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Trial

Prospective comparison of a fast 1.5-T biparametric with the 3.0-T multiparametric ESUR magnetic resonance imaging protocol as a triage test for men at risk of prostate cancer

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Objective

To compare prospectively the diagnostic performance of a biparametric (T2-weighted imaging [T2WI] and diffusion-weighted imaging [DWI]) 1.5-T fast magnetic resonance imaging (fMRI) protocol with the standard 3.0-T multiparametric MRI (mpMRI) protocol of the European Society of Urological Imaging (ESUR) in men referred for a prostate biopsy.

Patients and Methods

Ninety patients with a prostate cancer (PCa) risk of ≥10% according to the SWOP calculator 4 underwent first fMRI and then the reference mpMRI. Patients with Prostate Imaging Reporting and Data System (PI-RADS) v.2 lesions ≥3/5 on the mpMRI were scheduled for MRI/ultrasonography (US) fusion-guided prostate biopsy. Performance of fMRI was assessed using receiver-operating characteristic curve analysis and mpMRI as reference. Calculation of inter-technique agreement on PI-RADS v.2 score by Cohen's κ.

Results

The diagnostic accuracy of fMRI shown by the lesion-based analysis was excellent: area under the curve (AUC) 0.961 ($P < 0.001$), sensitivity 95%, specificity 97%, positive predictive value (PPV) 99%, negative predictive value (NPV) 89%. The patient-based analysis showed an AUC for fMRI of 0.975 ($P < 0.001$), a sensitivity of 98%, a specificity of 97%, a PPV of 98% and an NPV of 97%. Agreement on the PI-RADS score between both protocols was found to be good (κ = 0.78 [0.57; 0.99]); fMRI missing PI-RADS 4 lesions in three patients. Biopsy results showed no cancer in two patients (two cores per nodule) and Gleason 6 cancer in one patient. There was only one false-positive fMRI, with a PI-RADS score of 4, whose biopsy was negative.

Conclusion

In the triage of men with a high risk of PCa for prostate biopsy, an f MRI protocol (1.5-T magnet, T2WI + DWI, <15 min) may safely replace the traditional ESUR 3.0-T mpMRI protocol, saving time and contrast injection.

Keywords

prostate cancer, prostate biopsy, prostate MRI, PI-RADS 2, triage test diagnosis

Introduction

Although MRI of the prostate has been shown to improve the accuracy of prostate cancer (PCa) detection, its incorporation into the standard diagnostic care pathway remains rather slow [1]. Lack of consensus on how to perform and read MRI, cost, lack of availability, and lack of prospective validations have been consistently cited as the main hurdles. The first organized European consensus was produced in 2011, followed by the publications of the prostate multiparametric MRI (mpMRI) guidelines and the Prostate Imaging Reporting and Data System (PI-RADS) v.1 and v.2 scoring systems by the European Society of Urological Imaging (ESUR) [2–4]. mpMRI has allowed the development of MRI-targeted biopsies using MRI/ultrasonography fusion software that has been shown to outperform standard TRUS-guided biopsy [5–7].

The standard ESUR mpMRI diagnostic protocol comprises T2-weighted imaging (T2WI), diffusion-weighted imaging

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(DWI) and dynamic contrast-enhanced (DCE) sequences [2]. The standard acquisition time of a mpMRI is ~30 min and mpMRI requires placing an i.v. line for the gadolinium injection used in the DCE sequence, and an anti-peristaltic drug. The added value of the DCE sequence has been debated since the introduction of PI-RADS v.2 scoring system in 2015 [4]. The DCE sequence only plays a limited role in the interpretation of equivocal PI-RADS 3 lesions in the peripheral zone on the DWI (if positive, upgraded to 4). In addition, concerns have arisen about the potential harmful effect of gadolinium accumulation [8]. For this reason, and because of the growing demand for prostate MRI, studies have investigated the potential of biparametric MRI (bpMRI), consisting of a T2WI and DWI sequence, in the detection of clinically significant PCa [9–15]. The majority of these studies were conducted retrospectively by re-analysing the MRI results without incorporating the perfusion sequences [16,17]. In addition, most MRI examinations were performed on a 3.0-T magnet [16,17].

The aim of the present study was to compare prospectively the diagnostic accuracy of two separate MRI methods performed on the same day: a fast bpMRI (T2WI, DWI) protocol at 1.5 T without endorectal coil and anti-peristaltic agent (fMRI) and the standard ESUR 3.0-T mpMRI (T2WI, DWI and DCE) as reference.

Materials and Methods

Study Population

Ninety consecutive patients entered the study between December 2014 and October 2016. Men were eligible if they were aged <75 years, were asymptomatic, and presented with an elevated PSA value, obtained through opportunistic screening and resulting in a PCa risk of >10% (<60-year-olds) or >15% (60–75-year olds) using the SWOP 4 PCa risk calculators (http://www.prostatecancer-riskcalculator.com) of the Prostate Cancer Foundation [18]. The calculator has been internally validated [19]. Patients were still eligible if they had a prior negative biopsy (free of PCa) if performed >1 year before inclusion. The only exclusion criteria were the contraindications of mpMRI: implanted devices; severe renal insufficiency (GFR <35 mL/min); and claustrophobia. The local ethics committee approved the study (2014/15OCT/515) and all patients were required to provide written informed consent.

MRI Protocols

The details of MRI protocols can be found in Table 1. A Fleet enema was administered before the MRI (Microlax®) Johnson & Johnson Consumer SA, Belgium.

The fMRI protocol was first performed on a 1.5-T MRI using a 16-channel pelvic phased array (GE MR 450W GEM, General Electric, Milwaukee) without endorectal coil. It consisted of triplanar T2WI (PROPELLER) and axial DWI with three *b*-values (b = 0–1 000–2 000). Scan time, including position and calibration, was < 15 min (12′38″ sequence acquisition time). Immediately after, the patient was given an intravascular anti-peristaltic agent (Glucagen®; Novo Nordisk, Belgium 1 mg/mL in absence of contraindications) before the mpMRI, which was performed on a 3.0-T clinical MRI system (Ingenia; Philips Healthcare, Best, the Netherlands) according to the ESUR guidelines [2]. It consisted of triplanar T2WI (turbo-spin echo), axial DWI (b = 0–500–1 000–1 500) and axial DCE imaging (eTHRIVES with intravenous Dotarem®; Guerbet, Belgium 0.2 mg/kg [45 sets of 24 images], temporal resolution <7 s, injection rate 2.5 mL/s). Scan time, including patient perfusion, position and calibration was ~25 min.

Image Analysis

The mpMRI protocol was agreed by consensus, according to the PI-RADS v.2 reporting system, by two radiologists with 2 and 10 years of experience in prostate imaging [4]. Each PI-

Table 1 MRI parameters.

Sequence type	fMRI protocol (±15 min*)				mpMRI protocol (± 25 including perfusion*)					
	T2 PROP			TSE-DWI	T2 TSE			EPI SPAIR-DWI	DCE - TFE SPAIR eTHRIVE	T1 mDIXON
Plane	Sag	Coro	Ax	Ax	Sag	Coro	Ax	Ax	Ax	Ax pelvic
TR (ms)	2 479	2 066	6 009	5 200	2 500	3 500	3500	4 000	Min	Min
TE (ms)	97	97	131	Min	120	120	120	Min	Min	Min
FOV (mm)	240	240	180	400	160	240	240	350	224	360
matrix	288	320	512	128	384	512	512	240	224	320
b-value				0;1 000;2 000				0;500; 1 000;1500		
Slice thickness (mm)	3	3	3	4	3	3	2,5	4	3	3
Scan time (seconds)	109	107	294	213	105	95	189	213	267	15
Total Scan time	12 min 3 sec				14 min 44 sec					

*TR, repetition time; TE, echo time; FOV, field of view; PROP, PROPELLER (Periodically Rotated Overlapping ParalleEL Lines with Enhanced Reconstruction); TSE, Turbo Spin Echo; DWI, diffusion weighted-imaging; SPAIR, SPectral Attenuated Inversion Recovery; DCE, dynamic contrast-enhanced imaging; eTHRIVE, Enhanced T1 High Resolution Isotropic Volume Excitation; mDIXON, 3D spoiled turbo gradient echo method; Ax, axial, Sag, sagittal; Coro, coronal; Min., minimum; min, minutes; sec, seconds. *Time including sequences, patient preparation and position*

RADS lesion ≥3/5 on the T2 map of mpMRI was manually delineated by the radiologist with a region of interest (ROI) to guide the targeted biopsy. They assessed positive DCE on raw images as an early enhancement corresponding to PI-RADS 3 lesions in the peripheral zone. To assess the benefit of DCE in an upgraded lesion, the final score was calculated as PI-RADS 3+1/5. The same radiologists reviewed anonymized fMRI after a minimum of 1 month to avoid bias. Referring urologists were informed in case a positive lesion was found on fMRI that was not seen on mpMRI. An additional biopsy was then scheduled.

Random and Prostate-Targeted Biopsy Using MRI/Ultrasonography Software Fusion Biopsy

Patients with a prostatic lesion classified PI-RADS ≥3/5 at mpMRI or patients with discordant fMRI underwent template-based 12-core biopsy and targeted biopsy of delineated ROI (2–4 cores/ROI) using the Urostation® system (Koelis, La Tronche, France). One pathologist reviewed the biopsy according to the International Society of Urological Pathology 2014 guidelines. Clinically significant PCa was defined as any cancer with Gleason score ≥7.

Statistical Analysis

Results are presented according to the START (standard of reporting for MRI-targeted biopsy studies) recommendations (Fig. 1) [20].

The primary endpoint of the study was the diagnostic accuracy of the biparametric 1.5-T fMRI protocol, taking the ESUR 3.0-T mpMRI protocol as reference on a per-patient and per-lesion basis. The diagnostic performance of mpMRI has been calibrated on a local series of radical prostatectomies (unpublished data). For the detection of any cancer, the sensitivity was 63%, the specificity 76%, the positive predictive value (PPV) 77% and negative predictive value (NPV) 63%. For the detection of clinically significant cancer, defined as any Gleason sum ≥7 the sensitivity was 74%, the specificity 87%, the PPV 65% and the NPV 90%. The sample size was calculated assuming a non-inferiority analysis of the fMRI protocol and the standard ESUR mpMRI protocol, taking into account a non-inferiority margin of 5% and a sensitivity of 73% for mpMRI. For a fixed power of 85% and an α-value of 5%, 167 examinations were required. An interim analysis was planned after 90 examinations.

For the present study the sensitivity, specificity, PPV, NPV and accuracy were calculated for fMRI with 95% CIs using mpMRI as reference. Receiver-operating characteristic (ROC) curve analysis has been calculated using SPSS v. 17.0 (SPSS Inc., Chicago, IL, USA) [21]. Inter-technique agreement on the PI-RADS score v.2 was analysed using Cohen's κ and its 95% CI [22]. The strength of the agreement was interpreted as follows: poor ($\kappa < 0.2$), weak ($0.2 < \kappa \leq 0.4$), moderate ($0.4 < \kappa \leq 0.6$), good ($0.6 < \kappa \leq 0.8$) and very good ($\kappa > 0.8$).

Results

Patient Characteristics

Details of the demographics of the patients and START results are listed in Fig. 1 and Table 2. The interim analysis of the study was triggered when 90 patients fulfilled the inclusion criteria, as per protocol. The median age was 63 years and the median detectable cancer risk, assessed using the SWOP calculator, was 32%. Eight patients were excluded because of interferences attributable to movements or total hip replacement. The following analysis was performed on the remaining 82 patients. A total of 82 lesions PI-RADS ≥3/5 were detected in 48 patients, 45 underwent a prostate biopsy, three refused it. The biopsy revealed prostatic intraepithelial neoplasia or Gleason score 6 PCa in 16 patients (35%) and Gleason score ≥7 PCa in 24 patients (53%). The distribution of maximum Gleason score by random and TRUS-guided biopsy is shown in Table 3.

MRI Results

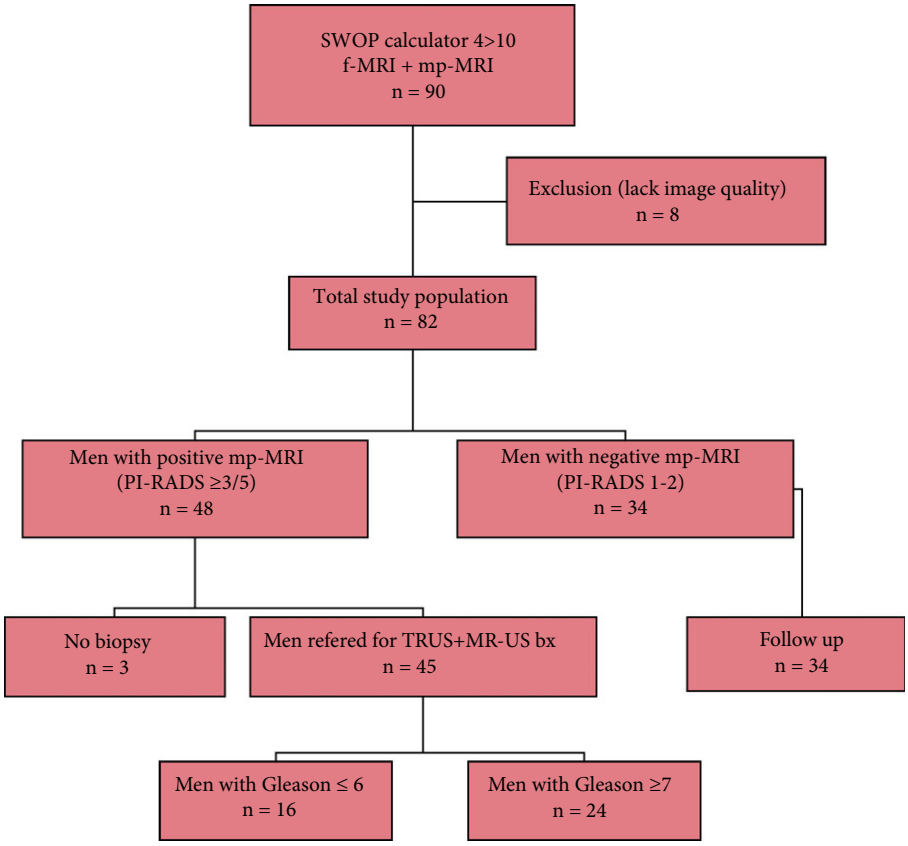
Agreement on the PI-RADS score between both protocols was found to be good, with a κ value of 0.78 (95% CI 0.57; 0.99). In consensus reading, the two radiologists assigned a concordant PI-RADS score to fMRI and mpMRI in 66 lesions. Details are shown in Table 2.

Primary Endpoints

There was a high agreement between fMRI and mpMRI results for the 82 lesions in the 48 patients (Table 2). The diagnostic accuracy of fMRI, using mpMRI as the 'gold standard', was very high, with per-patient and per-lesion area under the curve (AUC) being 0.975 and 0.961, respectively ($P < 0.001$; Table 4). Based on this, and after discussion with the local ethics committee, the trial was ended prematurely.

The per-patient and per-lesion mean NPVs for fMRI were 97 and 87%, respectively (Table 4). fMRI missed PI-RADS 4 lesions in three patients. Biopsy results showed no cancer in two patients (two cores per nodule) and Gleason 6 in one patient (four cores). There was only one false-positive case, with a PI-RADS score of 4 on fMRI not seen on mpMRI, for which the biopsy was negative (two cores; Table 5). In addition, one patient was diagnosed with a PI-RADS score of 3 on mpMRI that was ranked PI-RADS 2 on the fMRI. The patient's biopsy was negative (two cores). Additional DCE upgraded lesion PI-RADS 3 to PI-RADS 4 in 12 lesions, leading to a Gleason score ≥7 in only two patients.

Fig. 1 Study flow chart. fMRI, fast MRI; mpMRI, multiparametric MRI; PI-RADS, Prostate Imaging Reporting and Data System;



Discussion

Although prostate MRI has been performed concomitant to TRUS since 1982, it is far from being used in every patient [23]. It is incorporated into national and international guidelines in men with prior negative biopsy findings, such as the 2014 National Institute for Health and Care Excellence (https://www.nice.org.uk/guidance) and the European Association of Urology guidelines [24]. A systematic review clearly suggests that image-guided prostate biopsy using MRI-derived targets clearly outperformed the standard ultrasonography-guided random approach [25]. The superiority of MRI-targeted prostate biopsy over TRUS-guided biopsy has been clearly demonstrated by the UK PRECISION and PROMIS trials [5,7].

So why are we not performing MRI before prostate biopsy more systematically? A survey has been conducted to understand the beliefs and practice patterns among urologists [1]. Most respondents acknowledge the value of MRI and MRI-targeted biopsy in clinical practice, but mentioned the lack of necessary infrastructure, the long waiting lists, and prohibitive costs as main factors limiting dissemination.

One way to increase the availability of MRI is to reduce the acquisition time and simplify the procedure. Several groups have investigated the value of a bpMRI, consisting of T2WI and DWI, in the detection of clinically significant PCa, thus questioning the value of the DCE sequence for sole initial diagnostic purpose [14,15,26–28]. The American College of Radiology and the ESUR have downgraded the role of DCE-MRI within the new PI-RADS version 2 as compared with earlier guidelines showing similar (or slightly better) results for the detection of PCa [2,29]. Most series, however, are retrospective, having extracted biparametric data from multiparametric investigations [14,15,26–28]. These studies were not streamlined for a shorter process, and all included the injection of an anti-peristaltic agent preventing bowel movements.

The present study confirms the limited benefit of a DCE sequence in a pure diagnostic setting. PI-RADS scoring was upgraded from 3 to 4 (2.4%) in only two patients, with a ultrasonography/MRI-targeted biopsy showing Gleason score 3 + 4. Skipping the DCE sequence reduces the acquisition time from 14 min 44 s to 12 min 14 s and, in addition, saves the time and nursing resources needed for the i.v. line.

The present fMRI protocol goes beyond simply omitting the DCE sequence. To our knowledge, the present study is the first to compare two MRI techniques on the same day at

Table 2 Patient demographic characteristics and START variables.

Patient characteristic	
Number of men included, *n*	82
Median (IQR) age, years	63 (45, 75)
Median (IQR) pre-biopsy PSA level, ng/mL	10.81 (2.3, 47.0)
Median (IQR) prostate volume, mL	44 (16, 115)
Suspicious DRE, *n* (%)	34 (41)
Men with prior negative biopsy, *n* (%)	14 (17)
Median (IQR) detectable cancer risk on SWOP calculator 4, %	32 (22–47)
Men with PI-RADS 3-5 lesions on mpMRI, *n* (%)	48 (58)
Men with PI-RADS 3-5 lesions on fMRI, *n* (%)	49 (60)
Number of PI-RADS 3-5 lesions on mpMRI, *n*	82
Number of mpMRI and fMRI concordance lesion PI-RADS 3--5, *n*	66
Number of concordant PI-RADS 3 between fMRI and mpMRI	12
Number of mpMRI lesion not visualized on fMRI, *n*	3
Upgraded PI-RADS 3 lesion on fMRI to PI-RADS 4 on mpMRI (DCE +)	12
Number of fMRI lesion ≥3/5 not visualized on mpMRI, *n*	1
Number of fMRI lesion PI-RADS 2 misclassified ≠ PI-RADS 3 on mpMRI	1
START variables	
Men who had systematic and fusion-guided biopsy*, *n*	45
Systematic 12-core transrectal biopsies per patient, *n*	12
Mean (SD) targeted MRI-US fusion-guided biopsies per patient	2.82 (2.57)
Mean (SD) targeted MRI-US fusion-guided biopsies per lesion	1.79 (1.85)
Men with a lesion ≥ PI-RADS 3/5 and negative fusion-guided biopsies, *n*	5
Men with Gleason ≥7 in PI-RADS 3/5, *n*	1
Median (IQR) men with Gleason ≥7 in PI-RADS 3+1 and PI-RADS 4/5, *n*	14 (2–12)
Men with Gleason ≥7 in PI-RADS 5/5, *n*	9

*IQR, interquartile range; fMRI, fast MRI; PI-RADS, Prostate Imaging Reporting and Data System; START, standard of reporting for MRI-targeted biopsy studies. Median prostatic volume was calculated by ultrasonography. *Only men with a PI-RADS lesion ≥ 3 were offered systematic and fusion-guided biopsy.*

Table 3 Cross-tabulation of maximum Gleason score reported on TRUS random biopsy and MRI-targeted biopsy.

	Gleason score	MRI-guided biopsy						
		Negative	PIN	3 + 3	3 + 4	4 + 3	≥4 + 4	Total
TRUS random biopsy	Negative	5	1	1				7
	3 + 3	4		11	2			17
	3 + 4	1		3	4	1		9
	4 + 3	2			1	4	1	8
	≥4 + 4				1		3	4
	Total	12	1	15	8	5	4	45

PIN, prostatic intraepithelial neoplasia.

Table 4 Performance of fast MRI compared with multiparametric MRI.

	Sensitivity % (95% CI)	Specificity % (95% CI)	PPV % (95% CI)	NPV % (95% CI)	AUC % (95% CI)	*P*
Per patient	98 (89–100)	97 (85–100)	98 (89–100)	97 (85–100)	0.97 (0.91–1.00)	<0.0001
Per lesion	95 (88–99)	97 (85–100)	99 (93–100)	89 (75–97)	0.96 (0.908–0.99)	<0.0001

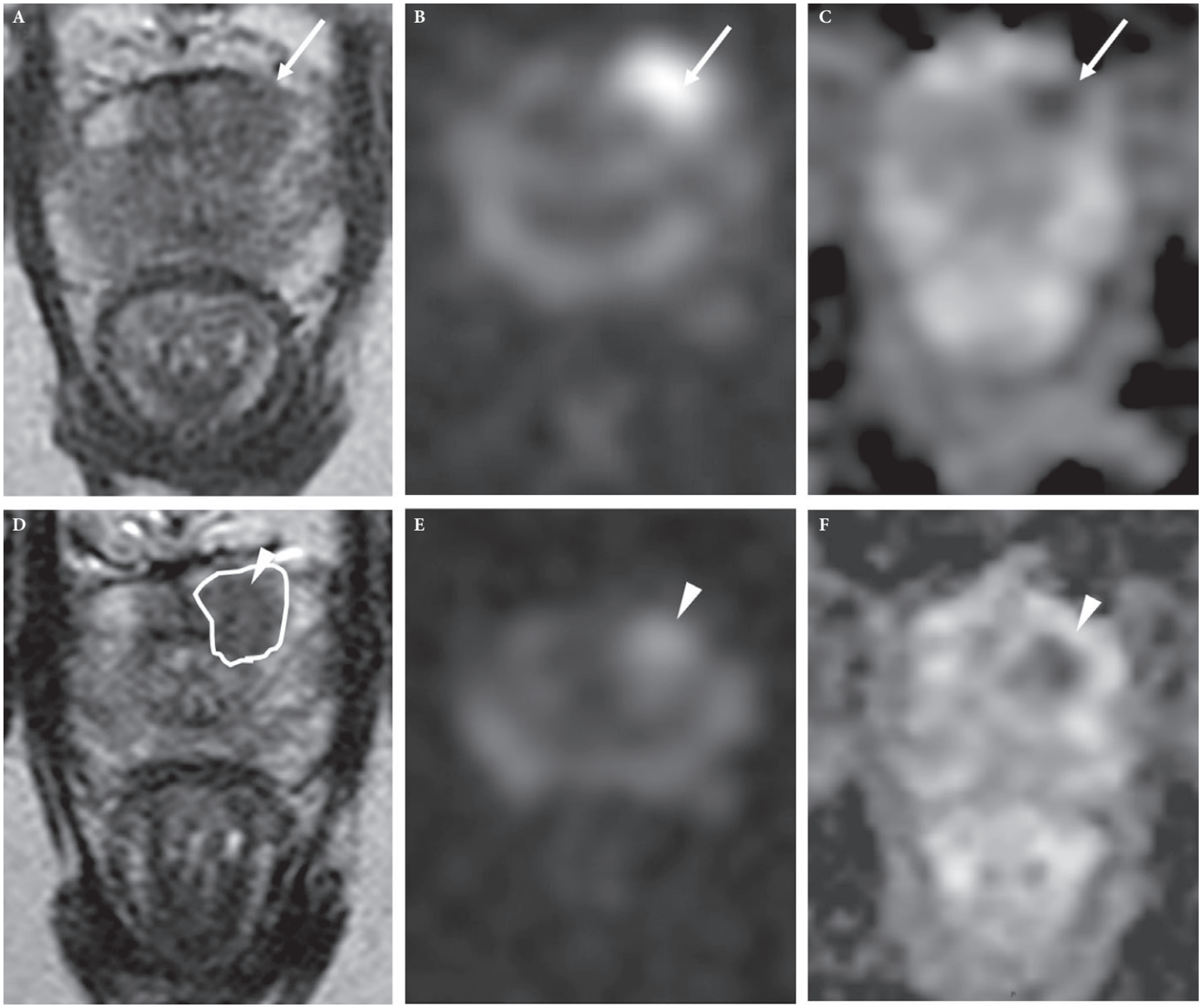
AUC, area under the curve; NPV, negative predictive value; PPV, positive predictive value.

Table 5 Pathological findings of misdiagnosed lesions.

Test result	Patient (*n*)	Location	PI-RADS score	Length (mm)	Pathology	Cores per lesion (*n*)
False-positive	1	TZ	4	11	Negative	2
False-negative	1	PZ	4	5	Gleason 3 + 3	4
	2	PZ	4	4–5	Negative	2
	1	PZ	3	18	Negative	2

False-negative, negative fast MRI (fMRI)/positive multiparametric MRI (mpMRI); false-positive, positive fMRI/negative mpMRI; PZ, peripheral zone; TZ, transitional zone.

Fig. 2 True-positive Prostate Imaging Reporting and Data System (PI-RADS) 4 lesion in a 59-year-old patient with a PSA of 5.27 ng/mL. Ultrasonography (US)/MRI fusion-guided biopsy showed a Gleason score 4 + 3. (**A–C)** Fast MRI protocol left anterior transitional zone lesion of 10 mm (arrow) hypointense on axial T2-weighted imaging (T2WI) (**A**), with restriction of diffusion on high *b* value (b = 2 000 s/mm²) (**B**), and an apparent diffusion coefficient of 0.58 × 10^{-3} mm²/s (**C**). (**D–F)** Multiparametric MRI protocol showing the same lesion (arrowhead) with manual region of interest on T2WI.



different strengths, a standard 3.0-T mpMRI and a 1.5-T optimized fMRI without an endorectal coil, saving the time and the resources (i.v. line) of the DCE sequence and anti-peristaltic agent. In theory, the fMRI could be more attractive considering the broader availability of 1.5-T MRI and a lower resource investment [30]. Overall, the diagnostic accuracy of the fMRI protocol exceeded the trial hypothesis with a per-patient and per-lesion AUC of 0.975 and 0.961, respectively (P < 0.001; Fig. 2). Based on this, it was decided to stop the trial at the interim analysis and not impose on patients two examinations on the same day . The fMRI protocol is now used as the standard test in our care pathway as it avoids biopsy in 40% of patients, with an acquisition time of 15 min.

In the present study, the significant PCa detection rate was similar between the two techniques, and no cancer Gleason score ≥7 cancer would have been missed by fMRI. Indeed, based on the mpMRI results and using a PI-RADS threshold of ≥3, 48 patients were recommended to undergo biopsy. Forty-five patients (55%) accepted, and 40 were diagnosed with PCa. Table 3 shows the distribution of Gleason scores.

Assuming that fMRI would have been used instead at the same PI-RADS cut-off of ≥3, four patients would not have been recommended a biopsy (three with false-negative results and one with PI-RADS score 2), leading to two Gleason 6 cancers being missed. One patient would have been recommended a biopsy, which would have reveal no cancer.

The fMRI resulted in one false-positive PI-RADS 4 lesion in the transition zone, probably resulting from a decreased image contrast (Fig. 3) [31]. The same artefact also probably explains the three false-negative lesions (Fig. 4), none of them revealing clinically significant PCa at the targeted biopsy. We did not study the contrast-to-noise ratio. This will be part of a future analysis.

It is challenging to compare the present study with the previous publications on bpMRI. Previous studies were usually based on a retrospective extraction of specific sequences from mpMRI, previous studies used lower *b*-values (up to b1000), which may have affected the detection rate of significant PCa in the peripheral zone. Others extracted only the axial T2 turbo-spin echo imaging and axial DWI from the mpMRI to reduce acquisition time drastically, but this does not fulfil the minimal two planes recommended by the

Fig. 3 False-positive lesion in a 63-year-old patient with a PSA of 8.41 ng/mL. Ultrasonography/MRI fusion-guided biopsy negative. (**A–C)** Fast MRI protocol Prostate Imaging Reporting and Data System (PI-RADS) 4 lesion of 9 mm in the right transitional zone, hypointense on T2-weighted imaging (**A**), with restriction of diffusion on high *b* value (b = 2 000 s/mm²) (**B**), and an apparent diffusion coefficient of 0.65 × 10^{-3} mm²/s (**C**). Panels **D–F** Multiparametric MRI protocol without significant lesion (arrowhead) and classified PI-RADS 2.

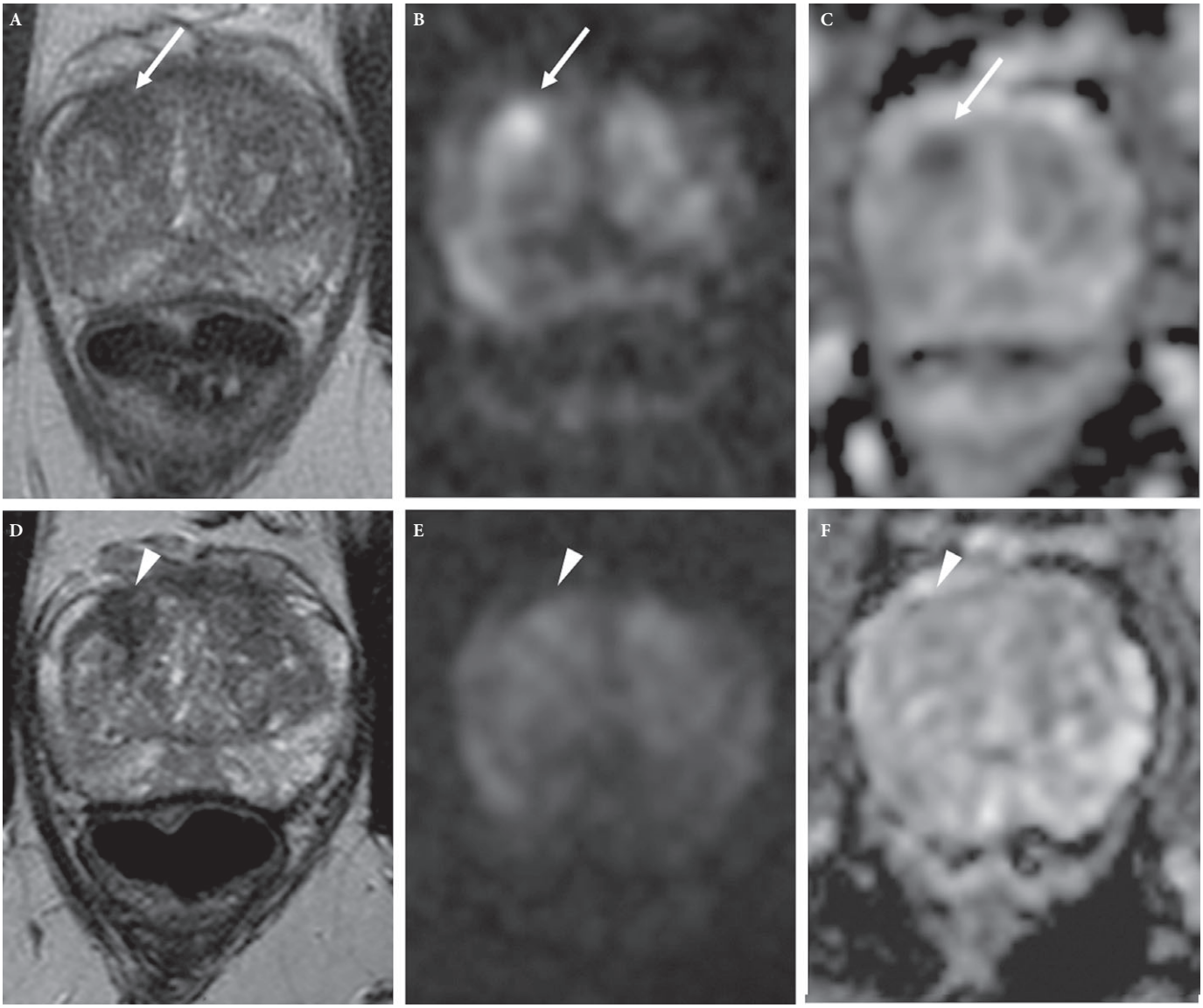
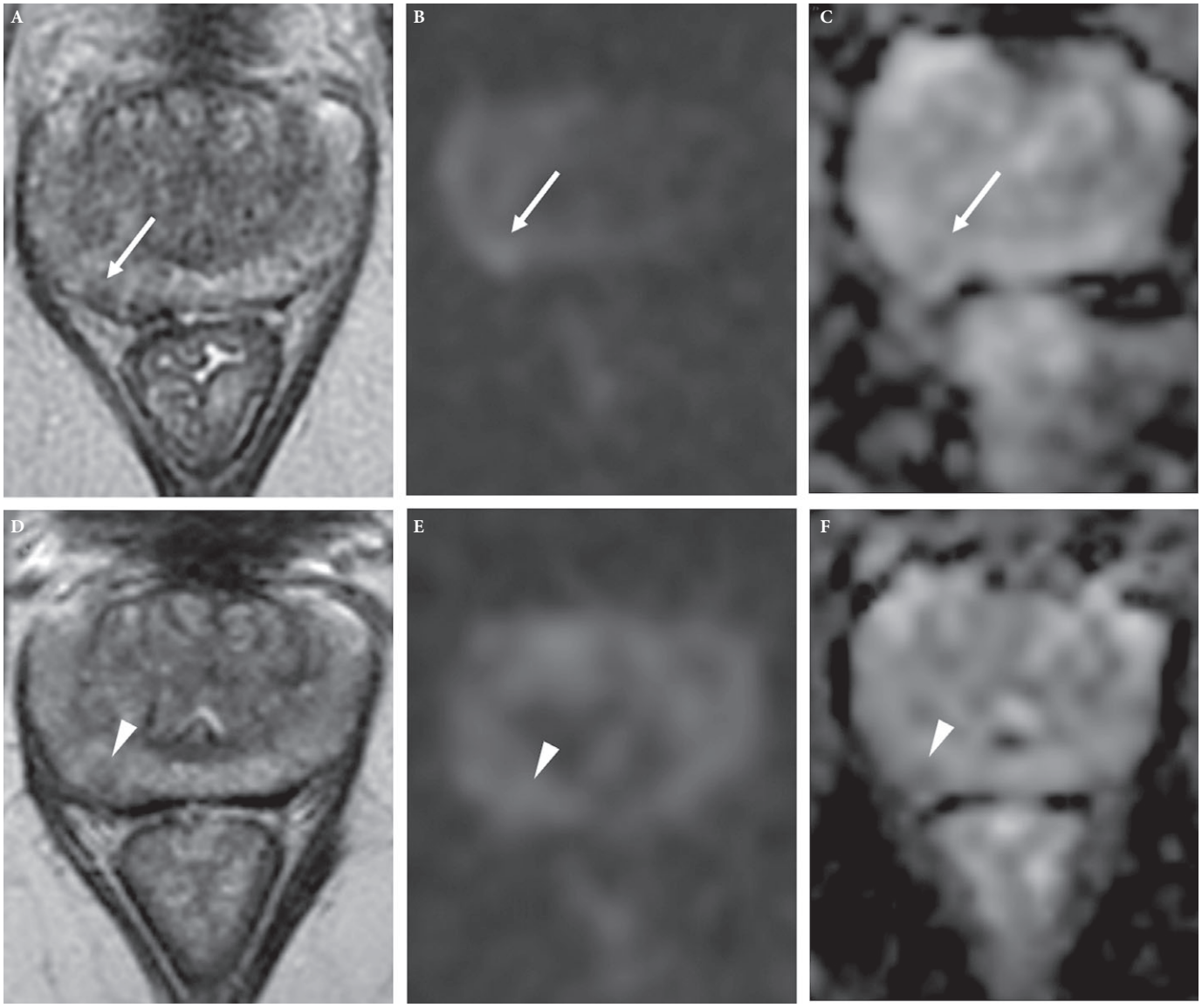


Fig. 4 False-negative lesion in a 62-year-old patient with a PSA of 7.52 ng/mL. Ultrasonography/MRI fusion-guided biopsy revealed Gleason 3 + 3. (**A–C)** Fast MRI protocol without significant lesion, retrospectively visible (arrow) on T2-WI (**A**) with mild restriction of diffusion on high *b* value (b = 2 000 s/mm²) (**B**), and an apparent diffusion coefficient of 1.1 × 10^{-3} mm²/s (**C**). Panels **D–F** mpMRI protocol PI-RADS 4 lesion of 4 mm (arrowhead) in the right postero-median peripheral zone with moderate restriction of diffusion (apparent diffusion coefficient: 1.04 × 10^{-3} mm^2/s) and positive dynamic contrast-enhanced imaging (not shown).



ESUR guidelines [2,10]. In the fMRI protocol, the acquisition of a coronal plane is maintained, providing additional values on seminal vesicle analysis and extracapsular extension. Only one prospective study has compared the diagnostic accuracy of bpMRI on a 3.0-T using targeted biopsy, with a lower detection rate of Gleason 3 + 3 (8% vs 16%) and missing only 2% of clinically significant PCa, defined as Gleason ≥3 + 4 [11].

The present study has several limitations and is based on two assumptions: that asymptomatic patients presenting for early detection with a negative mpMRI may be denied an initial biopsy and that, in case a biopsy is recommended, random biopsy and MRI-targeted biopsy should be performed. We understand that these two assumptions are debatable. The present study assumes that MRI-targeted biopsy is the standard diagnostic pathway allowing a biopsy for a given PI-RADS score to be dismissed. Despite an abundance of literature there is still some controversy in the field. As mentioned, our institutional care pathways was adapted after calibrating the diagnostic accuracy of ESUR mpMRI on a series of prostatectomy specimens. As a result, the exact diagnostic accuracy of the fMRI protocol is not known. It is

important to keep in mind that the aim of the study was not to improve the diagnostic accuracy of MRI but rather streamline the test by providing a faster simpler protocol that was equivalent based on a direct comparison of the number of men referred to biopsy and the characteristics of the detected PCa.

Men were not selected by PSA and DRE but based on the results of a published risk calculator validated in our population, in line with the recommendation of the European Association of Urology guidelines [19,24]. Selection of patients using the SWOP calculator explains the high prevalence of the disease, which may generate a verification bias, affecting the intrinsic diagnostic accuracy of MRI.

Prostate MRI were read by consensus between two radiologists (without intra- or inter-reader agreement being assessed), reflecting the recommendation of our institution for problematic cases, reducing false-positive results and because the moderate reproducibility of PI-RADS v.2 lexicon is known [32]. The fMRI result was anonymized and read 1 month after to avoid lecture bias. In addition, it should be acknowledged that the two MRI scanners used were produced by two different manufacturers and therefore there were many differences between the two types of MRI scans.

The fMRI protocol was optimized for PCa detection only and had not been tested for staging, treatment planning or monitoring of patients on active surveillance. This may result in having to repeat the MRI in some patients when more precise information is requested for the patient treatment. We believe that such a risk or duplicate examination can be mitigated by excluding patients at very PCa high risk at the time of diagnosis, i.e. those with a PSA >20 ng/mL, symptoms suggesting PCa or a clinical T3/T4 stage. Our group has recently advocated an augmented care pathway for these high-risk patients, combining a standard ESUR mpMRI and whole-body DWI as a diagnostic, local and systemic staging test [33].

In conclusion, despite some persistent controversy, MRI and MRI-targeted biopsies are undisputed point-of-care tests in a modern PCa detection pathway. The dissemination of MRI, however, is clearly limited by the access to the technology and, in some countries, by cost. Considering the number of prostate biopsies performed, it is unlikely that MRI resource programming will match prostate MRI demand in a decent time horizon. There is thus a major need for MRI optimization. This study confirms, using a prospective approach, that an optimized specific 15 min MRI on 1.5-T without DCE is a valid alternative to mpMRI as a triage test to refer men at high risk of PCa for prostate biopsy.

Conflict of Interest

None declared.

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Abbreviations: bpMRI, biparametric MRI; DCE, dynamic contrast-enhanced; DWI, diffusion-weighted imaging; ESUR, the European Society of Urological Imaging; fMRI, fast MRI; mpMRI, multiparametric MRI; NPV, negative predictive value; PCa, prostate cancer; PI-RADS, Prostate Imaging Reporting and Data System; PPV, positive predictive value; ROI, region of interest; T2WI, T2-weighted imaging.