Comparison of systematic randomized 12-core transrectal ultrasonography-guided prostate biopsy with magnetic resonance imaging-transrectal ultrasonography fusion-targeted prostate biopsy

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We aimed to compare the complications and pathological outcomes between systematic 12-core transrectal ultrasonography guided prostate biopsy (TRUS-PB) and magnetic resonance imaging-TRUS fusion targeted prostate biopsy (MRI-TRUS FTPB). We examined 10,901 patients who underwent prostate biopsy from May 2003 to December 2017 retrospectively. Among them, 10,325 patients underwent 12-core TRUS-PB and 576 patients underwent MRI-TRUS FTPB. The clinicopathological features and complications in both groups were compared. After propensity score matching, there were no significant differences in the clinical features and complication rates between both groups ($P > .05$). In the multivariate analyses, the prostate volume was shown to be the only significant predictor of overall complications, infectious complications, bleeding related complications, and Clavien-Dindo grade ≥ 2 complications after prostate biopsy ($P < .001$). The present study demonstrates the safety of MRI-TRUS FTPB in terms of complications, compared with that of TRUS-PB. Although the combination of MRI-TRUS FTPB and 12-core TRUS-PB provides enhanced diagnostic power, MRI-TRUS FGB alone could provide a reasonable diagnostic value for prostate cancer if the apparent diffusion coefficient suspicious grade of prostate cancer is ≥ 4. When the Likert suspicious grade of prostate cancer on the apparent diffusion coefficient map of multiparametric MRI was 3, 13.9% (27/194) of the patients were diagnosed with clinically significant prostate cancer (csPCa); 44.4% (12/27) of them were confirmed as csPCa at the MRI-targeted cores. When the apparent diffusion coefficient suspicious grade was ≥ 4, 43.0% (108/251) were diagnosed with csPCa; 76.8% (83/108) of them were confirmed to have csPCa at the MRI-targeted cores.

Abbreviations: ADC = apparent diffusion coefficient, AUR = acute urinary retention, BMI = body mass index, BPH = benign prostatic hyperplasia, csPCa = clinically significant prostate cancer, DM = diabetes mellitus, FTPB = fusion targeted prostate biopsy, HR = harzard ratio, IQR = interquartile range, mpMRI = multiparametric MRI, MRI = magnetic resonance imaging, PCa = Prostate cancer, PSA = prostate-specific antigen, TRUS-PB = transrectal ultrasonography guided prostate biopsy.

Keywords: prostate biopsy, prostate cancer, PROSTATE MRI

1. Introduction

Prostate cancer (PCa) is the most predominantly diagnosed cancer in men and the third most common cause of death among malignancies in men.[1] Although assessment of the serum prostate-specific antigen (PSA) level has been introduced as a screening test since 1980s, prostate biopsy has remained a reliable measuring method for the definite diagnosis of clinically significant PCa (csPCa).

The current standard technique of prostate biopsy involves the use of transrectal ultrasonography-guided prostate biopsy (TRUS-PB). After being first introduced in 1968, systematic randomized 12-core TRUS-PB has become the routine procedure for diagnosing PCa.[2,3] However, the sensitivity and specificity of TRUS-PB for PCa are rather low. Further, 10% to 25% of men with a negative TRUS-PB finding were diagnosed with PCa after repeat biopsy.[4,5]

With the introduction of magnetic resonance imaging (MRI) in the urology field, MRI-guided biopsy has become a potential approach for more improved diagnostic values than traditional 12-core TRUS-PB.[6,7] There are three techniques in MRI-guided biopsy: in-bore MRI-targeted biopsy performed in the MRI suite using real-time MRI guidance; MRI-TRUS fusion-targeted prostate biopsy (MRI-TRUS FTPB), which allows direct target

biopsy of MRI-identified lesions using MRI-TRUS fusion images; and cognitive registration TRUS-targeted biopsy. Among these three techniques, MRI-TRUS FTPB is widely used,[8] including in our institution.

Although several millions of TRUS-PB procedures are performed annually worldwide, several complications related to prostate biopsy have been reported. These complications could range from nontrivial and mild to severe and life threatening. The most common complications after prostate biopsy include infectious complication, bleeding, and urinary retention.[9–11]

A prior report showed that the rate of hospital admission owing to complications within 30 days after prostate biopsy was 6.9%, it is reported to be increasing in recent years, especially because of infectious complications.[12] Therefore, the increasing number of men requiring hospitalization for complication after TRUS-PB has become a great concern.[13]

In the present study, we investigated the various clinicopathological factors, complications, and PCa detection rates after prostate biopsy, to compare TRUS-PB and MRI-TRUS FTPB.

2. Materials and Methods

The electronic medical records of 10,944 patients who underwent a multicore prostate biopsy at our institution from May 2003 to December 2017 were analyzed retrospectively after anonymization. This study was conducted in compliance with the Helsinki Declaration principles and approved by our local ethics committee (IRB No: B-1804/465-001).

Clinical characteristics including age, body mass index (BMI), diabetes mellitus (DM), serum PSA level, prostate volume, number of prior biopsy cases, number of biopsy cores, and complications after prostate biopsy were evaluated. Forty-three patients whose number of biopsy cores was <10 were excluded. Thus, the clinicopathological data of 10,901 patients were finally analyzed. Of all patients, the number of men who underwent routine 12-core TRUS-PB (US group) and MRI-TRUS FTPB (MR group) was 10,367 and 577, respectively. In our institution, MRI-TRUS FTPB has been performed since September 2015.

The decision to perform TRUS-PB or MRI-TRUS FTPB as the initial prostate biopsy was based on the results of consultation with the patients. When a rising PSA level and abnormal PCa screening MRI findings in biopsy naïve men or the prostate volume was large, initial MRI-TRUS FTPB was recommended to minimize sampling error. In case of repeat biopsy, the patients with negative pathological result on prior biopsy, but with consistently elevated serum PSA levels were recommended to undergo PCa screening MRI and MRI-TRUS FTPB.

Each PCa screening MRI was performed as multiparametric MRI (mpMRI), obtaining T1-weighted images, T2-weighted images, diffusion-weighted images, but not dynamic contrast-enhanced images. Because of the lack of dynamic contrast-enhanced images for screening mpMRI in our institution, we used the Likert scale system instead of the Prostate Imaging Reporting and Data System (PI-RADS). For the suspicious lesions on the apparent diffusion coefficient (ADC) map and T2-weighted images, one experienced (over 20 years) radiologist scored the suspicious grade of csPCa from 1 to 5, according to the Likert scale (grade 1, highly unlikely to be present; grade 2, unlikely to be present; grade 3, equivocal; grade 4, likely to be present; and grade 5, highly likely to be present). Thereafter, MRI-TRUS FTPB was performed using the PercuNav system (Philips Healthcare, Toronto, ON, Canada) at more than 12 cores, including systematic randomized 12 cores (right and left apices, right and left mid-prostate, right and left bases, right and left lateral apices, right and left mid-lateral, right and left lateral bases) and MRI-targeted cores additionally.

To prevent infection, the patients underwent a single glycerin enema and prophylactic intravenous antibiotics

(fluoroquinolone or cephalosporin) administration on the day of the biopsy (30–60 minutes before biopsy). Well-experienced radiologist in our institution performed the prostate biopsy, which is a standard multicore biopsy under local anesthesia. After undergoing biopsy, the patients were instructed to visit the emergency center or the urologic outpatient clinic if they develop high fever, severe bleeding, or severe urinary symptoms including acute urinary retention (AUR). Each patient was followed up within 2 weeks.

In this study, we gathered patient demographics including age at prostate biopsy, BMI, DM, serum PSA level, history of prostate biopsy, admission status at biopsy, biopsy technique (TRUS-PB and MRI-TRUS FTPB), total number of cores obtained, pathological results of biopsy, rehospitalization status within 30 days after biopsy, and complications.

We used the modified Clavien-Dindo classification system to grade complication after prostate biopsy.[14–16] We also defined csPCa as cancer with Gleason score 3 + 4 or greater (i.e., ≥50% of any core containing cancer or ≥33% of standard biopsy cores positive for cancer).

Statistical analysis was performed using the SPSS software version 19.0 (SPSS Inc., Chicago, IL) and MedCalc software version 18.5 (MedCalc Software, Ostend, Belgium). We used the paired t test and chi-square analysis to compare the US group with the MR group. We also used propensity score matching to correct the selection bias owing to the differences in the demographic factors between the two groups, including age at biopsy, BMI, comorbidity, serum PSA level, prostate volume, history of biopsy, and number of biopsy cores. A multivariate analysis was also performed using the Cox proportional hazards regression model to identify the independent predictive factors of complication after prostate biopsy. All statistical tests were two-sided, and $P < .05$ indicated a significant result.

3. Results

The overall characteristics of the patients before and after propensity score matching are shown in Table 1. All patients were divided into two groups according to the prostate biopsy techniques: US group and MR group. Before propensity score matching, the mean age of the US and MR group patients was 65.20 ± 9.32 and 64.82 ± 8.90 years, respectively. Their mean BMI was 24.34 ± 2.75 and 24.48 ± 2.61 kg/m², respectively. Their median PSA level was 6.65 (interquartile range: 4.35–10.97) ng/mL and 7.20 (interquartile range: 4.87–11.17) ng/mL, respectively. The number of prostate biopsy cores was higher in the MR group than in the US group (14.13 ± 0.71 vs 12.51 ± 1.02, respectively). There were no significant differences in age, BMI, DM, PSA level, and prostate size between both groups ($P > .05$). After propensity score matching, almost all differences before matching disappeared.

The complication rates of all patients and both groups are presented in Table 2. Before and after propensity score matching, there were no significant differences in the overall complication rates between the US group and MR group ($P = .167$ and $P = .676$, respectively). There was also no significant difference in the Clavien-Dindo scale of the complications between both groups before and after matching ($P = .656$ and $P = .658$, respectively).

The multivariate logistic regression analysis findings of the complications after prostate biopsy are shown in Table 3, showing that prostate volume was a significant predictor of the overall complications (hazard ratio [HR]: 1.011, $P < .001$), infectious complications (HR: 1.010, $P = .037$), bleeding-related complications (HR: 1.011, $P < .001$), and Clavien-Dindo grade ≥ 2 complications (HR: 1.011, $P = .005$).

In Tables 4 and 5, we analyzed the detection rates of overall PCa and csPCa according to the suspicious grade of csPCa on the ADC map of mpMRI. When the ADC suspicious grade was

Table 1

Comparison of the clinicopathological features among the patients who underwent TRUS-PB (US group) and MRI-TRUS FTPB (MR group) before and after propensity score matching.

	Before propensity score matching				After propensity score matching			
	Entire patients (n = 10,901)	TRUS-PB (n = 10,325)	MRI-TRUS FTPB (n = 576)	P value	Entire patients (n = 1122)	TRUS-PB (n = 561)	MRI-TRUS FTPB (n = 561)	P value
Mean age (yr)	65.18 ± 9.30	65.20 ± 9.32	64.82 ± 8.90	.342	64.60 ± 9.34	64.33 ± 9.71	64.87 ± 8.95	.333
Mean BMI (kg/m^2)	24.34 ± 2.75	24.34 ± 2.75	24.48 ± 2.61	.300	24.39 ± 2.69	24.30 ± 2.74	24.50 ± 2.61	.265
Diabetes mellitus	1586 (14.5%)	1516 (14.7%)	70 (12.2%)	.094	137 (12.2%)	69 (12.3%)	68 (12.1%)	.927
Median PSA level (ng/mL)	6.69 (IQR: 4.38–10.99)	6.65 (IQR: 4.35–10.97)	7.20 (IQR: 4.87–11.17)	.735	7.34 (IQR: 4.90–11.35)	7.49 (IQR: 5.00–11.38)	7.18 (IQR: 4.84–11.17)	.928
Prostate volume (mL)	44.67 ± 21.75	44.75 ± 21.83	43.19 ± 20.14	.110	43.80 ± 21.55	44.30 ± 22.74	43.29 ± 20.26	.446
Prior biopsy				<.001				.858
(−)	9333 (85.6%)	9058 (87.7%)	275 (47.7%)		551 (49.1%)	277 (49.4%)	274 (48.8%)	
(+)	1568 (14.4%)	1267 (12.3%)	301 (52.3%)		571 (50.9%)	284 (50.6%)	287 (51.2%)	
Number of biopsy cores	12.59 ± 1.07	12.51 ± 1.02	14.13 ± 0.71	<.001	14.18 ± 1.27	14.23 ± 1.65	14.12 ± 0.69	.180
Pathology				<.001				<.001
Prostate cancer	3902 (35.8%)	3689 (35.7%)	213 (37.0%)		409 (36.5%)	202 (36.0%)	207 (36.9%)	
BPH/prostatitis	6933 (63.6%)	6579 (63.7%)	354 (61.4%)		671 (62.4%)	356 (63.5%)	345 (61.5%)	
Other	66 (0.6%)	57 (0.6%)	9 (1.6%)		12 (1.1%)	3 (0.5%)	9 (1.6%)	

BMI = body mass index, BPH = benign prostatic hyperplasia, IQR = interquartile range, MRI-TRUS FTPB = magnetic resonance imaging-transrectal ultrasonography fusion-targeted prostate biopsy, PSA = prostate-specific antigen, TRUS-PB = transrectal ultrasonography-guided prostate biopsy, US = ultrasonography.

Table 2

Comparison of the incidence of complications in the US group and MR group before and after propensity matching.

	Before propensity matching				After propensity matching			
	Entire patients (n = 10,901)	TRUS-PB (n = 10,325)	MRI-TRUS FTPB (n = 576)	P value	Entire patients (n = 1122)	TRUS-PB (n = 561)	MRI-TRUS FTPB (n = 561)	P value
Complication (+)	218 (2.00%)	211 (1.94%)	7 (0.06%)	.167	16 (1.43%)	9 (0.80%)	7 (0.62%)	.676
Sepsis	7 (0.06%)	7 (0.06%)	0		0	0	0	
Fever	47 (0.43%)	47 (0.43%)	0		3 (0.27%)	3 (0.27%)	0	
Dysuria	17 (0.16%)	16 (0.15%)	1 (0.01%)		2 (0.18%)	1 (0.09%)	1 (0.09%)	
Hematuria	82 (0.75%)	80 (0.73%)	2 (0.02%)		3 (0.27%)	1 (0.09%)	2 (0.18%)	
Hematochezia	11 (0.10%)	9 (0.08%)	2 (0.02%)		3 (0.27%)	1 (0.09%)	2 (0.18%)	
Hematospermia	2 (0.02%)	2 (0.02%)	0		0	0	0	
AUR	42 (0.39%)	41 (0.38%)	1 (0.01%)		3 (0.27%)	2 (0.18%)	1 (0.09%)	
Others	10 (0.09%)	9 (0.08%)	1 (0.01%)		2 (0.18%)	1 (0.09%)	1 (0.09%)	
Clavien–Dindo grade				.656				.658
I	161 (73.9%)	156 (71.56%)	5 (2.29%)		11 (68.75%)	6 (37.5%)	5 (31.25%)	
II	33 (15.1%)	33 (15.14%)	1 (0.46%)		2 (12.5%)	2 (12.5%)	1 (6.25%)	
IIIa	7 (3.21%)	6 (2.75%)	0		2 (12.5%)	1 (6.25%)	0	
IIIb	9 (4.13%)	8 (3.67%)	1 (0.46%)		1 (6.25%)	0	1 (6.25%)	
IV	8 (3.67%)	8 (3.67%)	0		0	0	0	

AUR = acute urinary retention, MRI-TRUS FTPB = magnetic resonance imaging-transrectal ultrasonography fusion-targeted prostate biopsy, TRUS-PB = transrectal ultrasonography-guided prostate biopsy, US = ultrasonography.

Table 3

Multivariate analyses of the complications after prostate biopsy.

	Overall complication			Infectious complication			Bleeding related complication			Clavien-Dindo grade ≥ 2 complication		
Variables	HR	95% CI	P value	HR	95% CI	P value	HR	95% CI	P value	HR	95% CI	P value
Age (yr)	1.014	0.999–1.030	.062	1.018	0.985–1.052	.297	1.014	0.992–1.036	.204	1.020	0.991–1.051	.180
Diabetes mellitus	1.399	0.975–2.006	.068	1.715	0.874–3.365	.117	1.408	0.981–2.020	.063	1.367	0.659–2.837	.401
PSA (ng/mL)	1.000	1.000–1.001	.402	1.000	0.997–1.003	.861	1.000	1.000–1.001	.397	1.000	0.998–1.002	.997
Prostate volume (mL)	1.011	1.007–1.016	**<.001**	1.010	1.001–1.019	**.037**	1.011	1.007–1.016	**<.001**	1.011	1.003–1.019	**.005**
Number of prior biopsy (initial vs non-initial)	1.112	0.741–1.669	.609	0.690	0.269–1.768	.439	1.139	0.759–1.708	.531	0.851	0.351–2.064	.721
Number of biopsy cores	1.036	0.915–1.174	.575	1.137	0.917–1.411	.243	1036	0.914–1.174	.581	1.028	0.799–1.322	.833
Method of biopsy (US guided vs MR fusion)	0.586	0.264–1.302	.189	0.318	0.042–2.420	.269	0.497	0.211–1166	.108	0.761	0.169–3.420	.722

BMI = body mass index, CI = confidence interval, HR = hazard ratio, MR = magnetic resonance, PSA = prostate-specific antigen, US = ultrasonography.

Table 4

Cancer detection rates on MRI-TRUS FTPB.

			Cancer(+) (n = 213)		
ADC level of suspicion	Overall	Cancer (−) (n = 363)	Cancer (+) not at MRI targeted cores	Cancer (+) at MRI targeted cores	P value
1	123	81 (65.9%)	42 (34.1%)	0	<.001
2	8	6 (75.0%)	2 (25.0%)	0	
3	194	155 (79.9%)	19 (9.8%)	20 (8.3%)	
4	168	114 (67.9%)	24 (14.3%)	30 (17.9%)	
5	83	7 (8.4%)	9 (10.8%)	67 (80.7%)	

ADC = apparent diffusion coefficient, MRI-TRUS FTPB = magnetic resonance imaging-transrectal ultrasonography fusion-targeted prostate biopsy.

Table 5

Clinically significant prostate cancer detection rates on MRI-TRUS FTPB.

|			Cancer(+) (n = 213)		
ADC level of suspicion	Overall	Cancer (−) (n = 363)	Clinical insignificant cancer at both techniques	Clinical significant cancer (+) not at MRI targeted cores	Clinical significant cancer (+) at MRI targeted cores	P value
1	123	81 (65.9%)	25 (20.3%)	17 (13.9%)	0	<.001
2	8	6 (75.0%)	1 (12.5%)	1 (12.5%)	0	
3	194	155 (79.9%)	12 (6.3%)	15 (7.7%)	12 (6.2%)	
4	168	114 (67.9%)	17 (10.1%)	15 (8.9%)	22 (13.1%)	
5	83	7 (8.4%)	5 (6.0%)	10 (12.0%)	61 (73.5%)	

ADC = apparent diffusion coefficient, MRI-TRUS FTPB = magnetic resonance imaging-transrectal ultrasonography fusion-targeted prostate biopsy.

3, 20.1% (39/194) and 13.9% (27/194) were confirmed to have PCa and csPCa respectively. Among them, 51.3% (20/39) and 44.4% (12/27) had a confirmed diagnosis of PCa and csPCa at the MRI-targeted cores. In contrast, when the ADC suspicious grade was ≥4, 51.8% (130/251) and 43.0% (108/251) were diagnosed with PCa and csPCa, respectively; 74.6% (97/130) and 76.8% (83/108) of them were confirmed to have PCa and csPCa at the MRI-targeted cores. When the ADC suspicious grade was 5, 91.6% (76/83) and 85.5% (71/83) were diagnosed with PCa and csPCa, respectively; 88.2% (67/76) and 85.9% (61/71) of those were confirmed to have PCa and csPCa at the MRI-targeted cores.

For ADC suspicious grade ≥4 lesions, the sensitivity and specificity for overall PCa were 75.8% and 65.6%, respectively. For ADC suspicious grade 5 lesions, the sensitivity and specificity were 52.3% and 96.4%, respectively. In terms of csPCa, the sensitivity and specificity were 83.8% and 64.8%, respectively for ADC suspicious ≥4 lesions. For ADC suspicious grade 5 lesions, the sensitivity and specificity were 61.6% and 95.4%. In contrast, the sensitivity and specificity of TRUS-PB were 10.7% and 91.1%, respectively. The mean estimated areas under the receiver operating characteristic curve (AUCs) of PCa for the lesions with ADC suspicious grades ≥3, ≥4, and 5 were 0.595, 0.710 and 0.746 respectively (Fig. 1). Meanwhile, those of csPCa for the lesions with ADC suspicious grades ≥3, ≥4, and 5 were 0.613, 0.743 and 0.785 respectively (Fig. 2). There were significant differences between grades ≥3 and ≥4 or 5 lesions (both $P < .001$) but not between grades ≥4 and 5 lesions ($P > .05$).

4. Discussion

Conventionally, PSA, digital rectal examination and TRUS-PB have been commonly used for screening and diagnosis of PCa. However, several new techniques have been introduced, including mpMRI, biomarker, and genomics.[17–19] In the recent few years, even artificial intelligence and machine learning technology have been introduced as promising tool for diagnosis, prediction of prognosis, and surgical treatment of PCa.[20]
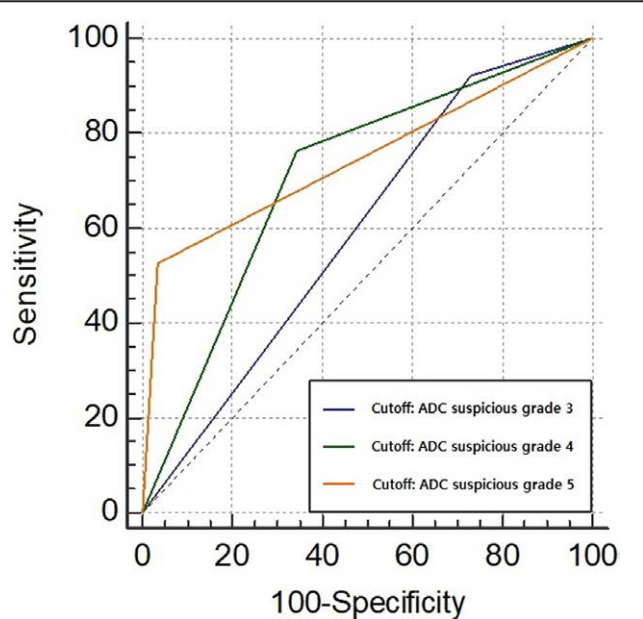
Figure 1. Comparison of the AUCs of PCa for the suspicious lesions on mpMRI according to cutoff values of ADC suspicious grades. ADC = apparent diffusion coefficient, AUCs = areas under the receiver operating characteristic curve, mpMRI = multiparametric MRI, PCa = prostate cancer.

Therefore, the combination of existing diagnostic methods has attracted attention. TRUS-PB has been widely performed as the standard diagnostic method for PCa since 1968. With the introduction of mpMRI in the field of urology, a number of studies have shown the advantages of MRI-guided prostate biopsy.[6,7] Rosenkrantz et al[21] recommended MRI-guided prostate biopsy with at least two targeted cores in patients with a previously negative prostate biopsy finding. Porreca et al[22] reported that detection rates of csPCa at MRI-targeted biopsy cores was higher than those at systematic biopsy cores (43.7% vs. 24.1%, $P = .01$).
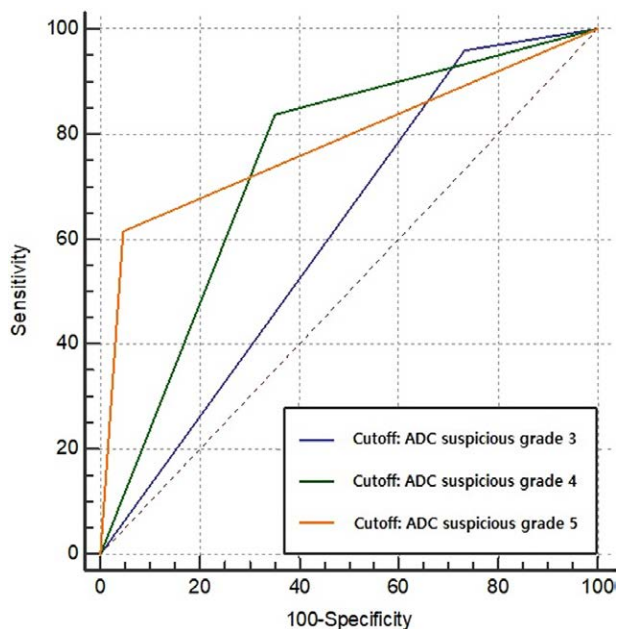
Figure 2. Comparison of the AUCs of csPCa for the suspicious lesions on mpMRI according to cutoff values of ADC suspicious grades. ADC = apparent diffusion coefficient, AUCs = areas under the receiver operating characteristic curve, csPCa = clinically significant prostate cancer, mpMRI = multiparametric MRI.

Among the three techniques of MRI-guided prostate biopsy such as in-bore MRI-targeted biopsy, MRI-TRUS FTPB and cognitive registration TRUS-targeted biopsy, Wegelin et al[8] reported that in-bore MRI-targeted biopsy demonstrates a superior performance in overall PCa detection compared with MRI-TRUS cognitive-targeted biopsy and a similar performance in overall PCa and csPCa detection compared with MRI-TRUS FTPB. Because of the ease to perform, MRI-TRUS FTPB is widely used in clinical field, including our institution.

To our knowledge, the present study is one of the largest studies to compare TRUS-PB with MRI-TRUS FTPB in terms of prostate biopsy-related complications and cancer detection. In our study, the patients who underwent MRI-TRUS FTPB showed no significant differences in the complication rate compared with those who underwent traditional 12-core TRUS-PB. We observed that prostate volume was a significant predictor of the overall complications, infectious complications, bleeding-related complications, and complications for which Clavien-Dindo scale was ≥2.

Several studies[23–26] have been conducted on the complications of prostate biopsy. A systematic review[27] on the overall complications after prostate biopsy reported that the major complications were bleeding-related complications including hematuria (10%–84%), hematospermia (1.1%–93%), rectal bleeding (1.3%–45%), infectious complications (0%–6.3%), and AUR (0.2%–1.7%). In MRI-guided prostate biopsy, the rates of hematuria, infectious complications, and AUR were all less than 1%.[28] These results are slightly higher than but similar to our results (Table 2). However, there were no significant differences in the overall complication rates between the US group and MR group, before and after propensity score matching in our study. When stratifying each complication according to the modified Clavien-Dindo scale, there was no significant difference between both groups.

In the multivariate analysis, MRI-TRUS FTPB was not a significant predictor for the overall complications. Only the prostate volume was shown to be a significant predictor of complications. A previous review[27] has suggested that the

large prostate volume could be a significant risk factor for infectious complications and bleeding-related complications, which was similar to our findings. However, the same article[27] suggested other risk factors for infectious complications including presence of DM, large number of biopsy cores and repeat biopsy, which were not shown to be significant risk factor in the present study. Such differences might be explained by the relative low rates of complications showed in the present study, compared to prior reports.[27,28] All patients strictly received glycerin enema and adequate prophylactic intravenous antibiotics within 30 minutes before biopsy, reducing the incidence rate of complications. This could mask the effects of other risk factors.

To analyze the likelihood of each lesion on MRI to be confirmed as PCa, the Likert scale systems such as PI-RADS have been accepted in clinical practice. de Cobelli et al[29] reported PI-RADS score on mpMRI was significantly related with Gleason score upgrading, extracapsular extension, unfavorable prognosis and large tumor volume after radical prostatectomy in patients with PCa who were eligible for active surveillance.

Several studies reported that the probability of diagnosing PCa at suspicious lesions on the mpMRI ADC map would be 8% to 70%.[25,30,31] Maggi et al[32] showed that RI-RADS score on mpMRI alone showed the sensitivity and specificity for PCa were 51.9% and 88.3%, respectively. For csPCa, the sensitivity and specificity were 61.3% and 83.9%, respectively. We also analyzed the ADC value of prebiopsy mpMRI and pathologic data in the 576 patients undergoing MRI-TRUS FTPB. Our results showed that a positive predictive value for ADC suspicious grade ≥4 lesions was 38.6%, which were similar to results of previous studies.[25,29,30,32]

Even though there are evidences that MRI-guided biopsy presents better diagnostic value for PCa than conventional systematic biopsy,[33] it is not clear whether combination of both methods would be better or not compared with each method alone.

Filson et al[34] and Fourcade et al[35] found that the combination of targeted and systematic prostate biopsies achieved the best results for the detection and prognosis of PCa. In contrast, Porreca et al[22] showed that additional systematic biopsy to MRI-targeted biopsy did not improve detection rate of csPCa.

In the present study, only 20.1% of the patients with ADC suspicious grade 3 were diagnosed with PCa; the diagnosis of 49.7% was missed at the MRI-targeted cores alone. In contrast, 91.6% of those with grade 5 lesions were confirmed to have PCa, and 88.2% of then showed positive results on the MRI-targeted cores. The AUC of the ADC suspicious grade ≥4 lesions was 0.710, showing significant difference compared with that of the grade ≥3 lesions (0.595, $P = .104$). In terms of csPCa, similar results were shown. Such results imply that patients with ADC suspicious grade ≤3 lesions should be recommended additional systematic randomized 12-core prostate biopsy.

This study has some limitations. Our study has a retrospective and single-institutional study design. We also evaluated the complication rates after prostate biopsy was performed at a single large volume institution. Thus, the present study results might not be applicable to low volume institution. Moreover, the direct clinicopathologic matching was not included between the locations of suspicious lesions on mpMRI and those of cancerous lesions from the specimens after radical prostatectomy. Some clinical factors, including anticoagulant agent history, were also not included owing to missing/insufficient data. Furthermore, the other screening methods besides MRI-TRUS FTPB, such as biomarker tests or genetic tests were not included in the present study.

Despite these limitations, this study is still noteworthy and it is remaining to be one of the largest studies of comparison

between TRUS-PB and MRI-TRUS FTPB in terms of prostate biopsy-related complications and cancer detection.

5. Conclusions

The present study supports the safety of MRI-TRUS FTPB compared with that of traditional 12-core TRUS-PB. The prostate volume was the only significant risk factor of overall complications, infectious complications, bleeding-related complications, and Clavien-Dindo grade ≥2 complications. In addition, the diagnostic accuracy of mpMRI was superior to that of TRUS. Although the combination of MRI-TRUS FTPB and 12-core TRUS-PB provides enhanced diagnostic power, MRI-TRUS FGB alone could provide a reasonable diagnostic value for PCa if the ADC suspicious grade of PCa is ≥4.

Author contributions

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Supervision: Sung Kyu Hong, Seok-Soo Byun, Sangchul Lee.
Writing – original draft: Byeongdo Song.
Writing – review & editing: Seok-Soo Byun, Sangchul Lee.

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