Assessing the Role of Bi- and Multi-Parametric MRI in Prostate Cancer-A Regional Study

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Abstract: Prostate MRI is a key diagnostic tool for prostate cancer (PCa), with current guidelines recommending multiparametric MRI (mpMRI), which includes T2-weighted (T2W), diffusion-weighted (DWI), and dynamic contrast-enhanced (DCE) imaging. However, biparametric MRI (bpMRI), which omits DCE, is suggested to reduce scan time, cost, and potential contrast-related side effects. Limited research exists comparing bpMRI's efficacy against mpMRI for detecting clinically significant prostate cancer (CsPCa) using the Prostate Imaging and Reporting Data System (PI-RADS v2.1).To compare the diagnostic performance of bpMRI and mpMRI for prostatic carcinoma and CsPCa detection. This study retrospectively evaluated 115 males over 40 years with elevated prostate-specific antigen (PSA) levels (≥15 ng/ml) who underwent mpMRI and had histopathological results. Two radiologists independently assessed suspected PCa lesions, assigning PI-RADS categories for bpMRI (report one) and mpMRI (report two). The reference standard was histopathological biopsy with Gleason scoring. Among 101 patients with suspected PCa, CsPCa was diagnosed in 45 cases using mpMRI, 39 with bpMRI, and 14 with DCE alone. The PI-RADS grading system showed strong agreement (kappa = 0.82) for bpMRI and near-perfect agreement (kappa = 0.912) for mpMRI. Sensitivity was slightly higher for mpMRI (98.4%) than bpMRI (96.7%) with (P < 0.001), while bpMRI demonstrated higher specificity (75.8% vs. 66.8%, P < 0.001) the detection rates of CsPCa for bpMRI and mpMRI were 51.50% and 53.40% respectively. The study concludes that bpMRI is non-inferior to mpMRI in CsPCa detection, making it a viable alternative while DCE remains valuable for PCa lesion detection.

Keywords: Bi- Parametric, Multi-Parametric, MRI, Prostate Cancer-A, Regional Study.

INTRODUCTION

Among male cancers, prostate cancer (PCa) is one of the most prevalent worldwide [1]. It is the fourth leading cause of cancer-related deaths and the second most frequent cancer, after lung cancer [2]. Based on predictions from the International Agency for Research on Cancer for 2022, these numbers are taken from the most recent edition of the American Cancer Society's (ACS) Global Cancer Facts & Figures, fifth edition [3]. Active PCa screening, as well as accurate local staging, are crucial for a good prognosis in prostate cancer patients. Prostate MRI is a well-established diagnostic technique for males with increased PSA and probable PCa [4]. While previous research suggests a bi-parametric MRI (bpMRI) strategy, recommendations support the use of multi-parametric MRI (mpMRI) [5]. Prostate mpMRI is increasingly being utilized to guide prostate cancer treatment [6]. This increased interest in mpMRI has resulted in considerable differences image capture. interpretation, and pre-biopsy image processing, which

The mpMRI has been utilized for tumor detection, local-regional staging (in terms of T- and N-stages), follow-up, active surveillance, and therapeutic response evaluation. The [American Urological Association] and [European Urological Association] advocate mpMRI in patients at high risk for PCa (e.g., family history and race), people with higher PSA with or without a negative biopsy or suspicious digital rectal exam, and patients with biopsy-confirmed PCa [9,10]. However, multiple investigations have found that DCE imaging provides no further benefit for PCa detection [11]. Many identified several possible benefits of performing prostate MRI without DCE, also known as biparametric MRI (bpMRI), including the absence of gadolinium toxicity, a reduction in examination time and expenses, and improved accessibility [12]. Before

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can impede patient care. The mpMRI is characterized as a combination of anatomical and functional imaging techniques that incorporate the acquisition of sequences following gadolinium-based injections. In other terms, it consists of three sequences: T2-weighted (T2W), diffusion-weighted (DWI), and dynamic contrast-enhanced (DCE) [7, 8]

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biopsy mpMRI and bpMRI head to head comparisons in previously published literature reviews & metaanalyses have yielded variable results [13]. The main indications for DCE in the Prostate Imaging Reporting and Data System [PI-RADS v2.1.] are pooled studies for patients with all PI-RADS lesions ranging from category 1 to 5. However, these reviews did not clearly provide insight into individual pooled PI-RADS ≥ 3 lesions, clinically significant prostate cancer (CsPCa) patients, scan quality, or reader experience.

[PI-RADS v2.1.] Defines clinically significant PCa as: Gleason score ≥ 7 – including 3+4 with notable but not predominant Gleason 4 component, tumor volume >0.5cc, and/or extra-prostatic extension. Whereas pathologists grade prostate tumors using the Gleason score [14]. Comparing the diagnostic performance of bpMRI and mpMRI in identifying CsPCa using the [PIv2.1.] scoring system and comparing RADS radiological staging for bpMRI and mpMRI using pathological biopsies as the reference standard of diagnosis were the objectives of this study. This review will discuss the different imaging methods used to diagnose prostate cancer, focusing on the benefits of biparametric MRI (bpMRI) compared to multiparametric MRI (mpMRI), and how contrast-enhanced imaging (DCE) is used according to the PI-RADS v2.1 scoring system. As a result the study will discuss our findings and compare them to as many studies as possible that shed similar light on the significance of this topic.

PATIENTS AND METHODS

Study design and settings: The research was carried out from March to November 2024 at Future medical imaging series, Baghdad, Iraq. 115 patients with PSA levels greater than 15 ng/ml who had never had a prostate biopsy participated in the study. The entire mpMRI method was used on the participants. When radiologists first reported the MRI, they only used the bpMRI (T2W and DWI) sequences because they were blind to the DCE. After that, they were unblinded to the DCE sequence and used the T2W, DWI, and DCE mpMRI sequences to re-report the MRI. Men had prostate biopsies if they had worrisome lesions on their mpMRI or bpMRI. The procedures that each subject went through are shown in Figure 1.

Ethical consideration: The study complied with the guidelines set by Research Ethics Committee at the Iragi National Cancer Research Center, approval number EDR314, issued on March 2nd, 2024.

Inclusion criteria: men without a history of prostate MRI or biopsy who are above the age of 40 and have an elevated PSA (more than 15 ng/ml) were included in the study.

Exclusion criteria: Conditions for exclusion included being under the age of 40, refusing to participate, using prostate treatment, being unfit for a prostate biopsy due to Heart Failure or irregularly treated coagulopathy,

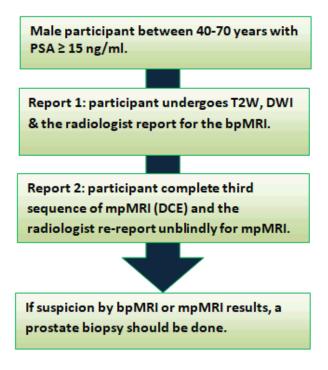


Figure 1: Flow chart of the study.

having a current or previous diagnosis of further malignancies, having a prior prostate biopsy or PCa, and having any contraindication for an MRI (e.g., some types of pacemakers).

Data collection: the study was based on including as many individuals as feasible who met the inclusion and exclusion criteria; the data was gathered over a period of seven months. Age, PSA, smoking history, past medical history, current and previous treatments, family history of PCa, and any chronic condition were among the demographic and clinical characteristics included in the data. The study gathered results of diagnostic tools (bpMRI, mpMRI), sample size, and characteristics (whole patient count, PCa patient count, CsPCa patient count, and PI-RADS score ranging from 1 to 5) from medical records and individual patient inquiries.

MRI interpretation and conduct: The study emphasizes the primary distinction between bpMRI and mpMRI as well as the role of DCE, particularly in PI-RADS ≥ 3 and CsPCa's lesions. The Prostate Imaging Quality [PI-QUAL] score method [15] was used to eliminate any scans with low quality, and the trial was conducted by highly qualified radiologists with good expertise reporting prostate MRIs. The radiologist first reported on DCE blindly after interpreting the T2WI and DWI sequences. To aid in the pooling of data regarding CsPCa patients, the report was tagged with suspicious areas and scored using the PI-RADS V.2.1 system, in addition to the Gleason score of 3+4. Once the DCE was reviewed, no changes could be made to report 1 (bpMRI). The radiologist then assessed the DCE imaging and wrote a second report that included all three sequences (T2WI, DWI, and DCE). The same radiologist was required to complete both reports 1 and

A 1.5 Tesla Siemens magneto Espree fitted with a 6-channel phased array body coil was utilized for all MRI diagnostics. The device comes with the TIM technology (Total Imaging Matrix) to facilitate high quality imaging & diminish the examination times. T2WI, DWI, and DCE examinations were among them. Data collection for DCE started concurrently with the initiation of an intravenous gadolinium-based contrast medium infusion at a rate of 1.5 ml/s (0.1 mmol/kg of body weight) and a 30 ml saline flush at the same rate as the contrast medium injection. Also, there was recognition of the T2WI, DWI, and DCE score for [PIRADSv2.1] evaluation categories. For the radiologists, who knew the patient's age but were blind

to the PSA level and histology findings, the MRI images of the lesions for every sequence had been prepared for assessment. First, T2WI and DWI images were evaluated independently by each radiologist. Each lesion was given a score between 1 and 5 for T2WI and 1 to 5 for DWI while being blinded to DCE images. Each tumor was then examined by DCE & a positive or negative DCE-MRI score was determined. Both bpMRI and mpMRI's total PI-RADS scoring evaluation had been determined & noted according to [PI-RADSv2.1.]. Figures 2-5 show image details of some of the cases that were examined.

STATISTICAL ANALYSIS

Using the Graphpad test, the kappa statistics for each lesion in bpMRI and mpMRI were used to calculate the agreement in the PI-RADS evaluation category. The definition of kappa values was as follows: (0.6-0.79) for moderate agreement, (0.8-0.9) for strong agreement and (>0.9) almost perfect agreement. Each result's bpMRI, mpMRI, and DCE were evaluated for diagnostic sensitivity, specificity and accuracy when CsPCa and PI-RADS category ≥3 was positive. The diagnostic performance for csPCa detection by bpMRI, mpMRI, and DCE in all lesions was assessed using receiver operating characteristic (ROC) analysis. The $\chi 2$ test was used to compare the area under the curve (AUC) between bpMRI, mpMRI, and DCE in all lesions based on the ROC analysis utilizing the Mcnamar & Delong test. Software called SPSS for Windows V. 22.o was used for all statistical studies. A significant level of P < 0.05 was considered statistically.

RESULTS

After determining their PSA levels, 115 suspected PCa patients between the ages of 40 and 70 were examined in this study; approximately 101 of these patients had PCa lesions. The number of patients having PI-RADS score's assessment categories 1 to 5. The PI-RADS categories were two groups: one with a score of < 3 and the other with a score of ≥3. According to the [PI-RADSv2.1], patients with a Gleason score of 3+4 or higher were evaluated in order to define CsPCa. The number of CsPCa patients was determined in reports 1 (by bpMRI) and 2 (by mpMRI). Table 1 summarizes the sample's characteristics in values of mean and /or percentages.

For all patients, the PI-RADS v2.1 assessment's kappa coefficient of agreement was 0.82 for bpMRI report 1 (strong agreement), 0.912 for mpMRI (nearly

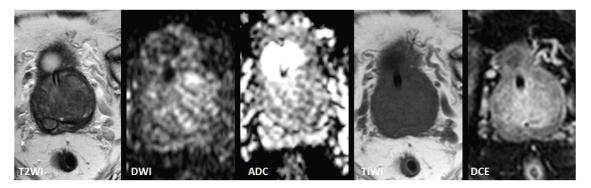


Figure 2: An 80-year-old man had a lesion in the right posterolateral base peripheral zone. He had a positive DCE, a confined heterogeneous T2W signal with encapsulation, and mild to moderate limited diffusion (PI-RADS-2: Extruded BPH).

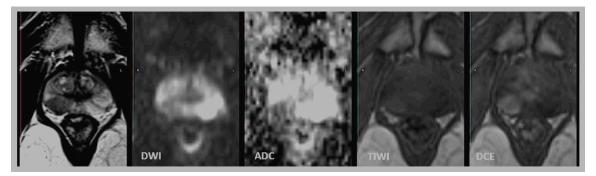


Figure 3: A 70-year-old male patient who had a high PSA level revealed a focal lesion in the right posteromedial/posterolateral mid-peripheral zone, along with positive DCE, homogeneous T2 hypointensity, notable ADC hypointensity, and no DWI hyperintensity. Prostate cancer (PI-RADS-3 upgraded to PI-RADS-4).

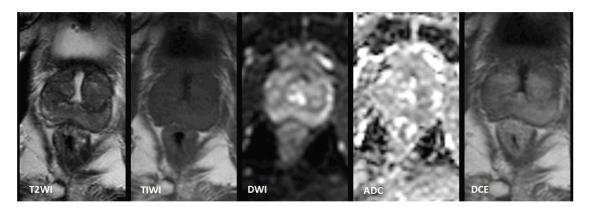


Figure 4: A localized lesion was found in the right anterior mid-peripheral zone of a 69-year-old male patient. He demonstrated mild/moderate DWI hyperintensity, T2W hypointensity, minor ADC hypointensity, and negative DCE (PI-RADS-3).

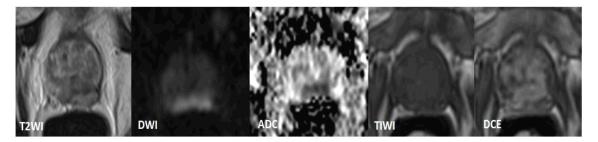


Figure 5: A 72-year-old man presented with a 2.9 cm focal lesion in the left posteromedial /posterolateral mid peripheral zone of prostate with marked DWI hyperintensity, marked ADC hypointensity, intermediate T2 signal intensity, and positive DCE and focal prostatic capsule bulge (PI-RADS-5).

Table 1: Characteristics of Study Sample

Variable	Value
Sample size	115
NO. suspected PCa	101
NO. of Patient with PIRADs score < 3	40
NO. of Patient with PIRADs score ≥3	61
NO. of csPCa by mpMRI	55
NO. of csPCa by bpMRI	49
NO. of csPCa by bpMRI & mpMRI	49
NO. of csPCa by DCE	14
Tumor volume(ml) in csPCa (mean)	45.6
Gleason score(mean)	7
Age/year(mean)	65
Family history percentage	21%
Smocking history Percentage	19%
PSA(ng/ml) mean in sample	19.3
PSA(ng/ml) mean according to:	
PIRADs score <3	17.5
PIRADs score ≥3	22

perfect agreement), 0.711 for bpMRI in CsPCa patients (moderate agreement), and 0.809 for mpMRI in CsPCa patients (strong agreement).

The diagnostic performance for PCa detection rates for reports 1 and 2 utilizing [PI-RADS v2.1] is shown in Figure 1. The diagnostic sensitivity of mpMRI was somewhat higher than that of bpMRI when comparing the diagnostic performance of both bpMRI and mpMRI for CsPCa detection (98.4% vs. 96.7%, P < 0.05). But the diagnostic specificity of bpMRI was significantly higher than that of mpMRI (75.8% vs. 66.8%; P < 0.001). In receiver operating characteristic curve (ROC) analysis, the area under the curve (AUC) for all lesions was higher in mpMRI and DCE than in bpMRI (AUC=0.93, 0.90, 0.89, respectively), with a p value <0.05 (Figure 1).

The bpMRI and mbMRI outcomes for the patient group with PI-RADS > 3 are 49% and 52%, respectively. In contrast, 51.50% and 53.40% of the CsPCa patient group were found with both imaging's type. However, as Figure 2 illustrates, the differences were noteworthy in both groups.

DISCUSSION

In mpMRI protocols, DCE is a great staging tool that will give detailed information about whether the cancer

has invaded the seminal vesicles, permeated the capsule, metastasized to the lymph nodes, or limited views of the bones. DCE can also provide information about blood flow, areas of hypo perfusion, and variations in endothelial permeability and micro-vessel density that can help with treatment selection, allow for frequent monitoring during treatment, and evaluate response to targeted therapy after treatment. Additionally, in PI-RADS v2.1, DCE plays a larger role in determining the PI-RADS assessment category when T2WI and DWI are of insufficient diagnostic quality.

While the [PI-RADS v2.1] guideline including DCE in mpMRI protocol, but many studies put the light on its side effects as mpMRI takes a variable amount of time about 30 to 40 minutes. Moreover, there is a danger of nephrogenic fibrosis, gadolinium buildup in the brain, and blood vessel fragility when using contrast based DCE imaging. Those studies tried to search on bpMRI as an alternatives diagnostic protocol to overcome those effects. To overcome these drawbacks, prostate bpMRI without the use of DCE is being evaluated as an alternative for PCa evaluation, with some studies reporting favorable findings. While several studies have shown that bpMRI has no advantage over mpMRI, doctors continued to prefer bpMRI for a variety of reasons, including cost and contraindications, such as end-stage renal illness. As a result, the study will

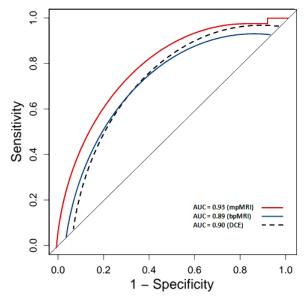


Figure 6: receiver operating characteristic (ROC) curve for diagnostic performance for clinically significant prostate cancer in PIRADS scoring of area under the curve (AUC) for mpMRI (red line), bpMRI (blue line) and DCE (dashed line). Discrimination line (AUC = 0.5, means a insignificant test and AUC=1, means perfectly significant test).

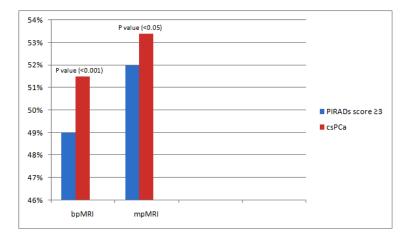


Figure 7: The percentage differences between bpMRI and mpMRI diagnostic performance in detection patients with PIRADS score ≥3 & clinically significant prostate cancer, (CsPCa).

discuss our findings and compare them to as many studies as possible that shed similar light on the significance of this topic.

In comparison to mpMRI, the results of this diagnostic analysis on the accuracy of bpMRI for PCa diagnosis employing the combination of T2 WI, DWI showed a high overall sensitivity and specificity with nearly no difference in CsPCa detection. According to the study's AUC and kappa agreement, bpMRI is not less accurate than mpMRI in diagnosing PCa. Additionally, the diagnostic accuracy at PI-RADS scoring indicates that bpMRI plays a substantial role that is comparable to that of mpMRI.

The study's results show that bpMRI and mpMRI have similar CsPCa diagnostic performance. This

research also discovered a novel role for DCE in the identification of CsPCa, paving the way for future investigations to uncover further roles for DCE.

To compare the effectiveness of mpMRI and bpMRI in PCa detection in people with increased PSA levels, Pesapane et al. conducted a retrospective analysis of 431 people in a comprehensive review. In this investigation, two radiologists with varying levels of prostate MRI interpretation experience were involved. After performing bpMRI readouts, mpMRI readouts using DCE were carried out. Significant statistical agreement was discovered. The bpMRI showed a sensitivity of 80% and a specificity of 74% for highgrade PCa cases. For mpMRI, the specificity was 78% and the sensitivity was 86%. According to the study's

overall findings, bpMRI's diagnostic performance is not significantly worse than mpMRI's [16] In contrast, lacob R. et al. concentrated on PI-RADS rating and prostate volume. For prostate volume, both approaches demonstrated good agreement (ICC 0.9963),demonstrating the validity of bpMRI in this regard [17]. The study's findings aligned with those of Cho J. et al., who analyzed 41 patients undergoing bpMRI and mpMRI between September 2015 and March 2017. Both imaging types had similar diagnostic accuracy (0.83 vs. 0.82), indicating no substantial differences in sensitivity or specificity [18].

About 44% of the participants in this study were diagnosed as having CsPCa by both bpMRI and mpMRI, whereas 33% (133/400) of the participants in an observational study conducted by Twilt J. *et al.* This discrepancy could be explained by the high PSA level in this study compared to Twilt J. *et al.*'s, which ranged from 0.10 to1.44 ng/ml [19]. But also similar to our findings; their investigation found that bpMRI has the same sensitivity and specificity at PI-RADS ≥3 as mpMRI in diagnosing csPCa at AUC.

A retrospective analysis of 236 individuals was conducted by Junker et al. to determine the effects of omitting DCE on tumor detection rates and diagnostic accuracy. One seasoned radiologist completed the trial by first reviewing MRI data in the past without using DCE, and then using DCE to evaluate the results during the same reading session; founding DCE detects 23 out of 236 patients [20]. Whereas, in the current study Table 1 indicates that a specific area was detected in 14 out of 101 instances. According to the Junker study, there were no discernible differences between bpMRI and mpMRI for clinically relevant malignancy, with 62.5% of PCa lesions having a Gleason score of 7 (3 + 4). Overall, the study's findings indicate that there were no appreciable variations in tumor diagnostic accuracy when DCE was excluded.

After reviewing published studies, Novrianto A. *et al.* [21] included 16 trials with 4,565 patients, 2,089 of whom had csPCa. Eight trials were prospective, and eight were retrospective. MpMRI had an AUC of 0.88, with 90% sensitivity and 58% specificity for diagnosing csPCa, while bpMRI had an AUC of 0.89, with 89% sensitivity and 71% specificity. There was no significant difference in diagnostic performance between mpMRI and bpMRI (p > 0.05). The research endeavors of Xu L. *et al.* [22] and Tamada T. *et al.* [23] provided invaluable insights that informed the development of our research strategy. By applying the general framework of these studies to our population sample and comparing the

results, we aimed to contribute the existing body of knowledge. If similar findings are obtained, they could potentially benefit numerous medical centers by mitigating the adverse effects of contrast agents, reducing costs, time, and effort, as well as enhancing clinical application. Notably, Xu L. et al. and Tamada T. et al. did not include PSA levels as an inclusion criterion in their studies, reporting mean PSA levels of 4.65 ng/ml and 6.92 ng/ml, respectively. In contrast, our study employed a PSA threshold of ≥15 ng/ml as a key inclusion criterion, with mean PSA level of 17.5 ng/ml in the PI-RADS score <3 group and 22 ng/ml in the PI-RADS score ≥3 group. This criterion was based on a thorough review of relevant studies, including those by Görtz M. et al. [24].Regarding the categorization of PI-RADS scores and (DCE) evaluation, Xu L. et al. stratified patients with PI-RADS ≥3 based on bpMRI category to assess differences in DCE (PCa) and (non-PCa) lesions, as well as between (csPCa) and (non-csPCa). In our research, we categorized the sample into PI-RADS ≥3 and PI-RADS <3 using each imaging technique separately, followed by a combined analysis of both bpMRI and mpMRI. Additionally, we examined the role of DCE across all categories, beyond its specific role in csPCa detection for AUC Performance. Both Xu L. et al. and Tamada T. et al. employed (AUC) analysis to compare the diagnostic performance of (bpMRI) and (mpMRI) across all lesions. Our study expanded on this comparison by specifically investigating the importance and diagnostic utility of (DCE) imaging for (csPCa).

Regarding interobserver agreement, Tamada T. et al. assessed the concordance of PI-RADS scores using Fleiss kappa statistics for mpMRI and bpMRI across all lesions. Our study built upon this analysis by evaluating interobserver agreement for csPCa cases, thereby providing a more robust assessment of the diagnostic accuracy of mpMRI and bpMRI in detecting csPCa. Furthermore, Tamada T. et al. compared the diagnostic sensitivity and specificity of bpMRI and mpMRI across three independent readers for all lesions, focusing on inter-reader reliability. In contrast, our study prioritized the identification of the most sensitive and specific technique for csPCa detection, rather than solely evaluating performance across all lesions. Ultimately, their results demonstrated that bpMRI is comparable to mpMRI in terms of diagnostic accuracy, a finding that is statistically consistent with our results.

CONCLUSIONS AND RECOMMENDATIONS

The study concludes that bpMRI is as effective as mpMRI for detecting csPCa at PI-RADS ≥3, with DCE

offering only a slight sensitivity boost. Experienced radiologists may benefit more from DCE. bpMRI holds potential as a substitute for mpMRI to meet increasing demand for prostate MRI. However, its safe clinical adoption requires prospective validation. A randomized multicenter diagnostic trial is recommended to compare bpMRI, mpMRI, and DCE, focusing on transferability and cost-effectiveness to address current limitations and guide future research.

Furthermore, it is recommended to assess the PI-RADS version 2.1 scoring system, which was initially created for mpMRI and CsPCa guidelines, in order to determine whether the integration of quantitative MRI, for example, can further improve the accuracy of bpMRI scoring and its overall diagnostic performance.

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