Interobserver agreement in prostate cancer detection using multiparametric MRI

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Summary

**Purpose:** The purpose of this prospective observational study was to evaluate the diagnostic performance of multiparametric (mp) magnetic resonance imaging (MRI) for prostate cancer detection and to assess the interobserver variability, using the Prostate Imaging Reporting and Data Systems (PI-RADS).

**Methods:** 50 patients (mean age 68.42±6.58 years) with suspected prostate cancer fulfilling the inclusion criteria and without any exclusion criteria were enrolled. All patients were examined with mp-MRI protocol, as per European Society of Urogenital Radiology (ESUR) guidelines, before systematic transrectal ultrasound (TRUS)-guided biopsy. All examinations were read by three independent radiologists with 3-year experience in prostate MRI. Sensitivity (Se), specificity (Sp), positive predictive value (PPV) and negative predictive value (NPV) were calculated. Interobserver agreement was evaluated using Kappa Cohen coefficient of agreement.

**Results:** mp-MRI and histopathological results of TRUS-guided biopsy showed a very good agreement in prostate cancer detection. The overall Se, Sp, PPV and NPV ranged between 93.3-96.7%, 55.0-80.0%, 76.3-87.9% and 88.2-94.1%, respectively. The Kappa Cohen coefficient of interobserver agreement was 0.643 between Readers 1 and 2, 0.664 between Readers 1 and Reader 3 and 0.568 between Readers 2 and 3.

**Conclusions:** Our results showed a high Se for the detection of prostate cancer with mp-MRI and a high NPV to rule out prostate malignancy. PI-RADS version 2 provides an adequate standardization of mp-MRI, allowing a good level of interobserver agreement.

**Key words:** cancer imaging, multiparametric MRI, prostate cancer

Introduction

mp-MRI allows a noninvasive assessment of the prostate and the surrounding structures, becoming in the recent years the main imaging technique for prostate cancer detection, localization and characterization [1,2].

To promote global standardization of prostate imaging, the ESUR developed the Prostate Imaging Reporting and Data Systems™ (PI-RADS) [3]. The first guideline published in 2012 established the minimum requirements for acquisition protocols and provided a structured reporting scheme – the PI-RADS score, adapted from the BI-RADS score used by breast radiologists [3]. The first PI-RADS score was based on a sum of scores for each lesion.
as assessed in different sequences of mp-MRI-T2-weighted imaging (T2WI), diffusion-weighted imaging (DWI), dynamic contrast-enhanced (DCE) MRI and optionally spectroscopy [3]. Based on initial experience and continued evolution in this field, an international expert panel developed in December 2014 a revised version - the PI-RADS 2.0 [1]. This version introduced the concept of “dominant sequence”. Therefore, DWI was established as the most important sequence for the assessment of the peripheral zone lesions and T2WI as the main sequence for the assessment of the transition zone [1]. In the second version of PI-RADS, DCE-MRI was offering a minor role, and spectroscopy was no longer recommended for routine practice [1]. In contrast to the first version, for each lesion a single score is to be calculated based on mp-MRI findings [1-7].

PI-RADS scoring systems have been validated in several research and clinical settings. Nevertheless, variations in the reported accuracy of detection of clinically significant prostate cancer using mp-MRI has been reported, with Se ranging between 66 and 84% and Sp between 68 and 92% [8,9].

The aim of this study was to evaluate the diagnostic performance of mp-MRI for the detection of prostate cancer and to assess the interobserver agreement when using PI-RADS version 2.

Methods

Study design and patients

This was a prospective observational single-center study performed between October 2012 and October 2016 in Cluj-Napoca. Consecutive male patients with clinically suspected prostate cancer based on prostate-specific antigen (PSA) values and/or clinical examination, with no prior prostate biopsy or with prior negative biopsy who were examined by mp-MRI were enrolled. Exclusion criteria included a prior history of prostate cancer and the lack of subsequent prostate biopsy after mp-MRI. The study was approved by the local ethics committee, and written informed consent was obtained from all patients prior to any study procedures. The study was performed in agreement with The Code of Ethics of the World Medical Association (Helsinki Declaration) for experiments involving human subjects.

MRI imaging protocol

MRI examinations were performed using a 1.5-T Magnetom Avanto scanner (Siemens Healthcare, Erlangen, Germany), with a 6-element body matrix coil (acquisition parameters are shown in Table 1). For all MRI assessments, we used the detection protocol provided by the ESUR guidelines in 2012 [3]. Patients were examined in feet-first-supine position, using the same MRI sequences: T2WI, DWI with ADC map, T2 fat-sat, T1WI, and DCE (Table 1). No prior bowel preparation was used. An endorectal coil (ERC; Medrad Bayer Medical Care Inc., Indianola, PA, USA) in combination with the body matrix coil was used in a subset of patients. The ERC was inflated with 40-60 ml of air for a good fit. For DCE, gadolinium-based contrast agent was administered i.v. as bolus at a dose of 0.1 mmol/kg body weight followed by a 20-ml saline flush.

Image interpretation

All MRI examinations were read by 3 independent radiologists (Readers 1, 2 and 3) with 3 years of experience in prostate MRI, who were blinded to each other’s readings. The radiologists were aware of the patient PSA history and clinical data. The images were analyzed using Syngo (VB17) software, commercially available applications and OsiriX MD viewer. All readers were required to independently fill a standardized mp-MRI reporting scheme modified after Weinreb et al. [1] and Rothke et al. [4] (Figure 1). Briefly, antero-posterior, transversal and longitudinal diameters were measured for each prostate. The longitudinal diameter was divided in 3 sections and thereby the base, midgland and apex of the prostate were assessed. All suspected lesions were

Table 1. Multiparametric MRI acquisition protocol

<table>
<thead>
<tr>
<th>Sequence</th>
<th>TR (ms)</th>
<th>TE (ms)</th>
<th>FOV (mm²)</th>
<th>Flip angle (°)</th>
<th>Matrix</th>
<th>B-values</th>
<th>Slice thickness (mm), no gaps</th>
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<td>4490</td>
<td>92</td>
<td>230</td>
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<td>224x520</td>
<td>-</td>
<td>3</td>
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<td>224x520</td>
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<td>3</td>
</tr>
<tr>
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<td>92</td>
<td>200</td>
<td>150</td>
<td>224x520</td>
<td>-</td>
<td>3</td>
</tr>
<tr>
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<td>98</td>
<td>360</td>
<td>150</td>
<td>143x192</td>
<td>-</td>
<td>3</td>
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<td>150</td>
<td>157x256</td>
<td>50, 500, 800, 1000, 1200</td>
<td>3</td>
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<td>12</td>
<td>400</td>
<td>150</td>
<td>174x256</td>
<td>-</td>
<td>3</td>
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<td>TSE</td>
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<td>2.4</td>
<td>410</td>
<td>150</td>
<td>145x320</td>
<td>-</td>
<td>3</td>
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</tbody>
</table>

Prostate cancer detection with multiparametric MRI

noticed and stratified according to PI-RADS 2 lexicon [1]
and for each MRI abnormality was assigned a PI-RADS
score. For all patients scanned between October 2012
and December 2014 (24 patients), 3 single-scores (scale
from 1 to 5) were initially defined for T2WI, DWI and
DCE-MRI, according to the ESUR 2012 guidelines [3] and
a PI-RADS sum-score was reported. Once the PI-RADS 2
scoring system was available, the initial sum-score was
reviewed and a revised PI-RADS score was reported. The
transition from PI-RADS v.1 to PI-RADS v.2 was made
in order to use the same scoring system for all patients
examined in the study.

Mp-MRI findings were reported as "positive" if
PIRADS 3, PIRADS 4 or PIRADS 5 abnormalities were
identified and "negative" if only PIRADS 1 or PIRADS 2
findings were present. All mp-MRI reporting schemes
were compared with the histopathological data. Image
interpretation and scoring was done before prostate bi-
opsy, and the radiologists were blinded to histopatho-
logical findings.

Prostate cancer definition

The reference standard was the result of systematic
TRUS-guided biopsy. The histopathological results were
considered positive, and thus patients were diagnosed
with prostate cancer, if Gleason score was ≥6.

The mp-MRI was considered "true positive" if bi-
opsy specimens showed pathologically positive results,
and "true negative" if biopsy result was negative.

Histopathological analysis

All enrolled patients underwent a systematic 12
core TRUS-guided biopsy; additional targeted biopsies
on MR-suspected lesions were obtained in 8 patients.

Tissue samples were fixed in 10% buffered formalin,
included in paraffin and sectioned at 5μm. Slides were
stained using hematoxylin-eosin following the manu-
ufacturer’s specifications. Difficult or equivocal cases
were evaluated by immunohistochemistry. The follow-
ing antibodies were used: p63 (Clone 7JUL, Novoca-
stra, Leica Biosystems Nussloch GmbH), high molecular
weight cytokeratin (clone 34betaE12, Novocastra, Leica
Biosystems Nussloch GmbH) and alpha-methylacyl-CoA
racemase (AMACR, P504S, clone EPMU1, Novocastra,
Leica Biosystems Nussloch GmbH). Heat-induced an-
tigen retrieval was performed with a pressure cooker
(HIER method) and the detection system employed was
Novolink Polymer Detection Kit (Novocastra, Leica Bio-
systems Nussloch GmbH).

Slides were examined by a pathologist with 8-year
experience in prostate pathology, using an Olympus
BX43 microscope.

Statistics

Data were analyzed using MedCalc 10.3.0.0 (Med-
calc Software bvba, Ostend, Belgium) and IBM SPSS
Statistics version 20 (SPSS Inc., Chicago, IL, USA). Nu-
merical variables were summarized using descriptive
statistics: proportion for qualitative variables, mean and standard deviation or median (quartile 1; quartile 3) for continuous variables. For the comparison of numerical variables, used were Student t-test and independent samples median test (depending on its distribution). For the detection of prostate cancer with mp-MRI, the area under the curve (AUC), Se, Sp, PPV, NPV overall and by mp-MRI performed with and without ERC for all three readers. Accuracy rate was calculated as number of true negative cases + number of true positive cases number of all cases assessed. Interobserver agreement was evaluated by Interrater agreement Cohen’s kappa coefficient. A p <0.05 was considered statistically significant.

Results

112 consecutive patients with clinically suspected prostate cancer were assessed by mp-MRI during the above-mentioned period. After excluding those who did not fulfill the inclusion and had exclusion criteria, 50 patients were enrolled and included in this analysis: 39 biopsy-naïve men and 11 men with prior negative biopsies. ERC was used in 28 (56%) of the patients: 2 biopsy-naïve men and 26 with prior negative biopsies (Table 2).

There was no statistically significant difference between the biopsy-naïve group and the negative biopsy group, with regard to age (mean age 68.66±6.93 years vs. 67.54±5.31 years, p=0.623) and PSA levels (median 13.5 ng/ml [7.4 ng/ml; 28.2 ng/ml]) vs. 11.0 ng/ml [8.9 ng/ml; 13.0 ng/ml], p=0.495).

Thirty of the 50 patients (60%) included in the study were positive for prostate cancer after TRUS-guided biopsy. Of these patients, 23 (76.7%) had a clinically significant prostate cancer according to the PI-RADS 2 criteria. Gleason score at biopsy ranged from 6 to 10: Gleason 3+3=6 (n=7), Gleason 3+4=7 (n=9), Gleason 4+3=7 (n=9), Gleason 4+5=7 (n=5), Gleason 4+4=8

Figure 2. A 68-year-old man with a PSA level of 250 ng/ml-mp-MRI without ERC. A: Axial T2WI TSE, B: Axial T2WI fat-sat TSE and C: Coronal T2WI TSE showing a hypointense mass (arrows) in the peripheral zone of the right prostatic lobe with definite extraprostatic extension. D: Axial DWI image and E: ADC map showing markedly hyperintense signal on high b-value (b 1200) and markedly hypointense mass on ADC (arrows). F: DCE-MRI demonstrates enhancement of right peripheral zone mass (arrow). According to the PI-RADS v2, each reader’s score for T2, DWI and DCE were: 5, 5 and 5 and +, the overall score was 5 (clinically significant cancer is highly likely to be present). Biopsy following mp-MRI was positive for prostate cancer in the right gland with a Gleason score of 7 (4+3). G: Prostate biopsy infiltrated by acinar adenocarcinoma Gleason score 4 (HE 100x). PSA: prostate-specific antigen, mp-MRI: multiparametric MRI, ERC: endorectal coil, TSE: turbo spin echo, HE: hematoxylin-eosin.
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(n=4), Gleason 4+5=9 (n=2), Gleason 5+4=9 (n=2), 
Gleason 5+5=10 (n=1). Figures 2 and 3 present the 
mp-MRI and TRUS-guided biopsy findings in two 
prostatic adenocarcinoma cases.

Table 2. Patient characteristics

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of patients</td>
<td>50</td>
</tr>
<tr>
<td>Age (years), mean±SD</td>
<td>68.4±6.6</td>
</tr>
<tr>
<td>PSA level (ng/ml), median (Q1; Q3)</td>
<td>12.6 (7.8;26.0)</td>
</tr>
<tr>
<td>Prior negative biopsy, n (%)</td>
<td>11 (22.0)</td>
</tr>
<tr>
<td>Gleason score, mean±SD</td>
<td>7.3±1.1</td>
</tr>
<tr>
<td>ERC used during the mp-MRI, n (%)</td>
<td>28 (56.0)</td>
</tr>
</tbody>
</table>

SD: standard deviation, Q1: quartile 1, Q3: quartile 3, n (%): number (percentage) of patients, PSA: prostate-specific antigen, ERC: endorectal coil

When data was analyzed overall, irrespective of the use of the ERC, of the 30 TRUS-guided biopsy positive cases, Reader 1 correctly identified 28 cases, Reader 2 correctly identified 29 and Reader 3 correctly identified 29 cases (true positive cases) - Figure 4. Se ranged between 93.3% for Reader 1 and 96.7% for Readers 2 and 3; Sp ranged between 55.0% for Reader 3 and 80.0% for Reader 2; NPVs ranged between 88.2% for Reader 1 and 94.1% for Reader 2. Calculated accuracy rates were 85.0, 90.0 and 80.0% for Readers 1, 2 and 3, respectively (Table 3, Figure 5A). Interobserver Kappa Cohen coefficients of agreement ranged between 0.568 for the agreement between Reader 2 and Reader 3 and 0.664 for the agreement between Reader 1 and Reader 3 (Table 4).

In patients for which an ERC was used, all readers correctly identified the 14 TRUS-guided biopsy positive cases (true positive cases) - Figure 4B. Se

Figure 3. Mp-MRI of a 73-year-old man with a PSA level of 42.39 ng/ml and prior negative TRUS-guided biopsy. A: Axial T2WI TSE, B: Axial T2WI fat-sat TSE and C: Sagittal T2WI TSE showing a homogeneous hypointense mass (arrows) in the transition zone of the prostate with extraprostatic extension. D: Axial DWI image and E: ADC map showing midly hyperintense signal on high b-value (b 1200) and moderately hypointense mass on ADC (arrow). F: DCE-MRI demonstrates enhancement of transition zone mass (arrow). Each reader scored the mass PIRADS 5 (T2 – PIRADS 5, DWI – PIRADS 5, DCE +). Biopsy following mp-MRI was positive for prostate cancer with a Gleason score of 6 (3+3). G: Prostate biopsy infiltrated by acinar adenocarcinoma Gleason score 3 (HE 20x) showing well-formed glands, with prominent nucleoli. H: Immunohistochemical stains for CK34 beta E12 highlight prostate basal cells in non-tumor glands which are absent in carcinoma area. I: The immunohistochemical stain for AMACR marks the tumor glands. PSA: prostate-specific antigen, mp-MRI: multiparametric MRI, TRUS: transrectal ultrasonography, HE: hematoxylin-eosin.
Figure 4. Diagnostic accuracy for the detection of prostate cancer between TRUS-guided biopsy (reference standard test) and mp-MRI by reader. Panel A displays overall results – with and without endorectal coil. Panel B displays results when the endorectal coil is used and Panel C displays results without endorectal coil. TRUS: transrectal ultrasonography, mp-MRI: multiparametric MRI, ERC: endorectal coil, R1: Reader 1, R2: Reader 2, R3: Reader 3.

Figure 5. Receiver operating characteristics for the detection of prostate cancer between TRUS-guided biopsy (reference standard test) and mp-MRI by reader. Panel A displays overall results – with and without endorectal coil. Panel B displays results when the endorectal coil is used and Panel C displays results without endorectal coil. MRI: multiparametric MRI, R1: Reader 1, R2: Reader 2, R3: Reader 3.
and NPVs were 100% in all Readers. Sp ranged between 64.3% for Reader 3 and 78.6% for Reader 2. Calculated accuracy rates were 85.7, 89.2 and 82.1% for Readers 1, 2 and 3, respectively (Table 3, Figure 5B). Interobserver Kappa Cohen coefficients of agreement ranged between 0.691 for the agreement between Reader 2 and Reader 3 and 0.772 for the agreement between Reader 1 and Reader 2 (Table 4).

In patients for which ERC was not used, of the 16 TRUS-guided biopsy positive cases, Readers 1, 2 and 3 correctly identified 14, 15, and 15 cases, respectively (true positive cases) - Figure 4C. Se ranged between 87.5% for Reader 1 and 93.8% for Readers 2 and 3; Sp ranged between 33.3% for Reader 3 and 83.3% for Readers 1 and 2; NPVs ranged between 66.7% for Reader 3 and 83.4% for Reader 2 (Table 3, Figure 5C). Interobserver Kappa Cohen coefficients of agreement ranged between 0.321 for the agreement between Reader 2 and Reader 3 and 0.506 for the agreement between Reader 1 and Reader 3 (Table 4).

**Discussion**

In the study presented here, evaluating the interobserver agreement of prostate cancer detection using mp-MRI and PIRADS v.2 scoring, we observed an overall good level of agreement, with Kappa Cohen scores ranging between 0.568 and 0.664. Interobserver agreement improved when ERC was used in combination with the body matrix coil, with Kappa Cohen coefficients increasing to 0.691-0.761. These results are consistent with previous reports on the interobserver agreement of prostate cancer.
cancer detection [10-15]. For the original PI-RADS score, Schimmöller et al. [10] found a good interobserver agreement for prostate tumor lesions (T2WI: k=0.66, DWI: k=0.80, DCE-MRI: k=0.63). This retrospective study included 67 consecutive patients and used MRI-guided biopsy as the reference standard; scoring was performed by 3 blinded readers with 4, 3 and 2 years of experience in prostate MRI. In another study using also the original PI-RADS score, Rosenkrantz et al. [11] reported a strong agreement between experienced readers and a moderate to poor agreement between experienced and inexperienced readers for tumors located in the peripheral zone and transition zone combined. In a recent study using the PI-RADS v.2, Muller et al. [12] reported a moderate level of interobserver agreement for readers of varying experience, with an overall k score of 0.46. The good level of interobserver agreement observed in our study might be explained by the similar level of experience of the readers in prostate MRI. The growing readers’ experience with mp-MRI and the improvement of PI-RADS versions in the future will probably improve the strength of agreement, especially between readers with similar level of experience. The higher interobserver agreement noticed in our mp-MRI studies performed with ERC in addition to phased array coil might be explained by the increased signal-to-noise ratio, with a higher spatial resolution of the prostate gland [1,13-15].

Our results confirm that mp-MRI and PI-RADS v.2 scoring system are sensitive tools in prostate cancer diagnosis. mp-MRI and histopathological results of TRUS-guided biopsy showed a very good agreement in prostate cancer detection. The overall Se ranged between 93.3 and 96.7% and overall Sp between 55.0 and 80.0%. The PPV and NPV values ranged between 76.5% and 87.9% and between 88.2 and 94.1%, respectively. The accuracy rates ranged between 85.0 and 90.0%. In other words, mp-MRI findings correctly identified 93.3 to 96.7% of true positive prostate cancer cases as assessed by TRUS-guided biopsy and the likelihood of someone with a positive finding on mp-MRI to have a positive TRUS-guided biopsy was 85.0 to 90.0%.

These results are in line with previous reports which showed that mp-MRI has a good diagnostic accuracy and may detect significant prostate cancer in biopsy-naïve men and in patients with prior negative biopsies [8,16]. In a diagnostic meta-analysis including 14 studies (of which 11 prospective studies) and 1785 patients, Hamoen et al. [8] reported a Se of 78% (95%CI:70%;84%) and a Sp of 79% (95%CI: 68%; 86%) for prostate cancer detection, with NPVs ranging from 58% to 95%. All studies used mp-MRI consisting of T2WI, DWI, and DCE-MRI; ERC was used in 2 studies. TRUS-guided biopsy was the reference test in 8 studies included in this meta-analysis. In a systematic review of the literature performed by Futterer et al. [16] which included 12 studies performed using anatomical T2WI plus at least 2 functional techniques, the authors found a wide variation of the reported accuracy for the detection of clinically significant prostate cancer. Reported Se spanned from 58 to 96%, Sp from 23 to 87%, NPV from 63 to 98% and PPV from 34 to 68%.

For the clinicians, high NPVs may be important as mp-MRI could be used to exclude the presence of significant disease [16]. Using transperineal template systematic biopsy as the gold standard, Abd-Alazziz et al. [17] showed that mp-MRI following at least one previous biopsy had a good performance in excluding the presence of clinically significant prostate cancer, with an NPV of 95%. The authors concluded that mp-MRI can be used to identify patients who can avoid further biopsies following a previous negative one [17]. In our study NPV values ranged between 88.2 and 94.1%, thus the likelihood of someone with a negative finding on mp-MRI to have a negative TRUS-guided biopsy was 85.0 to 90.0%. Of the 30 patients with a biopsy-proved prostate cancer after TRUS-guided biopsy in our study, 76.6% had a clinically significant cancer, as defined by PI-RADS v.2. The high percentage of clinically significant cancer cases in our series of patients may explain the high Se and NPV reported.

Analyzing the benefits of using the ERC, we observed that the overall Se and NPV increased with the use of ERC for all readers. As for the improved interobserver agreement, the use of ERC in addition to phased array coil allowed a more reliable cancer delineation [1,13-15].

Our study has several limitations which may have influenced the results – such as the reporting of positive mp-MRI per patient and not per lesion and the lack of accurate correlation between the localization of suspicious lesions on TRUS-guided biopsy and mp-MRI. As previously mentioned [18], this may be overcome using MRI-ultrasound fusion technique or MR-in bore biopsy. Compared to systematic biopsy, MRI-guided biopsy may increase the detection of clinically significant tumors. Although the overall cancer detection rate may not be higher in the imaging arm, this may improve biopsy performance and diagnostic accuracy of prostate cancer [10,19-23]. This is a single center study enrolling a small sample size; thus, its results cannot be generalized and further investigations including larger samples are needed to confirm our findings.
Conclusions

Our results showed high Se for the detection of prostate cancer with mp-MRI and high NPV to exclude prostate malignancy. PI-RADS v.2 provides an adequate standardization of mp-MRI, allowing a good level of interobserver agreement between readers with the same level of experience in prostate MRI.

Conflict of interests

The authors declare no conflict of interests.

References