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Original Article

Enhanced detection of clinically significant prostate cancer in targeted and non-targeted regions using BiopSee® MRI/ultrasound fusion biopsy

Ken Nakahara, Daisuke Obinata, Sho Hashimoto, Kazuki Ohashi, Yuki Inagaki, Tsuyoshi Yoshizawa, Junichi Mochida, Kenya Yamaguchi, Satoru Takahashi

Department of Urology, Nihon University School of Medicine, Tokyo, Japan

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Abstract: Objectives: This study evaluated the cancer detection profile of magnetic resonance imaging/transrectal ultrasound fusion-guided biopsies (fusion biopsy) using the BiopSee® system in patients assessed with the Prostate Imaging Reporting and Data System (PI-RADS) version 2.1, focusing on clinically significant prostate cancer (csPCa) detection in regions of interest (ROI) and non-ROI areas. Methods: We retrospectively analyzed 59 patients who underwent fusion biopsy between February and November 2024. Detection rates of csPCa (grade group ≥ 2) were compared between the ROI and non-ROI regions, and clinical and biopsy characteristics were compared between patients with and without csPCa. Univariate logistic regression analysis was performed to identify predictors of csPCa. Results: The median patient age was 74 years, with a median prostate-specific antigen (PSA) level of 8.93 ng/mL. The csPCa detection rate was significantly higher in the ROI than in the non-ROI regions (61% vs. 44%, P = 0.012). Across the cohort, PI-RADS 4 and 5 lesions were more common than PI-RADS 3 lesions. A higher PI-RADS score (4 or 5) was identified as a significant predictor of csPCa detection (odds ratio 5.14, P = 0.034), whereas age, PSA, number of ROIs, and biopsy core numbers were not significant predictors. Conclusions: Fusion biopsy using the BiopSee® system achieved a high csPCa detection rate in targeted ROIs, especially for PI-RADS 4 and 5 lesions, while also highlighting the importance of combining systematic biopsy with targeted approaches because of the substantial proportion of csPCa detected in non-ROI regions.

Keywords: Transrectal ultrasound-guided biopsy, magnetic resonance imaging/transrectal ultrasound fusion biopsy, prostate cancer, prostate imaging reporting and data system

Introduction

The incidence of prostate cancer, one of the most common cancers in men, is increasing worldwide [1]. The widespread use of prostate-specific antigen (PSA) screening has enabled the early diagnosis of prostate cancer, and prostate biopsy is the standard diagnostic method in the case of elevated PSA levels. However, conventional systematic biopsy presents several challenges. Systematic biopsy relies on random sampling, and the detection rate of clinically significant prostate cancer (csPCa) is often low, with missed cancer reported in 50-80% of cases [2-4]. Additionally, PSA screening and prostate biopsy have been associated with the overdetection and overtreatment of indolent cancer [5].

To address these issues, multiparametric magnetic resonance imaging (mpMRI) has become increasingly important in prostate cancer diagnosis in recent years. The European Society of Urogenital Radiology has developed the Prostate Imaging Reporting and Data System (PI-RADS) to improve the diagnostic accuracy of MRI, with version 2.0 (PI-RADS v2.0) followed by the recently reported update to version 2.1 (PI-RADS v2.1) [6]. PI-RADS v2.1 is specifically designed to revise the evaluation methodology for transition zone lesions and improve the consistency of interpretation [7]. The use of mpMRI can better determine the indication for biopsy in patients with abnormal PSA levels and can help in targeted biopsy by identifying regions of interest (ROIs) that are more likely to harbor csPCa.

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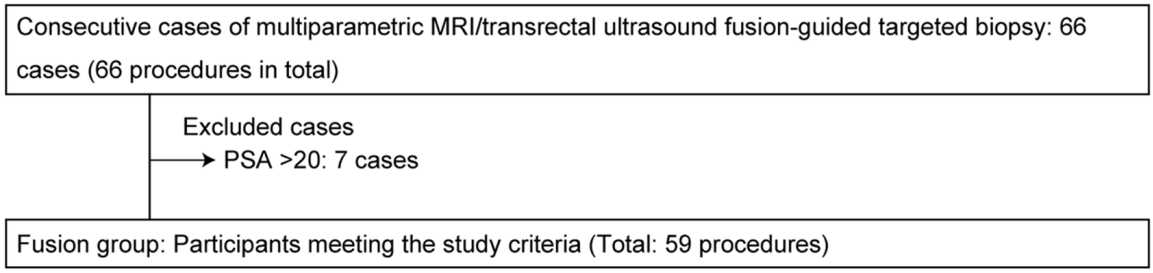

Figure 1. Flowchart of the study participants. A total of 66 patients (66 procedures) underwent targeted multiparametric MRI/TRUS fusion biopsy, with 59 patients (59 procedures) meeting the criteria for inclusion in the fusion group.

Currently, there are two methods of targeted biopsy using MRI: cognitive biopsy and software-assisted MRI/transrectal ultrasound (TRUS) fusion-guided biopsy (fusion biopsy) [8]. Among these, fusion biopsy is considered more accurate and reproducible, particularly when integrated with dedicated platforms [9, 10]. However, despite growing adoption, questions remain regarding the detection patterns in targeted (ROI) and non-targeted (non-ROI) areas, especially in light of the updated PI-RADS v2.1 scoring system. Moreover, the diagnostic performance of specific fusion biopsy platforms, such as BiopSee®, a transperineal system with real-time 3D tracking, has not been extensively studied in this context [11].

In this study, we analyzed the cancer detection profile of software-assisted fusion biopsy using the BiopSee® system in patients evaluated with PI-RADS v2.1. We focused on the detection rates of csPCa within the ROI and non-ROI regions and evaluated the predictive utility of csPCa.

Materials and methods

Study design and ethical approval

This retrospective observational study was conducted in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology guidelines [12]. The Ethical Review Board and Research Ethics Committee of the Nihon University School of Medicine approved the study (approval number: 190611-3). Informed consent was obtained through an opt-out method, and patients' data were anonymized.

Biopsy indication and patient selection

In our clinical practice, when mpMRI reveals suspicious lesions with a PI-RADS version 2.1 score of 3 or higher and sufficient size and clarity to allow targeted sampling, the patient is considered eligible for fusion biopsy. Accordingly, between February and November 2024, 66 patients with abnormal prostate MRI findings underwent their first prostate biopsy using fusion biopsy via the BiopSee® system at our institution. Abnormal MRI findings were defined as lesions with a PI-RADS v2.1 score ≥ 3. The inclusion criteria for this study were patients with abnormal MRI findings who underwent their first fusion biopsy using the BiopSee® system within the specified period. The exclusion criterion was a PSA level of > 20 ng/mL. Accordingly, seven patients were excluded, and 59 patients (59 procedures) were included in the study as the fusion biopsy group (**Figure 1**). CsPCa was defined as a grade group ≥ 2.

Grouping criteria

To enable comparison of cancer detection rates and analysis of predictive factors associated with csPCa, grouping was based on the presence or absence of csPCa, defined as a grade group ≥ 2, as well as on whether biopsy samples were taken from targeted ROI identified by mpMRI or from non-ROI.

Observation indicators and evaluation methods

The primary observation indicator in this study was the detection rate of csPCa. Secondary

Table 1. Patient characteristics (n = 59)

Median (IQR) age at surgery (years)	74 (67-77)
Median (IQR) initial PSA level (ng/mL)	8.93 (6.28-11.4)
Median (IQR) biopsy cores	16 (15-16)
Median (IQR) target biopsy cores	4 (4-6)
Grade group at the diagnosis of prostate cancer	
1	1 (1.6)
2	6 (10.1)
3	7 (11.8)
4	11 (18.6)
5	15 (25.4)

PSA: prostate-specific antigen; Fusion: Magnetic resonance imaging/ultrasound image fusion transperineal biopsy; TRUS: Transrectal prostate biopsy; IQR: interquartile range.

Table 2. Comparison between ROI and non-ROI biopsies

	ROI	Non-ROI	*P*-value
Representative grade group (%)			
1	3 (5.0)	8 (13.5)	
2	8 (13.5)	2 (3.3)	
3	7 (11.8)	6 (17.6)	
4	9 (15.2)	6 (17.6)	
5	12 (20.3)	12 (20.3)	
csPCa presence (%, McNemar test)	36 (61)	26 (44)	0.012

ROI: region of interest.

observation indicators included the distribution of PI-RADS scores (3, 4, or 5), patient characteristics (age, PSA level), and the number of biopsy cores. The detection rates of csPCa were evaluated separately in ROI and non-ROI. Clinical and biopsy characteristics were compared between patients with and without csPCa. Statistical analyses were performed using JMP Pro version 17 (SAS Institute Japan Inc., Tokyo, Japan) and GraphPad Prism 10 for macOS (GraphPad Software Inc., La Jolla, CA, USA). Continuous variables were expressed as medians (interquartile ranges [IQRs]) and compared between the two groups using the Mann-Whitney U test. Categorical variables were analyzed using Fisher's exact test. The McNemar test, a non-parametric method for paired nominal data, was used to compare the presence of csPCa between ROI and non-ROI regions within the same patients. Clinically significant predictors of csPCa were evaluated using univariate analysis. Statistical significance was set at $P < 0.05$.

Results

Patient characteristics

The median age of patients was 74 years (IQR: 67-77 years), and the median PSA value at diagnosis was 8.93 ng/mL (IQR: 6.28-11.4 ng/mL) in the fusion biopsy group (**Table 1**). The median number of biopsy cores was 16 (IQR: 15-16) in the fusion group. The median number of targeted biopsy cores was four (IQR: 4-6) (**Table 1**). The distribution of grade group was 66.1% (39/59).

Comparison between ROI and non-ROI

We compared cancer detection in ROI and non-ROI areas within each patient (**Table 2**). A comparison of cancer detection between ROI and non-ROI biopsies showed that the detection rate of csPCa was considerably higher in ROI samples. csPCa was detected in 61% of the ROIs and 44% of the non-ROIs, with a statistically significant difference confirmed by McNemar's test ($P = 0.012$).

Comparison between patients with and without csPCa

A comparison of clinical and biopsy characteristics between patients with and without csPCa is summarized in **Table 3**. There were no statistically significant differences in age at biopsy (median 74 vs. 71 years, $P = 0.12$), initial PSA levels (median 9.2 vs. 7.6 ng/mL, $P = 0.16$), or total number of biopsy cores (median 16 vs. 16, $P = 0.92$) between the csPCa-positive and csPCa-negative groups. However, the distribution of the PI-RADS scores differed significantly between the two groups ($P = 0.042$). Across the entire cohort, PI-RADS 4 or 5 lesions were more frequently observed, whereas PI-RADS 3 lesions were relatively rare. In particular, the csPCa-positive group had a higher proportion of PI-RADS 5 lesions compared to the csPCa-negative group (11 vs. 2 patients).

Predictors of csPCa

Furthermore, univariate logistic regression analysis was performed to identify the factors

Table 3. Comparison of clinical and biopsy characteristics between patients with and without csPCa

	csPCa		*P*-value
	Negative (n = 20)	Positive (n = 39)	
Median (IQR) age at surgery (years)	71 (62-75)	74 (67-77)	0.12
Median (IQR) initial PSA level (ng/mL)	7.6 (5.1-10.2)	9.2 (6.7-11.8)	0.16
Median (interquartile range) biopsy cores	16 (16)	16 (15-16)	
PIRADS	12 (20.3)	12 (20.3)	0.042
3	6	3	
4	12	25	
5	2	11	

csPCa: clinically significant prostate cancer; IQR: interquartile range; PIRADS: Prostate Imaging Reporting and Data System.

Table 4. Univariate logistic regression analysis for identifying factors influencing the detection of csPCa in ROI

Variable	B	SE	Wald	Sig.	Exp (B)
Age	0.061	0.039	2.45	0.11	1.06
Initial PSA level	0.10	0.079	1.79	0.18	1.11
PI-RADS 3 vs. 4 and 5	1.63	0.77	4.48	0.034	5.14
Number of ROIs	-0.44	0.44	1.01	0.31	0.63
Number of Biopsy Cores	-0.29	0.24	1.44	0.19	0.74

csPCa: clinically significant prostate cancer; ROI: region of interest; PI-RADS: Prostate Imaging Reporting and Data System.

influencing the csPCa detection rate in the ROIs (**Table 4**). The results showed that PI-RADS scores of 4 and 5 were associated with a significantly higher prostate cancer detection rate than PI-RADS scores of 3 (odds ratio 5.14, P = 0.034), suggesting that a higher PI-RADS score was a strong predictor of cancer detection. In contrast, age, PSA level, number of ROIs, and number of biopsy cores showed no significant effects.

Discussion

This study evaluated the diagnostic performance of fusion biopsy using PI-RADS version 2.1, focusing on the detection of csPCa in the ROI and non-ROI areas.

In this study, the detection rate of csPCa was significantly higher in ROI than in non-ROI regions (61% vs. 44%, P = 0.012), confirming the utility of targeted fusion biopsy in MRI-identified lesions. Previous studies have also demonstrated that MRI-ultrasound fusion-targeted biopsy considerably improves the detection of csPCa (Gleason Score [GS] ≥ 7) while reducing the detection of low-risk cancers (GS 6) compared to the systematic 12-core biopsy [13]. In a retrospective analysis of 601 men, focusing on those undergoing initial biopsy, fusion biopsy detected a higher proportion of high-grade cancer (30% vs. 25%) and a lower proportion of low-grade cancer (11% vs. 21%) compared to systematic biopsy. These findings highlight the ability of fusion biopsy to improve the detection of clinically significant cancers while minimizing overdiagnosis of low-risk cancers [13]. However, 44% of csPCa cases are still detected in non-ROI areas, underscoring the importance of combining systematic biopsy with targeted approaches. A recent high-volume single-center study of biopsy-naïve men demonstrated that 12.9% of csPCa cases were missed when using fusion biopsy alone but were detected when systematic biopsy was also performed [14]. Notably, these missed cases were often located in regions adjacent to the ROI, underscoring the critical role of systematic biopsy in capturing multifocal and MRI-invisible csPCa that would otherwise go undetected by targeted biopsy alone [14]. These findings highlight the complementary role of systematic biopsy in providing a more comprehensive sampling of the entire prostate gland, thereby enhancing diagnostic accuracy and ensuring appropriate risk stratification and treatment planning.

Similarly, previous studies have reported that fusion biopsy alone may miss 8.8% of Grade Group 3 or higher cancers, whereas the combination of fusion biopsy and systematic biopsy achieves the highest detection rate for these clinically significant cancers [15]. These obser-

vations suggest that diagnostic strategies relying solely on MRI-positive regions carry an inherent risk of missing csPCa and further reinforce the indispensable role of systematic biopsy in non-ROI areas. Supporting this notion, a previous report demonstrated that 25.8% of csPCa cases were detected by trans-synovial template saturation biopsy in patients with no abnormal findings on mpMRI (Likert score 1-2) [16]. These findings reaffirm the importance of systematic biopsy in non-ROI areas, complementing targeted biopsy of MRI-visible regions.

Analysis of MRI PI-RADS scores and prostate cancer detection rates showed that a higher PI-RADS score was associated with a higher detection rate of csPCa and that negative cases were more common in PI-RADS 3. Consistent with this trend, a previous large-scale investigation reported a csPCa detection rate of 17.2% for PI-RADS 3, 44.9% for PI-RADS 4, and 73.4% for PI-RADS 5 lesions [8]. These data underscore the strong correlation between the PI-RADS score and the likelihood of detecting csPCa in targeted biopsies. In contrast, no significant differences were observed in clinical factors such as age, PSA levels, or total biopsy core numbers. These results highlight the usefulness of PI-RADS scoring, particularly PI-RADS 5, in identifying high-risk lesions. Conversely, the inclusion of PI-RADS 3 cases may have contributed to under-detection in some cases due to their lower predictive value. A recent prospective study found no significant difference in csPCa detection rates between targeted biopsy using four vs. nine cores for ROI lesions [17]. This suggests that simply increasing the number of targeted biopsy cores may have limited impact on improving diagnostic accuracy. Furthermore, the missed csPCa cases with four-core targeted biopsy were limited to PI-RADS 3 and 4 lesions [17]. Another report further indicates that for PI-RADS 5 lesions, omitting systematic biopsy carries a low risk of missing csPCa [18]. However, because PI-RADS 4 lesions made up the majority of cases in our study (37/59 cases), it is more accurate to conclude that combining targeted biopsy with systematic biopsy is essential. This combination is particularly important in cases with multifocal disease or PI-RADS 3 lesions, as supported by our findings and those of previous studies [14-16].

Although the current MRI/US fusion biopsy platforms are approved by the Food and Drug Administration, each system has inherent strengths and weaknesses. Furthermore, two main approaches exist for performing the biopsy: the transperineal and transrectal routes. Recent randomized trials have demonstrated that the transperineal approach can maintain diagnostic accuracy while markedly reducing the risk of infection [19]. Fusion platforms also differ in how they register images - rigid versus elastic registration. Rigid systems are known for their ease of use and shorter procedure times, as highlighted in a recent study [20]. However, in that study, the BiopSee® system, which is also a rigid platform, was not included [20]. Moreover, few objective comparisons between systems have been made [2]. Ito et al. reported that fusion biopsy with the BioJet® system showed a higher csPCa detection rate than cognitive biopsy [21]. Herein, fusion biopsy using the BiopSee® system improved the cancer detection rate in the ROI; however, no direct comparison with the BioJet® was made. Diagnostic accuracy may differ depending on the characteristics of the ROI and the biopsy strategy.

Nevertheless, this study has some limitations. First, its retrospective design and relatively small sample size warrant further validation through prospective studies with larger cohorts. Second, this study was conducted at a single institution, which may limit the generalizability of the findings. Future multicenter prospective studies are needed to validate the impact of PI-RADS-based targeting and effectiveness of fusion biopsy across different platforms.

In conclusion, our results indicate that fusion biopsy has a remarkably higher csPCa detection rate in targeted biopsies of the ROI, particularly in PI-RADS 4 and 5 cases. In contrast, PI-RADS 3 lesions had a low cancer detection rate, indicating that optimization of biopsy indications based on the PI-RADS score is essential for improving diagnostic accuracy.

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Disclosure of conflict of interest

None.

Address correspondence to: Dr. Daisuke Obinata, Department of Urology, Nihon University School of Medicine, 30-1, Oyaguchikamicho, Itabashi-ku, Tokyo 173-8610, Japan. Tel: +81-3-3972-8111; Fax: +81-3-3972-5970; E-mail: obinata.daisuke@nihon-u.ac.jp

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