Prostate MRI technical parameters standardization: A systematic review on adherence to PI-RADSv2 acquisition protocol

Renato Cuocolo[a], Arnaldo Stanzione[a,*], Andrea Ponsiglione[a], Francesco Verde[a], Antonio Ventimiglia[a], Valeria Romeo[a], Mario Petretta[b], Massimo Imbriaco[a]

[a] Department of Advanced Biomedical Sciences, University of Naples "Federico II", Via Pansini 5, Naples, Italy
[b] Department of Translational Medical Sciences, University of Naples "Federico II", Via Pansini 5, Naples, Italy

A B S T R A C T

Purpose: The Prostate Imaging-Reporting and Data System has been developed to standardize prostate MRI in terms of acquisition, interpretation and reporting. It received a major revision in late 2014 (PI-RADSv2). Recently, doubts have been raised on imaging facilities adherence to its acquisition protocol. With this systematic review, we assessed adherence to PI-RADSv2 minimum technical specifications in literature, to achieve a better understanding of issues limiting their diffusion.

Method: Multiple medical literature databases were extensively searched to retrieve original studies published after January 2016 performing prostate MRI. Information pertaining acquisition protocols and patient enrolment were recorded for analysis. Technical parameters were dichotomized in relation to adherence to the corresponding minimal technical requirements.

Results: A total of 150 studies were included for analysis. Only 5% reported every technical parameter specified in the PI-RADSv2 document requirements, none of which completely met guideline specifications. Overall, 19% were in line with PI-RADSv2 for all reported MRI acquisition parameters. The adherence was lowest for T2-weighted frequency in-plane resolution (12%), diffusion-weighted imaging field of view (40%), apparent diffusion coefficient map low *b*-value (27%) and dynamic contrast-enhanced imaging temporal resolution (43%). Considering its role in image interpretation, it must be highlighted that only 59% of studies reporting diffusion-weighted imaging high *b*-value follow recommendations.

Conclusions: Adherence to PI-RADSv2 minimum technical standards is heterogeneous in the scientific community. Our findings endorse the need for greater diffusion of PI-RADSv2 guidelines to achieve protocol standardization and support the notion that some requirements might benefit from streamlining to improve clinical applicability.

1. Introduction

Over the last years, there has been a growing interest towards MRI and its application in prostate cancer (PCa) management. The current version of the European Association of Urology (EAU) guidelines recommend its use for both PCa detection and staging and recognize its role in the evaluation of patients enrolled for active surveillance [1]. Indeed, the recent publication of large prospective studies [2,3] provided further strong evidences suggesting that MRI could revolutionize the paradigm of PSA/systematic biopsy based PCa screening, which remains controversial [4–7]. With specific regard to the detection of PCa, it has to be acknowledged that the release of guidelines to standardize prostate MRI acquisition, interpretation and reporting highly

contributed to boost prostate MRI visibility and credibility among practitioners. The current reference standard is represented by the Prostate Imaging - Reporting and Data System (PI-RADS) which has been updated to a second version (PI-RADSv2) released in the second half of 2014, and the above mentioned EAU guidelines clearly state that prostate MRI should be acquired and interpreted adhering to PI-RADS instructions [8,9]. In PI-RADSv2, the multiparametric MRI (mpMRI) protocol relies on three fundamental sequences, represented by T2-weighted (T2w), diffusion weighted (DWI) and dynamic contrast enhanced (DCE) sequences. The document states minimum technical standards for each of these sequences, and it is interesting to note that their establishment is the first stated aim in the guidelines. Nevertheless, MRI diagnostic accuracy is still perfectible, with some

weaknesses to be found in inter-reader reproducibility and a well-reported learning curve [10–12]. Moreover, it has been highlighted that significant differences in terms of protocol and diagnostic accuracy can be found in clinical practice [13]. This appears to be at least partly due to the strict technical requirements imposed by PI-RADSv2 guidelines. With this work, we aimed to verify whether the same issues reported in clinical practice are also reflected in the scientific panorama with a systematic review of the recent literature.

2. Materials and methods

This systematic review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement (checklist available in the supplementary materials) [14].

2.1. Literature search

Multiple medical literature database (Scopus, Web of Science and PubMed) were systematically searched by 3 investigators. In particular, 2 (F.V. and A.V.) independently performed the literature search, with a third researcher (V.R.) who intervened in case of disagreement. Time filters were used to limit the collection to papers published between January 1, 2016 and October 31, 2018. In detail, the following search string was used with database-appropriate syntax:

((((((Prostate magnetic resonance imaging[Title/Abstract]) OR Prostate magnetic resonance[Title/Abstract]) OR Prostate MRI[Title/Abstract]) OR Prostate MR[Title/Abstract]) OR Prostate multiparametric[Title/Abstract]) OR PI-RADS[Title/Abstract]) OR PIRADS [Title/Abstract]

2.2. Selection criteria

A first screening of all titles and abstracts was performed to eliminate duplicates found across different databases. Case reports, letters to the editor, editorials, reviews, meta-analyses and papers published exclusively in languages other than English were excluded. Subsequently, all full texts were read in order to identify original studies performed on human subjects which stated to have performed mpMRI and included protocol details on at least one parameter for which PI-RADSv2 suggests technical specifications. Finally, studies for which patient recruitment ended prior to January 2016 were excluded.

2.3. Statistical analysis

From the full text and/or supplementary materials of the included studies, the information pertaining mpMRI acquisition protocols and patient enrolment period were recorded and organized in a spreadsheet for subsequent analysis. Technical parameters were dichotomized in relation to adherence to the corresponding minimal technical requirements [9]. When multiple scanners with different field strengths were employed, the highest was considered for statistical means. Similarly, when a study included more than one imaging protocol, parameters were considered as in line with specifications only if all protocols fell within PI-RADSv2 guidelines. For analysis purposes, articles were divided in groups based on scanner field strength and the beginning date of patient recruitment (i.e. before January 2016 or after).

3. Results

After removing duplicates, 1216 studies were found during the literature search. Following the application of the above-stated selection criteria, a total of 150 were included in the final analysis. A flowchart of the selection process is shown in Fig. 1. Overall, 108 studies employed only 3 Tesla (3 T) scanners, 26 only 1.5 T (1.5 T), with 16 employing both field strengths. MRI scans among included studies were acquired between 2006 and 2018. When considering patient recruitment, only
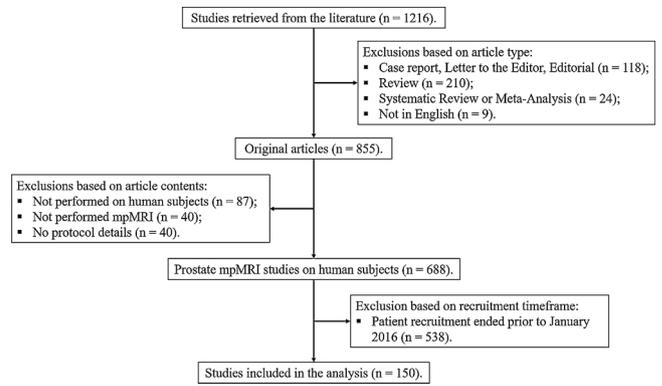

Fig. 1. Flowchart of the study selection process.

23 studies (15%) were published in the period of interest using exclusively data acquired from January 2016. Images were acquired using an endorectal coil (ERC) in 16/138 (12%) studies, with 12 studies not reporting coil details.

In total, 15% of studies (22/150) reported protocol details regarding all the 5 technical requirements specified for T2w sequences, only 8% of studies (12/150) did the same for DWI and apparent diffusion coefficient (ADC) maps while, in the case of DCE, 10% of studies (15/150) reported complete acquisition parameters in relation to PI-RADSv2 requirements. The detailed results of the analysis performed for each sequence are presented in Tables 1–3, showing percentages of unreported data, adherence to requirements and comparison between studies begun before or after 2016 and performed on 3 T or 1.5 T. Only 5% of studies (7/150) reported every technical parameter specified in the PI-RADS v2 document requirements, none of which completely adhered to the guideline. Of all studies, 28/150 (19%) were in line with PI-RADSv2 for all reported mpMRI acquisition parameters.

Regarding the statistical analysis, no significant differences were found among T2w sequence parameter adherence between studies whose patient acquisition started prior to 2016 and those after that date. Conversely, compliance to interslice gap indications was significantly better for exams performed on 3 T scanners. Among DWI parameters, only field of view (FOV) dimensions improved for exams performed after 2016, while Echo Time (TE) improved on 3 T compared to 1.5 T scanners. Finally, a paradoxical worsening of adherence to Repetition Time (TR) was observed for scans performed after 2016 for DCE, while studies using 3 T scanners performed significantly better in terms of temporal resolution.

4. Discussion

The definition of minimum technical specifications for a standardized mpMRI prostate protocol is one of the main aims of the PI-RADSv2 guidelines. Our systematic review of 150 studies published after its introduction has shown great heterogeneity both in reporting acquisition protocol details and poor overall adherence to the guidelines. First, for 12 of the 23 technical parameters object of the assessment, at least 50% of the papers did not report acquisition details. It would be ideal for authors that employ PI-RADSv2 scores for lesion evaluation in their studies to also include more detailed information on the acquisition protocol as this is an integral part of the guideline. As for the adherence to specific parameters, the major concerns were found with T2w frequency in-plane resolution (12%), DWI FOV (40%), ADC map low b-value (27%) and DCE temporal resolution (43%). Interestingly, merely 12% (16/138) of the studies declared to use an ERC. It could be speculated that this finding could be possibly due to a higher prevalence in the use of 3 T scanners. However, we found that the use of the ERC did not depend on scanners field strength, as among the 16 instances, it was adopted in 7 1.5 T and 8 3 T studies, while one

Table 1

Reporting and adherence details for T2-weighted image acquisition technical parameters according to PI-RADSv2 guidelines.

T2w Parameter	PI-RADSv2 Specification	NR	Adherence	Before 2016	After 2016	p	1.5 T	3 T	p
Slice thickness	3 mm	28% (42/150)	87% (94/108)	86% (79/92)	94% (15/16)	0.688	90% (19/21)	86% (75/77)	1.000
Inter-slice gap	No gap	62% (93/150)	61% (35/57)	60% (28/47)	70% (7/10)	0.725	22% (2/9)	69% (33/48)	0.020*
FOV	12-20 cm	43% (65/150)	67% (57/85)	67% (49/73)	67% (8/12)	1.000	67% (10/15)	67% (47/70)	1.000
In-plane resolution (phase)	≤ 0.7 mm	46% (69/150)	48% (39/81)	49% (33/67)	43% (6/14)	0.772	36% (5/14)	51% (34/67)	0.384
In-plane resolution (frequency)	≤ 0.4 mm	46% (69/150)	12% (10/81)	13% (9/67)	7% (1/14)	1.000	0% (0/14)	15% (10/67)	0.197

T2w = T2-weighted; NR = Not reported; FOV = Field of view; * = p < 0.05.

employed scanners with both field strengths.

Regarding T2w imaging resolution, it may be hypothesized that the standard set by PI-RADSv2 is too demanding if adherence is low in both the clinical and scientific setting, both prior to and after the publication of the guidelines. It also must be noted that evidences justifying such high resolution are currently limited, while our results show that the vast majority (88%) of studies officially lacking in terms of resolution did not require it in order to obtain their results. The FOV employed for DWI is one of the few parameters in which an increase in the percentage of adherence can be found over time. While few, studies where patient acquisition began after January 2016 have almost all employed the suggested FOV range. This could represent a positive note as more up-to-date scanners and greater awareness may improve the application of the guidelines' suggestions in this field. The issue of ADC low b-value could be explained by the common practice, in imaging of other organs, of using a b-value of $0 \, s/mm^2$ paired to the relatively low difference in image quality when following the $50–100 \, s/mm^2$ suggestion. Finally, DCE temporal resolution also was lacking, even considering the less restrictive 10-second indication and not the 7-second ideal one identified by PI-RADSv2. It should be noted however that the adherence to this parameter was significantly better for studies employing 3 T scanners.

A recent study by Esses et al. analyzed adherence to PI-RADSv2 technical parameters in imaging facilities by evaluating 107 examinations performed in as many different Institutions [13]. In such a clinical setting, their results highlighted the same major issues we found in academic studies, regarding T2w in-plane resolution, especially in the frequency direction, DWI FOV and DCE temporal resolution. Likewise, the use of sufficiently high ($\geq 1400 s/mm^2$) b-values for DWI was similar (58% in their study and 59% in our results) and not satisfactory given the paramount importance of this sequence. Indeed, for evaluation of peripheral zone lesions, high b-value DWI and ADC maps are considered the dominant sequence to score suspicious lesions. Another noteworthy analogy in the results derived from our systematic review of the literature and the previous study by Esses et al. is the limited improvements in imaging protocols over time in terms of PI-RADSv2 adherence, if not outright worsening in some respects.

A recent update to the PI-RADSv2 guidelines has been published (PI-RADSv2.1), addressing both some of the technical aspects as well as

image interpretation [15]. In Table 4, a comparison of PI-RADSv2 and PI-RADSv2.1 mpMRI protocols is shown, highlighting how few parameters were modified in the current revision. On the other hand, the two changes were made in areas that resulted of low adherence in our results, potentially solving the issue. In particular, b-values of $0–100 \, s/mm^2$ are now considered valid for the calculation of ADC maps, even if the $50–100 \, s/mm^2$ is still preferable. In the studies we reviewed, this update potentially brings adherence from 27% to 100%, appearing as a significant change. Similarly, DCE temporal resolution was made less stringent, and 15 s represent the new upper limit, compared to the 10 or 7 s previously suggested. Both changes probably reflect a compromise between real world clinical practice, as shown in our results, and ideal diagnostic performance of the suggested mpMRI protocol. In the light of our results, and those of previous studies [13], this revision still could have missed an opportunity to address some of the other potential issues of current PI-RADSv2 and PI-RADSv2.1 protocol guidelines. In particular, the high spatial resolution requirements for T2w imaging ($\leq$ 0.7 x 0.4 mm) showed especially poor implementation in both clinical practice and the research setting, probably due to time and/or signal-to-noise ratio constraints. As good accuracy is generally reported notwithstanding, a more robust validation of this aspect should be performed to justify its persistence or, as done for ADC low b-value and DCE temporal resolution, an optimal middle ground with real-world clinical practice could be found. Finally, PI-RADSv2.1 has started to address the issue of systematic use of gadolinium-based contrast agents for prostate MRI [15]. Many studies have shown a comparable diagnostic accuracy of biparametric MRI, without contrast administration, and mpMRI, especially in the setting of lesion detection and characterization [16–21]. This has led to an ongoing debate on the real added value of DCE [5,22–29]. This issue is further highlighted by the development of advanced software tools aimed at aiding in detection, characterization and staging of csPCa that often do not require contrast-enhanced images to achieve good diagnostic accuracy [30–35].

We chose to review articles published after January, 1 2016 since PI-RADSv2 guidelines were released during late 2014. Indeed, this time gap appears reasonable for clinical implementation of a very detailed image acquisition protocol. Furthermore, we decided to divide studies in two groups based on patient recruitment time, instead of using publication date as a criterion. These choices allowed an unbiased

Table 2

Reporting and adherence details for diffusion weighted image acquisition technical parameters according to PI-RADSv2 guidelines.

DWI Parameter	PI-RADSv2 Specification	NR	Adherence	Before 2016	After 2016	P	1.5 T	3 T	P
Slice thickness	≤ 4 mm	37% (55/150)	90% (85/95)	90% (75/83)	83% (10/12)	0.610	88% (15/17)	90% (70/78)	1.000
Inter-slice gap	No gap	68% (102/150)	56% (27/48)	54% (22/41)	71% (5/7)	0.445	57% (4/7)	56% (23/41)	1.000
FOV	16-22 cm	48% (72/150)	40% (31/78)	35% (25/71)	86% (6/7)	0.014*	38% (5/13)	40% (26/65)	1.000
In-plane resolution (phase)	≤ 2.5 mm	53% (79/150)	79% (56/71)	79% (50/63)	75% (6/8)	0.673	60% (6/10)	82% (50/61)	0.202
In-plane resolution (frequency)	≤ 2.5 mm	53% (79/150)	92% (65/71)	94% (59/63)	75% (6/8)	0.133	100% (10/10)	90% (65/71)	0.585
TR	≥ 3000 ms	42% (63/150)	91% (79/87)	91% (70/77)	90% (9/10)	1.000	94% (15/16)	90% (64/71)	1.000
TE	≤ 90 ms	46% (69/150)	89% (72/81)	87% (62/71)	100% (10/10)	0.592	69% (9/13)	93% (63/68)	0.033*
High b-value	$\geq 1400 s/mm^2$	3% (4/150)	59% (86/146)	56% (70/124)	73% (16/22)	0.168	48% (12/25)	61% (74/121)	0.267
ADC map low b-value	50-100	63% (95/150)	27% (15/55)	30% (14/46)	11% (1/9)	0.417	40% (4/10)	24% (11/45)	0.434
ADC map high b-value	800-1000	68% (103/150)	75% (35/47)	76% (29/38)	67% (6/9)	0.674	100% (7/7)	70% (28/40)	0.166

DWI = Diffusion weighted imaging; ADC = Apparent diffusion coefficient; TR = Repetition time; TE = Echo time; NR = Not reported; FOV = Field of view; * = p < 0.05.

Table 3

Reporting and adherence details for dynamic contrast enhanced sequence acquisition technical parameters according to PI-RADSv2 guidelines.

DCE Parameter	PI-RADSv2 Specification	NR	Adherence	Before 2016	After 2016	P	1.5 T	3 T	P
Slice thickness	3 mm	45% (68/150)	63% (52/82)	62% (44/71)	73% (8/11)	0.738	69% (9/13)	62% (43/69)	0.760
Inter-slice gap	No gap	76% (114/150)	89% (32/36)	90% (27/30)	83% (5/6)	0.535	80% (4/5)	90% (28/31)	0.466
In-plane resolution (phase)	≤ 2 mm	57% (85/150)	89% (58/65)	88% (49/56)	100% (9/9)	0.580	70% (7/10)	93% (51/55)	0.067
In-plane resolution (frequency)	≤ 2 mm	57% (85/150)	97% (63/65)	96% (54/56)	100% (9/9)	1.000	90% (9/10)	98% (54/55)	0.286
TR	< 100 ms	49% (73/150)	96% (74/77)	99% (68/69)	75% (6/8)	0.027*	100% (13/13)	95% (61/64)	1.000
TE	< 5 ms	51% (77/150)	99% (72/73)	100% (65/65)	88% (7/8)	0.110	100% (11/11)	98% (61/62)	1.000
Temporal resolution	< 10 s	52% (78/150)	43% (31/72)	71% (44/62)	60% (6/10)	0.482	33% (4/12)	77% (46/60)	0.006*
Total duration	≥ 2 min	59% (88/150)	98% (61/62)	98% (52/53)	100% (9/9)	1.000	100% (12/12)	98% (49/50)	1.000

DCE = Dynamic contrast enhanced imaging; TR = Repetition time; TE = Echo time; NR = Not reported; FOV = Field of view; * = p < 0.05.

Table 4

Point-by-point comparison of changes in technical parameter acquisition introduced by PI-RADSv2.1.

	PI-RADSv2	PI-RADSv2.1
T2w Parameter		
Slice thickness	3 mm	no change
Inter-slice gap	No gap	no change
FOV	12–20 cm	no change
In-plane resolution (phase)	≤ 0.7 mm	no change
In-plane resolution (frequency)	≤ 0.4 mm	no change
DWI Parameter		
Slice thickness	≤ 4 mm	no change
Inter-slice gap	No gap	no change
FOV	16–22 cm	no change
In-plane resolution (phase)	≤ 2.5 mm	no change
In-plane resolution (frequency)	≤ 2.5 mm	no change
TR	≥ 3000 ms	no change
TE	≤ 90 ms	no change
High b-value	≥ 1400s/mm^2	no change
ADC map low b-value	50–100	0-100 (preferably 50-100)
ADC map high b-value	800–1000	no change
DCE Parameter		
Slice thickness	3 mm	no change
Inter-slice gap	No gap	no change
In-plane resolution (phase)	≤ 2 mm	no change
In-plane resolution (frequency)	≤ 2 mm	no change
TR	< 100 ms	no change
TE	< 5 ms	no change
Temporal resolution	< 10 s (preferably < 7 s)	< 15 s
Total duration	≥ 2 min	no change

T2w = T2-weighted; DWI = Diffusion weighted imaging; ADC = Apparent diffusion coefficient; DCE = Dynamic contrast enhanced imaging; TR = Repetition time; TE = Echo time; FOV = Field of view.

assessment of studies published in the period of interest and in turn of the real impact of PI-RADSv2 technical recommendations since their introduction. Notably, in our systematic review, the majority of studies (127/150, 85%) that have been published after the introduction of PI-RADSv2 are based on data previously acquired, with 6 of them using data acquired even before the release of the first version of PI-RADS. When evaluating the subgroup of studies whose image acquisition began after January 2016, a low degree of changes was found in imaging protocols over time; this interesting result confirms the evidences collected in a previous work by Esses et al. [13]. Moreover, the few changes that do occur may be due to "natural" technical improvements (e.g. DWI FOV) or are paradoxical in other cases, with worse adherence to acquisition protocol recommendations at later dates. Altogether, these findings reflect the disconnect between PI-RADS imaging guidelines and both real-world and scientific practice in the field of PCa. While PI-RADSv2 lesion scores continue to show good accuracy [36], the concurrent limited adherence to the technical recommendations of the guidelines seems to indicate that simply not enough time has passed since the revision of the original PI-RADS to allow for widespread adoption in terms of imaging protocols. This is especially relevant as PI-RADSv2 has already undergone itself a partial revision. Future revisions of the PI-RADS guidelines might benefit in terms of adherence from clear auditing criteria for assessing guideline implementation and simplified protocol focusing on truly essential technical requirements, such as the high b-value DWI, and on image interpretation.

This study has some limitations that should be acknowledged. Our assessment was limited to a relatively short period of time (34 months), even though it included exams performed in a wider range (2006–2018). While the number of studies was high, there was heterogeneous reporting of imaging protocol details. Furthermore, as this review was purely focused on the imaging protocol from a technical standpoint, no assessment of diagnostic accuracy was made, as it was outside the aim of the study.

In conclusion, adherence to PI-RADSv2 minimum technical standards is heterogeneous in the scientific community, resulting especially poor for T2w in-plane resolution, DWI FOV, ADC map low b-value and DCE temporal resolution. No significant improvement in terms of compliance with PI-RADSv2 guidelines was found over time. Our findings further reinforce the need for greater diffusion of protocol standardization through application of the PI-RADS guidelines which could in turn be also aided by less stringent requirements in some cases.

Declaration of Competing Interest

None.

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