abstract

In a cohort of 70 consecutive patients with suspected prostate cancer and ≥ 1 suspicious area at the preliminary multiparametric magnetic resonance imaging study, in-bore endorectal magnetic resonance imaging-guided biopsy demonstrated a high detection rate, especially for clinical significant tumors and lesions located in the central and anterior regions of the gland, with a very low number of cores needed and a negligible incidence of complications.

Introduction: We investigated the diagnostic performance of in-bore endorectal magnetic resonance imaging-guided biopsy (MRI-GB) with a 1.5-T MRI scanner using a 32-channel coil in patients with suspected prostate cancer (PCa).

Patients and Methods: Seventy patients with ≥ 1 suspicious area found on the preliminary multiparametric MRI scan were enrolled. The index lesion was defined as the lesion with the greatest Prostate Imaging Reporting and Data System, version 2 (PIRADS-v2), score. MRI-GBs were performed with a nonmagnetic biopsy device, needle guide, and titanium double-shoot biopsy gun with dedicated software for needle tracking. Clinically significant PCa was defined as the presence of Gleason score ≥ 7 in the biopsy specimen. Results: Seventy index lesions were scheduled for MRI-GB. The median PIRADS-v2 score and the median number of cores per patient was 4 of 5 (interquartile range, 3-5) and 2 (interquartile range, 1-3), respectively. The PCa detection rate was 45.7%. Of the 70 patients, 24 (75%) had clinically significant PCa, with a significant correlation between the PIRADS-v2 score and the Gleason score in the MRI-GB cores (r = 0.839; 95% confidence interval, 0.535-0.951; P = .003). According to the PIRADs-v2 scheme, the proportion of PCa in the central and anterior regions of the gland was greater in the entire population and in the subgroup of patients with a history of negative transrectal ultrasound-guided biopsy findings (P ≤ .01 for all). On multivariate analysis, a PIRADS-v2 score of 5 of 5 correlated significantly with the likelihood of PCa at biopsy (hazard ratio, 4.69; 95% confidence interval, 0.92-23.74; P = .04). No major complications were recorded. Conclusion: MRI-GB has a high detection rate for PCa, especially for lesions located in the central and anterior regions of the prostate.
In-bore MRI-guided Prostate Biopsy

Introduction
Prostate Cancer (PCa) is the most common neoplasm diagnosed in men and the second most common cause of death after lung cancer. Transrectal ultrasound-guided random biopsy (TRUS-GB) is the current reference standard procedure for PCa diagnosis, although the limited detection rate actually represents the most relevant concern. PCa is often small and not uniformly distributed within the gland and will be isoechogenic or slightly hypoechogenic in 37% to 50% of cases. Moreover, in a non-negligible percentage of cases (25%-30%), it can arise from the anterior part of the gland (anterior horn of the peripheral gland, central or transitional zones, and fibromuscular stroma). Thus, a random TRUS-GB can miss ≤ 40% to 50% of PCa cases, with a relevant number of clinically significant tumors, especially in larger glands. Taking a greater number of cores can improve the overall detection rate (DR); however, many more cases of indolent PCa will inevitably be overdiagnosed, leading to the potential for overtreatment, which will negatively affect patients’ quality of life. Furthermore, the treatment of patients with previous negative biopsy findings and persistent clinical suspicion of PCa remains a challenging issue. The detection rate decreases with repeat biopsy (10%-20% for the second mapping and 5%-9% for the third); however, the risk of complications increases, especially with an increasing of number of cores taken. Magnetic resonance imaging (MRI) has shown remarkable accuracy in the detection of clinically significant PCa (csPCa) when using radical prostatectomy specimens as the reference standard. Combining functional studies such as diffusion-weighted imaging (DWI), dynamic contrast-enhanced MRI (DCE-MRI), magnetic resonance spectroscopy (MRS), and multi-parametric MRI (mpMRI) improves the identification of PCa foci within the gland with very high diagnostic accuracy. MRI-guided prostate biopsy (MRI-GB) can improve PCa detection, especially of clinically significant tumors, which are more frequently undersampled during random TRUS-GB. An increasing body of evidence has suggested that mpMRI can improve the tumor’s risk group classification and could reduce false-negative rates and the necessity for repeat biopsies in both biopsy-naïve patients and those with previous negative biopsy findings. Therefore, when high-quality prostate magnetic MRI is available, MRI-targeted biopsy should be strongly considered for any patient with previous negative biopsy findings and persistent clinical suspicion for prostate cancer, as reported by the recent American Urological Association Consensus Statement. The techniques for targeted biopsy include visual estimation TRUS-GB (cognitive technique), software core-registered MRI—ultrasound fusion (fusion technique), and in-bore MRI-GB. Despite data from published studies suggesting that MRI-GB provides greater cancer detection compared with the cognitive technique, no significant advantage was found for MRI-GB compared with the fusion technique concerning overall PCa detection and clinical significant cancer detection. The potential limitations of MRI-GB include an inability to perform coconitant systematic TRUS biopsy, especially in biopsy-naïve patients, because systematic biopsy in ≤ 16% of men with no suspicious MRI target could reveal csPCa. In contrast, the in-bore technique has the advantage of providing direct and real-time proof of the correct sampling, potentially reducing errors during the targeting process. The aim of the present report was to prospectively evaluate the feasibility, DR, efficiency, and complication rate in a pure in-bore MRI-GB series.

Materials and Methods
Study Method and Population
From July 2015 to April 2016, a cohort of 70 consecutive patients undergoing MRI-GB were prospectively enrolled. All patients had a clinical suspicion of PCa because of an elevated prostate-specific antigen (PSA) serum level and/or abnormal digital rectal examination (DRE) findings and ≥ 1 suspicious area on the mpMRI scan. According to the European Society of Urogenital Radiology guidelines, the presence of csPCa on mpMRI was defined as equivocal, likely, or highly likely according to the Prostate Imaging Reporting and Data System, version 2 (PIRADS-v2), score of 3 of 5, 4 of 5, or 5 of 5, respectively. The local institutional review board approved the present study.

MRI Examination and Analysis
All the mpMRI examinations were performed with a 1.5-T whole body scanner (Achieva XR; Philips Medical Systems, Best, Netherlands) with a 32-channel phased-array surface coil and endorectal coil (ERC). After local 3-plane acquisition, required for the correct positioning of the sequences, the morphologic and functional studies were performed. Morphologic studies of the prostate gland were obtained using turbo spin echo T2-weighted sequences (echo time, 100 ms; repetition time, 4074 ms; slice thickness, 3 mm; slice spacing, 0.3 mm; field of view, 180 × 180 mm; matrix size, 276 × 205) in the sagittal, axial, and coronal planes, including the seminal vesicles and the entire prostate gland. For the functional study, DWI, DCE-MRI, and MRS acquisition were performed. DWI acquisition was performed in the axial plane, using a single-shot echo-planar imaging sequence, with 3 b-values (0, 600, and 1500 s/mm2), a slice thickness of 3 mm, field of view of 180 × 180 mm, and matrix size of 80 × 71. DCE-MRI was obtained using 3-dimensional (3D) T1-weighted, high-resolution isotropic volume examination sequence during the intravenous injection of a contrast bolus of 0.1 mmol/kg body weight of meglumine gadobenate (Multihance; Bracco Diagnostics, Milan, Italy) at a flow rate of 3.5 mL/s, followed by 15 mL of saline solution. Twenty-three 3D data sets, 1 before and 22 after, contrast administration were acquired with a 10-second temporal resolution and a total duration of 4 minutes (depending on the volume of the prostate gland). The first data set acquired before contrast agent administration was used to detect any residual blood from the previous biopsy. The MRS was obtained using the 3D chemical shift imaging sequence and the following parameters: matrix 10 × 10 × 12 phase-encoding steps with a nominal voxel size of < 0.5 cm3; spectral selective suppression of water and lipid signals; interactive automatic shimming up to a line width at half height of the water resonance peak of 15 to 20 Hz. The volume of interest was aligned to the axial T1-weighted images and centered on each prostate to maximize coverage of the whole gland, minimizing contamination by the surrounding tissue. Finally, a turbo spin echo T2-weighted sequence (echo time, 100 ms; repetition time, 3445 ms; slice thickness, 4 mm; slice spacing, 0.4 mm; field of view,
once, if targeting was not certain, according to the lesion size or
for alignment of the biopsy arm in the space (because of the gadolinium inserted into the needle guide
target localization (DynaCAD; Invivo) were also used. These tools
prostate and identify the target lesion. For MRI-GB, a nonmagnetic
and sagittal T2-weighted images were obtained to visualize the
gland. Periprostatic nerve blockade for local anesthesia with
was performed to evaluate any anatomic or pathologic condition that
the procedure and prolonged for
lones (ciprofloxacine 500 mg) twice daily, starting from the day before
 Figure 2A
longitudinal axis of the Magnetic Resonance Imaging Scanner

Biopsy Procedure

The biopsies were performed transrectally, within 2 weeks of
mpMRI, by a single urologist (A.S.) with considerable experience in
MRI-GB, using the 1.5T MRI scanner (Achieva XR; Philips Medical
Systems), with the patients in the prone position. An 18-guage
automatic core needle and a titanium double-shot biopsy gun were
used. All patients received oral antibiotic prophylaxis with quinolones
ciprofloxacine 500 mg) twice daily, starting from the day before
the procedure and prolonged for ≥ 2 days after. Before biopsy, DRE
was performed to evaluate any anatomic or pathologic condition that
could hinder transrectal biopsy and to approximate the position of
the gland. Periprostatic nerve blockade for local anesthesia with
lidocaine 2% was administered immediately before the biopsy. Axial
and sagittal T2-weighted images were obtained to visualize the
prostate and identify the target lesion. For MRI-GB, a nonmagnetic
portable biopsy device (DynaTRIM; Invivo, Gainesville, FL;
Figure 1) and a dedicated software package for device tracking and
target localization (DynaCAD; Invivo) were also used. These tools
allow one to direct the needle, which is visible on the MRI scans
because of the gadolinium inserted into the needle guide
(Figure 2A), within a 3-dimensional system for alignment of the biopsy arm in the space (Figure 2B). Multiple
T2-weighted acquisitions in the axial and sagittal planes along the
axis of the needle allow one to assess the correct position with respect to
the target lesion to establish the direction and depth of the needle
movements (Figure 3). These procedures can be repeated more than
once, if targeting was not certain, according to the lesion size or
subjective judgment of the operator. Only the index lesion in each
patient was scheduled for MRI-GB. The number of cores taken was
related to the size of the lesion. The cores were taken out along the
long axis of the lesion, with a maximum of 2 biopsies taken for each
needle. Finally, the patients were evaluated 1 hour and 7 to 10 days
after the procedure to evaluate and record possible complications.
The specimens were processed by routine pathologic fixation with
formalin solution and evaluated by a single dedicated uropathologist
with 20 years of experience. Cancer cells retrieved in the MRI-GB
specimens were used as the reference standard to determine the
positivity of the biopsy. The criteria for clinical significance con-
cerning the biopsy specimen was a biopsy Gleason score of ≥ 7.

Statistical Analysis

The mean, median, and interquartile range were recorded for
continuous variables. Frequencies and proportions were recorded for
categorical variables. The Mann-Whitney U test and χ2 test were
used to compare the statistical significance of differences in the
medians and proportions, respectively.

The Spearman rank correlation test was used to assess the corre-
lation between the PIRADS-v2 score at mpMRI and the Gleason
score (GS) in the MRI-GB cores. The efficiency of the in-bore bi-
opsy strategy was calculated by considering the total number of cores
taken divided by the number of PCa and csPCa retrieved. Uni- and
multivariate logistic regression analyses were used to assess the rela-
tion between overall PCa and csPCa detection and clinical fea-

Results

The clinical, radiologic, and pathologic characteristics of the
entire population are listed in Table 1. Of 70 patients, 29 (41.4%)
were biopsy naive and 41 (58.6%) had ≥ 1 previous negative set of random TRUS-GB findings. One patient (3.7%) had previously undergone treatment of benign prostatic hyperplasia, with an incidental finding of PCa, and another patient (3.7%) was enrolled in an active surveillance protocol for indolent PCa (GS 3+3 in 1 core with a PSA level < 10 ng/mL). At the prebiopsy mpMRI study, a total of 94 suspected lesions were identified, and 70 index lesions were scheduled for MRI-GB. The median diameter of the index lesion was 12 mm (range, 3-32 mm; interquartile range [IQR], 9-17). The MRI-GB findings were positive in 32 of 70 patients with a DR of 45.7%. Of the 41 patients with ≥ 1 previous set of TRUS-GB, 17 had PCa found at MRI-GB, with a DR of 41.5%. The DR in the 29 biopsy-naive patients was 51.7% (15 of 29). In the patient previously treated surgically for benign prostatic hyperplasia, MRI-GB retrieved a csPCa in the peripheral zone of the gland, and a csPCa (GS 3+4) was revealed in the patient formerly enrolled in active surveillance protocol and then scheduled for radical prostatectomy. The total PSA level and PSA density were significantly greater in patients with positive MRI-GB findings ($p < .008$ for all). Of the 32 patients with positive biopsy findings, 24 (75%) were found to have csPCa on histologic examination. Of these 24 patients, 11 had GS of 7 (8 with primary GS 3 and 3 with primary GS 4) and 13 patients had GS of ≥ 8.

Regarding the PI-RADS-v2 score, the patients diagnosed with PCa had a PIRADS-v2 score that was significantly greater than those with negative biopsy findings ($p = .001$). Overall, in the
patients with a PI-RADS-v2 score of 3 of 5, 4 of 5, and 5 of 5, PCa was retrieved in 8, 13, and 11 cases, respectively. Of these PCa cases, 3 (3 of 8; 37.5%), 12 (12 of 13; 92.3%), and 9 (9 of 11; 81.8%) were csPCa, respectively. Overall, considering the anatomic distribution of the index lesions using the PIRADs-v2 scheme, the probability of PCa was greater for the lesions located in the central zone (11 of 15; 73.3%) than for those in the peripheral zone (21 of 55; 38.5%; \( P = .014 \)). Lesions located in the central zone had a significantly greater median diameter than that of those in the peripheral zone (17 mm [IQR, 13-23 mm] vs. 12 mm [IQR, 9-14 mm]; \( P < .001 \)). The distribution of the positive lesion according to the location is listed in Table 2. In the subset of the 29

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Entire Population (n = 70)</th>
<th>Positive Biopsy Patients (n = 32)</th>
<th>Negative Biopsy Patients (n = 38)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>Median 63</td>
<td>66</td>
<td>61</td>
<td>.014</td>
</tr>
<tr>
<td></td>
<td>IQR 58-67</td>
<td>60-70</td>
<td>57-64</td>
<td></td>
</tr>
<tr>
<td>PSA (ng/mL)</td>
<td>Median 6.9</td>
<td>8.4</td>
<td>5.6</td>
<td>.008</td>
</tr>
<tr>
<td></td>
<td>IQR 4.97-9.05</td>
<td>5.96-14.8</td>
<td>4.87-8.55</td>
<td></td>
</tr>
<tr>
<td>PSA density (ng/mL/cm^3)</td>
<td>Median 0.14</td>
<td>0.18</td>
<td>0.10</td>
<td>.004</td>
</tr>
<tr>
<td></td>
<td>IQR 0.09-0.24</td>
<td>0.11-0.29</td>
<td>0.08-0.17</td>
<td></td>
</tr>
<tr>
<td>Prostate volume (cm^3)</td>
<td>Median 50</td>
<td>42</td>
<td>53</td>
<td>.166</td>
</tr>
<tr>
<td></td>
<td>IQR 34-65</td>
<td>32-66</td>
<td>36-65</td>
<td></td>
</tr>
<tr>
<td>Previous TRUS-GB (n)</td>
<td>None 15 (46.8)</td>
<td>29 (41.4)</td>
<td>14 (36.8)</td>
<td>.335</td>
</tr>
<tr>
<td></td>
<td>≥1 17 (53.2)</td>
<td>41 (58.6)</td>
<td>24 (63.2)</td>
<td></td>
</tr>
<tr>
<td>Index lesion diameter (mm)</td>
<td>Median 12</td>
<td>13</td>
<td>11</td>
<td>.16</td>
</tr>
<tr>
<td></td>
<td>IQR 9-17</td>
<td>10-17</td>
<td>8-17</td>
<td></td>
</tr>
<tr>
<td>Index lesion site</td>
<td>Peripheral zone 55 (78.5)</td>
<td>21 (65.6)</td>
<td>34 (89.4)</td>
<td>.02</td>
</tr>
<tr>
<td></td>
<td>Central zone 15 (21.4)</td>
<td>11 (34.4)</td>
<td>4 (10.6)</td>
<td></td>
</tr>
<tr>
<td>Index lesion location</td>
<td>Anterior 19 (27.1)</td>
<td>14 (43.7)</td>
<td>5 (13.1)</td>
<td>.006</td>
</tr>
<tr>
<td></td>
<td>Posterior 51 (72.9)</td>
<td>18 (56.3)</td>
<td>33 (86.9)</td>
<td></td>
</tr>
<tr>
<td>PI-RADS-v2 score</td>
<td>3 of 5 32 (45.7)</td>
<td>8 (25.0)</td>
<td>24 (63.1)</td>
<td>.001</td>
</tr>
<tr>
<td></td>
<td>4 of 5 25 (35.7)</td>
<td>13 (40.6)</td>
<td>12 (31.6)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5 of 5 13 (18.6)</td>
<td>11 (34.4)</td>
<td>2 (5.3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Median 4</td>
<td>4</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>IQR 3-4</td>
<td>3-5</td>
<td>3-4</td>
<td></td>
</tr>
<tr>
<td>Gleason score at MRI-GB</td>
<td>6 8</td>
<td>8</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7 (3+4; 4+3) 11 (8; 3)</td>
<td>11 (8; 3)</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>≥8 13 13</td>
<td>13</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>Cores taken per patient</td>
<td>Median 2</td>
<td>2</td>
<td>2</td>
<td></td>
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<tr>
<td></td>
<td>Range 1-6</td>
<td>1-6</td>
<td>1-6</td>
<td>.078</td>
</tr>
<tr>
<td></td>
<td>IQR 1-3</td>
<td>1-2</td>
<td>2-3</td>
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</tbody>
</table>

Data presented as n (%).
Abbreviations: IQR = interquartile range; MRI-GB = magnetic resonance imaging-guided biopsy; PI-RADS-v2 = Prostate Imaging Reporting and Data System, version 2; PSA = prostate-specific antigen; TRUS-GB = transrectal ultrasound-guided biopsy.
*Mann-Whitney U test.
**Fisher’s exact test.
biopsy-naive patients, the proportion of PCa retrieved in the anterior lesions (3 of 6; 50.0%) was comparable to that observed in the posterior lesions (13 of 23; 56.5%). PCa was more likely to be found in the central zone (8 of 11; 72.7%) compared with peripheral lesions (11 of 34; 32.4%), but the difference was not statistically significant (P = .6). In contrast, in the 41 men with ≥1 previous biopsy, the proportion of tumors found in the central and anterior sites of the gland was significantly greater. PCa was found in 6 of 7 of the centrally located lesions (85.7%) compared with 11 of 34 peripheral lesions (32.4%; P = .01). MRI-GB revealed PCa in 11 of 13 anterior lesions (84.6%) compared with 6 of 28 lesions (21.4%) located in the posterior sites of the gland (P < .001; Figures 3 and 4). In the 32 men with positive MRI-GB findings, the correlation between the PIRADS-v2 score and GS in the MRI-GB cores was statistically significant (r = 0.839; 95% confidence interval [CI], 0.535-0.951; P = .003). Stratifying the index lesions according to the median diameter of 12 mm, 2 groups were identified: 28 lesions < 12 mm and 42 lesions ≥ 12 mm. The MRI-GB cores were more likely to be positive in the latter group (54.7% vs. 32.2% for lesions ≥ 12 mm and < 12 mm, respectively), with a slightly statistical significance (P = .058). Overall, 153 cores were taken, with a median number per patient of 2 (range, 1-6; IQR 1-3). No significant difference was found between those with negative and those with positive biopsy findings in terms of the number of cores taken. A per-biopsy core analysis revealed a PCa DR of 41.1% (63 of 153) and a median maximum cancer length of 6.2 mm (IQR, 4.5-9.2 mm). The number of cores needed to detect 1 man with PCa or csPCa (efficiency) was 4.7 and 6.3, respectively.

On univariate analysis, age ≥ 65 years (P = .005), PSA ≥ 10 ng/mL (P = .01), anterior localization of the index lesion (P = .005), PIRADS-v2 score of 4 of 5 (P = .04), and PIRADS-v2 score of 5 of 5 (P = .001) correlated with biopsy positivity. Multivariate analysis showed that only a PIRADS-v2 score of 5 of 5 (hazard ratio [HR], 4.69; 95% CI, 0.92-23.74) was an independent predictor of MRI-GB positivity (P = .04; Table 3). Similarly, a PIRADS-v2 score of 4 of 5 (HR, 7.09; 95% CI, 1.45-34.73) and 5 of 5 (HR, 9.14; 95% CI, 0.77-48.49) were independent predictors of csPCa on multivariate analysis (P = .02 and P = .04, respectively; Table 4).

The mean procedure time was 51 ± 9 minutes. No hospitalizations for major postbiopsy complications were recorded. Self-limiting mild hematuria, rectal bleeding, and hematochezia were observed in 2 (2.8%), 1 (1.6%), and 3 (4.2%) patients, respectively, with no urinary retention.

**Discussion**

The results of the present study show that MRI-GB has a high DR for PCa with a low number of cores taken, especially for lesions located in the central and anterior regions of the prostate, which are typically not evaluated during standard TRUS-GB. In addition, the PIRADS-v2 score correlated strongly with high-grade csPCa. Recently, mpMRI has been increasingly used with the aim of improving PCa diagnosis and guiding targeted prostate biopsies to overcome the limitations of contemporary standard TRUS-GB. MRI-targeted prostate biopsies can potentially reduce the sampling error associated with conventional biopsy by providing better disease localization and characterization. Several MRI-GB methods have been proposed. In the cognitive technique, TRUS-GB is planned using a mental reconstruction of MRI scans provided by the operator. Despite the reduced costs, this method has a long learning curve and is extremely dependent on the physician's expertise to obtain an accurate sampling of the index lesions. MRI-US fusion biopsy is simply described as a method to align a pre-registered MRI scan with an intraprocedural US scan to identify and target suspected lesions within the gland through dedicated hardware platforms targeting areas found during mpMRI and not clearly visible during US scanning. The advantages are the high reproducibility and the real-time feedback, although these are counterbalanced by the high up-front cost of the device. Another advantage of the fusion technique is the ability to perform a systematic biopsy during the same session, because ≤ 16% of men with no suspicious MRI target could be found to have csPCa on systematic biopsy.

Most urologists are more confident with TRUS-GB, and despite the initial difficulties related to the learning curve within the fusion process, it could become more widespread for routine clinical practice. In contrast, the in-bore technique consists of the execution of biopsies directly inside the MRI scanner with dedicate

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**Table 2**

<table>
<thead>
<tr>
<th>Index Lesion Sites at mpMRI (According to PIRADS-v2)</th>
<th>Negative MR-GB Findings</th>
<th>Positive MR-GB Findings</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Biopsy-naive patients (n = 20)</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Peripheral (n = 21)</td>
<td>11 (52.4)</td>
<td>10 (47.6)</td>
<td>.6</td>
</tr>
<tr>
<td>Central (n = 8)</td>
<td>3 (37.5)</td>
<td>5 (61.5)</td>
<td></td>
</tr>
<tr>
<td>Posterior (n = 23)</td>
<td>11 (47.8)</td>
<td>12 (52.2)</td>
<td>.9</td>
</tr>
<tr>
<td>Anterior (n = 6)</td>
<td>3 (50.0)</td>
<td>3 (50.0)</td>
<td></td>
</tr>
<tr>
<td><strong>Patients with ≥1 previous negative TRUS-GB (n = 41)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peripheral (n = 34)</td>
<td>23 (67.6)</td>
<td>11 (32.4)</td>
<td>.01</td>
</tr>
<tr>
<td>Central (n = 7)</td>
<td>1 (14.3)</td>
<td>6 (85.7)</td>
<td></td>
</tr>
<tr>
<td>Posterior (n = 28)</td>
<td>22 (78.6)</td>
<td>6 (21.4)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Anterior (n = 13)</td>
<td>2 (15.4)</td>
<td>11 (84.6)</td>
<td></td>
</tr>
</tbody>
</table>

Data presented as n (%).

Abbreviations: MR-GB = magnetic resonance imaging-guided biopsy; PIRADS-v2 = Prostate Imaging Reporting and Data System, version 2; TRUS-GB = transrectal ultrasound-guided biopsy.

*Statistically significant.
nonmagnetic biopsy devices. The disadvantages of in-bore MRI include the longer operative time, higher costs, initial expertise required with the software dedicated to drive the targeted cores, and inability to perform concomitant systematic TRUS-GB. However, the advantages consist of real-time feedback with needle placement, fewer sampled cores, and a low likelihood of missing the target. Therefore, the use of in-bore MRI-GB has the potential to reduce the sampling error associated with an unselective standard biopsy scheme by providing better disease localization. Moreover, accurate risk stratification through improved cancer sampling could affect therapeutic decision making. Our experience with MRI-GB has confirmed the feasibility and reproducibility of an in-bore strategy with a 1.5-T MRI scanner using a 32-channel coil. Both 1.5-T and 3-T scanners are currently used for PCa detection, with the latter becoming increasingly preferred, owing to the higher signal/noise ratio (SNR) and, consequently, improved image quality. A comparison between the diagnostic performance of the 2 systems is lacking, although many investigators\textsuperscript{10-14} have obtained comparable results, even with various technological equipment and experience levels. Many factors affect image quality other than the magnetic field strength; thus, optimization of the acquisition parameters and the use of appropriate contemporary technology are very important to obtain adequate and reliable diagnostic examination findings.\textsuperscript{24} The image quality can be improved using an ERC, in addition to the pelvic phased-array coil, which produces an increase in the SNR. Although the use of the ERC increases the performance of the sequence parameters, the 3-T MRI scanner provides sufficient image quality even without an ERC.\textsuperscript{24} In contrast, with the 1.5-T MRI systems, the use of an ERC should be considered indispensable with the older scanners. However, some contemporary scanners that use a relatively high number of external phased-array coil elements and radiofrequency channels (eg, \(\geq 16\)) might be capable of achieving an adequate SNR without an ERC.\textsuperscript{24} The debate regarding whether a high field strength can eliminate the need for an

Figure 4 Magnetic Resonance Images of a 69-year-old Patient, With a Prostate-specific Antigen Level of 15.4 ng/mL, Prostate Gland of 110 cm\(^3\). The Patient Had Already Undergone 2 Standard Transrectal Ultrasound-guided Biopsies With 32 Cores Taken. (A) Sagittal T\(_2\)-weighted Image Showing Significant Hypertrophy of the Central Gland and the Index Lesion (Diameter, 21 mm) in the Anterior Transition Zone of the Left Third Middle of the Prostate (Arrow), With High Restriction of the Diffusivity, and (B) Hypointensity in the Axial Apparent Diffusion Coefficient Map. The Final Prostate Imaging Reporting and Data System, Version 2, Score Was 5 of 5. Sagittal (C) and Coronal Oblique (D) T\(_2\)-weighted Images Showing the Needle Within the Lesion During the In-bore Biopsy Procedure (Arrows). With 2 Cores Taken, the Final Diagnosis Was PCa, Gleason Score 4 + 4
ERC is ongoing, and a direct comparison of both strategies for cancer detection and/or staging is lacking. The overall DR (45.7%) in the present study was high and aligned with previous reports considering men with previous set of TRUS-GB (DR, 41.5%).\textsuperscript{20,25-28} Furthermore, it is very important to highlight that >75% of these men were found to have csPCa, ensuring excellent efficiency in detecting clinically significant tumors (6.3 cores to diagnose 1 patient with csPCa) and certainly more powerful than repeating standard TRUS-GB. Although we cannot yet recommend mpMRI as a first-line diagnostic tool in every case owing to its low availability and high costs,\textsuperscript{2} the use of a targeted biopsy can be often suggested in the repeat biopsy setting because it can achieve significantly greater cancer DRs, overcoming those reported with repeat systematic biopsy.\textsuperscript{6,7} Hambrock et al\textsuperscript{17} reported a cancer DR of 59%, of which 93% were clinically significant in 68 men with >2 TRUS-GB findings who had undergone mpMRI and then MRI-GB. When comparing the MRI-GB group with a matched reference group who had undergone repeat TRUS-GB, MRI-GB detected significantly more tumors than standard repeat TRUS-GB (22% in the second and 15% in the third TRUS-GB). A recent systematic review described the clinical results of MRI-GB obtained from 10 series.\textsuperscript{29} The most common inclusion criteria were an elevated PSA level (>4 ng/mL) and/or suspicious DRE findings combined with previous TRUS-GB with negative findings. Diagnostic MRI was mostly performed using an ERC, and MRI-GBs were performed using a closed-bore system at 1.5-T or 3-T field strength. The overall PCa DRs ranged from 8% to 59% (median, 42%), with 81% to 93% clinically significant tumors. However, unlike our experience, real-time needle targeting was generally not performed with intraprocedural imaging. More recently, in their preliminary experience with the in-bore technique using a 1.5-T magnet equipped with a 32-channel body coil and an ERC, Panebianco et al\textsuperscript{30} showed a DR of 80% for PCa in 23 patients with 2 cores obtained for each patient. Remarkably, 90% of these PCa lesions had a GS of 7. These percentages were greater than those reported in previous series with same equipment, although the inclusion criteria were slightly more selective. However, the number of patients with a history of

| Table 3 | Univariate and Multivariate Competing Risks Regression Model Predicting Diagnosis of PCa at MRI-GB |
|---|---|---|---|---|
| Variable | Univariate Analysis | P Value | Multivariate Analysis | P Value |
| Age (y) | | | | |
| <65 | 1.0 (Ref) | .005\textsuperscript{a} | 2.34 (0.73-7.44) | .14 |
| ≥65 | 0.23 (0.08-0.64) | .01\textsuperscript{a} | 0.56 (0.21-1.45) | .83 |
| PSA (ng/mL) | | | | |
| <10 | 1.0 (Ref) | .15 | NA | NA |
| ≥10 | 3.67 (1.36-9.85) | .234 | 4.47 (0.55-35.96) | .82 |
| PSA density (ng/mL/cm\textsuperscript{3}) | | | | |
| Previous TRUS-GB | None | 1.0 (Ref) | NA | NA |
| Site of index lesion | Peripheral | 1.0 (Ref) | NA | NA |
| Central | 0.61 (0.35-1.06) | NA | NA |
| Lesion location | Posterior | 0.005\textsuperscript{a} | NA | NA |
| Anterior | 4.17 (1.54-11.32) | 2.89 (0.87-9.61) | 4.17 (1.04-10.27) | .04\textsuperscript{a} |
| PIRADS-v2\textsuperscript{19} | 3 of 5 | 1.0 (Ref) | 1.0 (Ref) | .01\textsuperscript{a} |
| 4 of 5 | 3.28 (1.04-10.27) | 2.06 (0.79-5.35) | 12.5 (2.97-52.7) | .04\textsuperscript{a} |
| 5 of 5 | 12.5 (2.97-52.7) | 4.69 (0.92-23.74) | NA | NA |
| Index lesion diameter (mm) | <12 | 1.0 (Ref) | NA | NA |
| ≥12 | 2.25 (0.86-5.85) | .097 | NA | NA |
| Prostate volume (cm\textsuperscript{3}) | 0.99 (0.98-1.00) | .26 | NA | NA |
| Cores taken per patient (n) | <2 | 1.0 (Ref) | NA | NA |
| ≥2 | 0.85 (0.65-1.11) | .25 | NA | NA |

Abbreviations: CI = confidence interval; HR = hazard ratio; MRI-GB = magnetic resonance imaging-guided biopsy; NA = not applicable; PCa = prostate cancer; PIRADS-v2 = Prostate Imaging Reporting and Data System, version 2; PSA = prostate-specific antigen; Ref = reference; TRUS-GB = transrectal ultrasound-guided biopsy.\textsuperscript{a}Statistically significant.
previous TRUS-GB was not reported. Furthermore, our experience reinforces 2 important issues related to the MRI-GB technique. First, the superiority of MRI-GB compared with TRUS-GB to decrease the detection of low-risk PCa. As reported in a recent review, MRI-GB resulted in greater detection of significant PCa compared with standard TRUS-GB (relative sensitivity, 1.26; 95% CI, 1.08-1.46).

The ability of MRI to prevent unnecessary TRUS-GB and reduce overtreatment could lead to lower costs and greater quality of life when the costs of follow-up and treatment are considered. In addition, the in-bore technique has the great advantage of real-time feedback for needle placement and correct sampling of the lesion compared with other MRI-guided procedures (MRI-US fusion), avoiding mistakes in sampling and potentially reducing false-negative results. However, in our cohort, among the patients with negative findings, 2 (5.3%) and 12 (31.6%) had PIRADS-v2 score 5 and 4 suspected lesions at MRI, respectively. Considering the high negative predicted value of MRI, the false-negative rates could have been related to the initial learning curve of the needle driving process for the in-bore technique. Otherwise, these results reflect the limits of mpMRI in the diagnosis of PCa. Although many investigators have reported high diagnostic accuracy, false-positive findings can result from the presence of benign confounding lesions (e.g., prostatitis, especially granulomatous, and stromal benign hypertrophy in the peripheral zone). In contrast, false-negative results are mainly caused by the reduced visibility of the tumor within the gland, affected by the size and architecture of the tumor. Also, small tumor foci, scattered and separated by normal glandular tissue, are not easy identifiable.

Anterior PCa remains a diagnostic challenge considering its underestimated frequency. Several series have demonstrated the high capability of mpMRI to detect PCa lesions localized in the anterior regions of the prostate that are missed by standard TRUS-GB. Ouzzane et al reported that the detection of PCa was improved by performing targeted cores after mpMRI. In a cohort of 324 patients who underwent mpMRI and 26-core (transperineal 14-core plus transrectal 12-core) biopsy, Komai et al found that 20% of men harbored an anterior lesion, and, on targeted biopsy, 86% were proved to have PCa. Moreover, 40% of PCa lesions were
missed during the first set of 12-core biopsy. However, accurate sampling of the anterior region of the gland is not practical using a TRUS-guided approach. Transperineal biopsy might be effective for evaluating these regions; however, many urologists are not familiar with this procedure.

In our study, the likelihood of PCa in the MRI-suspected lesion located in the central zone was high, especially in those with previous negative biopsy findings, and 81% were csPCa. Nonetheless, in men with ≥ 1 previous set of negative TRUS-GB findings, PCa was found in 84.6% of the anterior lesions. These findings are promising and reinforce the clinical role of MR-GB, considering its significant effect in the identification of tumors that are distant from the sites typically evaluated during standard TRUS-GB. Our results highlight the excellent correlation between the PIRADS-v2 score at mpMRI and the likelihood of finding PCa and high GS in MRI-GB cores. These data have shown the good diagnostic performance of the MRI-GB procedure and the high capability of mpMRI to predict the biologic aggressiveness of neoplastic lesions. However, because ≤ 16% of men with no suspicious MRI target were found to have csPCa on systematic biopsy, the inability to perform concomitant systematic TRUS biopsy in conjunction with MRI-GB is the main disadvantage of the in-bore technique, especially in biopsy-naïve patients. The overall PCa DR and DR of csPCa was greatest when targeted biopsy and systematic biopsy were evaluated in conjunction with each other. The additional findings of systematic biopsy reflect the multifocality of PCa; therefore, the combination of both biopsy methods would still represent the best approach for the prediction of the final tumour grade. In contrast, in patients with previous negative biopsy findings and persistent PCa suspicion, MRI-GB without repeat systemic biopsy could represent the best management after recent and adequate systemic prostate sampling.

We did not found any major complications in our cohort, and only minor and self-limiting bleeding, fever, and impairment of lower urinary tract symptoms were recorded. These results are encouraging and underscore the benefit of the MRI-targeted approach in potentially reducing the risk of complications of prostate biopsies.

The present study was not devoid of limitations. First, the number of patients was quite small. Second, the analyzed patients included only those men with positive findings at mpMRI; thus, this selected patient population might have had a positive influence on the number of tumors detected. Third, the study lacked follow-up data and no prostate specimen histologic examinations can confirm the results of negative MRI-GB findings. Additional series with radical prostatectomy specimen as the reference standards are required to corroborate the benefit of a MRI-GB procedure. Finally, it is important to highlight that MRI-GB can initially represent a time-consuming and expensive procedure. We did not calculate the global costs of the procedure; however, as reported by other investigators, the initial costs could be reduced by the lower incidence of unnecessary radical treatment for indolent tumors diagnosed by systematic biopsy and the reduction of complications.

Conclusion

In our experience, MRI-GB resulted in the greater detection of PCa, with a very low number of cores needed and a negligible incidence of complications. MRI-GB is optimal for the diagnosis of anterior lesions, especially in patients with previous negative biopsy findings. Further investigations are needed to evaluate the clinical results compared with those from systematic or fusion biopsy.

Clinical Practice Points

- MRI-GBs can improve PCa detection, especially of csPCa.
- In the present cohort, 75% of patients with positive biopsy findings had csPCa. MRI-GB was optimal for the diagnosis of anterior lesions, especially in patients with previous negative biopsy findings.
- MRI-GB can detect PCa, with a very low number of cores needed and a negligible incidence of complications.
- mpMRI of the prostate can be suggested in the repeat biopsy setting to identify tumors distant from the sites typically evaluated during standard TRUS-GBs.

Disclosure

The authors declare that they have no competing interests.

References


