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Original Article

Does magnetic resonance imaging–guided biopsy improve prostate cancer detection? A comparison of systematic, cognitive fusion and ultrasound fusion prostate biopsy

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ABSTRACT

Background: The increase in the use of multiparametric magnetic resonance imaging for the detection of prostate cancer has led to the rapid adoption of MRI-guided biopsies (MRGBs). To date, there is limited evidence in the use of MRGB and no direct comparisons between the different types of MRGB. We aimed to assess whether multiparametric MRGBs with MRI-US transperineal fusion biopsy (FB) and cognitive biopsy (CB) improved the management of prostate cancer and to assess if there is any difference in prostate cancer detection with FB compared with CB.

Methods: Patients who underwent an MRGB and a systematic biopsy (SB) from June 2014 to August 2016 on the Central Coast, NSW, Australia, were included in the study. The results of SB were compared with MRGB. The primary outcome was prostate cancer detection and if MRGB changed patient management.

Results: A total of 121 cases were included with a mean age of 65.5 years and prostate-specific antigen 7.4 ng/mL. Seventy-five cases (62%) had a Prostate Imaging and Reporting Data System 4–5 lesions and 46 (38%) had a Prostate Imaging and Reporting Data System 3 lesions. Fifty-six cases underwent CB and 65 underwent FB.

Of the 93 patients with prostate cancer detected, 19 men (20.5%) had their management changed because of the MRGB results. Eight men (9%) had prostate cancer detected on MRGB only and 12 men (13%) underwent radical prostatectomy or radiotherapy based on the MRGB results alone.

There was a trend to a higher rate of change in management with FB compared with CB (29% vs. 18%).

Conclusions: This is one of the first Australian studies to assess the utility of MRGB and compare FB with CB. MRGB is a useful adjunct to SB, changing management in over 20% of our cases, with a trend toward FB having a greater impact on patient management compared with CB.

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1. Introduction

The current standard diagnostic procedure for men suspected of having prostate cancer is a transrectal ultrasound (TRUS)–guided biopsy or more recently transperineal template grid biopsy, both which involves a systematic, nontargeted sampling of the entire prostate gland. Systematic biopsy (SB) has a detection rate between 27% and 44%,^{1–3} with only marginal improvement in prostate

cancer detection with saturation biopsy techniques.⁴ The emergence of multiparametric magnetic resonance imaging (mpMRI) has now allowed for the identification of suspicious regions in the prostate for cancer before biopsy and may improve the detection of significant prostate cancer with directed biopsies.⁵

MRI-guided biopsy (MRGB) is an emerging technique with the promise of improving cancer detection rates, increasing accuracy of pathological grading, and potentially decreasing the number of biopsy cores taken. Two systematic reviews have suggested that MRGB has the ability to detect significant prostate cancer in similar or higher rates than standard biopsy; however, the lack of properly

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designed multicenter trials limits the recommendation for the widespread use of MRGB.^{6,7}

There are three different types of MRGB, and the optimal technique remains to be determined. The first is cognitive-targeted biopsy, where the operator reviews the MRI images and then manually correlates them with the real-time TRUS images to biopsy the suspicious area. The advantage of this technique is that it does not require any additional, specialized equipment to perform; however, there can be a significant potential for error with sampling the correct region.⁸ Studies have shown that cognitive biopsy (CB) has a similar prostate cancer detection rate to SB, but with a higher proportion of positive cores.⁹ The second technique is real-time, in gantry MRGB which has a major disadvantage of being the most complex, requiring prolonged access to expensive MRI machines and being unable to be incorporated into current routine prostate biopsy practices. The third technique is MRI fusion biopsy (FB), where software fuses the MRI images with real-time TRUS images to guide the operator to biopsy the suspicious regions.

Previous MRGB studies have suggested that targeted biopsy combined with SB is superior to SB alone in detecting significant prostate cancer.^{9–13} Recent studies directly comparing MRGB with SB have also suggested that FB is associated with increased detection of high-risk prostate cancer, whereas decreasing the detection of low-risk prostate cancer.^{14–16} One randomized, controlled trial did not find any difference in the cancer detection rate between FB and SB, but did note that FB improved the detection of anterior tumors.¹⁷ A recent meta-analysis of 42 studies found that MRGB improved the detection of clinically significant prostate cancer, but did not improve the overall prostate cancer detection rate.¹⁸ Very few studies have directly compared the prostate cancer detection rates between the different modalities of MRGB. The meta-analysis by Wegelin et al¹⁸ showed in a pooled analysis that there was no difference between FB and CB, but noted the lack of direct head to head studies. Two studies have found no difference in the cancer detection rate between CB and MRI-fusion transrectal-targeted biopsy.^{11,19} A recent study comparing in-gantry MRGB with CB found that there was no difference in the detection of significant prostate cancer, although the in-gantry MRGBs did have a higher percentage of positive-targeted cores than CB.²⁰ To date there have been no studies directly comparing FB performed with a transperineal approach with CB.

The aim of this study is to assess if MRGB improves significant prostate cancer detection and if it provides additional information over SB. The secondary aim of this study was to identify if there were any differences in the rates of significant prostate cancer detection and changes in patient management between FB and CB.

2. Subjects and methods

Patients who underwent simultaneous MRGB and an SB from June 2014 to August 2016 on the Central Coast, NSW, Australia, were included in this study. Institutional review board's approval for this project was authorized (project 0715-056C) by the NSW Health Central Coast Local Health District Research Committee.

2.1. Imaging

All patients underwent mpMRI at a single radiology service, on 1.5T MRI (General Electric Optima MR360, Boston, USA), with an eight-channel body array coil (General Electric Signa HD), with 10 sequences (T1- and T2-weighted whole pelvis, T2-weighted triplanar HR SFOV, diffusion-weighted imaging at b10, b400, b800, and b1400, and dynamic contrast-enhanced imaging) obtained in accordance with the standardized protocols set out by the Prostate Imaging and Reporting Data System (PI-RADS). The mpMRI

technical specifications were slightly changed in August 2015 in accordance with PI-RADS version 2.0, which stipulated the acquisition of diffusion-weighted images with b1400 values (before August 2015, the b values used for diffusion-weighted imaging were b400 and b800). All mpMRI imaging was interpreted by at least two experienced MRI radiologists.

2.2. Biopsy

All patients with PI-RADS ≥ 3 lesions underwent targeted MRGB in conjunction with SB by four urologists each with a prior experience of at least 600 TRUS-guided prostate needle biopsies. MRGB was either CB or FB, according to patient and operator preference. CB was performed via TRUS-guided biopsy. To perform CB, the operator reviewed the mpMRI images and correlated the suspicious areas with those viewed on the real-time TRUS images to perform a TRUS-guided biopsy of the suspicious region.

FB was performed using the BioJet Fusion Software System (DK Technologies, Herlev, Denmark) combined with a transperineal grid TRUS platform (BK Medical, Herlev, Denmark). A radiologist experienced in prostate mpMRI was in attendance with PI-RADS ≥ 3 lesions marked on MRI and fused to the real-time TRUS images for targeted biopsy (Fig. 1). No in-gantry (real-time) MRGBs were performed. The number of targeted biopsies performed was at the discretion of the urologist.

Pathology specimens were processed and reported according to ISUP protocols by pathologists from external pathology providers. The pathologists had access to the biopsy results when analyzing the radical prostatectomy specimens.

2.3. Outcome and data analysis

All data were collected in a prospectively maintained database. The results of SB and MRGB were compared with each other and with the available radical prostatectomy specimens. Outcomes measured were significant prostate cancer detection and if MRGB results changed patient management. Significant prostate cancer was defined as Gleason score $\geq 3 + 4 = 7$. Change in patient management was defined as:

1. No cancer to cancer diagnosis (active surveillance or definitive treatment)
2. Cancers suitable for active surveillance (Gleason 3 + 3 = 6 or low volume Gleason 3 + 4 = 7) to significant prostate cancer (definitive treatment recommended)
3. Upgrade from Gleason 3 + 4 = 7 or 4 + 3 = 7 to Gleason $\geq 4 + 4 = 8$ (high-risk disease) changing operative technique to include pelvic lymphadenectomy and non-nerve spare on the side of high-risk disease.

Gleason score at radical prostatectomy was compared with both SB and MRGB.

Data were analyzed with Predictive Analytics Software Statistics version 23.0 (IBM, Chicago, IL, USA).

Normality tests were performed on all continuous variables. Comparisons between groups for normally distributed variables were performed with independent samples *t* test. Nonparametric Kruskal–Wallis tests were performed for values which were not normally distributed. Fisher exact tests were performed on discrete variables.

3. Results

A total of 121 men were included during the study period for analysis. Fifty-seven men underwent CB, whereas 65 men underwent FB. Patients undergoing FB had significantly more biopsy cores

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