# Comparison of the Diagnostic Performance of PI-RADS V1 and PI-RADS V2 for the Detection of Prostate Cancer: A Meta-Analysis

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**Purpose:** In order to comprehensively determine the diagnostic accuracy of the Prostate Imaging Reporting and Data System version 1 (PI-RADS V1) and PI-RADS version 2 (PI-RADS V2) in prostate cancer (PCa) diagnosis.

**Materials and Methods:** The literatures were screened from the databases, including the Pubmed, Embase, Web of science and Cochrane Library up to January 20th, 2020. The meta-analysis was conducted by Meta-DiSc and quality assessment was performed by using the QUADAS. Furthermore, the sensitivity, specificity, likelihood ratio (LR), diagnostic odds ratio (DOR), as well as receiver operating curve (ROC) related to diagnostic accuracy were pooled.

**Results:** A total of 6 articles containing 814 participants (379 patients) were included in the study. For PI-RADS V1, the combined sensitivity, specificity, PLR, NLR and DOR were 0.82 (95% CI: 0.77-0.85), 0.81 (95% CI: 0.77-0.85), 4.58 (95% CI: 2.55-8.22), 0.24 (95% CI: 0.18-0.34) and 24.00 (95% CI: 10.38-55.51). With regard to PI-RADS V2, the combined sensitivity, specificity, PLR, NLR and DOR were 0.88 (95% CI: 0.84-0.91), 0.81 (95% CI: 0.77-0.84), 4.34 (95% CI: 1.98-9.49), 0.16 (95% CI: 0.08-0.32) and 33.39 (95% CI: 15.05-74.05), respectively. Furthermore, except that the sensitivity of PI-RADS V2 was significantly greater than that of PI-RADS V1 ($P$ = 0.027), there was no remarkably difference in other indicators for the diagnosis of PCa between the two versions.

**Conclusion:** Both PI-RADS V1 and PI-RADS V2 showed good diagnostic performance for PCa diagnosis; moreover, there was no difference in the diagnostic effect between them.

**Keywords:** PI-RADS V1; PI-RADS V2; Prostate cancer; Multiparametric MRI

## INTRODUCTION

Prostate cancer (PCa), accounting for 20% of all cancers diagnosed, has been the second most common cancer with more than 1.1 million new cancer cases annually[1,2]. Usually, due to the some symptoms of PCa with similar to those of other diseases, such as prostatitis, benign prostatic hyperplasia, cystitis and urinary tract infection, the rate of the early detection and resection rate of PCa is only approximately 10–20% [3]. Currently, method for PCa detection includes prostate-specific antigen test, digital rectal examination (DRE), and biopsies. Specifically, the elevated serum prostate-specific antigen (PSA) level is the most frequently used biomarker for PCa detection [4], but it has been criticized because of the lack of specificity diagnostic accuracy [5,6].

Multi-parametric magnetic resonance imaging (Mp-MRI), including anatomic T2-weighted imaging (T2W) with functional diffusion-weighted imaging (DWI) and dynamic contrast-enhanced (DCE), is characterized by noninvasive, multi-parameter, high soft tissue resolution, as well as the high subject tolerance. Hence, it has been widely used in clinical localization, qualitative and staging diagnosis, as well as risk and prognosis evaluation of PCa [7-9]. Mp-MRI can provide the better diagnostic accuracy in the detection of PCa, and accordingly, the standardized reporting system for it has been published. In 2012, the first version (V1) of the Prostate Imaging Reporting and Data System (PI-RADS) was published by the European Society of Urogenital Radiology (ESUR)[10]. Generally, PI-RADS V1 scores showed high diagnostic accuracy for PCa diagnosis [11,12]; however, the clear instructions on how to integrate the overall score were lacking. Hence, the updated PI-RADS version 2 (V2) was established by the American College of Radiology, which has improved some of the

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**Table 1.** Characteristics of the included literatures.

| Author | Public Year | Country | Study year | Gold standard | N/n* | Prostate zone (PZ/TZ) | Control characteristics | Age (years) | Group | TP | FP | FNTN | TN |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Auer T | 2016 | Austria | NA | Histo-pathological | 103/32 | 89/14 | BPH | 63.0 ± 8.0 | PI-RADS v1 | 84 | 1 | 19 | 31 |
| | | | | | | | | | PI-RADS v2 | 82 | 4 | 21 | 28 |
| Feng ZY | 2016 | China | 2013.6-2015.7 | Radiography | 150/251 | 95/55 | Non-PCa | 64.4(34-88) | PI-RADS v1 | 127 | 48 | 23 | 203 |
| | | | | | | | | | PI-RADS v2 | 144 | 40 | 6 | 211 |
| Kasel-seibert M | 2016 | Germany | 2013.7-2015.3 | Histo-pathological | 31/51 | NA | Benign | 65(48-81) | PI-RADS v1 | 22 | 17 | 9 | 34 |
| | | | | | | | | | PI-RADS v2 | 24 | 10 | 7 | 41 |
| Polanec S | 2016 | Austria | 2011.6-2015.9 | Radio-graphy,Histopathological | 33/32 | 25/8 | Benign | 65.3 (62.3-87.4) | PI-RADS v1 | 31 | 21 | 2 | 11 |
| | | | | | | | | | PI-RADS v2 | 32 | 12 | 1 | 20 |
| Tewes S | 2016 | Germany | 2012.12-2014.12 | Histo-pathological | 31/23 | 26/5 | Non-PCa | 69.6 ± 9.6 | PI-RADS v1 | 24 | 2 | 7 | 21 |
| | | | | | | | | | PI-RADS v2 | 28 | 4 | 3 | 19 |
| Wang XM | 2018 | China | 2015.9-2016.7 | Histo-pathological | 31/46 | 0/31 | BPH | 72.3±7.5 | PI-RADS v1 | 21 | 2 | 10 | 44 |
| | | | | | | | | | PI-RADS v2 | 23 | 3 | 8 | 41 |

*: Prostate cancer/ Control; TP: true positives; TN: true negatives; FP: false positives; FN: false negatives; QUADAS: quality assessment tool of diagnostic accuracy studies; PI-RADS: prostate imaging reporting and data system; PZ, peripheral zone; TZ, transition zone; NA: not available; BPH: benign prostatic hyperplasia.

limitations of PI-RADS V1. Due to the differences between PI-RADS V1 and PI-RADS v2 scoring methods, many literatures have studied the diagnostic efficacy of the two methods in PCa, but the results are not completely consistent[13-15]. Hence, the aim of the present study was to comprehensively analyze the diagnostic value of PI-RADS V1 and PI-RADS V2 in PCa detection by using a meta-analysis, which will provide a basis for PCa screening.

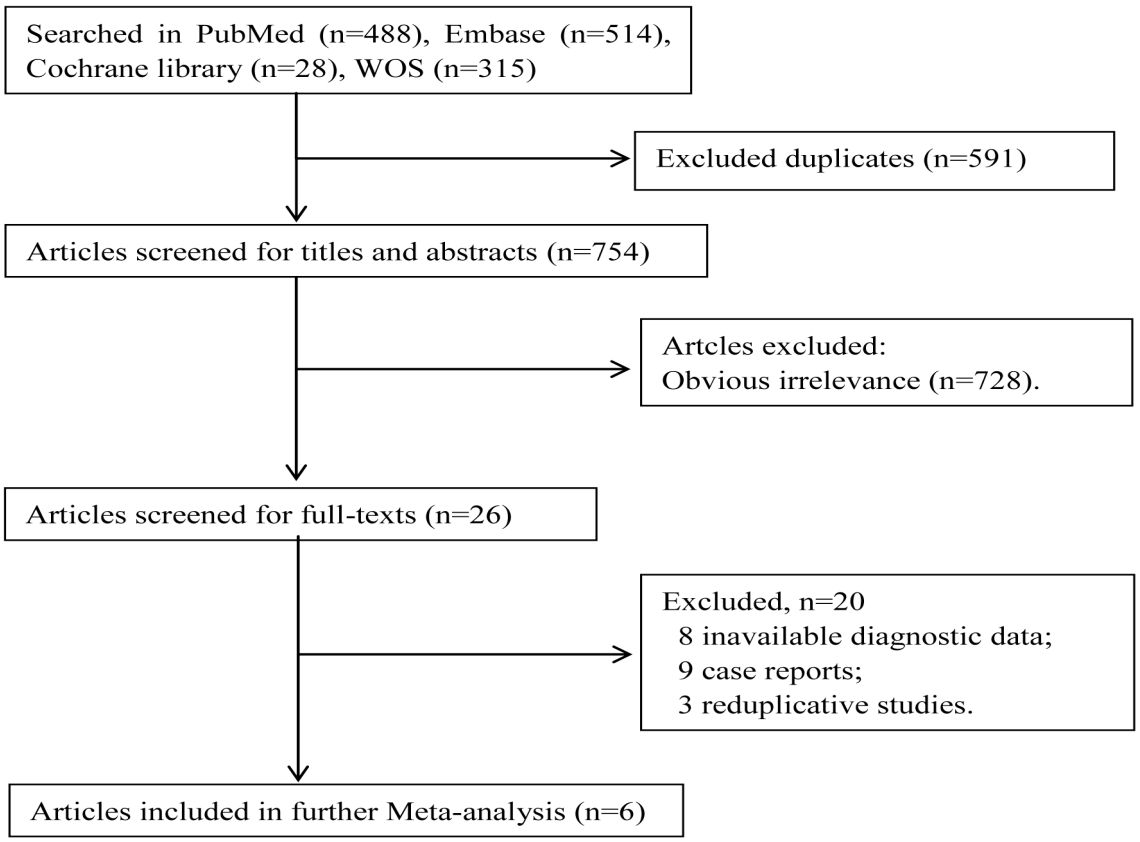


**Figure1.** Flow diagram of the articles included in this systematic review.

**Table 2.** Results of diagnostic analysis.

| Indicators | PI-RADS V1(95%CI) | PI-RADS V2(95%CI) | Z | *P* |
|---|---|---|---|---|
| Sensitivity | 0.82(0.77-0.85) | 0.88(0.84-0.91) | 2.321 | 0.027 |
| Specificity | 0.81(0.77-0.85) | 0.81(0.77-0.84) | 0.074 | 0.941 |
| PLR | 4.58(2.55-18.22) | 4.34(1.98-9.49) | 0.100 | 0.920 |
| NLR | 0.24(0.18-0.34) | 0.16(0.08-0.32) | 1.087 | 0.277 |
| DOR | 24.00(10.38-55.51) | 33.39(15.05-74.05) | 0.496 | 0.620 |

## MATERIALS AND METHODS

### *Literature search*

The literature searches were conducted on the basis of the databases, including Pubmed (http://www.ncbi.nlm.nih.gov/pubmed), Embase (http://www.embase.com), Web of science (http://webofknowledge.com) and Cochrane Library (http://www.cochranelibrary.com/) up to January 20th, 2020. The keywords were as follows: ("prostate cancer" OR "prostatic carcinoma" OR "carcinoma of prostate" OR (Prostatic Neoplasms)) AND ("prostate imaging reporting and data system" OR "PI-RADS V1" OR "PI-RADS V2") AND (Diagnostic OR diagnose OR sensitivity OR specificity). The language was restricted to English.

Inclusion and exclusion criteria

Inclusion criteria was as follows: 1) patients with PCa (P); 2) English literature published on PI-RADS V2; 3) PI-RADS V1 diagnostic effect in patients with PCa; 4) can provide true positive number, false positive number, false negative number and true negative number of participants; 5) diagnostic test for the diagnostic value of PCa.

Exclusion criteria was as following: 1) the study with incomplete data that cannot be used for statistical analysis; 2) review, letters, and other non-treatises of literature. In addition, for the literature with repeated publication or the same population data used in multiple studies, only the latest study or the one with the most complete information was included.

### *Data extraction and quality assessment*

All data from included studies was retrieved by two independent researchers: first author, year of publication, study year, country, the gold standard in the diagnosis of PCa, age composition of included participants, the number of true positive (TP), false positive (FP), true negative (TN), and false negative (FN) results for either PI-RADS V1 and PI-RADS V2 analysis.

Quality assessment of the included studies was performed by using the quality assessment of diagnostic accuracy studies tool (QUADAS)[16]. 11 items were evaluated according to the three criteria of "yes" (meeting this standard), "no" (not meeting or not being mentioned), and "unclear" (partly meeting or not getting enough information from the literature). Specifically, once there was a difference of opinion in the process of literature data extraction and quality evaluation, a consensus will be reached after a group discussion with the third researcher.

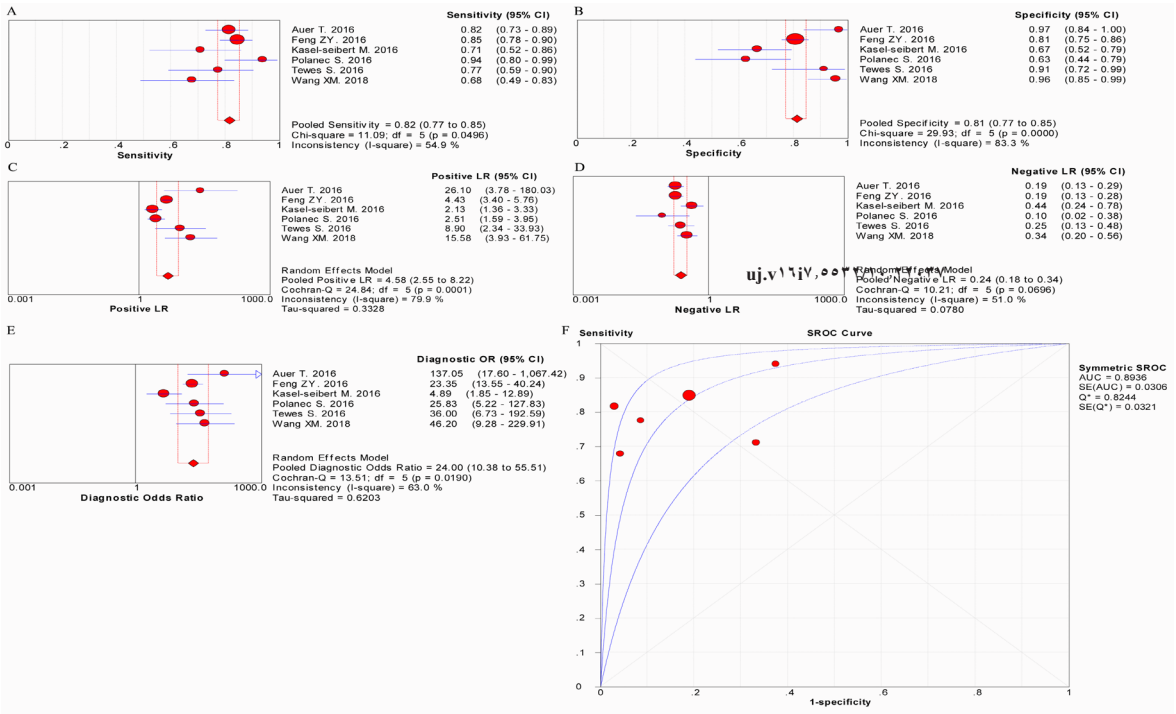


**Figure 2.** The pooled sensitivity (A) and specificity (B), PLR (C), NLR (D), DOR (E), and SROC (F) estimates for PI-RADS V1 detection of PCa patients.

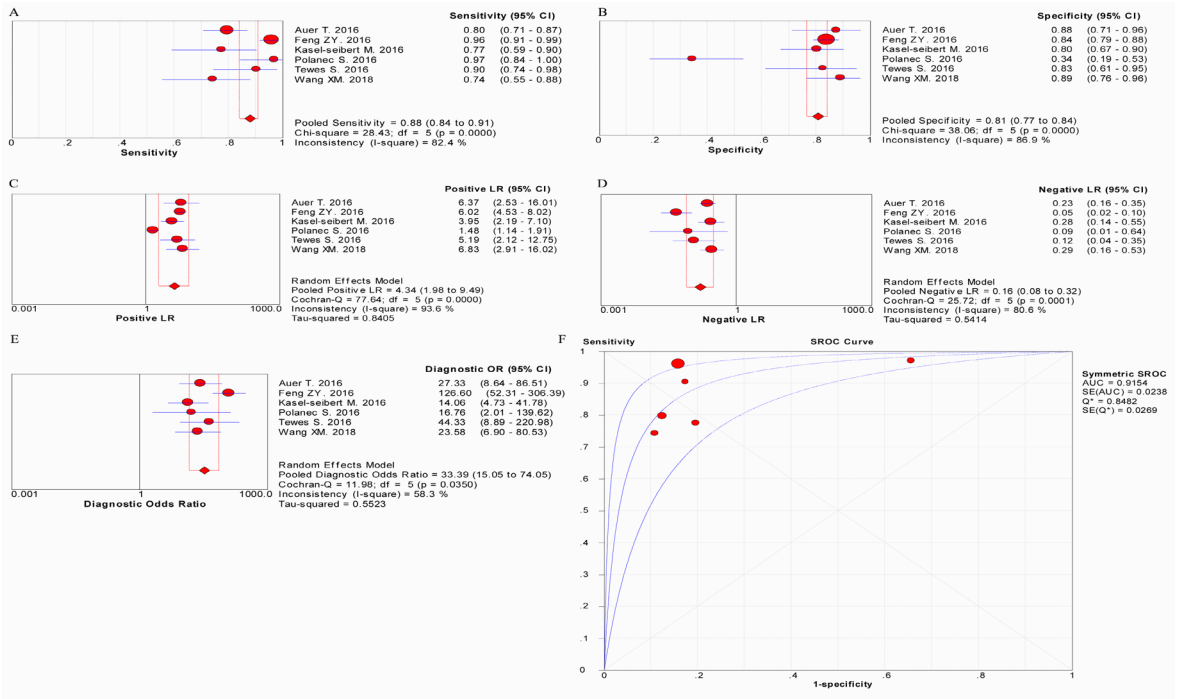


**Figure 3.** The pooled sensitivity **(A)** and specificity **(B)**, PLR **(C)**, NLR **(D)**, DOR **(E)**, and SROC **(F)** estimates for PI-RADS V2 detection of PCa patients.

### *Statistical analysis*

Meta-analysis was conducted with Meta-DiSc (version 1.4), and the effect indicators, including sensitivity, specificity, positive likelihood ratio (PLR), negative likelihood ratio (NLR), and diagnostic odds ratio (DOR). The threshold effect was evaluated by the spearman correlation coefficient of the sensitivity logarithm and the (1-specificity) logarithm. And the heterogeneity was determined based on the Cochran's Q test and the $I^2$ index[17]: If significant heterogeneity was detected ($P < 0.05$, $I^2 > 50\%$), the combined effect value was calculated by the random effect model (dersimonian-laird); otherwise, fixed-effect model was used (mantel-haenszel) (18). The differences between PI-RADS V1 and V2 in diagnostic indicators were determined with Z test, and the publication bias of Egger's test was conducted by using Stata software.

## RESULTS

### *Characteristics of the included literatures*

According to the flow diagram for literature selection (**Figure 1**), a total of 652 studies were preliminarily screened from Pubmed (n = 323), Embase (n=307) and Cochrane Library (n=22), including 234 duplicated articles. After title and abstract screen, 345 unrelated researches were excluded. Next, through the full text reading, finally 6 articles with 814 participants (379 patients) were included in the study (13,14,19-22). As illustrated in **Table 1**, the characteristics of 6 studies were summarized. The data showed that all included articles were published between 2016 and 2018, and the location included the Australia, China and Germany. Additionally, the basic characteristics of demography revealed average age of all participants was 63-72, among which the elderly were the majority. Furthermore, PI-RADS V1 $\geq$ 10 or $\geq$ 4 and PI-RADS V2 $\geq$ 4 or $\geq$ 3 had been regarded as the cut-off values in the diagnosis of PCa.

As shown in Supplementary table 1, the quality of included articles was evaluated according to 11 items of QUADAS. The results showed that the bias of the included studies was small, indicating that the methodological quality was high.

The combination of quantitative data

. Spearman correlation coefficient for V1 and V2 were 0.429 ($P = 0.397$) and 0.600 ($P = 0.428$), respectively, indicating there was no threshold effect and other statistics should be combined. The results with random effects model (DerSimonian-Laird) revealed that the combined sensitivity was 0.82 (95% CI: 0.773-0.853), specificity was 0.81 (95% CI: 0.77-0.85), PLR was 4.58 (95% CI: 2.55-8.22), NLR was 0.24 (95% CI: 0.18-0.34) and DOR was 24.00 (95%CI: 10.38-55.51) for PI-RADS V1 (**Figure 2A-2E**). Similarly, based on the random effects model, the combined sensitivity, specificity, PLR, NLR and DOR for PI-RADS V2 were 0.88 (95% CI: 0.84-0.91), 0.81(95% CI: 0.77-0.84), 4.34 (95% CI: 1.98-9.49), 0.16 (95% CI: 0.08-0.32) and 33.39 (95%CI: 15.05-74.05) (Figure 3A-3E), respectively.

The SROC curve was symmetric and random effect model (DerSimonian-Laird) was adopted. The area under curves of SROC for V1 and V2 were 0.8938 (Q = 0.8244) and 0.9154 (Q = 0.8482) (**Figure 2F and Figure 3F**). After the Z test, the data revealed that there was no statistical difference between PI-RADS V1 and V2 in the diagnosis of PCa (AUC, $Z = 0.557$, $P = 0.577$).Q, $Z = 0.568$, $P = 0.570$). Taken together, sensitivity of PI-RADS V2 for the detection of PCa was obviously higher than that of PI-RADS V1 ($Z = 2.213$, $P = 0.027$; **Table 2**), suggesting the diagnostic effect of PI-RADS V2 was superior to V1. However, the dif-

ference of specificity, PLR, NLR or DOR between PI-RADS V1 and V2 was not significant, respectively (all, $P > 0.05$).

### *Publication bias*

The Egger's test indicated that there was no publication bias in the diagnosis of PCa in PI-RADS V1 and V2 (t = 0.22, $P = 0.823$; t = 0.85, $P = 0.428$), which proves that our results are reliable.

## DISCUSSION

In the present study, we for the first time compared the diagnostic performance of mpMRI with PI-RADS V1 and V2 in the PCa detection. The results of meta-analysis demonstrated that both PI-RADS V1 and V2 both presented high diagnostic value. Furthermore, in addition to the fact that PI-RADS V2 was more sensitive than V1, there was no difference in the other indicators between the two versions. Therefore, in general, there was no difference in the diagnostic effect between the two versions. Till now, although several studies have been reported to conduct the meta-analyses of PI-RADS, the difference of diagnostic effect between PI-RADS V1 and V2 has not been reported till now. For example, Maggi[23] and Zhai[24] et al only separately investigate the diagnostic performance of PI-RADS 3; moreover, Barkovich et al[25] only quantitatively and qualitatively assesses the methodologic heterogeneity of the PI-RADSv2 literature and estimate the proportions of Gleason scores (GSs) diagnosed across PI-RADSv2 categories.

Because of the high diagnostic accuracy for PCa detection and reproducible interpretation, mpMRI has been widely used by urologists. Hence, comprehensible and clearly defined criteria for standardized analysis of MRI for PCa should be urgent. As the initial version, PI-RADS V1 has been reported to have a good inter-observer agreement and high diagnostic accuracy (26,27). Compared with the sequence of T2-WI, DWI, and DCE in PI-RADS V1 was considered to have equal discriminatory power, PI-RADS V2 introduces the concept of "dominant sequence", which believes that DWI is the key sequence of PZ and T2-WI is the dominant sequence in TZ (28,29). And if there is no evidence of invasive behavior, the main difference between a finding with a score of 4 and that with a score of 5 on T2-W and DWI is a diameter less than 1.5 cm or equal /greater than 1.5 cm[30,31]. In recent years, numerous studies have validated the value of PI-RADS V2 but, as expected, have also identified a number of ambiguities and limitations, some of which have been documented in the literature with potential solutions offered[32]. It has been reported PI-RADS V2 in clinical practice retains higher accuracy over systematic TRUS biopsies for PCa diagnosis[33]. Till now, a series of studies have reported some key differences between PI-RADS V1 and V2, but the comparisons between the two versions have been controversial. For instance, Thomas et al[13] revealed that PI-RADS V1 showed a significantly larger discriminative ability for the detection of PCa, due to the more false negative results in PI-RADS v2. Inversely, Moritz[14] has demonstrated PI-RADS V2 could be a reliable reporting system for PCa assessment. And Hoffmann et al[34] reports PI-RADS V2 is reproducible between radiologists but does not have improved accuracy for diagnosing anterior tumors of the prostate when compared to PI-RADS V1. In the present study, the results of a comprehensive comparison with meta-analysis suggested that there was no statistical difference between PI-RADS V1 and V2 in the diagnosis of PCa.

Furthermore, the sensitivity of PI-RADS V2 for PCa diagnosis in our study was significantly higher than that of PI-RADS V1, but there was no significant difference in specificity, PLR, NLR and DOR between PI-RADS V1 and PI-RADS V2. Actually, the summed PI-RADS V2 outperformed V1 in the assessments of PCa has been understood as a consequence of cancer location. Briefly, PI-RADS V2 has been reported to be the preferable method to evaluate the transitional zone (TZ) due to a higher sensitivity, whereas PI-RADS V1 performed better in (peripheral zone) PZ[35]. Hence, in the process of mpMRI, the versions of PI-RADS should be selected based on the tumor site.

Usually, the inter-reader agreement has been regarded as one of the most important limitations in the use of mpRMI. A previous study reports that the low inter-user agreement of mpMRI may reduce the overall applicability of this methodology in all centers[36]. In the present study, the results of the inter-reader agreement analysis (**Supplementary table 2**) showed that inter-reader agreement of PI-RADS V2 and PI-RADS V1 were different in the included studies. In fact, based on the the heterogeneity of the sensitivity or specificity the included literature, we can also find that the diagnostic accuracy of PI-RADS V2 and PI-RADS V1 varies in different studies.

Heterogeneity has been regarded as a critical element in meta-analysis[37]. In this study, we discussed the diagnostic value of PI-RADS V1 and V2 in PCa detection, and significant heterogeneity was detected among the overall pooled analyses mainly due to the following aspects: 1) differences in race, country and region; 2) differences in living habits, cultural exchanges and living environment; 3) differences caused by age, sample size and other factors. Furthermore, there were no significant publication bias between the included studies, which suggested that the data of our meta-analysis are reliable. However, this study still had limitations; for example, due to the relatively small number of literatures and incomplete stratification information, the study was unable to obtain the source of its heterogeneity.

## CONCLUSIONS

In summary, the results with meta-analysis showed the differences of diagnostic accuracy of PI-RADS V1 and V2 were not significant for detection of PCa. However, to further verify the results, a larger cohort from multi-center institutions are still needed.

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## CONFLICT OF INTEREST

The authors declare that they have no competing interests.

## Appendix:

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