Am J Clin Exp Urol 2024;12(4):162-172
www.ajceu.us /ISSN:2330-1910/AJCEU0156745

Original Article

Prognostic significance of the PI-RADS score in men with prostate cancer undergoing radical prostatectomy

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Received March 22, 2024; Accepted July 24, 2024; Epub August 25, 2024; Published August 30, 2024

Abstract: Objectives: MRI-targeted biopsy (T-Bx) for which Prostate Imaging Reporting and Data System (PI-RADS) assessment categories are useful has been shown to more accurately detect clinically significant prostate cancer. However, the prognostic significance of the PI-RADS in prostate cancer patients needs further investigation. In the present study, we compared radical prostatectomy findings and postoperative oncologic outcomes in men with prostate cancer initially undergoing T-Bx for PI-RADS 3 vs. 4 vs. 5 lesions. Methods: We assessed consecutive patients undergoing T-Bx with concurrent systematic biopsy (S-Bx), followed by radical prostatectomy. Within our Surgical Pathology database, we identified a total of 207 men where prostatic adenocarcinoma was detected on either S-Bx or T-Bx, or both. Results: Prostate cancer was detected on S-Bx only (n = 32; 15%), T-Bx only (n = 39; 19%), or both S-Bx and T-Bx (n = 136; 66%). These patients had PI-RADS 3 (n = 42; 20%), 4 (n = 86; 42%), or 5 (n = 79; 38%) lesions, while T-Bx detected cancer in 31 (74%) of PI-RADS 3 cases, 72 (84%) of PI-RADS 4 cases, and 72 (91%) of PI-RADS 5 cases. There were no significant differences in any of the clinicopathologic features examined, including tumor grade on biopsy or prostatectomy and pT or pN stage, among the PI-RADS 3 vs. 4 vs. 5 groups, except a significantly higher rate of positive margin and significantly larger tumor volume in PI-RADS 5 cases than in PI-RADS 3 cases. Univariate and multivariable analyses revealed significantly higher risks of biochemical recurrence after prostatectomy in patients with PI-RADS 5 lesion than in those with PI-RADS 3 or 4 lesion. Additionally, compared with respective controls, detection of any grade cancer (P = 0.046) or Grade Group 2 or higher cancer (P = 0.005) on T-Bx was associated with a significantly higher risk of recurrence in patients with PI-RADS 5 lesion, but not in those with PI-RADS 3 or 4 lesion. Conclusion: PI-RADS 5 lesions were thus found to independently predict a significantly poorer postoperative prognosis. Moreover, the failure of detection of any grade cancer or clinically significant cancer on T-Bx of PI-RADS 5 lesion may particularly indicate favorable outcomes in radical prostatectomy cases.

Keywords: PI-RADS, prognosis, prostate cancer, radical prostatectomy, systematic biopsy, targeted biopsy

Introduction

Prostate cancer has represented one of the most common malignancies, and the incidence of worldwide cancer-related deaths is likely increasing considerably (*e.g.* 307,500 in 2012 [1], 375,304 in 2020 [2]). Definitive therapy, such as radical prostatectomy, often offers a cure in men with localized disease, but these patients have a considerable risk of developing postoperative recurrence [3, 4]. Accurate stratification of such risks not only after definitive therapy but also at the time of initial diagnosis is thus crucial for improving patient care.

The most widespread method for the definitive diagnosis of prostate cancer remains the ultrasonography-guided systematic biopsy (S-Bx), which relies primarily on anatomic guidance to achieve evenly spaced biopsies within the gland, without the pre-procedure information of tumor location [5]. However, this technique is known to lead to the underdiagnosis of high-risk cancer, as well as the overdetection and overtreatment of indolent disease [5-7].

Over the last decade, detection of clinically significant prostate cancer [*e.g.* Gleason score 3 + 4/Grade Group (GG) 2 or higher lesion] has been noticeably improved by the introduction of

https://doi.org/10.62347/BODM5001

the Prostate Imaging Reporting and Data System (PI-RADS) classification on multiparametric magnetic resonance imaging (mpMRI) and biopsy of the target lesion [8-11]. In the PI-RADS system initially standardized in 2009 [12] and most recently updated in 2019 [13], 5-point scale scores given based on mpMRI findings predict the likelihood of clinically significant prostate cancer [*i.e.* scores 1 (clinically significant cancer highly unlikely to be present), 2 (unlikely), 3 (equivocal), 4 (likely), and 5 (highly likely)]. A combination of S-Bx and targeted biopsy (T-Bx) is thus expected to yield much higher sensitivity, while a meta-analysis has demonstrated that T-Bx alone does not more effectively detect clinically significant prostate cancer than S-Bx [14]. Accordingly, conducting a mpMRI before initial biopsy is currently recommended [15].

In contrast to the known role of T-Bx in prostate cancer diagnosis, however, the prognostic significance of its detection on S-Bx vs. T-Bx remains controversial. We recently demonstrated a significantly higher risk of biochemical recurrence following radical prostatectomy in patients whose cancer had been detected on T-Bx only or both S-Bx and T-Bx than in those on S-Bx only (*i.e.* concurrent T-Bx negative) [16]. Nonetheless, the clinical impact of the PI-RADS score, particularly that on postoperative patient prognosis, needs to be further determined. In the present study, we compared radical prostatectomy findings and oncologic outcomes in men with prostate cancer who had initially undergone T-Bx for PI-RADS 3 vs. 4 vs. 5 lesions.

Materials and methods

Study population

Following the approval from the Institutional Review Board at the University of Rochester Medical Center (#00003996), including the request to waive the documentation of patient consent, we retrospectively assessed consecutive 207 patients who had undergone T-Bx with concurrent 6-site S-Bx, followed by robot-assisted radical prostatectomy for prostatic adenocarcinoma, both performed at our institution between 2015 and 2018. Excluded cases were those who had undergone: 1) T-Bx/S-Bx at an outside institution; 2) T-Bx in 2014 (due to the learning curve of the MRI interpretation and biopsy technique at our institution, as described previously [16, 17]); and 3) neoadjuvant therapy prior to prostatectomy.

Data analysis

We collected clinical data, including preoperative prostate-specific antigen (PSA) value, PI-RADS assessment category, and postoperative follow-up information (*e.g.* PSA value), via the hospital's integrated electronic health record system (last accessed in May 2024), as well as biopsy and radical prostatectomy findings, including Gleason score/GG, pT and pN stages (according to the current American Joint Committee on Cancer/Union for International Cancer Control TNM staging system for prostate cancer [18]), surgical margin status, and estimated cancer volume. As clinical follow-up data, biochemical recurrence was defined as a single PSA level of ≥ 0.2 ng/mL or the introduction of adjuvant therapy in patients undergoing no adjuvant therapy immediately after prostatectomy (n = 187) and as an increase in PSA value of ≥ 2 ng/mL [19] or the introduction of salvage therapy in those with adjuvant treatment, including hormonal therapy (n = 3), radiotherapy (n = 10), or both (n = 7), before disease progression. Meanwhile, Gleason score/GG on biopsy and prostatectomy (according to the most recent recommendations by genitourinary pathology societies [20, 21]), as well as pT staging on prostatectomy, was re-evaluated by a senior author (H.M.), as we recently described [22]. In radical prostatectomy specimens showing GG2 (n = 3) or GG3 (n = 12) cancer, less than 5% of a minor tertiary pattern 5 was not incorporated into analysis.

The Student's *t*-test and the chi-square test or Fisher's exact test were used for analyzing continuous and non-continuous variables, respectively. Time-to-event estimates of biochemical recurrence-free survival were calculated by the Kaplan-Meier method and compared by the log-rank test. The Cox proportional hazards model was then used to evaluate the prognostic factors in a multivariable setting. Harrell's C index [23] was also calculated in the Cox regression. All statistical analyses were performed, using EZR software [24] (R version 4.0.2; The R Foundation for Statistical Computing) or Prism version 10.2.3 (GraphPad Software). A *P* value of less than 0.05 was considered to be statistically significant.

Table 1. Clinicopathologic characteristics of the entire cohort

Age at Bx [median (IQR)/mean ± SD, year]	66 (62-69)/65.5 ± 5.6
Preoperative PSA [median (IQR)/mean ± SD, ng/mL]	7.27 (5.345-10.785)/9.28 ± 6.59
PI-RADS score (index lesion)	
3	42 (20%)
4	86 (42%)
5	79 (38%)
Cancer detection on Bx	
S-Bx only	32 (15%)
T-Bx only	39 (19%)
Both S-Bx and T-Bx	136 (66%)
Bx Grade Group (highest)	
1	25 (12%)
2	95 (46%)
3	45 (22%)
4	31 (15%)
5	11 (5%)
RP Grade Group	
1	4 (2%)
2	104 (50%)
2 (with minor tertiary 5)	3 (1%)
3	61 (29%)
3 (with minor tertiary 5)	12 (6%)
4	4 (2%)
5	19 (9%)
pT	
2/2+	110 (53%)
3a	89 (43%)
3b	8 (4%)
pN	
0	190 (92%)
1	8 (4%)
X	9 (4%)
Surgical margin	
Negative	163 (79%)
Positive	44 (21%)
RP tumor volume [median (IQR)/mean ± SD, g]	5.4 (3.1-8.6)/6.7 ± 5.7
Adjuvant therapy before recurrence	
Not performed	187 (90%)
Performed	20 (10%)

Bx, biopsy; PSA, prostate-specific antigen; RP, radical prostatectomy; S-Bx, systematic biopsy; T-Bx, targeted biopsy.

Results

PI-RADS and clinicopathologic features

In a retrospective, blinded manner, we examined a total of 207 sets of prostate biopsy (S-Bx + T-Bx) and corresponding radical prostatectomy. **Table 1** summarizes the clinicopathologic characteristics of these patients. Prostate cancer was initially identified on S-Bx only (n = 32; 15%), T-Bx only (n = 39; 19%), or both S-Bx and T-Bx (n = 136; 66%), while the PI-RADS assessment category in the index MRI lesion in each case was 3 (n = 42; 20%), 4 (n = 86; 42%), or 5 (n = 79; 38%). T-Bx detected any grade cancer or GG2 or higher cancer in 31 (74%) or 23 (55%)

Table 2. Clinicopathologic findings of 175 T-Bx-positive cases with PI-RADS 3 vs. 4 vs. 5 lesions

	PI-RADS 3	PI-RADS 4	PI-RADS 5	*P* (3 vs. 4)	*P* (3 vs. 5)	*P* (4 vs. 5)
N	31	72	72			
Detection of cancer on T-Bx[a]	74%	84%	91%	0.185	0.011	0.153
Detection of ≥ GG2 cancer on T-Bx[a]	55%	71%	81%	0.071	0.002	0.131
Age (mean, year)	66.2	64.8	66.3	0.239	0.936	0.111
PSA (mean, ng/mL)	9.01	8.68	10.05	0.789	0.459	0.217
Cancer detection on Bx				0.480	0.584	0.109
T-Bx only	7 (23%)	12 (17%)	20 (28%)			
Both S-Bx and T-Bx	24 (77%)	60 (83%)	52 (72%)			
Bx GG (highest)				0.112	0.125	0.310
1	4 (13%)	5 (7%)	3 (4%)			
2	16 (52%)	30 (42%)	36 (50%)			
3	7 (23%)	22 (31%)	13 (18%)			
4	1 (3%)	13 (18%)	15 (21%)			
5	3 (10%)	2 (3%)	5 (7%)			
RP GG				0.583	0.440	0.236
2	18 (58%)	35 (49%)	37 (51%)			
3	10 (32%)	31 (43%)	22 (31%)			
4	0 (0%)	1 (1%)	3 (4%)			
5	3 (10%)	5 (7%)	10 (14%)			
pT stage				0.992	0.376	0.185
2/2+	18 (58%)	42 (58%)	31 (43%)			
3a	12 (39%)	28 (39%)	38 (53%)			
3b	1 (3%)	2 (3%)	3 (4%)			
pN stage				0.582[c]	0.318[c]	0.441[c]
0	29 (94%)	68 (94%)	66 (92%)			
1	0 (0%)	2 (3%)	5 (7%)			
X	2 (6%)	2 (3%)	1 (1%)			
Surgical margin				0.217	0.018	0.112
Negative	29 (94%)	60 (83%)	51 (71%)			
Positive	2 (6%)	12 (17%)	21 (29%)			
Tumor volume on RP (mean, g)	5.3	6.8	8.1	0.239	0.013	0.224
Adjuvant therapy[b]				1.000	1.000	1.000
Not performed	28 (90%)	65 (90%)	64 (89%)			
Performed	3 (10%)	7 (10%)	8 (11%)			

Bx, biopsy; GG, Grade Group; PSA, prostate-specific antigen; RP, radical prostatectomy; S-Bx, systematic biopsy; T-Bx, targeted biopsy. [a]Rates in the entire cohort (n = 207) including T-Bx-negative cases. [b]Adjuvant therapy before recurrence. [c]pN0 vs. pN1.

of PI-RADS 3 cases, 72 (84%) or 61 (71%) of PI-RADS 4 cases, and 72 (91%) or 64 (81%) of PI-RADS 5 cases, respectively (see **Table 2**). Thus, any cancer ($P = 0.011$) and GG2 or higher cancer ($P = 0.002$) were significantly more often detected in PI-RADS 5 lesions than in PI-RADS 3 lesions.

We first compared clinicopathologic findings at the time of biopsy, as well as prostatectomy, in our cohort excluding 32 T-Bx-negative cases (**Table 2**). Compared with PI-RADS 3 cases, PI-RADS 5 cases showed a significantly higher rate of positive surgical margin (6% vs. 29%; $P = 0.018$) and significantly larger tumor volume (mean: 5.3 g vs. 8.1 g; $P = 0.013$) on prostatectomy. However, there were no significant differences in other features examined, including tumor grade and stage, between PI-RADS 3 and PI-RADS 5 patients. Moreover, no significant differences in any of these clinicopathologic features between the PI-RADS 3 vs.

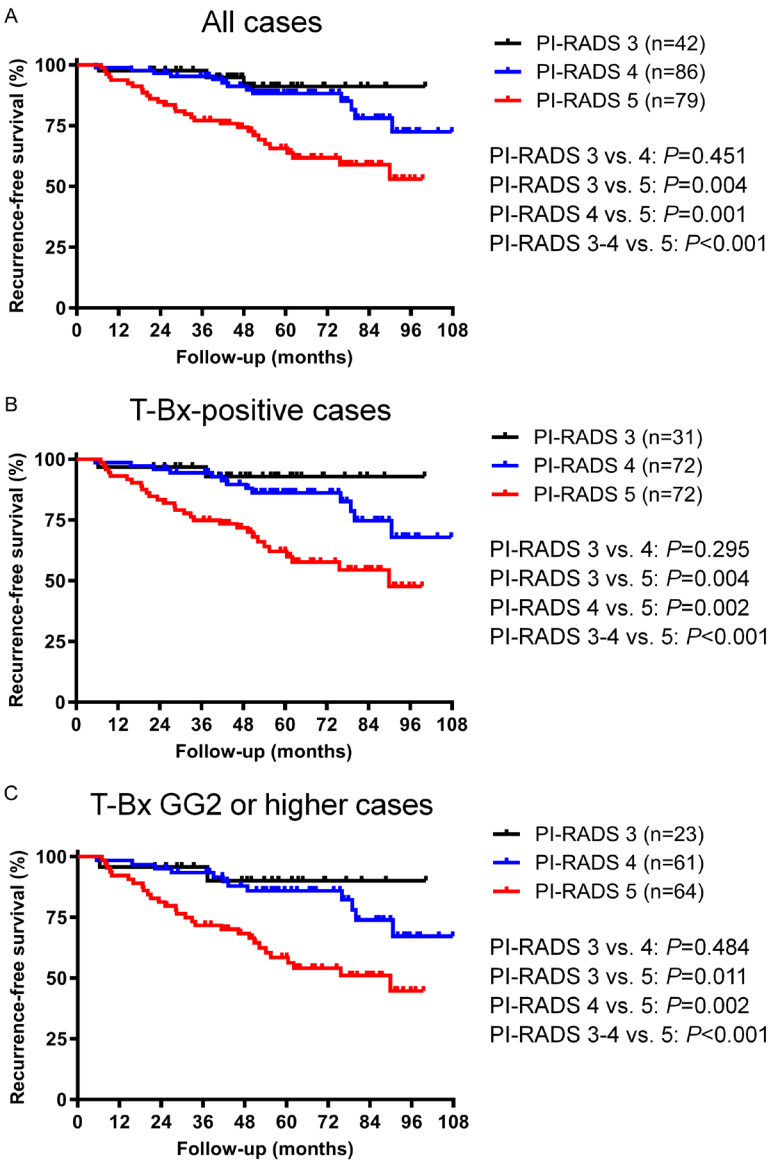

Figure 1. Prognostic significance of PI-RADS scores in patients undergoing radical prostatectomy. Kaplan-Meier curves for postoperative recurrence-free survival in the entire cohort of patients (A; n = 207), only T-Bx-positive patients (B; n = 175), and only patients with GG2 or higher cancer detected on T-Bx (C; n = 148), according to the PI-RADS scores.

PI-RADS 4 groups or PI-RADS 4 vs. PI-RADS 5 groups were observed.

Prognostic role of PI-RADS

We then performed univariate survival analysis to determine the prognostic impact of PI-RADS categories after prostatectomy. In the entire cohort including T-Bx-negative cases, PI-RADS 5 was associated with a significantly higher risk of biochemical recurrence, compared with PI-RADS 3 [hazard ratio (HR) 4.833, 95% confidence interval (CI) 2.317-10.08, P = 0.004], 4 (HR 2.772, 95% CI 1.509-5.094, P = 0.001), or 3 or 4 (HR 3.150, 95% CI 1.717-5.778, P < 0.001) (**Figure 1A**). There was no significant difference in recurrence-free survival between PI-RADS 3 and PI-RADS 4 patients (HR 1.601, 95% CI 0.531-4.829, P = 0.451). Similarly, in the T-Bx-positive cohort, the risk of recurrence was significantly higher in patients with PI-RADS 5 lesion than in those with PI-RADS 3 (HR 6.315, 95% CI 2.937-13.58, P = 0.004), 4 (HR 2.658, 95% CI 1.448-4.878, P = 0.002), or 3 or 4 (HR 3.128, 95% CI 1.703-5.747, P < 0.001) lesion (**Figure 1B**). Moreover, when cases where T-Bx showed only GG1 cancer were additionally excluded (*i.e.* only those with clinically significant cancer on T-Bx), PI-RADS 5 showed significance for recurrence, compared with PI-RADS 3 (HR 5.256, 95% CI 2.370-11.66, P = 0.011), 4 (HR 2.779, 95% CI 1.504-5.133, P = 0.002), or 3 or 4 (HR 3.114, 95% CI 1.691-5.732, P < 0.001) (**Figure 1C**).

To determine if the PI-RADS category was an independent predictor of postoperative disease recurrence, multivariable analysis was performed with the factors available prior to prostatectomy, such as PSA, tumor volume on S-Bx and T-Bx, and biopsy GG, using the Cox model. When PI-RADS 5 was used as a reference, both PI-RADS 3 and PI-RADS 4 were associated with significantly reduced risks of recurrence in the entire cohort (**Table 3**), patients whose T-Bx was positive for any grade cancer (**Table 4**), or those whose T-Bx showed GG2 or higher cancer (**Table 5**).

Table 3. Multivariable analysis for the factors available after biopsy in the entire cohort of patients

	HR	95% CI	*P*
PSA	1.048	1.011-1.086	0.011
Tumor volume on S-Bx	1.007	0.974-1.042	0.666
Tumor volume on T-Bx	1.011	0.997-1.024	0.118
Highest Grade Group at biopsy			
1		Reference	
2	1.470	0.265-8.165	0.660
3	5.750	1.070-30.89	0.041
4	4.243	0.829-21.71	0.083
5	8.181	1.329-50.36	0.023
PI-RADS			
3	0.277	0.080-0.954	0.042
4	0.408	0.205-0.811	0.011
5		Reference	

CI, confidence interval; HR, hazard ratio; PSA, prostate-specific antigen; S-Bx, systematic biopsy; T-Bx, targeted biopsy.

Table 4. Multivariate analysis for the factors available after biopsy in patients where targeted biopsy showed any grade cancer

	HR	95% CI	*P*
PSA	1.063	1.024-1.104	0.001
Tumor volume on S-Bx	1.020	0.984-1.057	0.287
Tumor volume on T-Bx	1.004	0.990-1.019	0.554
Highest Grade Group at biopsy			
1		Reference	
2	0.635	0.078-5.150	0.671
3	2.454	0.310-19.44	0.395
4	1.508	0.180-12.65	0.705
5	3.499	0.390-31.39	0.263
PI-RADS			
3	0.190	0.044-0.823	0.026
4	0.387	0.194-0.771	0.007
5		Reference	

CI, confidence interval; HR, hazard ratio; PSA, prostate-specific antigen; S-Bx, systematic biopsy; T-Bx, targeted biopsy.

Table 5. Multivariate analysis for the factors available after biopsy in patients where targeted biopsy showed GG2 or higher cancer

	HR	95% CI	*P*
PSA	1.061	1.022-1.102	0.002
Tumor volume on S-Bx	1.024	0.988-1.061	0.200
Tumor volume on T-Bx	1.003	0.988-1.018	0.677
Highest Grade Group at biopsy			
2		Reference	
3	3.616	1.563-8.365	0.003
4	2.139	0.848-5.397	0.108
5	4.751	1.530-14.76	0.007
PI-RADS			
3	0.216	0.049-0.943	0.042
4	0.351	0.172-0.714	0.004
5		Reference	

CI, confidence interval; HR, hazard ratio; PSA, prostate-specific antigen; S-Bx, systematic biopsy; T-Bx, targeted biopsy.

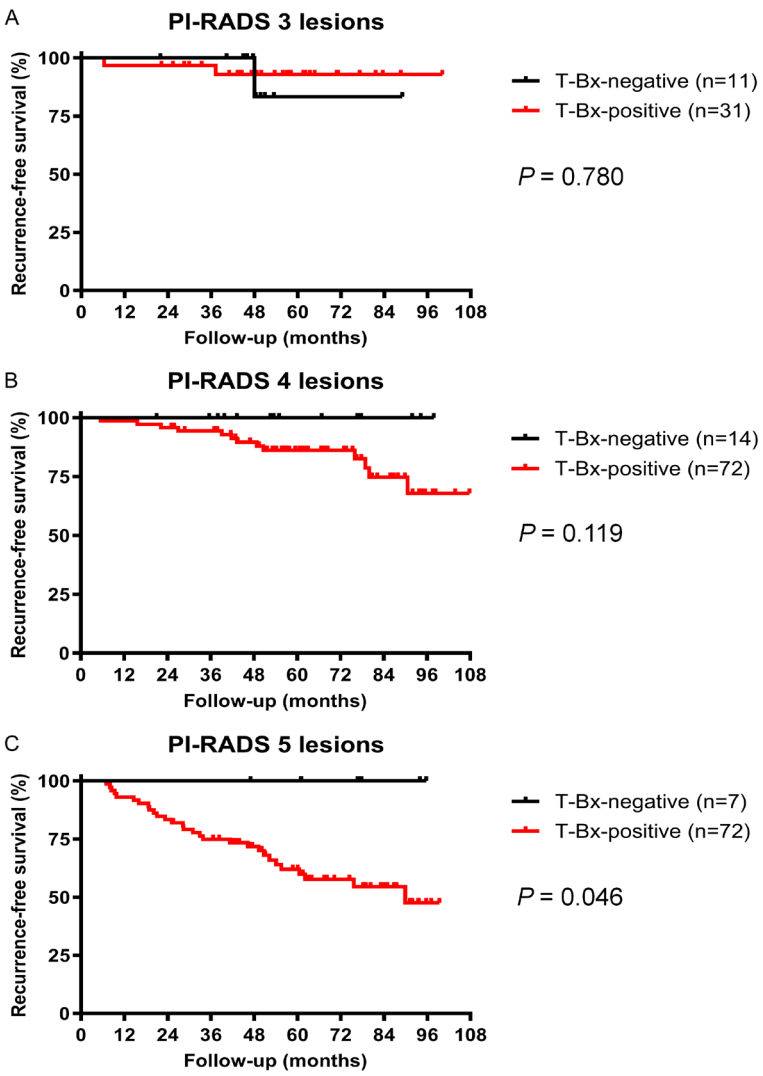

Figure 2. Prognostic significance of the detection of cancer on T-Bx in subgroups of patients with each PI-RADS score lesion. Kaplan-Meier curves for postoperative recurrence-free survival in the entire cohort of patients with PI-RADS 3 (A; n = 42), 4 (B; n = 86), or 5 (C; n = 79) lesion, according to the absence vs. presence of any grade cancer detected on T-Bx.

Harrell's C index analysis was then performed to compare the prognostic performance of the PI-RADS assessment category vs. the D'Amico risk group classification [25], a useful point system determined by preoperative PSA level, biopsy Gleason score, and clinical T stage, in the present cohort. The concordance indexes for the PI-RADS score and D'Amico risk group were 0.665 (95% CI 0.590-0.740) and 0.638 (95% CI 0.562-0.714), respectively.

We further assessed the prognostic value of cancer detection on T-Bx in subgroups of patients with each PI-RADS score. The presence of cancer in PI-RADS 3 (P = 0.780; **Figure 2A**) or 4 (P = 0.119; **Figure 2B**) lesions was not strongly associated with worse recurrence-free survival. However, PI-RADS 5 patients had a significantly higher risk of recurrence when cancer was detected on T-Bx (HR 3.145, 95% CI 1.021-9.686, P = 0.046; **Figure 2C**). Similarly, the risk of recurrence was not significantly different between PI-RADS 3 (P = 0.669; **Figure 3A**) or 4 (P = 0.140; **Figure 3B**) cases with vs. without GG2 or higher cancer on T-Bx, whereas its detection in PI-RADS 5 lesions was associated with a significantly higher risk of recurrence (HR 3.570, 95% CI 1.464-8.706, P = 0.005; **Figure 3C**).

Discussion

Previous studies have indicated the benefit of undergoing combined T-Bx with S-Bx [8-11, 16], although this may possibly lead to the overdetection and/or overtreatment of indolent prostate cancer. Specifically, T-Bx is well-known to be useful for the detection of clinically significant cancer. In addition, T-Bx has contributed to detecting prostate cancer in those where prior S-Bx was negative [26]. Thus, the accuracy of S-Bx and/or T-Bx in prostate cancer diagnosis has been extensively studied. Meanwhile, the PI-RADS categories have been widely employed in daily clinical practice throughout developed countries as a reliable tool for considering whether to perform T-Bx [15]. Importantly, the role of the PI-RADS as a prognostic factor after definitive therapy for prostate cancer has not been fully investigated. We therefore compared the histopathology of prostate cancer in S-Bx/T-Bx and corresponding radical prostatectomy specimens and the prognosis of patients with different PI-RADS scores.

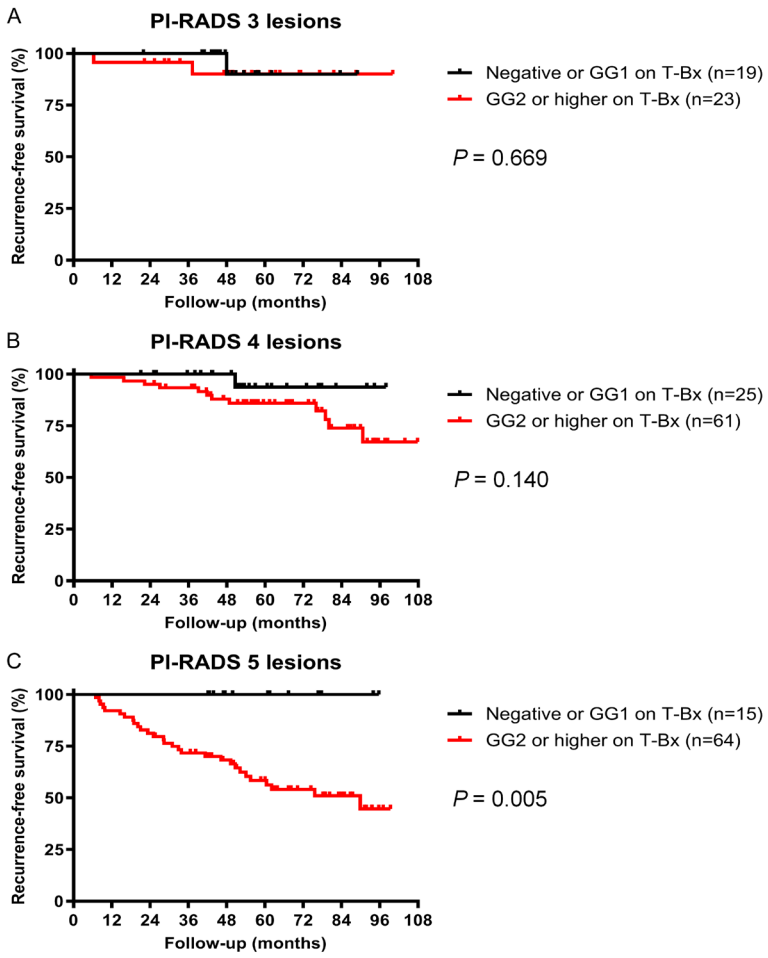

Figure 3. Prognostic significance of the detection of clinically significant cancer on T-Bx in subgroups of patients with each PI-RADS score lesion. Kaplan-Meier curves for postoperative recurrence-free survival in the entire cohort of patients with PI-RADS 3 (A; n = 42), 4 (B; n = 86), or 5 (C; n = 79) lesion, according to the absence vs. presence of GG2 or higher cancer detected on T-Bx.

The aims of the present study included the determination of any differences in clinicopathologic features of prostate cancer from those where mpMRI identified PI-RADS 3 vs. 4 vs. 5 lesions. We thus examined a total of 207 radical prostatectomy cases upon T-Bx. As expected, any grade cancer or clinically significant (*i.e.* ≥ GG2) cancer was more often detected when the PI-RADS score was higher. Indeed, the detection rates of GG2 or higher cancer in PI-RADS 3 (55%), 4 (71%), or 5 (81%) lesions in our cohort were higher than those in a meta-analysis of prospective studies (17%, 46%, or 75%, respectively) [27], although all our patients underwent radical prostatectomy and those exhibiting no cancer on both S-Bx and T-Bx or undergoing active surveillance were not included. Meanwhile, the positive margin rate and estimated tumor volume on prostatectomy were significantly higher and larger, respectively, in T-Bx-positive cases with PI-RADS 5 lesion than in those with PI-RADS 3 lesion. However, we failed to demonstrate significant differences in the clinicopathologic features, including tumor grade and stage, and the need for adjuvant therapy before recurrence, among the PI-RADS 3 vs. 4 vs. 5 groups.

Again, the prognostic value of the PI-RADS category, especially following definitive therapy for prostate cancer, has not been well established. It has been documented in a multi-institutional study involving 804 patients that the odds ratios (PI-RADS 3 as a reference) for postoperative biochemical recurrence for PI-RADS 4 and PI-RADS 5 in univariate analysis are 1.79 (95% CI 0.78-4.11, $P = 0.1$) and 5.25 (95% CI 2.34-11.75, $P < 0.001$), respectively [28]. We here obtained comparable results and further demonstrated that PI-RADS 5 (vs. 3 or 4) independently predicted the risk of recurrence after prostatectomy in the entire cohort of patients including T-Bx-negative cases, as well as subgroups of patients such as T-Bx-positive cases only and those with clinically significant cancer detected on T-Bx. In our multivariable analyses, we used PI-RADS 5 as a reference to indicate significance between PI-RADS 4 vs. 5. In accordance with the results of the previous study [28], the differences in recurrence-free survival between the PI-RADS 3 and PI-RADS 4 groups were not statistically significant in any of these 3 cohorts. Meanwhile, the Harrell's C index of the PI-RADS score for recurrence-free survival was found to be even superior to that of the widely used D'Amico risk category in our cohort. Moreover, in further subgroup analyses, the presence of

either any grade cancer or clinically significant cancer on T-Bx of PI-RADS 5 lesions was found to be associated with significantly worse postoperative outcomes. Thus, the failure of cancer detection in PI-RADS 5 lesions, but not in PI-RADS 3 or 4 lesions, could predict significantly favorable outcomes, presumably because PI-RADS 5 is associated with more aggressive cancer. These observations further support that detection of clinically significant prostate cancer in PI-RADS 5 lesions is crucial for predicting the prognosis.

Potential limitations in our present work include its retrospective nature and that being performed in a single academic institution. In addition, we compared only radical prostatectomy patients, and the significance of the PI-RADS category in those managed differently (*e.g.* active surveillance, radiation therapy, hormonal therapy) was not evaluated. Finally, T-Bx started in April 2014 at our institution, and the follow-up duration after radical prostatectomy was relatively short (mean: 68 months; median: 64 months in those who were alive at the last contact). Accordingly, further studies in larger patient cohorts with longer follow-up are warranted to validate our results.

In conclusion, after assessing cases undergoing T-Bx with concurrent S-Bx, we found that PI-RADS 5 lesions (vs. PI-RADS 3 or 4) were strongly associated with poorer postoperative oncologic outcomes, as an independent prognosticator, but not with adverse histopathology on radical prostatectomy. Remarkably, compared with respective control patients, the risk of postoperative recurrence was considerably lower when T-Bx of PI-RADS 5 lesions failed to detect any grade cancer or clinically significant cancer. The present findings thus suggest that the presence vs. absence of clinically significant prostate cancer particularly on T-Bx of PI-RADS 5 lesions represents useful information for risk stratification.

Disclosure of conflict of interest

None.

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