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Rectal preparation significantly improves prostate imaging quality: assessment of the PI-QUAL score with visual grading characteristics

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Conflicts of Interest

Michael A Arnoldner, Stephan H Polanec, Mathias Lazar, Sam Kadhjavi, Paola Clauser, Nina Pötsch, Ursula Schwarz-Nemec, Stephan Korn, Nicolai Hübner, Shahrokh F Shariat, Thomas H Helbich and Pascal AT Baltzer have no conflicts of interest or financial ties to disclose.

Compliance with Ethical Standards

All procedures performed in studies involving human participants were in accordance with the ethical standards of the research committee of the Vienna Medical University (EK 2057/2017) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This article does not contain any studies with animals performed by any of the authors.

Informed Consent

Informed consent was obtained from all individual participants included in the study.

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Short Running Title

mpMRI of the prostate – rectal preparation and image quality

CREDIT Author Statement
Rectal preparation significantly improves prostate imaging quality: assessment of the PI-QUAL score with visual grading characteristics
Abstract

Purpose: To investigate the effects of a rectal preparation regimen, that consisted of a rectal cleansing enema and an endorectal gel filling protocol, on prostate imaging quality (PI-QUAL).

Methods: Multiparametric MRI (mpMRI) was performed in 150 consecutive patients divided into two groups of 75 patients. One group received a rectal preparation with a cleansing enema and endorectal gel filling (median age 65.3 years, median PSA level 6 ng/ml). The other patient group did not receive such a preparation (median age 64 years, median PSA level 6 ng/ml). Two uroradiologists independently rated general image quality and lesion visibility on diffusion-weighted imaging (DWI), T2-weighted (T2w), and dynamic contrast-enhanced (DCE) images using a five-point ordinal scale. In addition, two uroradiologists assigned PI-QUAL scores, using the dedicated scoring sheet. Data sets were compared using visual grading characteristics (VGC) and receiver operating characteristics (ROC)/ area under the curve (AUC) analysis.

Results: VGC revealed significantly better general image quality for DWI (AUC R1 0.708 (0.628-0.779 CI, p <0.001; AUC R2 0.687 (0.606-0.760 CI, p <0.001) and lesion visibility for both readers (AUC R1 0.729 (0.607-0.831 CI, p <0.001); AUC R2 0.714 (0.590-0.818CI, p <0.001) in the preparation group. For T2w imaging, rectal preparation resulted in significantly better lesion visibility for both readers (R1 0.663 (0.537-0.774 CI, p = 0.014; R2 0.663 (0.537-0.774 CI, p = 0.014)). Averaged PI-QUAL scores were significantly improved with rectal preparation (AUC R3/R4 0.667, CI 0.581-0.754, p <0.001)
Conclusion: Rectal preparation significantly improved prostate imaging quality (PI-QUAL) and lesion visibility. Hence, a rectal preparation regimen consisting of a rectal cleansing enema and an endorectal gel filling could be considered.

Key words: MRI, mpMRI, prostate, prostate cancer, quality standards, PI-QUAL
Introduction

Multiparametric MRI (mpMRI) is an established tool for the diagnostic work-up of patients with a clinical suspicion of prostate cancer (PCa) based on elevated levels of prostate specific antigen (PSA) and/or an abnormal digital rectal examination[1, 2]. Consequently, most men are recommended to undergo pre-biopsy mpMRI of the prostate[3]. mpMRI, when used before prostate biopsy, allows for improved detection of clinically significant cancer and helps to safely avoid unnecessary biopsies[4]. The Prostate Imaging Reporting and Data System version 2 (PI-RADS v2) has recently been updated (PI-RADS v2.1), keeping the multiparametric approach of combining Diffusion-Weighted Imaging (DWI), Dynamic Contrast Enhanced (DCE) and T2-weighted sequences[5]. Recent studies highlighted the importance of adequate image quality for the diagnosis of clinically significant PCa(csPCa)[6-9] and a dedicated prostate imaging quality scoring system has been introduced (PI-QUAL)[6]. Conventional DWI relies on echoplanar imaging (EPI) and is prone to susceptibility artefacts induced by rectal gas[10, 11]. In PI-RADS v2.1, there is still no consensus about the optimal rectal preparation[5]. Some studies have investigated the effects of rectal preparation and rectal distension, with conflicting results[10-13]. To the best of our knowledge, there is no data on the value of endorectal gel-filling and a rectal cleansing enema for the optimal preparation regimen for mpMRI. Hence, the purpose of this prospective randomized study was to investigate the effects of endorectal gel-filling and a rectal cleansing enema on prostate imaging quality and lesion visibility using visual grading characteristics.
Materials and Methods

Patient population

This prospective study was approved by the local institutional review board (BLINDED FOR REVIEW) and written, informed consent was obtained from each patient. The study cohort included 150 consecutive patients who were recruited during a 16 months period. Clinical indications for mpMRI included elevated PSA, suspicious digital rectal examination findings, and local staging in case of biopsy- or TURP-proven prostate cancer. Exclusion criteria were contraindications for MRI in general, age below 18 years and prior adverse reaction to gadolinium contrast material.

Magnetic Resonance Imaging

All examinations were performed on a 3 Tesla MRI unit (TrioTim, Siemens Healthineers, Erlangen, Germany) using the vendor-specific combined spine-array and body-array coils. Half of the patients (75/150, random allocation) in this study received a rectal preparation with a self-administered enema and a rectal filling with 50 ml ultrasound gel (Vue ultrasound gel, Optimum Medical, Leeds, UK). Patients were instructed to use the enema (130ml of Klistier, Fresenius, Germany) at home on the day of the examination with as little time gap as possible to the MR exam. Gel filling was performed on the scanner table in the lateral decubitus position by the examining radiologist. The other patient group was examined without such a preparation regimen. All patients received a single dose of an antispasmodic agent intramuscularly (10 mg of hyoscine butyl-bromide, Sanofi, Paris, France) immediately prior to entering the MR suite.
The imaging protocol was in line with PI-RADS v2.1 recommendations. During 19 minutes measurement time, multiplanar T2w images, axial DWI, and axial DCE images were acquired[5]. The protocol is detailed in Table 1.

**Image Analysis**

Qualitative image analysis was performed on a dedicated PACS workstation (Impax, AGFA Mortsel, Belgium) by four uro-radiologists (R1-R4) with five to seven years of experience in genitourinary MRI (100-400 prostate MRI scans per year) (BLINDED FOR REVIEW). The images were anonymized and independently reviewed in random order without any knowledge regarding clinical and pathological findings. General image quality was assessed by R1 and R2, using a five-point categorical image criterion scale ranging from 1 (non-diagnostic) to 5 (excellent). Anatomic details for visual grading included delineation of the prostate capsule, the seminal vesicles, the neurovascular bundle and the sphincter muscles (table 2). Motion and distortion artefacts were also included in the grading. Index lesions, if present, were independently scored by R1 and R2 regarding lesion visibility, ranging from 1 (non-diagnostic) to 5 (excellent). PI-QUAL scores (table 3) were independently assigned by R3 and R4 using the dedicated PI-QUAL scoring sheet introduced by Giganti et al.[6].

**Statistical analysis**

Data were entered into spreadsheet software. All statistical analyses were performed using Medcalc 19.6 (Medcalc Software bvba, Ostend, Belgium) and IBM SPSS Statistics (IBM, Armonk, US). For Visual Grading Ratings (including PI-QUAL), Receiver Operating Characteristics analysis was used. The procedure is adapted for
Visual Grading Characteristics analysis as follows (details regarding VGC analysis are provided in Bath et al.[14]): the classification variable is the ordinal visual grading scale (e.g. lesion visibility) while the reference variable is the image acquisition method (e.g. rectal preparation versus no rectal preparation). If significantly different from 0.5, the resulting ROC curve in this case indicates superiority of the rectal preparation group. P-values < 0.05 were considered statistically significant. The study is powered to detect an AUC of 0.65 at alpha and beta error levels of 5% and 20%, respectively. No formal Bonferroni correction was applied for this exploratory analysis. Interrater agreement was assessed using Cohen’s kappa with standard quadratic weighting. Cohen’s kappa coefficients were interpreted as follows: 0.21–0.40, minimal agreement; 0.41–0.60, moderate agreement; 0.61–0.80, substantial agreement; 0.81–0.90, strong agreement; > 0.90, almost perfect agreement.

Results

All patients completed the MR exam. The median age at imaging was 65.3 years (range 37.6 - 84.5 y) in the preparation group and 64 years (range, 35.2 – 80.4 y) in the non-preparation group. The median PSA levels were 6.5 ng/ml (range, 0.4 – 30.1) in the preparation group and 6 ng/ml (range, 0.4 – 18.4) in the non-preparation group, respectively.

**VGC analysis for general image quality, lesion visibility and PI-QUAL scores**

VGC analysis revealed significantly better image quality in patients who received rectal preparation for DWI in both readers (AUCs 0.708 and 0.687, p <0.001) and for
T2w imaging in one reader (R1 AUC 0.617, p = 0.011). For R1, DCE also showed superior image quality after rectal preparation (AUC 0.645, p = 0.001). VGC analysis revealed significantly better lesion visibility in patients who received rectal preparation for DWI and T2w images in both readers (AUCs ranging from 0.663 – 0.729, p values ranging from <0.001 - 0.014). Averaged PI-QUAL scores were significantly improved with rectal preparation (AUC R3/R4 0.667, CI 0.581-0.754, p <0.001). Detailed AUC results and VGC curves are displayed in table 4 and fig. 1. MR images of patients with and without rectal preparation are shown in fig. 2 - 4.

**Interrater agreement**

The interrater agreement of R3 and R4 for PI-QUAL scoring was moderate, with a kappa of 0.42 (CI 0.29-0.55). R1 and R2 showed good agreement for T2w (0.77, CI 0.68-0.87) and DWI (0.7, CI 0.6-0.81). For DCE, agreement between R1 and R2 was minimal with a kappa of 0.38 (CI 0.24-0.52)

**Discussion**

The results of our prospective randomized study show that the combination of endorectal gel filling and the use of a cleansing enema improves prostate imaging quality (PI-QUAL) by a statistically and clinically significant margin. Especially DWI and T2 weighted sequences were significantly improved with rectal preparation.

The importance of image quality has recently been stressed by Giganti et al. who introduced the PI-QUAL scoring system with clinical implications for the detection of clinically significant PCa[6]. To the best of our knowledge, this is the first study to evaluate image quality in patients with and without rectal preparation with VGC. This
statistical method strengthens our study as it provides area under the curves that can be used as a single measure of difference in image quality between the two compared groups. Visual grading analysis is both intuitive to interpret and avoids certain statistical pitfalls. Since the rating data from the observers is ordinal, non-parametric, rank-invariant statistical methods are required. However, visual grading data is commonly transformed to numerical values and calculations of mean values and/or standard deviations of ratings are examples of statistically wrong operations that are often used[14]. VGC has been used in various fields of imaging including the prostate [15][16].

According to PI-RADS v2.1, there is still no consensus about the optimal patient preparation prior to mpMRI or bpMRI of the prostate. The presence of stool in the rectum is known to interfere with an endorectal coil (ERC) or, when not used, to cause susceptibility artefacts, especially on DWI sequences. Hence, recommendations are given to decrease rectal stool filling. This can be achieved with rectal emptying by defecation or enema prior to the exam[5]. This is in accordance to our results that showed significantly better image quality for DWI, for both readers, using rectal preparation. We used rectal filling with ultrasound gel as it is known to diminish rectal gas, leading to potentially better image quality on DWI[17] for patients receiving an MRI of the rectum. To the best of our knowledge, there are no reports available as to whether additional rectal filling with ultrasound gel in mpMRI of the prostate is favorable or not. While iatrogenic endorectal filling theoretically may increase peristalsis that causes motion artefacts, especially on T2w images, we believe that this issue can be addressed with the injection of an antispasmodic agent, such as hyoscine butyl-bromide (HBB) or glucagon [18-20]. A recent national UK audit found wide variation
in overall image-quality scores across sites, with 40% of patients having non-diagnostic-quality bpMRI. This audit also reported that DWI quality is inversely related to rectal filling [21]. Caglic et al. [13] also evaluated the effects of rectal diameter on DWI and T2w image quality and concluded that rectal distension has a significant negative effect on the quality of both T2w and DWI images. However, our intention with rectal filling is not to distend the rectum, but rather to diminish rectal gas, and thus, reduce B0 inhomogeneity. Hence, care should be taken that no additional air is insufflated during gel filling. However, small amounts of rectal gas cannot be completely avoided.

A different approach to reduce rectal gas is scanning with a rectal tube in place throughout the examination[22]. Furthermore, Reischauer et al. compared the image quality of DWI in patients that either received an enema or rectal gas suction via a rectal catheter prior to the exam and observed favorable outcomes for the enema group[23]. In addition, adhering to a clear liquid diet combined with a self-administered enema has also been shown to decrease DWI distortion artefacts in prostate MRI[24].

In contrast to our findings, a study by Lim et al. [12] failed to show any benefits to a rectal cleansing enema, as there was no lessening of imaging artefacts or improved imaging quality observed using a surface coil at 3T. However, in the non-enema group of the aforementioned study, only a minority of the patients had moderate to large amounts of rectal stool and no patients had large amounts of rectal gas in either group. The use of a preparatory enema has also been investigated for rectal MRI at 1.5T, and it could be shown that both the incidence and severity of gas-related susceptibility artefacts can be reduced significantly[25]. Furthermore, Coskun et al. [10] reported that the use of an enema may diminish rectal gas, but effects on
image quality were inconsistent among readers. Hence, they concluded that no
definite recommendation can be given. In contrast to our preparation regimen, the
aforementioned studies did not use a combination of both a cleansing enema and
rectal filling with ultrasound gel.

In contrast to Giganti et al. who reported high interobserver reproducibility for PI-
QUAL (Cohen's kappa of 0.85)[26], our agreement in a strictly blinded analysis of this
new quality assessment tool was only moderate (kappa of 0.42).

In PI-RADS v2.1, DWI remains the lead sequence for the peripheral zone (PZ) of the
prostate. As up to 83% [27] of prostate cancers are located in the PZ, good imaging
quality on DWI is crucial for reliable interpretation. Efforts have been made to
increase DWI performance, e.g., using a pulse sequence with reduced FOV
excitation rather than conventional echoplanar imaging (EPI)[28]. Since mpMRI is a
cost-effective first test for the diagnosis of PCa[29] examination duration is of high
importance. Rectal filling is performed in the MR suite with the patient already
positioned on the scanner table and only consumes a minimum amount of time. If
there are time concerns, adjustment of the DWI sequence with the use of a
computed high b-value has the potential to decrease time acquisition by 220 seconds
per patient [30].

BpMRI of the prostate, consisting of T2w imaging and DWI, has been shown to be a
reasonable alternative to mpMRI[31]. With an ongoing trend toward shortening of
protocols, reliable image quality is crucial. Our study shows that these two
sequences benefit the most from an appropriate rectal preparation regimen. This
underlines the importance of appropriate patient preparation, especially for bpMRI.
This study has several limitations. First, we did not evaluate the effects of rectal preparation on the rectum itself, but rather, on general image quality and lesion visibility. However, the significant VGC results in favor of preparation for the DWI sequence allows an indirect conclusion that the amount of rectal gas was less in the preparation group. Although visual grading characteristics are an established and suitable method for image comparison studies[15, 16, 32], we did not investigate potential confounders such as general bowel filling and motile activity as well as age, body size and composition etc. This was mainly due to the low case numbers which also hampers an accurate, generalizable quantification of the clinical relevance of rectal preparation regarding false negative outcomes. While the readers had no information about the rectal preparation status, it is likely that the reading was not blinded, since it is obvious on imaging whether the rectum was filled with gel or not. Finally, this study did not entail an enema-only cohort. Future research on rectal preparation might be needed to evaluate differences in image quality between enema-only and enema-gel preparation cohorts.

In conclusion, rectal preparation with a cleansing enema and endorectal gel filling results in significantly better prostate imaging quality (PI-QUAL) and lesion visibility. Hence, this rectal preparation regimen could be considered for mpMRI of the prostate.
Table 1. Imaging Parameters

| Sequence        | Voxel size (mm) | TR  | TE  |
|-----------------|----------------|-----|-----|
| T2 TSE axial    | 0.6 x 0.6 x 3  | FA 150º | 4000 | 101 |
| T2 TSE sagittal | 0.6 x 0.6 x 3  | FA 150º | 4000 | 101 |
| T2 TSE coronal  | 0.6 x 0.6 x 3  | FA 150º | 4000 | 101 |
| DWI             | 1.6 x 1.6 x 3.6| b values: 0, 100, 800 and 1400 (calculated) s/mm² | 3300 | 60 |
| T1 TWIST DCE    | 1 x 1 x 3.6    | FA 2.5/10/20 | 3.85 | 1.42 |

Table 2. Visual grading scoring scale

| Score | Criteria |
|-------|----------|
| 1     | non-diagnostic |
| 2     | poor |
| 3     | sufficient |
| 4     | good |
| 5     | excellent |

Table 2 continues

| Score | Criteria |
|-------|----------|
| 1     | anatomic details are insufficiently displayed; DWI/ADC is highly distorted |
| 2     | anatomic details are poorly displayed; DWI/ADC is distorted |
| 3     | anatomic details are sufficiently displayed; DWI/ADC is distorted but sufficient |
| 4     | anatomic details are well seen; DWI/ADC shows no to minimal artefacts |
| 5     | anatomic details are perfectly displayed; DWI/ADC has no artefacts and excellent morphology |

Table 3. PI-QUAL scoring system[6]

| PI-QUAL Score | Criteria |
|---------------|----------|
| 1             | All mpMRI sequences are below the minimum standard for diagnostic quality |
| 2             | Only one mpMRI sequence is of acceptable diagnostic quality |
| 3             | At least two mpMRI sequences taken together are of acceptable diagnostic quality |
| 4             | Two or more mpMRI sequences are independently of optimal diagnostic quality |
| 5             | All mpMRI sequences are of optimal diagnostic quality |
### Table 4. Area under the VGC curves for general image quality ratings and lesion visibility scores for both readers

|                              | AUC  | 95% CI       | P-value  |
|------------------------------|------|--------------|----------|
| **General image quality (n=150)** |      |              |          |
| Reader 1 DCE                 | 0.645| 0.563-0.722  | 0.001    |
| Reader 2 DCE                 | 0.575| 0.492-0.656  | 0.107    |
| Reader 1 T2w                 | 0.617| 0.534-0.695  | 0.011    |
| Reader 2 T2w                 | 0.580| 0.497-0.660  | 0.087    |
| Reader 1 DWI                 | 0.708| 0.628-0.779  | <0.001   |
| Reader 2 DWI                 | 0.687| 0.606-0.760  | <0.001   |
| **Lesion visibility**        |      |              |          |
| Reader 1 DCE                 | 0.550| 0.423-0.671  | 0.489    |
| Reader 2 DCE                 | 0.519| 0.394-0.643  | 0.783    |
| Reader 1 T2w                 | 0.663| 0.537-0.774  | 0.014    |
| Reader 2 T2w                 | 0.663| 0.537-0.774  | 0.014    |
| Reader 1 DWI                 | 0.729| 0.607-0.831  | <0.001   |
| Reader 2 DWI                 | 0.714| 0.590-0.818  | <0.001   |

Note: an AUC >0.5 indicates a higher VGC score in patients with bowel preparation, and an AUC <0.5 a higher VGC score in patients without bowel preparation.

AUC: Area under the Receiver Operating Characteristics curve; CI: confidence interval; DCE: Dynamic Contrast-Enhanced; DWI: Diffusion-Weighted Imaging
**Figure 1a.** (Color)

[Diagram showing General image quality with line graphs and different lines representing R1 DCE, R2 DCE, R1 T2W, R2 T2W, R1 DWI, and R2 DWI.

**Figure 1b.** (Color)

[Diagram showing Lesion visibility with line graphs and different lines representing R1 DCE, R2 DCE, R1 T2W, R2 T2W, R1 DWI, and R2 DWI.]
Figure 2.
Figure 3.

Figure 4.
**Figure Legends**

**Figure 1.** Visual grading characteristics for general image quality and lesion visibility (a) and averaged PI-QUAL scores (b).

**Figure 2.** Excellent general image quality and lesion visibility in a patient who received rectal preparation (PI-RADS 4 lesion in the left peripheral zone); T2w (A), ADC map (B), DWI high b - value (C), DCE subtraction image (D). Visual grading scores: T2w: 5; DWI: 5; DCE: 5. PI-QUAL score: 5.

**Figure 3.** Severe susceptibility artefacts are shown on DWI/ADC due to large amounts of rectal gas in a patient without rectal preparation (T2w (A), ADC map (B), DCE subtraction image (C), DWI (D)). Visual grading scores: T2w: 3; DWI: 2; DCE: 3. PI-QUAL score: 3.

**Figure 4.** Severe susceptibility artefacts are shown on DWI/ADC due to rectal gas in a patient without rectal preparation. T2w shows motion artefacts (T2w (A), DWI (B), ADC map (C)). Visual grading scores: T2w: 2; DWI: 2.
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CREDIT Author Statement
Arnoldner MA: Writing - Original Draft, Validation, Investigation
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Shariat SF: Writing - Review & Editing
Dear Authors,

many thanks for your substantial revision - the second reviewer who is an expert in the field of prostate MR image quality has some additional comments - I also think that the score in the figure legend should be revised and I also do see value of this additional table. I leave the suggested change in wording the title up to you.

Thank you very much

Yours sincerely,

Section Editor

Dear Editor!

We have revised the title according to the reviewer’s suggestion. We have added a supplementary item with a table that includes all the PI-QUAL ratings and the rectal preparation status. We have replaced the non-fat saturated DCE images with subtracted images as requested.

Yours sincerely,

The Authors