Prospective evaluation of using multiparametric magnetic resonance imaging in cognitive fusion prostate biopsy compared to the standard systematic 12-core biopsy in the detection of prostate cancer

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Abstract Purpose: There is mounting evidence to suggest that multiparametric magnetic resonance imaging (mpMRI)-guided biopsy is better than systematic biopsy for the diagnosis of prostate cancer (PCa). Cognitive fusion biopsy (CFB) involves targeted biopsies of areas of suspicious lesions noted on the mpMRI by transrectal ultrasound (TRUS) operator. This study was undertaken to determine the accuracy of mpMRI of the prostate with Prostate Imaging–Reporting and Data System (PI-RADS) version 2 in detecting PCa. We also compare the cancer detection rates between systematic 12-core TRUS biopsy and CFB.

Materials and Methods: Sixty-nine men underwent mpMRI of the prostate followed by TRUS biopsy. In addition to 12-core biopsy, CFB was performed on abnormal lesions detected on MRI.

Results: Abnormal lesions were identified in 98.6% of the patients, and 59.4% had the highest PI-RADS score of 3 or more. With the use of PI-RADS 3 as cutoff, the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of MRI for the detection of PCa were 91.7%, 57.8%, 53.7%, and 92.8%, respectively. With the use of PI-RADS 4 as cutoff, the sensitivity, specificity, PPV, and NPV of mpMRI were 66.7%, 91.1%, 80%, and 83.7%, respectively. Systematic biopsy detected more PCa compared to CFB (29% vs. 26.1%), but CFB detected more significant (Gleason grade \geq 7) PCa (17.4% vs. 14.5%) (*P* < 0.01). CFB cores have a higher PCa detection rate as compared to systematic cores (*P* < 0.01).

Conclusions: mpMRI has a good predictive ability for PCa. CFB is superior to systematic biopsy in the detection of the significant PCa.

Keywords: Biopsy, image-guided biopsy, magnetic resonance imaging, prostate, prostatic neoplasms

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INTRODUCTION

Multiparametric magnetic resonance imaging (mpMRI) of the prostate provides detailed anatomical and functional information. It identifies the areas of potential malignancy and enables targeted biopsy. In a meta-analysis that compared findings on mpMRI with those in biopsy and prostatectomy samples, this imaging modality was found to have high sensitivity and specificity (0.74 and 0.88, respectively) and a good negative predictive value (NPV) of 0.65–0.94 for the detection of prostate cancer (PCa).^[1]

In the past, the lack of a standardized reporting system hampered the use of prebiopsy mpMRI. In response, the European Society of Urogenital Radiology published its Prostate Imaging–Reporting and Data System (PI-RADS) in 2012 with the hope of achieving more uniformity in reporting mpMRI findings.^[2] A meta-analysis showed that although PI-RADS has good diagnostic accuracy for PCa, the authors could not recommend the best threshold at which to initiate the biopsy.^[3] In 2015, a revised version (PI-RADS Steering Committee and several working groups.^[4] Like the earlier version, this guideline failed to identify the best threshold to initiate the biopsy.

Studies on mpMRI-guided targeted biopsy have shown improved detection of PCa, and more importantly, better detection of clinically significant PCa, when compared with 12-core transrectal ultrasound (TRUS)-guided systematic biopsy.^[5,6] There are generally two ways to perform MRI-guided biopsy, i.e., MRI-ultrasound fusion biopsy and cognitive fusion biopsy (CFB). CFB involves targeted biopsies in the areas of suspicious lesions noted on the mpMRI by the TRUS operator. Unlike MRI-ultrasound fusion biopsy, CFB does not require any expensive hardware; however, its effectiveness may vary according to the operator's expertise. Studies concluded that these two techniques have similar efficacy and that there is no significant difference in their cancer detection rate.^[7,8]

Given that the collective experience in mpMRI and CFB is still evolving, this study was undertaken to compare the diagnostic ability of a combination of mpMRI based on PI-RADS version 2 and CFB with that of standard 12-core TRUS biopsy and to determine the most suitable PI-RADS score for use as the threshold for the initiation of biopsy.

MATERIALS AND METHODS

This prospective single-center study was conducted at Hospital Universiti Kebangsaan, Malaysia. The inclusion criteria included clinical suspicion of PCa (a prostate-specific antigen [PSA] level >4 ng/ml, abnormal findings on digital rectal examination, or incidental finding of a suspicious prostate lesion on imaging performed for another reason) or PCa on active surveillance. Patients who had a contraindication to MRI were excluded from the study. The study protocol was approved by the Institutional Review Board of Universiti Kebangsaan Malaysia (Approval No: FF-2015-326) and informed consent was obtained in all cases prior to any of the study procedures.

All patients underwent mpMRI using a 3-T scanner (Magnetom Spectra, Siemens Healthineers, Erlangen, Germany), and the images were reported in accordance with PI-RADS version 2 by an appointed senior radiologist (SS Othman). Subsequently, all patients underwent a systematic 12-core biopsy performed by one of the urologists (GH Tan, EH Goh, or P Singam). Two doses of a glycerin enema were administered, and a 5-day course of an oral fluoroquinolone was started on the day before the scheduled procedure. If a positive lesion was noted on MRI during the biopsy, an additional CFB was obtained. If the target lesion was within the area of the systematic 12-core biopsy, the core was regarded as both a systematic core and a targeted core in the final analysis. All specimens were examined by an appointed senior histopathologist (A Yahya). The Gleason score (GS) and percentage of positive cores were reported. In this study, we defined PCa as statistically significant if the Gleason grade was ≥ 4 .

The relationship between the PSA category and MRI findings was evaluated using the Mantel–Haenszel linear-by-linear association Chi-squared test. Receiver-operating characteristic curve analysis was performed to determine the diagnostic ability of mpMRI. The pathological results of both biopsy techniques and of biopsy cores obtained using both the techniques were compared using the Chi-squared test and independent *t*-test, respectively. All statistical analyses were performed using SPSS version 23.0 (IBM Corp., Armonk, NY, USA). $P \leq 0.05$ was considered statistically significant.

RESULTS

Baseline characteristics

Sixty-nine men were enrolled in the study. The median age was 65.71 years (interquartile range [IQR]: 61–71). The median PSA was 10.0 ng/ml (IQR: 7.4–13.3). The median interval between mpMRI and TRUS biopsy was 18 days (IQR: 11–88). None of the patients developed an infection or urinary retention after the biopsy. One patient developed hematuria that required the evacuation of a clot under general anesthesia.

Multiparametric magnetic resonance imaging for the detection of prostate cancer

The median prostate volume as measured by MRI was 50.4 ml (IQR: 35.2–61.6). The radiologist was able to identify at least one abnormal lesion in 98.6% of patients based on the mpMRI scans. On average, two lesions were found in each patient [Figure 1]; 59.4% of the patients had lesions that were PI-RADS \geq 3 and 29.0% had lesions that were PI-RADS \geq 4. There was a significant association between the PSA category and the highest PI-RADS score [Figure 2].

Figure 3 shows the biopsy results in relation to the MRI findings. The sensitivity, specificity, positive predictive value (PPV), and NPV of mpMRI for the detection of PCa using a PI-RADS score of 3 as the cutoff value were 91.7%, 57.8%, 53.7%, and 92.8%, respectively; the respective values using a score of 4 as the cutoff were 66.7%, 91.1%, 80%, and 83.7%.

Receiver-operating characteristic curve analysis showed that for patients with a PSA level ≤ 10 ng/ml, a PI-RADS cutoff score of 3 was better able to predict PCa (area under the curve [AUC]: 0.799, 95% confidence interval [CI]: 0.645–0.954, P < 0.005) than a cutoff score of 4 (AUC: 0.727, 95% CI: 0.531–0.924, P = 0.031) [Figure 4]. In contrast, for patients with a PSA level >10 ng/ml, a cutoff PI-RADS score of 4 was better able to predict PCa (AUC: 0.851, 95% CI: 0.704–0.999, P = 0.01) than a cutoff score of 3 (AUC: 0.697, 95% CI: 0.522–0.873, P = 0.058) [Figure 5].



Cognitive fusion biopsy versus systematic biopsy

Table 1 compares the number of cases of PCa and significant PCa detected by systematic biopsy and CFB in patients with PSA ≤ 10 ng/ml and those with PSA ≥ 10 ng/ml. The respective PCa detection rates using systematic biopsy and CFB were 29% and 26.1%, with an overall rate of 34.3%. The histopathology results for cases of PCa detected by each biopsy method are shown in Figure 7. More cases of significant PCa were detected by CFB than by systematic biopsy (17.4% vs. 14.5%, $P \leq 0.01$). Crucially, CFB detected additional three cases of Gleason 7 PCa and a case of Gleason 8 PCa that were missed by systematic biopsy. However, CFB missed six cases of Gleason 6 PCa. Furthermore, a Gleason 7 PCa and a Gleason 6 PCa. Furthermore, a Gleason 7 PCa and a Gleason 6 by CFB.

Comparing the pathology results for the biopsy cores obtained using the two techniques [Table 2], the PCa detection rate was significantly higher for CFB than for



Figure 1: Number of lesions noted on each magnetic resonance scan



Figure 2: Association between prostate-specific antigen and highest PI-RADS score. PI-RADS: Prostate Imaging Reporting and Data System



Figure 3: Detailed biopsy results in relation to findings on magnetic resonance imaging



Figure 5: Receiver-operating characteristic curve comparing the predictive ability of a PI-RADS cutoff score of 3 with that of a cutoff score of 4 in patients with a prostate-specific antigen level <10 ng/ml. PI-RADS: Prostate Imaging Reporting and Data System

systematic biopsy ($P \le 0.05$). However, there was no statistically significant difference in the rate of clinically significant cancers detected (P = 0.203) or in the mean percentage of cancer found within the cores obtained using the two techniques (P = 0.795).

DISCUSSION AND CONCLUSIONS

The role of 12-core TRUS biopsy as the gold standard for the diagnosis of PCa has been widely challenged. Poor sensitivity and undergrading are some of the key concerns. The cancer detection rate using systematic biopsy is 45%



Figure 4: Receiver-operating characteristic curve comparing the predictive ability of a PI-RADS cut-off score of 3 with that of a cut-off score of 4 in patients with a prostate-specific antigen level <10 ng/ml. PI-RADS, Prostate Imaging Reporting and Data System



Figure 6: Comparison of receiver-operating characteristic curves using PI-RADS cutoff scores of 4 and 3 in the detection of significant prostate cancer. PI-RADS: Prostate Imaging Reporting and Data System

when prostate volume was <35 ml and decreased to 28% when the prostate volume was >55 ml.^[9] Moreover, systematic biopsy also misses anterior lesions, which have been reported to account for 18% of PCa.^[10] Furthermore, it underestimates the Gleason grade, leading to inaccurate risk stratification and selection of potentially inappropriate therapeutic options. The GS for prostate biopsy and that for radical prostatectomy has been reported to be concordant in only 56.9%–69.0% of cases.^[11,12]

There is mounting evidence to suggest that MRI-guided biopsy is better than a systematic biopsy for the diagnosis of PCa. A combination of T2-weighted, diffusion-weighted, dynamic contrast-enhanced, and spectroscopic imaging

Table 1: Prostate cancer and of significant prostate cancer detected by systematic biopsy and cognitive fusion biopsy in	
patients with prostate-specific antigen \leq 10 (ng/ml) and those with prostate-specific antigen >10 (ng/ml)	

	Cancer detection in PSA <10 (ng/mL) group, <i>n</i> =34	Cancer detection PSA >10 (ng/mL) group, <i>n</i> =35	Patients who underwent prostate biopsy, <i>n</i> =69
PCa diagnosed by systematic biopsy, n (%)	9 (26.5)	11 (31.4)	20 (29)
PCa diagnosed by CFB, <i>n</i> (%)	8 (23.5)	10 (28.6)	18 (26.1)
PCa diagnosed by combined systematic	12 (35.2)	12 (34.3)	24 (34.3)
biopsy and CFB targeted biopsy, n (%)		-	· · ·

PCa: Prostate cancer, CFB: Cognitive fusion biopsy, PSA: Prostate-specific antigen

Table 2: Pathology	results for	the biopsy	cores obtained	l using the	e two tec	hniques
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	Systematic 12-core biopsy	Cognitive fusion biopsy	Р
Number of biopsy cores	828	190	-
Number of positive cores	122	47	-
Number cores with GS7 or more	75	36	
Positive rates (%)	14.7	24.7	0.01
Mean cancer core percentage (%)	37.5	38.6	0.795
The proportion of clinically significant (GS \geq 7) cancer among positive cores (%)	61.5	76.6	0.064
GS: Gleason score			



Figure 7: Overall histopathology results for prostate cancers detected by each prostate biopsy procedure. Cognitive fusion biopsy detected three additional cases of prostate cancer with a Gleason score of 7 and a case with a Gleason score of 8 that were missed by systematic biopsy. However, cognitive fusion biopsy missed six cases of Gleason 6 prostate cancer and reported one case each of Gleason 7 and Gleason 8 prostate cancer detected by transrectal ultrasound-guided systematic biopsy as Gleason 6

enables the identification of areas suspicious for malignancy that should be targeted for biopsy. In the past, there were no standardized diagnostic criteria for reporting mpMRI. In 2012, the European Society of Urogenital Radiology introduced PI-RADS. A meta-analysis of 14 studies (1785 patients) showed that PI-RADS version 1 had good diagnostic accuracy for PCa. The pooled data showed sensitivity and specificity of 78% and 79%, respectively, with NPV values ranging from 58% to 95%.^[13] In 2015, a revised version of PI-RADS was published.^[4] Version 2 outlines more specific criteria for T2-weighted and diffusion-weighted scoring of lesions and assigns an overall score (of 1–5) by integrating findings across all MRI sequences. A meta-analysis of six studies that performed a head-to-head comparison of the two versions of PI-RADS showed that PI-RADS version 2 demonstrated higher pooled sensitivity than PI-RADS version 1 (95% vs. 88%) but similar specificity (73% vs. 75%).^[14] PI-RADS version 2, like the earlier version, does not recommend a threshold to initiate the biopsy.

Two techniques for MRI-guided biopsy have been described, and each has its strengths and weaknesses. MRI-ultrasound fusion biopsy uses a computer system to superimpose images from mpMRI and real-time ultrasound to allow targeted biopsy. This method improves the PCa detection rates to about 50%-60%.[15-17] However, this method requires expensive software and its own computer system. CFB (also described as "cognitive registration" or "visual biopsy" in the literature) requires the TRUS operator to mentally relocate the target lesions detected on mpMRI based on zonal topography and anatomical landmarks. The main advantage of this method is to avoid the need for expensive equipment. Nevertheless, its effectiveness may vary greatly depending on the expertise of the operator. A study by Delongchamps et al. showed that MRI-ultrasound fusion biopsy detected up to 20% more cancers than a random biopsy and that CFB did not perform better than the random biopsy.^[18] However, recent studies have shown that these two techniques have comparable performance with no significant difference in their cancer detection rate.^[7,8]

In the present study, we assessed the accuracy of mpMRI using PI-RADS version 2 for the detection of PCa that was suspected on clinical grounds and in patients on active surveillance. We compared the mpMRI findings with the histopathological findings from systematic 12-core biopsy and CFB. Furthermore, we compared CFB and 12-core systematic biopsy for their ability to detect PCa and clinically significant PCa. Although our study was designed to answer questions similar to those addressed in earlier studies, some critical distinctions can be made. First, unlike the other studies, all mpMRI findings were reported based on the PI-RADS version 2 rather than PI-RADS version 1. Second, our study included both patient-based and core-based analysis.

A meta-analysis showed that the use of a PI-RADS score 3 as a threshold for biopsy had high sensitivity (88%) and low specificity (45%) for PCa detection, whereas the use of a PI-RADS score 4 had higher specificity (76%) but lower sensitivity (66%) for PCa detection.^[14] Like the previous studies, our study showed that a PI-RADS cutoff score of 3 had better sensitivity and a higher NPV but had less specificity and a poorer PPV than a cutoff score of 4. We also found that a PI-RADS cutoff score of 3 was better able to predict PCa in patients with a PSA level $\leq 10 \text{ ng/ml}$, whereas a cutoff score of 4 could better predict PCa in those with a PSA level >10 ng/ml. This finding is likely attributable to low-grade cancers being detected when a lower PI-RADS cutoff score is used in patients with a lower PSA level. An important observation in this study was that only two cases of insignificant PCa were missed when a PI-RADS cutoff score of 3 was used, whereas six cases of PCa, including three cases of significant PCa (all detected via CFB), were missed when a cutoff score of 4 was used. Therefore, we believe that a PI-RADS cutoff score of 3 should be used to initiate the biopsy to prevent underdiagnosis of significant PCa.

The findings of the present study demonstrate that CFB performed better than a systematic biopsy in the detection of PCa. Even though CFB detected fewer cases of PCa, it detected significantly more cases of significant PCa than the systematic biopsy. Core-based analysis revealed that significantly more cases of PCa were detected among the fewer CFB cores obtained. However, CFB missed the diagnosis in two cases of significant (Gleason 6) PCa. Therefore, CFB cannot reliably replace systematic biopsy and should be used in conjunction with systematic biopsy to improve the detection of PCa. In both cases of undergrading, systematic biopsy detected high-grade cancer at the right mid and base area when the suspicious MRI lesion was at the right apex. There are a few possible

explanations for this observation. First, a suspicious lesion may include both significant and insignificant PCa, and targeted biopsies missed the significant PCa. Second, given that high-grade cancers were detected in proximity to the suspicious lesions, there may have been some overlap in the biopsies, and the samples obtained may have contained tissues from the suspicious lesions. Finally, mpMRI is difficult to interpret, even by an experienced radiologist. With increased experience using the new version of PI-RADS and constant feedback of biopsy results to radiologists, the accuracy of reporting should improve.

It is interesting to note that our overall cancer detection rate is lower than in similar studies (45.7%–76%),^[8,18-20] with the exception of the study by Park *et al.* in Korea, which found an overall rate of 29.5%.^[21] We attribute this lower detection rate to the low prevalence of PCa in our region. The reported prevalence of PCa varies by more than 25-fold among different parts of the world and remains low in the Asian populations, with estimated rates of 10.5 and 4.5/100,000 in Eastern and South-Central Asia, respectively.^[22] According to the Malaysia National Cancer Registry Report 2007–2011, PCa accounted for 6.7% of all cancers in the Malaysian men.^[23] This raises the issue of the cost-effectiveness of performing MRI-guided biopsy in a region with a low prevalence of PCa. A regional economic analysis is needed to answer this question.

There are several limitations to this study. First, the study cohort was small in comparison with the other relevant studies. Second, all MRI and histopathology results were analyzed by a single radiologist and histopathologist, which may affect the accuracy of the findings. Third, the study used the histopathological results of systematic biopsy and CFB for the analysis. In the absence of prostatectomy specimens, the number of false-negative results is unknown and the diagnostic accuracy of mpMRI might be overestimated. Finally, a lack of standardization of the CFB protocol resulted in many lower PI-RADS lesions not being biopsied, which may also have affected the accuracy of our analysis.

In conclusion, in this prospective study, mpMRI of the prostate was highly sensitive for detecting suspicious lesions for targeted biopsy and had a good ability to predict PCa. Furthermore, fewer CFB cores detected more cases of PCa than was the case with systematic biopsy cores. Larger cohort studies that include a regional-based economic analysis will help to define the role of prebiopsy mpMRI and CFB in our region. Financial support and sponsorship

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Conflicts of interest

There are no conflicts of interest.

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