



Superior detection of significant prostate cancer by transperineal prostate biopsy using MRI-transrectal ultrasound fusion image guidance over cognitive registration

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Abstract

Background The BioJet system allows the fusion of magnetic resonance imaging (MRI) images with real-time transrectal ultrasonography to accurately direct biopsy needles to the target lesions. To date, the superiority of targeted biopsy using the BioJet system over cognitive registration remains unknown.

Methods This retrospective study included 171 biopsy-naïve men with elevated prostate-specific antigen (2.5–20 ng/mL) and MRI-positive lesions; 74 and 97 men underwent a four-core targeted biopsy per MRI-positive target lesion and a 14-core systematic biopsy transperineally using the BioJet system and cognitive registration, respectively. Detection rates of significant cancer, defined as grade group ≥ 2 or maximum cancer length ≥ 5 mm, were compared between the BioJet system and cognitive registration using propensity score matching and a multivariate logistic regression model.

Results After propensity score matching (67 men for each group), the detection rates of significant cancer were significantly higher in the BioJet group than in the cognitive group for both targeted (76% vs. 46%, $P = 0.002$) and systematic (70% vs. 46%, $P = 0.018$) biopsy. Multivariate analysis of the entire cohort also showed that the BioJet system was independently associated with significant cancer detection by targeted and systematic biopsy ($P < 0.01$), along with a higher prostate-specific antigen density and a higher prostate imaging reporting and data system score.

Conclusions Transperineal prostate biopsy using the BioJet system is superior to cognitive registration in detecting significant cancer for targeted and systematic biopsies.

Keywords Prostate cancer · MRI-TRUS fusion biopsy · BioJet · Targeted biopsy · Systematic biopsy

Introduction

Previous studies, including a randomized control study, have revealed the efficacy of magnetic resonance imaging (MRI)-guided targeted biopsy (TgB) over systematic biopsy without MRI [1–3]. Recently, MRI-transrectal ultrasound (TRUS)

fusion TgB has shown superiority over cognitive visual registration transrectal TgB [4, 5] whereas others have shown comparable outcomes in terms of significant cancer (SC) detection [6, 7].

A recent systematic review showed the superiority of the transperineal approach over the transrectal approach in terms of SC detection and infectious complications in fusion TgB [8]. We performed MRI-guided cognitive TgB via a transperineal approach and reported its efficacy in detecting SC [9]. To the best of our knowledge, no study has compared the diagnostic performance of transperineal MRI-guided TgB with fusion and cognitive registration. Furthermore, few studies have compared the diagnostic performance of systematic biopsy (SyB) between these two methods. Visualization of MRI-positive target lesions in fusion image-guided biopsy may potentially improve SC detection by SyB.

Since the start of the fiscal year 2022, the Japanese universal health insurance system has covered MRI-TRUS

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image-guided fusion biopsy. The BioJet system (D&K Technologies, Germany) is an equipment that allows the fusion of MRI images with real-time TRUS by using a position-encoded stepper to accurately direct biopsy needles. More accurate targeting can be expected using the BioJet system compared to cognitive registration. The superiority of the BioJet system was reported for SC detection in the transitional zone (TZ) in a per-core-based analysis compared to TgB using real-time virtual sonography [10], which reportedly yields superior cancer detection over cognitive registration [11]. Although a pilot study demonstrated superior SC detection by the BioJet TgB compared with SyB in 250 cases [12], another pilot study directly comparing BioJet TgB with cognitive TgB in 50 men did not show the superiority of BioJet TgB in terms of SC detection [13].

In this single-institutional retrospective study, we compared the diagnostic performance of TgB and SyB using the BioJet system with that of transperineal cognitive TgB and SyB. Propensity score matching (PSM) for potential confounders was used to reduce their influence on the associations between biopsy methods and SC detection.

Patients and methods

The Institutional Review Board approved the study protocol (#2464). This retrospective study included 171 biopsy-naïve men with positive MRI findings and elevated prostate-specific antigen levels (PSA, 2.5–20 ng/mL). Between October 2020 and August 2022, 74 men underwent TgB and 14-core SyB using the BioJet system. Between April 2019 and October 2020, 97 men underwent transperineal cognitive TgB and 14-core SyB procedures. The biopsy using the BioJet system was performed as an advanced medical technology approved by the Japanese Ministry of Health, Labor, and Welfare before April 2022. All biopsy procedures were performed transperineally.

The pre-biopsy MRI findings were prospectively evaluated using the Prostate Imaging-Reporting and Data System (PI-RADS, version 2) at a radiology-urology conference attended by a urologist (S.I.) and three urologists (F.K., M.I., and S.K.) with ≥ 10 years of experience. PI-RADS scores ≥ 3 were defined as positive. Sagittal location of target lesions was assigned to apex or base according to their location relative to the prostate sagittal middle line.

Biopsy using the BioJet system is typically performed under saddle block anesthesia by injecting 1 mL of high specific gravity marcaine through the L3/4 or L4/5 intervertebral foramen. Three-dimensional images of the prostate and MRI-positive target lesions were generated from MRI images using the BioJet system and fused with the real-time image of TRUS (Fig. 1a, b). For TgB, four cores per target lesion were biopsied under the guidance of real-time fusion images using

a guide-grid template. Similarly, for SyB, 14 cores were biopsied from predefined sites, as previously described (Fig. 1c) [14] using fusion images. SyB using the BioJet system was performed under the guidance of fusion images. When the target lesion overlapped a predefined SyB site, a SyB core was taken without avoiding the target lesion. An experienced urologist (M.I.) conducted the biopsy using the BioJet system.

Cognitive biopsy was performed freehand, typically under local anesthesia by experienced urologists (M.I., S.K., and M.T.) or trainees under the supervision of an expert, as previously described [14]. The sites and number of SyB and TgB core samples per target lesion were identical to those of the BioJet biopsy.

SC was defined as grade group (GG) ≥ 2 or maximum cancer length (MCL) ≥ 5 mm [9]. We compared biopsy outcomes between BioJet and cognitive registration for both TgB and SyB, including SC detection, number of SC cores, and MCL. In addition, outcomes of SyB were compared in lobes ipsilateral to and contralateral to the target lesions, and MRI-negative regions between BioJet and cognitive registration. MRI-negative regions were defined as predefined SyB sites where the target lesions did not overlap axially. PSM at a 1:1 ratio was carried out with a caliper of 0.25 to adjust for possible baseline confounders, including age, PSA density, family history of prostate cancer, findings of the digital rectal examination, PI-RADS score according to zonal location, diameter of MRI-positive target lesions, and zonal and sagittal location of target lesions. PI-RADS score was distinguished by peripheral zone (PZ) and transitional zone (TZ) in PSM considering the possible difference of SC detection rate by the zonal location [10, 15].

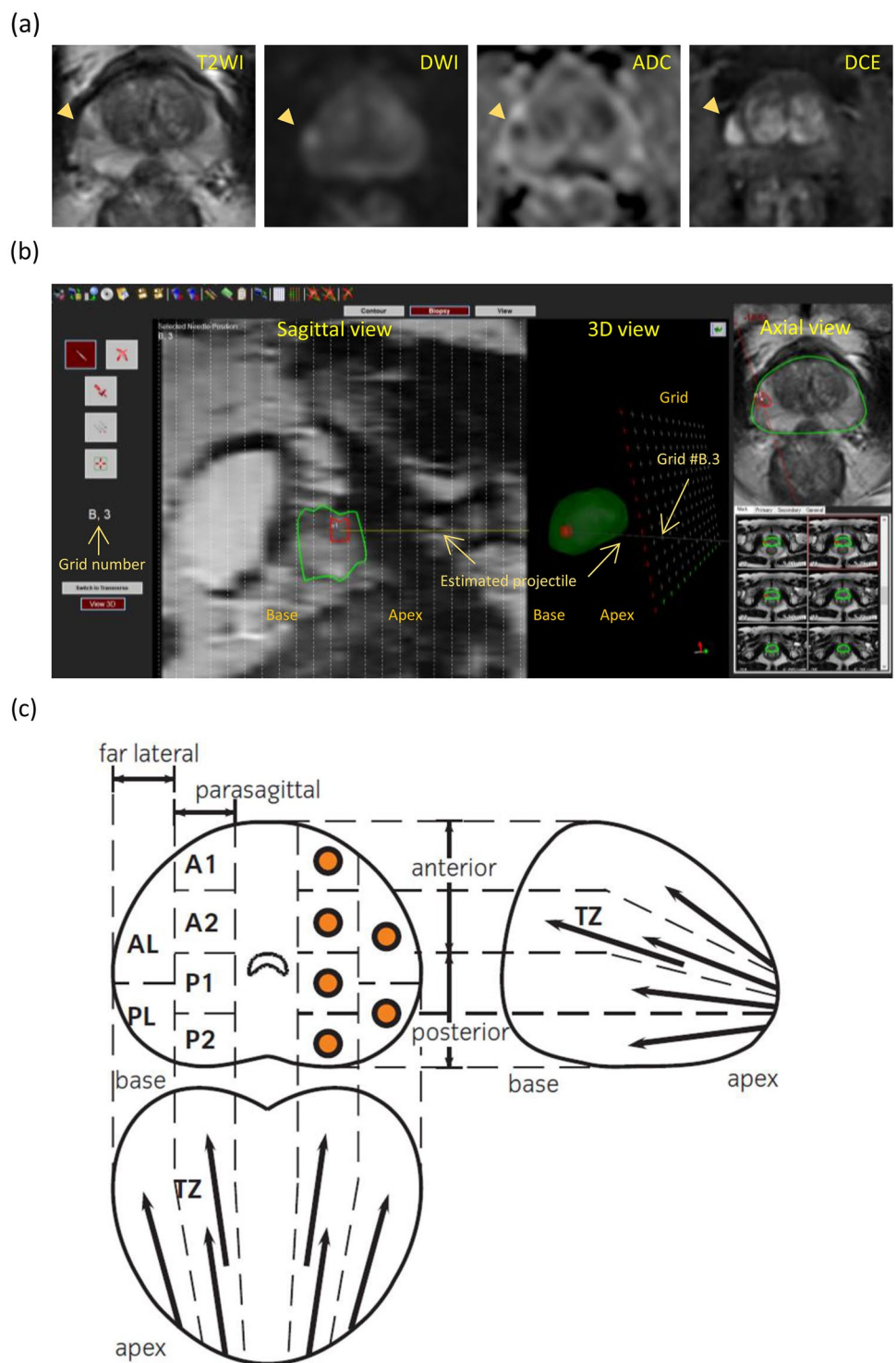
Diagnostic performance in terms of SC detection was compared between BioJet and cognitive biopsy in subgroups stratified by PSA level (< 10 ng/mL and ≥ 10 ng/mL), prostate volume (PV) (< 30 mL and ≥ 30 mL), PI-RADS scores, PSA density (< 0.2 ng/mL² and ≥ 0.2 ng/mL²), zonal (PZ and TZ), and sagittal location (apex and base) of target lesions.

Statistical analyses were performed with EZR software (version 1.54) [16] and R (version 4.2.1). Differences in continuous variables were evaluated using the Wilcoxon rank-sum test. Differences in categorical variables were evaluated using Fisher's exact test in the entire cohort and the Mantel-Haenszel test in the PSM cohort. Logistic regression analysis was used to evaluate variables associated with SC detection. A reduced multivariate model was developed using the stepwise backward method. A two-tailed *P* value < 0.05 was considered statistically significant.

Results

Table 1 lists the demographics of 171 men who underwent BioJet ($n = 74$) or cognitive biopsy ($n = 97$) before and after PSM. After PSM, both groups consisted of 67

Fig. 1 Magnetic resonance imaging (MRI)-transrectal ultrasound fusion images used during the BioJet biopsy. **a** A Prostate Imaging-Reporting and Data System score 4 lesion found on pre-biopsy MRI. Arrowheads indicate a target lesion on T2-weighted imaging, diffusion-weighted imaging, apparent diffusion coefficient map, and dynamic contrast enhancement imaging. **b** Three-dimensional images of the prostate (green color) and a target lesion (red color) generated in the BioJet system. Under the guidance of these images, a biopsy needle was inserted through an appropriate grid. **c** Schema of 14-core systematic biopsy sites. A, anterior; P, posterior; AL, anterolateral; PL, posterolateral; TZ, transitional zone



men. There were no significant between-group differences in clinical variables other than anesthesia methods before and after PSM.

Table 2 shows biopsy outcomes in the BioJet and cognitive groups before and after PSM. After PSM, the SC detection rate by TgB was significantly higher in the BioJet group than in the cognitive group (76% vs. 46%,

$P=0.002$). No significant differences were observed in the number of SC cores or MCL between BioJet and cognitive TgB. BioJet SyB also showed a significantly higher SC detection rate than cognitive SyB (70% vs. 46%, $P=0.018$), along with a significantly greater number of SC cores (median 1 vs. 0, $P=0.045$) and longer maximum cancer length (median 6 vs. 2, $P=0.041$) in the whole lobe

Table 1 Demographics of men who underwent BioJet and transperineal cognitive biopsy before and after propensity score matching

Variables	Total cohort, N (%)				Propensity-matched cohort, N (%)			
	Total	BioJet	Cognitive	<i>P</i> value	Total	BioJet	Cognitive	<i>P</i> value
Total	171	74	97		134	67	67	
Age*	70 (65–74)	70 (65–74)	71 (65–74)	0.90	70 (64–74)	68 (64–73)	70 (65–74)	0.59
BMI*	23.6 (21.3–25.7)	23.7 (21.6–25.9)	23.6 (21.3–25.6)	0.61	23.6 (21.6–25.6)	23.5 (21.6–25.9)	23.7 (21.6–25.6)	0.93
PSA* (ng/mL)	7.3 (5.5–10.9)	7.5 (5.6–10.7)	7.2 (5.3–11.4)	0.90	6.9 (5.2–10.7)	7.3 (5.4–10.2)	6.8 (5–10.9)	0.84
Prostate volume (mL)*	29.1 (21.9–38.3)	28.7 (22.0–34.6)	29.5 (21.9–41.6)	0.43	27.9 (21.2–34.5)	28.6 (22–34.5)	26.3 (20.3–34.5)	0.45
PSA density (ng/mL ²)	0.24 (0.18–0.36)	0.28 (0.17–0.40)	0.24 (0.18–0.35)	0.38	0.27 (0.18–0.36)	0.25 (0.17–0.34)	0.28 (0.18–0.4)	0.82
Presence of family history	16 (9)	8 (11)	8 (8)	0.60	13 (10)	7 (10)	6 (9)	1
Comorbidities								
Diabetes	32 (19)	14 (19)	18 (19)	1	24 (18)	11 (16)	13 (19)	0.81
Anticoagulant use	12 (7)	6 (8)	6 (6)	0.77	9 (7)	6 (9)	3 (4)	0.51
Positive DRE				0.70				0.77
Yes	32 (19)	15 (20)	17 (18)		18 (13)	10 (15)	8 (12)	
No	139 (81)	59 (80)	80 (82)		116 (87)	57 (85)	59 (88)	
PI-RADS score				0.70				0.84
3	18 (11)	9 (12)	9 (9)		15 (11)	9 (13)	6 (9)	
4	89 (52)	38 (51)	51 (53)		78 (58)	37 (55)	41 (61)	
5	64 (37)	27 (36)	37 (38)		41 (31)	21 (31)	20 (30)	
3 (PZ)	5 (3)	3 (4)	2 (2)		4 (3)	3 (4)	1 (1)	
4 (PZ)	50 (29)	22 (30)	28 (29)		46 (34)	21 (31)	25 (37)	
5 (PZ)	35 (20)	17 (23)	18 (19)		24 (18)	11 (16)	13 (19)	
3 (TZ)	13 (8)	6 (8)	7 (7)		11 (8)	6 (9)	5 (7)	
4 (TZ)	39 (23)	16 (22)	23 (24)		32 (24)	16 (24)	16 (24)	
5 (TZ)	29 (17)	10 (14)	19 (20)		17 (13)	10 (15)	7 (10)	
Diameter of MRI-positive lesion (mm)*	12.1 (9.4–16)	12.0 (9.4–16)	12.2 (9.4–15.9)	0.51	11.7 (9.3–15.5)	11 (9.3–15.2)	11.9 (9.3–15.5)	0.72
Zonal location				0.36				0.54
Peripheral zone	90 (53)	42 (57)	48 (49)		74 (55)	35 (52)	39 (58)	
Transitional zone	81 (47)	32 (43)	49 (51)		60 (45)	32 (48)	28 (42)	
Sagittal location				0.48				0.48
Apex	129 (75)	58 (78)	71 (73)		106 (79)	51 (76)	55 (82)	
Base	42 (25)	16 (22)	26 (27)		28 (21)	16 (24)	12 (18)	
Anesthesia				<0.001				<0.001
Local	87 (51)	0 (0)	87 (90)		59 (44)	0 (0)	59 (88)	
Spinal	80 (47)	71 (96)	9 (9)		71 (53)	64 (96)	7 (10)	
General	4 (2)	3 (4)	1 (1)		4 (3)	3 (4)	1 (1)	

* Median (interquartile range); BMI, body mass index; PSA, prostate-specific antigen; DRE, digital rectal examination; PI-RADS, Prostate Imaging-Reporting and Data System. PZ, peripheral zone. TZ, transitional zone

after PSM. BioJet SyB showed a significantly higher SC detection rate than cognitive SyB in the lobes ipsilateral to the target lesions (61% vs. 40%, $P=0.021$) but not in the contralateral lobes. To assess the background where

BioJet SyB was superior to cognitive SyB in SC detection, we compared SyB outcomes between the two approaches within and outside TgB lesions (Supplementary Table 1). Despite a smaller number of SyB cores within TgB

Table 2 Biopsy outcomes of men who underwent BioJet and transperineal cognitive biopsy before and after propensity score matching

Variables	Total cohort, N (%)				Propensity-matched cohort, N (%)			
	Total	BioJet	Cognitive	<i>P</i> value	Total	BioJet	Cognitive	<i>P</i> value
Total	171	74	97		134	67	67	
Targeted biopsy								
Any cancer detection	122 (71)	61 (82)	61 (63)	0.006	97 (72)	54 (81)	43 (64)	0.073
SC detection	103 (60)	57 (77)	46 (47)	<0.001	82 (61)	51 (76)	31 (46)	0.002
Number of SC cores*	1 (0–3)	2 (1–3)	0 (0–3)	0.006	1 (0–3)	2 (1–3)	0 (0–2)	0.012
Maximum cancer length*	6.0 (0–10)	8.0 (3.6–10)	4.0 (0–10)	0.011	6 (0–9.3)	8 (3–10)	4 (0–9)	0.012
Systematic biopsy								
Any cancer detection	120 (70)	58 (78)	62 (64)	0.045	96 (72)	52 (78)	44 (66)	0.20
SC detection								
Whole lobe	100 (58)	53 (72)	47 (48)	0.003	78 (58)	47 (70)	31 (46)	0.018
Lobes ipsilateral to target lesions	87 (51)	47 (64)	40 (41)	0.005	68 (51)	41 (61)	27 (40)	0.021
Lobes contralateral to target lesions	35 (20)	13 (18)	22 (23)	0.45	27 (20)	11 (16)	16 (24)	0.39
Number of SC cores*								
Whole lobe	1 (0–2)	1 (0–3)	0 (0–2)	0.018	1 (0–2)	1 (0–3)	0 (0–2)	0.045
Lobes ipsilateral to target lesions	1 (0–2)	1 (0–3)	0 (0–2)	0.015	1 (0–2)	1 (0–3)	0 (0–2)	0.053
Lobes contralateral to target lesions	0 (0–0)	0 (0–0)	0 (0–0)	0.40	0 (0–0)	0 (0–0)	0 (0–1)	0.27
Maximum cancer length*	4.0 (0–9.0)	6.0 (1.2–9.0)	3.0 (0–8.0)	0.023	4 (0–9)	6 (1–9)	2 (0–8)	0.041
Complications								
Infection	0 (0)	0 (0)	0 (0)		0 (0)	0 (0)	0 (0)	
Acute urinary retention	2 (1)	1 (1)	1 (1)	1	2 (1)	1 (1)	1 (1)	1

* Median (interquartile range); SC, significant cancer; GG, grade group

lesions (median: 1 for both groups, $P = 0.022$), BioJet SyB detected SC within TgB lesions more efficiently than cognitive SyB (42% vs. 22%, $P = 0.021$) after PSM. The SC detection rate of SyB in MRI-negative regions (*i.e.*, outside TgB lesions) was not statistically different between the two groups in the whole lobe (58% vs. 42%, $P = 0.082$) and in lobes ipsilateral to (54% vs. 42%, $P = 0.23$) and contralateral to TgB lesions (21% vs. 28%, $P = 0.42$).

In the entire cohort, two men (1%) experienced acute urinary retention (one from each group), and none experienced infectious complications (Table 2).

Subgroup analyses in the PSM cohort showed that BioJet TgB was significantly superior to cognitive TgB in terms of SC detection irrespective of PV, PSA density, zonal and apical location of the target lesions, and in subgroups with a PI-RADS score of 4 and lower PSA level (Fig. 2a). BioJet SyB was also significantly superior to cognitive SyB in subgroups with a PI-RADS score of 4, higher PV, lower PSA level, higher PSA density, TZ and basal locations of the target lesions (Fig. 2b).

Multivariate analysis was conducted in the entire cohort for TgB and SyB to confirm the superiority of BioJet biopsy over cognitive registration in detecting SC. As shown in Table 3, BioJet biopsy was significantly and independently associated with SC detection by both TgB and SyB with respective odds ratios (OR) (95% confidence intervals

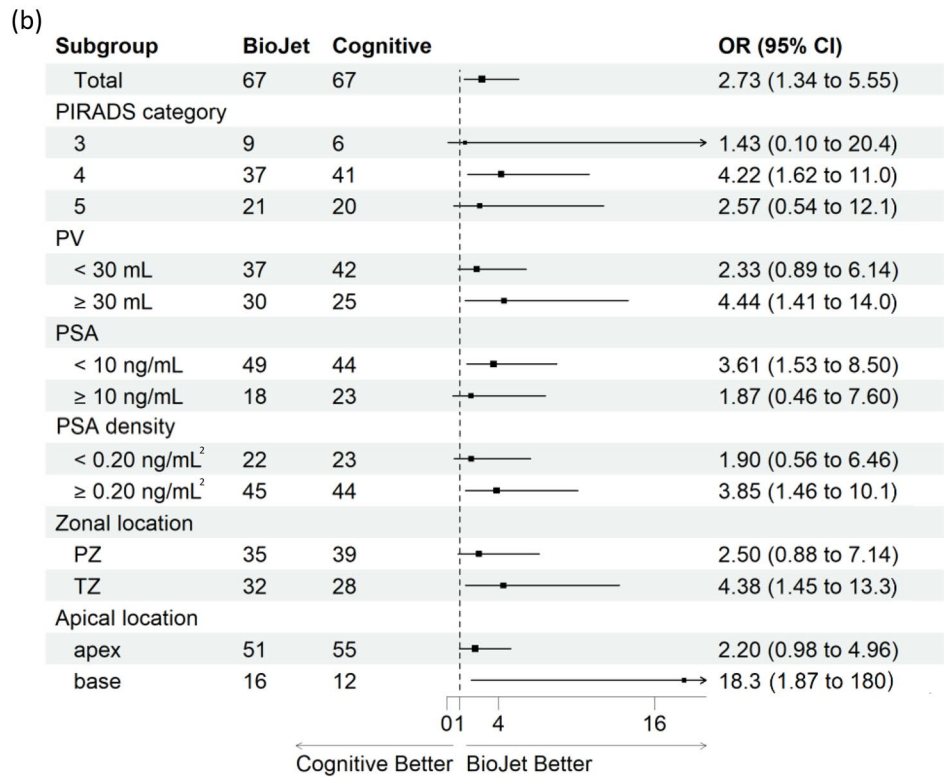
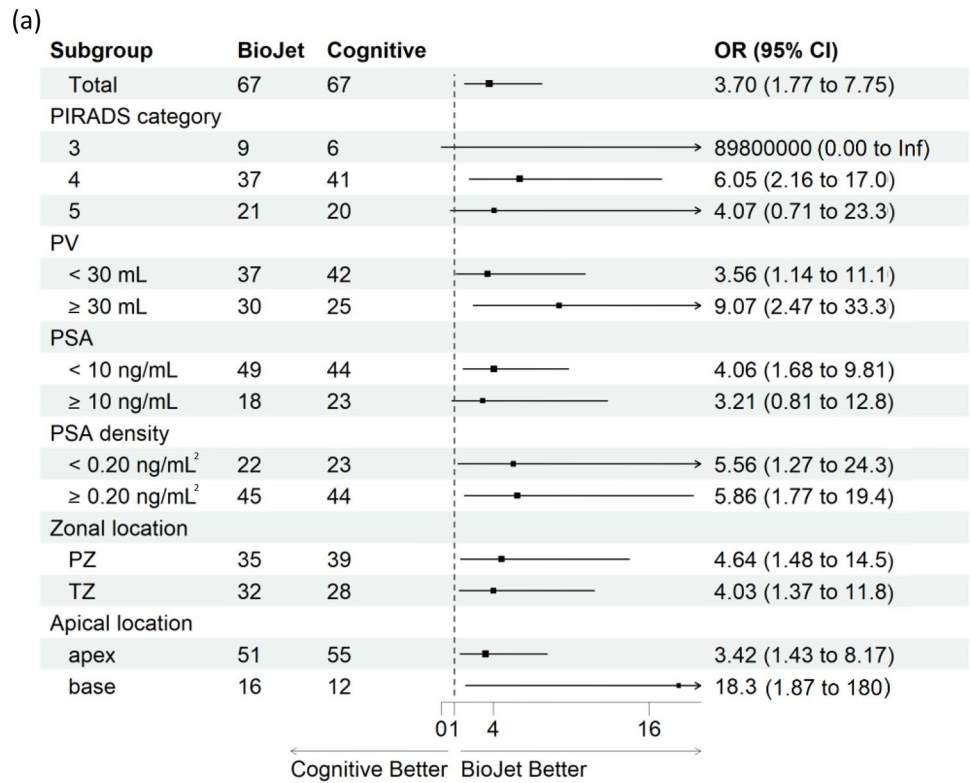
[CI]) of 5.10 [2.21–11.8] ($P < 0.001$) and 3.20 [1.50–6.85] ($P = 0.003$). Higher PSA density and higher PI-RADS scores were also significantly and independently associated with SC detection by both TgB and SyB, whereas the apical location of target lesions was similarly associated with SC detection by SyB (Table 3).

Discussion

In this study, we showed the superiority of MRI-TRUS fusion image-guided biopsy using the BioJet system over transperineal cognitive biopsy for SC detection by TgB and SyB. These findings were obtained from PSM analysis to minimize the influence of potential confounders. Furthermore, our findings were confirmed by performing a multivariate analysis of the entire study cohort. To the best of our knowledge, this is the first study to demonstrate the superiority of transperineal fusion biopsy using the BioJet system over transperineal cognitive biopsy to detect SC.

Regarding TgB, the superior detection of SC by BioJet biopsy over cognitive registration could be attributed to the accurate capture of target lesions under the guidance of MRI-TRUS fusion images. Notably, the superiority of BioJet biopsy was also observed for SyB. In our study, BioJet SyB performed better than cognitive SyB in the detection of SC

Fig. 2 Forest plot of odds ratios and 95% confidence intervals of BioJet biopsy versus cognitive biopsy in detecting significant cancer in subgroups stratified by PSA level (<10 ng/mL and ≥10 ng/mL), PV (<30 mL and ≥30 mL), PI-RADS scores, and zonal and sagittal location of target lesions; **a** targeted biopsy, **b** systematic biopsy. PI-RADS, Prostate Imaging-Reporting and Data System; PV, Prostate volume; PSA, Prostate-specific antigen; PZ, Peripheral zone; TZ, Transitional zone



in the whole lobe and lobes ipsilateral to target lesions but not in the contralateral lobes. In our BioJet SyB practice, a SyB core is taken without avoiding the target lesion when

it overlapped a predefined SyB site. The guidance of fusion images is likely to confer efficient SC detection in SyB sites overlapping TgB lesions.

Table 3 Variables associated with significant cancer detection

Variables	Targeted biopsy				Systematic biopsy			
	Univariable		Multivariable		Univariable		Multivariable	
	OR*	<i>P</i> value	OR	<i>P</i> value	OR	<i>P</i> value	OR	<i>P</i> value
Age	1.02 (0.98–1.06)	0.28			1.03 (0.99–1.08)	0.094		
BMI	0.99 (0.90–1.09)	0.86			1.01 (0.92–1.11)	0.80		
PSA (ng/mL)	1.08 (1.00–1.18)	0.061			1.12 (1.03–1.22)	0.009		
Prostate volume (mL)	0.92 (0.90–0.95)	<0.001			0.97 (0.94–0.99)	0.003		
PSA density (ng/mL ²)	6570 (211–205 × 10 ³)	<0.001	1140 (28.4–459 × 10 ²)	<0.001	453 (28.3–7240)	<0.001	61.6 (3.46–1100)	0.005
Presence of family history, yes vs. no	0.63 (0.23–1.77)	0.38			0.69 (0.24–1.92)	0.47		
Diabetes, yes vs. no	1.58 (0.69–3.58)	0.28			1.23 (0.56–2.71)	0.61		
Anticoagulant use, yes vs. no	0.92 (0.28–3.02)	0.89			0.99 (0.30–3.27)	0.99		
Positive DRE, yes vs. no	2.79 (1.13–6.89)	0.026			1.72 (0.76–3.90)	0.19		
PI-RADS score	3.30 (1.90–5.72)	<0.001	4.33 (1.66–11.3)	0.003	2.96 (1.73–5.06)	<0.001	3.09 (1.31–7.29)	0.010
Diameter of MRI-positive lesion (mm)	1.06 (0.99–1.13)	0.081			1.06 (0.99–1.13)	0.075		
Zonal location, PZ	2.65 (1.41–4.98)	0.002			2.77 (1.48–5.21)	0.001		
Sagittal location, apex vs. base	3.86 (1.86–8.06)	<0.001			3.47 (1.68–7.19)	<0.001		
Anesthesia, spinal vs. local	3.00 (0.40–22.7)	0.29			2.33 (0.31–17.5)	0.41		
Biopsy method, BioJet vs. cognitive	3.72 (1.90–7.28)	<0.001	5.10 (2.21–11.8)	<0.001	2.68 (1.41–5.11)	0.0026	3.20 (1.50–6.85)	0.003

OR, odds ratio; BMI, body mass index; PSA, prostate-specific antigen; DRE, digital rectal examination; PI-RADS, Prostate Imaging-Reporting and Data System; PZ, peripheral zone

Although a recent randomized study showed the superiority of MRI-guided fusion TgB over cognitive TgB via the transrectal approach [5], the superiority of fusion image guidance over cognitive registration remains controversial, particularly when TgB is performed via the transperineal approach. Two comparative studies using the transperineal approach for TgB using the BioJet system have been published. One study comparing BioJet and cognitive TgB showed comparable SC detection rates (68% and 64%, respectively) [13]. In another study, although BioJet TgB showed superior SC detection for target lesions in the TZ on a per-core basis, SC detection rates were comparable between BioJet TgB and TgB using real-time virtual sonography on a per-patient basis (62% vs. 59%, respectively) [10]. Our study, yielding respective SC detection rates of 76% vs. 51%, is the first to demonstrate the superiority of BioJet TgB over cognitive TgB in detecting SC.

In our study, a single experienced urologist (M.I.) performed biopsies using the BioJet system, whereas cognitive biopsies were performed by various urologists, including trainees under the supervision of experienced urologists,

which could have biased biopsy outcomes in favor of the BioJet group. A previous study on BioJet biopsy showed comparable outcomes between experts and residents unless the target lesions were < 8 mm [17]. Our BioJet cohort included only seven men (9%) with index lesions of < 8 mm. We also reported comparable biopsy outcomes between senior urologists and trainees in transperineal cognitive Tg [18]. Therefore, we considered the influence of interoperator variability to be limited in our study.

The present study has some limitations. First, there was a possible bias associated with a retrospective study using a small single-institutional cohort, although the PI-RADS scores were prospectively evaluated and PSM was used to minimize between-group differences in the participants' backgrounds. External validation with a large multicenter cohort is necessary to confirm our findings. Second, saddle block anesthesia was utilized for BioJet biopsies in most cases while local anesthesia was for cognitive biopsies. We cannot deny the possibility that operators have tried to shorten procedure time to reduce pain when performing cognitive biopsies under local anesthesia. However, the local

anesthesia method we utilize can also control pain during biopsy as reported previously [19]. Third, we did not compare biopsy outcomes between the prostatectomy specimens. More studies are warranted to validate biopsy outcomes by referring to the pathology of the prostatectomy specimens.

Conclusion

MRI-TRUS fusion image-guided transperineal biopsy using the BioJet system is superior to transperineal MRI-targeted cognitive biopsy in detecting SC using TgB and SyB.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s10147-023-02404-z>.

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Author contributions Masaya Ito: Conceptualization, data curation, formal analysis, investigation, supervision, and writing—original draft preparation; Ichiro Yonese: Data curation, formal analysis, investigation, visualization, and writing—review & editing; Masahiro Toide: Investigation, writing—review & editing; Shuozo Ikuta: Investigation, writing—review & editing; Shuichiro Kobayashi: Investigation, writing—review & editing; Fumitaka Koga: Conceptualization, investigation, supervision, and writing—review & editing.

Declarations

Conflict of interest The authors declare no conflicts of interest. The study protocol was approved by the Institutional Review Board (approval #2464).

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