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An independent practice validation of the Prostate Imaging Reporting and Data System version 2 scoring system and the introduction of PDP (prostate-specific antigen density × PI-RADSv2) score to assist with further risk assessment

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Abstract

Objectives: To provide concise information to clinicians on how to better interpret multiparametric magnetic resonance imaging for prostate cancer risk stratification.

Materials and methods: We analyzed 2 separate cohorts. For patients receiving a Prostate Imaging Reporting and Data System version 2 (PI-RADSv2) score of 1 or 2, we reviewed the charts of 226 patients who underwent multiparametric magnetic resonance imaging of the prostate ordered from 2015 to 2017 to determine who developed clinically significant prostate cancer (csPCa) by August 27, 2020. For patients receiving PI-RADSv2 a score of 3, 4, or 5, we reviewed the results of 733 fusion biopsies on solitary lesions. Statistical analysis was used to further determine risk factors for csPCa.

Results: Ten percent of men with PI-RADSv2 a score of 1 eventually developed csPCa. Seven percent with a score of 2 were eventually diagnosed with csPCa. Only 1 of 226 with a score of 1 or 2 developed metastasis. For PI-RADSv2 scores of 3, 4, and 5, csPCa was detected in 16%, 45%, and 67% of fusion biopsies. Peripheral zone (PZ) PI-RADSv2 score of 4 or 5 and prostate-specific antigen density (PSA-D) were significant predictors of csPCa on multivariable analysis. Using a PSA-D × PI-RADSv2 score of ≤0.39, we identified 38% of men with a PI-RADSv2 score of 3 in the PZ or 3, 4, or 5 in the transition zone who could have avoided a benign biopsy.

Conclusions: The vast majority of patients with PI-RADSv2 scores 1 and 2 can be safely monitored with close surveillance. Lesions with PI-RADSv2 scores of 4 and 5 in the PZ should be biopsied. Peripheral zone lesions with a PI-RADSv2 score of 3 and transition zone lesions with 3, 4, or 5 can be risk-stratified using the PSA-D × PI-RADSv2 score to determine who may safely avoid a biopsy and who should proceed to fusion biopsy.

Keywords: Biopsy; Magnetic resonance imaging; Prostate cancer

1. Introduction

Numerous trials have demonstrated that multiparametric magnetic resonance imaging (mpMRI) of the prostate is a useful tool for detecting and diagnosing clinically significant prostate cancer (csPCa).[1,2] The goals of integrating mpMRI are to avoid prostate biopsies in low-risk patients and detect csPCa, which would have otherwise been missed by a standard biopsy.[3] Previously, mpMRI has been shown to reduce the number of unnecessary biopsies by 27% to 29%, while detecting 30% to 38% more csPCa.[2–5]

Currently, using Prostate Imaging Reporting and Data System version 2 (PI-RADSv2), prostates are assigned scores of 1 to 5, corresponding to a specified risk of diagnosing csPCa on biopsy. Prostate Imaging Reporting and Data System version 2 scores have yet to be validated in an independent practice setting. There also remains uncertainty as to how urologists and their patients should proceed based on these scores. In addition, there is evidence that transition zone (TZ) lesions with the same PI-RADSv2 score are less predictive of csPCa than peripheral zone (PZ) lesions.[6,7]

Recent studies have reevaluated the utility of prostate-specific antigen density (PSA-D), in detecting csPCa, specifically in conjunction with PI-RADSv2 scores.[8,9] We also explore the utility of combining PSA-D, after correcting (doubling) for 5-alpha reductase inhibitor use, with PI-RADSv2 scores, creating the novel PDP score (PSA-D × PI-RADSv2) to risk stratify patients (Eq. 1). Because low PI-RADSv2 scores and low PSA-D have both been associated with lower risk of csPCa, we postulated that the product of the two would be useful to identify men who would be at low risk of finding csPCa on a fusion biopsy. In this study, we propose a clinical guide to help urologists and their patients interpret PI-RADSv2 scoring. The simplicity of this score allows for urologists to quickly calculate this in the office.

$$\text{PDP} = \text{PSA density} \times \text{PI–RADSv2} \qquad \text{Equation 1}$$

2. Materials and methods

2.1. Patient selection

After obtaining approval from an institutional review board (IRB no. 2020/06/17), we examined the records of 226 patients who

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underwent mpMRI of the prostate ordered between 2015 and 2017 and received PI-RADSv2 score of 1 or 2 to determine the likelihood of developing csPCa by August 27, 2020. We also established a retrospective database of 2035 patients who underwent mpMRI followed by fusion biopsy with either BioJet (DK Technologies, Barum, Germany) or DynaCAD/UroNav (Invivo, Gainesville, FL) devices at our institution from March 2015 to February 2020. Inclusion criteria for our study were as follows: (1) a solitary lesion with PIRADSv2 score ≥3 detected on mpMRI and (2) no prior diagnosis of prostate cancer. Patients with multiple lesions were excluded to help eliminate confounding variables. We identified 733 patients who met the initial criteria, of whom 432 men had a single PZ lesion and 301 men had a single TZ lesion. Twelve dedicated prostate MRI radiologists read the mpMRI scans using PI-RADSv2 scoring, with 2 radiologists cross-reading each scan.[10] Eleven urologists performed the fusion biopsies. For our analyses, we doubled the PSA for patients on 5-alpha reductase inhibitors at the time their PSA was drawn.[11] Clinically significant prostate cancer was defined as Gleason grade group ≥2 (Gleason ≥3 + 4). For each patient, we sampled a minimum of 12 separate regions and performed fusion biopsies on targeted regions. Prostate volume was measured by the radiologists using volumetric software for the mpMRI.

2.2. Statistical analysis

For patients undergoing fusion biopsies for PI-RADSv2 scores of 3, 4, and 5, we evaluated several demographic and clinical factors, including age, race, PSA, PSA-D, number of prior biopsies, gland size on MRI, MRI magnet used, and target lesion size. We used Welch unpaired *t* test for age, Mann-Whitney rank test for continuous variables, and Fisher exact test for ordinal variables to determine associations between patient factors and the detection of csPCa. We ran a multivariable logistics regression to estimate the adjusted odds ratio (OR) for age, lesion size, PI-RADSv2 score, PSA-D, and PDP. We generated a receiving operating characteristic (ROC) curve for our novel PDP score and used Youden index to determine an appropriate cut point. The overall yields for csPCa were calculated for PI-RADSv2 scores, PSA-D, and PDP and cross-tabulated. Statistical analysis was performed using R Statistical Software (version 4.0.2) (R Core Team, Vienna, Austria), and $p < 0.05$ was considered statistically significant.

3. Results

Of the 226 patients with PI-RADSv2 scores of 1 and 2 on MRIs ordered from 2015 to 2017, 21 received a score of 1. Two hundred five patients received a score of 2. The median clinical follow-up from MRI date was 35 months. For men with a PI-RADSv2 score of 1, 2 of 21 (10%) went on to develop csPCa as of August 27, 2020. For patients with a PI-RADSv2 score of 2, 15 of 205 (7%) developed csPCa over the same time frame. Eleven of the 17 patients with a PI-RADSv2 score of 1 or 2 who eventually were found to have prostate cancer had Gleason 3 + 4 disease. Only 1 patient of the 226 (0.4%) was found to have metastatic disease by August 27, 2020.

Seven hundred thirty-three men were included in the fusion biopsy portion of this study for solitary lesions with a PI-RADSv2 score of 3, 4, or 5. Thirty-eight percent (278/733) of these men were found to have csPCa. Forty-four percent (191/432) of men with solitary PZ lesions with a score of 3, 4, or 5 had csPCa. Twenty-nine percent (87/301) of men with solitary TZ lesions with a score of 3, 4, or 5 had csPCa. On multivariable analysis, lesion size was not a significant predictor of csPCa in any of the groups, and age was not a significant predictor for csPCa in the PZ or TZ (Table 1). Prostate-specific antigen density was a significant predictor of csPCa in all groups. Prostate Imaging Reporting and Data System version 2 score was a significant predictor of csPCa in the PZ but did not reach clinical significance in the TZ. A PSA-D level of 0.3 or greater, when compared with a PSA-D level of less than 0.15, was a strong predictor of csPCa, with an OR of 5.2 and 14.0 in PZ and TZ lesions, respectively. A PI-RADS score of 4, when compared with a PI-RADS score of 3, was a significant predictor of csPCa in PZ lesions (OR, 5.0), but not in TZ lesions (OR, 1.7). Similarly, a PI-RADS score of 5, when compared with a PI-RADS score of 3, was a significant predictor of csPCa in PZ lesions with an OR of 15.1.

For patients with a PI-RADSv2 score of 3, the yield was fairly low in both PZ (17%) and TZ (13%) lesions. Prostate Imaging Reporting and Data System version 2 scores performed well with PZ lesions scores of 4 and 5, predicting csPCa in 53% and 84%, respectively. The yield of csPCa on biopsy for PI-RADSv2 scores of 4 (31%) and 5 (51%) in the TZ was not as high when compared with the PZ. However, in these populations, combining PI-RADSv2 scores and PSA-D was predictive of csPCa. Prostate-specific antigen density was not found to be useful in substratifying the risk in patients with

Table 1

Multivariable adjusted odds ratio for PSA-D, PI-RADSv2 scores, lesion size, and age in predicting csPCa.

	All prostate	*p*	Peripheral zone	*p*	Transition zone	*p*
PSA-D, ng/dL per mL						
<0.15	1 (Ref)		1 (Ref)		1 (Ref)	
0.15–0.29	2.7 (1.8–3.9)	<0.0001	3.2 (2.0–5.3)	<0.0001	2.6 (1.3–5.3)	0.006
≥0.3	6.3 (3.9–10.3)	<0.0001	5.2 (2.6–10.4)	<0.0001	14.0 (6.3–31.1)	<0.0001
PI-RADSv2 score						
3	1 (Ref)		1 (Ref)		1 (Ref)	
4	3.7 (2.4–5.6)	<0.0001	5.0 (3.0–8.4)	<0.0001	1.7 (0.8–3.6)	0.19
5	6.7 (3.4–13.3)	<0.0001	15.1 (5.2–43.2)	<0.0001	2.6 (0.9–7.3)	0.08
Lesion size, cm						
<1.5	1 (Ref)		1 (Ref)		1 (Ref)	
≥1.5	1.1 (0.6–2)	0.86	1.3 (0.5–3.3)	0.53	1.2 (0.4–3.2)	0.76
Age, yr						
<67	1 (Ref)		1 (Ref)		1 (Ref)	
≥67	1.4 (1.0–2.0)	0.06	1.4 (0.9–2.3)	0.12	1.7 (0.9–3.1)	0.09

csPCa = clinically significant prostate cancer; PI-RADSv2 = Prostate Imaging Reporting and Data System version 2; PSA-D = prostate-specific antigen density.

Table 2

Yield of csPCa stratified by PI-RADSv2 score, PSA-D, and PDP in each fusion biopsy group.

	All prostate (n = 733)			Peripheral zone (n = 432)			Transition zone (n = 301)		
	PI-RADS 3	PI-RADS 4	PI-RADS 5	PI-RADS 3	PI-RADS 4	PI-RADS 5	PI-RADS 3	PIRADS 4	PI-RADS 5
PSA-D, ng/dL per mL									
<0.15	8% (15/192)	32% (48/152)	44% (17/39)	7% (8/113)	41% (41/99)	67% (14/21)	9% (7/79)	13% (7/53)	17% (3/18)
0.15–0.29	27% (20/75)	52% (51/99)	74% (40/54)	35% (14/40)	61% (39/64)	96% (26/27)	17% (6/35)	34% (12/35)	52% (14/27)
≥0.3	53% (10/19)	71% (39/55)	79% (38/48)	50% (7/14)	73% (24/33)	86% (18/21)	60% (3/5)	68% (15/22)	74% (20/27)
PDP									
<0.39	6% (9/160)	28% (21/76)	33% (3/9)	5% (5/93)	39% (19/49)	50% (3/6)	6% (4/67)	7% (2/27)	0% (0/3)
≥0.39	29% (36/126)	51% (117/230)	70% (92/132)	32% (24/74)	58% (85/147)	87% (55/63)	23% (12/52)	39% (32/83)	54% (37/69)

csPCa = clinically significant prostate cancer; PDP = PSA-D × PI-RADSv2; PI-RADSv2 = Prostate Imaging Reporting and Data System version 2; PSA-D = prostate-specific antigen density.

PZ lesion PI-RADSv2 scores of 4 and 5 because the risk of csPCa remained elevated even in patients with low PSA-D (Table 2).

Figure 1 demonstrates the difference in mean PDP scores for all prostate, PZ, and TZ lesions. Overall, for patients without csPCa, the mean PDP score was 0.58, whereas for those with csPCa, the mean PDP score was 1.3. For PZ lesions, the mean PDP score for patients without csPCa was 0.44, whereas for patients with csPCa, the mean PDP score was 1.2. Lastly, for TZ lesions, patients without csPCa had a mean PDP score of 0.62, whereas those with csPCa had a mean PDP score of 1.7. The means differed significantly ($p < 0.001$) between patients with and without csPCa for all patients regardless of the location of their lesion.

The area under the ROC curve for PDP in PZ lesions with a PI-RADSv2 score of 3 and TZ lesions with a score of 3, 4, or 5 is 0.81 (95% confidence interval [CI], 0.76–0.85; $p < 0.0001$, Fig. 2). Using the ROC curve, a cutoff of 0.39 was established for the PDP scores. Patients with a PDP score <0.39 were found to be without csPCa in 97% of men with PZ PI-RADSv2 scores of 3 and 94% of men with a TZ PI-RADSv2 score of 3, 4, or 5. After adjusting for age and lesion size, men with TZ lesions with PI-RADSv2 scores of 3, 4, and 5 and PDP scores ≥0.39 had an OR of 8.3 (95% CI, 3.6–19.1) for csPCa. For men with a PI-RADSv2 score of 3 in PZ lesions with a PDP score of ≥0.39, the adjusted OR for csPCa was 6.7 (95% CI, 2.6–17.6). If we look at these patients together (PZ PI-RADSv2 score of 3 and TZ scores of 3, 4, and 5), 188 patients with a PDP score of <0.39 would have avoided a biopsy. One hundred seventy-nine of 188 (95%) would have avoided a biopsy negative for csPCA. Nine of these 188 (5%) would have missed csPCa. Using this PDP cutoff, 38% (179/468) of patients with a PI-RADSv2 score of 3 in the PZ or 3, 4, or 5 in the TZ could have avoided a biopsy negative for csPCa.

4. Discussion/Conclusions

Prostate Imaging Reporting and Data System version 2 performed well at risk stratifying our patients for csPCa. Lesions with a PI-RADSv2 score 1 or 2 had a very low chance of developing csPCa. Conversely, patients with PZ lesions of PI-RADSv2 scores of 4 and 5 were likely to have csPCa on fusion biopsy and should be biopsied, regardless of PSA-D or PDP. Consistent with previous studies, our patients with a PI-RADSv2 score of 3 in the PZ and scores of 3, 4, and 5 in the TZ seem to be more difficult to counsel based on their PI-RADSv2 scores alone.[12,13] Our data show that the PDP score can be used in these populations to achieve the goal of limiting biopsies in low-risk patients. A PDP score ≥0.39 is a good predictor for csPCa in both PZ lesions with a PI-RADSv2 score of 3 (OR, 6.7) and TZ lesions with a PI-RADSv2 score of 3, 4, or 5 (OR, 8.3).

Based on our findings, our recommendation is to carefully follow-up patients with PI-RADSv2 scores of 1 and 2. Only 7.5% of our patients with a score of 1 or 2 were eventually diagnosed with csPCa,

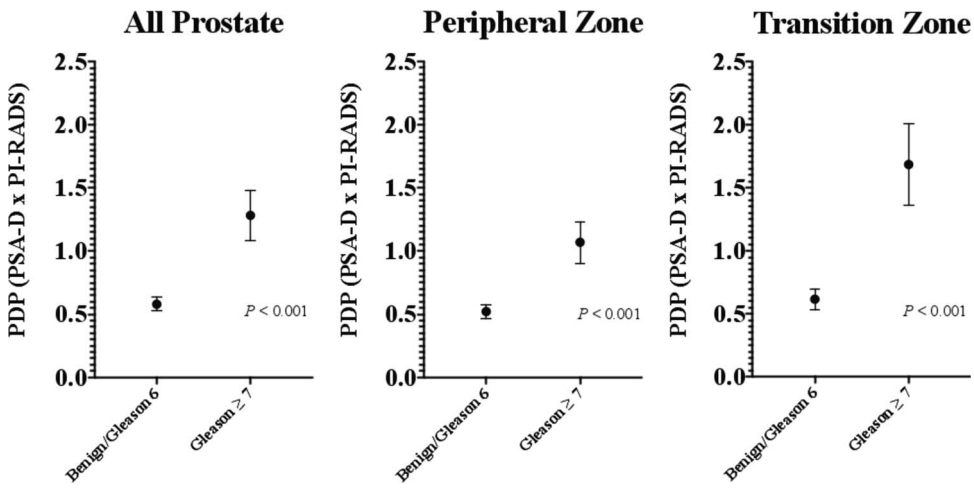

Figure 1. Comparison of PDP scores in patients with csPCA versus patients with no csPCA. csPCA = clinically significant prostate cancer; PDP = prostate-specific antigen density × PI-RADSv2; PSA-D = prostate-specific antigen density.

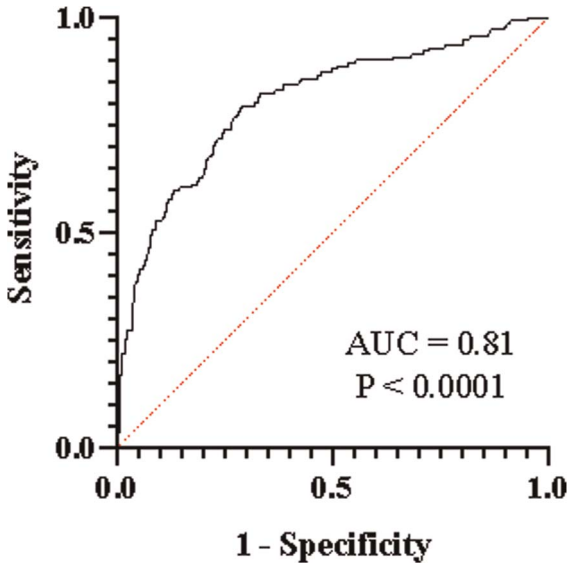

Figure 2. ROC curve for PDP in PZ lesions with PI-RADSv2 score= 3 and TZ = 3–5. AUC = area under the ROC curve; PDP = prostate-specific antigen density × PI-RADSv2; PI-RADSv2 = Prostate Imaging Reporting and Data System version 2; PZ = peripheral zone; ROC = receiving operating characteristic; TZ = transition zone.

with a median follow-up of 35 months. Most of these patients had very low volume of Gleason pattern 4 or 5, which mpMRI is not designed to detect. One patient (0.4%) developed metastatic disease over this time frame. We recommend fusion biopsy for all lesions with PI-RADSv2 scores of 4 (53% yield) and 5 (84% yield) in the PZ.

For PI-RADSv2 scores of 3 in PZ and 3, 4, or 5 in the TZ, we recommend further stratifying them with the PDP score. For patients with a PDP score of <0.39, we recommend close follow-up, whereas for patients with a PDP score of ≥0.39, we recommend fusion biopsy (Table 3). For close follow-up, we recommend a PSA 3 to 6 months after MRI and then every 6 months thereafter. Given that previous studies have shown that patients with known prostate cancer can delay surgery up to 6 months before adversely affecting the pathologic outcome, it is logical that it should be very safe to observe patients closely with low-risk mpMRI.[14,15] Using our system, an additional 24% (179/733) of patients with a PI-RADSv2 score of 3, 4, or 5 can safely avoid a biopsy. For the 9 patients with a csPCa and PDP score of <0.39, 1 patient ultimately had non-csPCa on prostatectomy, and the remaining 8 patients had Gleason 7 prostate cancer.

This study has numerous limitations. First, our retrospective analysis of PI-RADSv2 scores of 1 and 2 could potentially miss some cancers as they did not undergo immediate biopsy or could have ultimately been diagnosed outside our institution. Second, although we are an independent practice, we are a very high-volume center that uses dedicated, subspecialized high-volume radiology practices for our double-read mpMRI reports. Prostate Imaging Reporting and Data System version 2 scores are highly dependent on the quality of the MRI and the radiologists reading them, and as such, our results may not translate to centers with inexperienced radiologists. In addition, our cohort was overwhelmingly made of White men, and our results may not translate to other ethnicities. Only 3 men had a PDP score of <0.39 with a PI-RADSv2 TZ lesion score of 5. In addition, our results are not generalizable and need to be validated in other cohorts.

Despite these limitations, our study is very important to the field of prostate cancer detection for numerous reasons. Our results provide a "real-world" evaluation of the PI-RADSv2 scoring system outside of an academic center, making it widely applicable as 73% of US urologists practice outside of academic medical centers.[16] Our study confirms that PI-RADSv2 scores of 1 and 2 indicate a very low risk of having csPCa and can often be safely managed with close surveillance. Of note, these data are based on seeing how these patients performed on long-term follow-up and not only a single biopsy.

There is still some reluctance by the urologic community to adopt mpMRI because of fear of missing some cancer diagnoses. Multiparametric MRI has been shown in previous studies to outperform random 12-core biopsies in detection of csPCa and avoiding biopsies negative for csPCa.[2,3] However, in these studies, as with our own data, it is unavoidable that there are some men with csPCa who may have been detected with a 12-core biopsy and were missed by having a low-risk mpMRI. Nonetheless, mpMRI has been consistently shown to be superior at detecting csPCa and avoiding unnecessary biopsies. The vast majority of our missed patients have a very small volume of Gleason pattern 4 or 5, which we would argue mpMRI is not designed to detect at such small volumes. With our study, we showed that only 1 patient with PI-RADSv2 scores of 1 and 2 ultimately went on to develop metastasis. Twelve-core biopsies miss numerous cancers that upfront mpMRI would have been able to detect.[2,3] An upfront MRI should be the standard of care for the evaluation of patients with an elevated PSA or prostate nodule.

Any man being evaluated by a urologist for an elevated PSA or prostate nodule should be offered a prostate biopsy, regardless of PI-RADSv2 or PDP score; however, this should be an informed and shared decision based on his individual risk. A useful explanation to a patient with a PI-RADSv2 score of 1 or 2 is his chance of being diagnosed with csPCa (and metastasis) in the next few years. Ultimately, it needs to be the patient's choice to decide whether to proceed with a random 12-core biopsy for their MRI with a PI-RADSv2 score of 1 or 2. For patients with a PI-RADSv2 score of 3, 4, and 5, explaining their chance of csPCa on a biopsy is also helpful in this shared decision-making process. We would argue that discussion of how to proceed based on a man's mpMRI results is really the

Table 3

Risk stratification for csPCa based on PI-RIADSv2 score.

	All prostate	Peripheral zone	Transition zone
1	10% (close surveillance)	-	-
2	7% (close surveillance)	-	-
3		17% (calculate PDP) PDP <0.39: 5% (close surveillance) PDP ≥0.39: 32% (biopsy)	13% (calculate PDP) PDP <0.39: 6% (close surveillance) PDP ≥0.39: 23% (biopsy)
4		53% (biopsy)	31% (calculate PDP) PDP <0.39: 7% (close surveillance) PDP ≥0.39: 39% (biopsy)
5		84% (biopsy)	51% (calculate PDP) PDP <0.39: 0% (close surveillance) PDP ≥0.39: 54% (biopsy)

csPCa = clinically significant prostate cancer; PDP = PSA density × PI-RADSv2 score (double the PSA if the patient is on a 5-alpha reductase inhibitor); PI-RADSv2 = Prostate Imaging Reporting and Data System version 2; PSA-D = prostate-specific antigen density.
For PI-RADS 1 and 2, the percentage chance of being diagnosed with csPCa within 35 months. For PI-RADS 3–5, the percentage chance of detecting csPCa on fusion biopsy. Authors' recommendations are outlined in the parentheses.

most appropriate place for shared decision-making in the screening process for prostate cancer. The broad categories of PI-RADSv2 have served their purpose for the initial integration of mpMRI; however, it is now time to further define these risks for our individual patients.

In men with a PI-RADSv2 score of 1 or 2, close surveillance is recommended. We recommend fusion biopsy to men with a PI-RADSv2 score of 4 or 5 in the PZ. We recommend using the PDP score to further risk stratify men with a PI-RADSv2 score of 3, 4, or 5 in the TZ and 3 in the PZ to determine who should be recommended fusion biopsy versus close surveillance.

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Statement of ethics

This study was approved by the institutional review board (No. 2020/06/17). Only de-identified data were used by anyone other than Kansas City Urology Care employees and only de-identified data are published. The IRB deemed this to be minimal risk and granted a waiver of individualized informed consent. All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Conflict of interest statement

No conflict of interest has been declared by the authors.

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Author contributions

PUP: Research design, writing of paper, performance of research, data analysis;
DB: Research design, data analysis;
CAH: Participated in research design, writing of paper, data analysis, overseeing the project and its design.

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