

ARTICLE



## Real life data of MRI-targeted biopsy – experience from a single nonacademic centre using cognitive fusion and 1.5 tesla scanning

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### ABSTRACT

**Objectives:** To date, it is unknown whether systematic biopsies can be safely omitted in patients with unsuspecting MRI findings or if systematic biopsies should be required when targeting focal lesions (PI-RADS 3–5).

**Methods:** A series of 366 patients (249 without a previous biopsy) were examined in a 1.5 Tesla MRI scanner. All patients were submitted to systematic biopsies (12–14 regions) with additional targeted biopsies (by cognitive fusion) of focal PI-RADS lesions (PI-RADS 3–5).

**Results:** In our series, patients with PI-RADS 1/2 findings had rates of adenocarcinoma of any grade, >GG1 and GG4/5 of 34%, 14% and 3%, respectively. The use of MRI prior to biopsy in our series increased the detection of clinically significant prostate cancer (CSPCa) in 28% of patients with focal lesions, and focal lesions were present in 293/366 (80%) of all patients. For CSPCa (>GG1), targeted biopsies improved the diagnosis in 28% of patients, while systematic biopsies resulted in an additional 19% of cancer cases in the series.

**Conclusion:** Systematic biopsies should still be considered in patients with PI-RADS 1/2 findings. Our findings also suggest a stronger benefit of the combined strategy of targeted and systematic biopsies than the findings of previous studies concerning the detection of CSPCa in biopsy-naïve patients.

**Abbreviations:** CIPCa: clinically insignificant (low-grade) prostate cancer; CSPCa: clinically significant prostate cancer; COG-BX: targeted biopsy using cognitive fusion of images; GG: Grade Group; M-MRI: Multiparametric magnetic resonance imaging; PI-RADS: Prostate Imaging – Reporting and Data System; SYS-BX: systematic biopsies; TRUS: Transrectal Ultrasound.

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### Introduction

Men with elevated serum levels of prostate-specific antigen (PSA) or abnormalities in their digital rectal examination results are common scenarios in current urologic practice. Usually, they are referred to an ultrasonography-guided prostate biopsy. This approach leads to the over-detection of clinically insignificant (low-grade) prostate cancer (CIPCa) and the under-detection of high-grade tumours. Despite current protocols favouring active surveillance for CIPCa, many patients undergo a radical treatment with known side effects. Even those who opt for active surveillance are subject to repeated biopsies, bearing the costs and side effects of this approach [1, 2].

Multiparametric magnetic resonance imaging (M-MRI) is advocated as a triage test to define patients with abnormal imaging findings that indicate prostate needle biopsies. M-MRI-targeted biopsies are at least equivalent to the standard 10–12 core biopsies for detecting CSPCa and to detect CIPCa in lower rates [3, 4]. The PRECISION trial was a multicentre, randomized, noninferiority trial that corroborated those findings. M-MRI-targeted biopsies detect higher rates of CSPCa (Gleason score 3 + 4 or higher) when compared to standard

biopsies (38% vs 26%) and lower rates of CIPCa (9% vs 22%). Among patients with a negative first biopsy, those submitted to standard biopsies more commonly had an indication for further diagnostic testing and had a higher rate of clinically significant cancer diagnosed in subsequent biopsies than patients submitted to M-MRI-guided biopsies (33% vs 0%) [2]. Other randomized trials showed a similar rate of detection of CSPCa among patients with normal digital rectal examination submitted to MRI guided biopsy (21%) and standard systematic biopsy (25%) [5].

In our practice, patients with M-MRI abnormalities (PI-RADS 3 or higher) are typically offered targeted biopsies in conjunction with 12 standard biopsies. The present study reports the experience from a single nonacademic centre using cognitive fusion and a 1.5 Tesla scanner in this scenario.

To date, it is not known whether systematic biopsies can be safely avoided in patients with unsuspecting MRI findings or if systematic biopsies should be required when targeting focal lesions (PI-RADS 3–5) [1, 6–12]. The targeted biopsy only strategy decreases the number of cores and associated discomfort and (probably) the detection rate of CIPCa.

Recent data suggest that systematic biopsies improve the detection rates of CSPCa by 5–15% when combined with targeted biopsies [9, 10]. Two large and recent multicentre prospective studies suggest that a combination of systematic and targeted biopsy may be the best approach. The additive rate for detection of adenocarcinoma with grade group (GG) > 1 is estimated to be of 5.2% for systematic biopsies and 7.0–7.6% for MRI-guided biopsies [11, 12].

We were able to compare the results of M-MRI-targeted biopsies with standard systematic sampling in the same patients.

## Material and methods

We retrospectively identified 551 outpatients who were referred for suspicion of prostate cancer because of elevated serum PSA levels or an abnormal digital rectal examination result and who underwent multiparametric magnetic resonance imaging (M-MRI)-guided transrectal prostate biopsy with cognitive fusion of images (COG-BX) and systematic biopsies (SYS-BX) between December 2015 and October 2018.

The inclusion criteria were as follows:

- All patients underwent M-MRI followed by COG-BX and SYS-BX at the same institution.
- The time interval of M-MRI, COG-BX and SYS-BX was shorter than 180 days.
- The same professional (a Radiologist with 7 years of experience in Prostate M-MRI and 22 years of experience in prostate biopsy) read all MRIs and performed all the prostate biopsies.

After this selection, 366 patients met the criteria for enrolment in the study.

## Magnetic resonance imaging

The M-MRI of the Prostate was performed in a 1.5 Tesla scanner (MagnetomEspreo [8 channel] and MagnetomAera [24 channel], Siemens Healthineers®, Erlangen, Germany) without an endorectal coil with the recommended protocol of the European Society of Urogenital Radiology (ESUR) and PI-RADS version 2 [13,14]. The following parameters were used:

- 3 mm thickness T2-weighted imaging in the sagittal, axial and coronal planes.
- 3 mm thickness diffusion-weighted imaging (DWI) in the axial plane with B values of 50, 1,000 and 1,500 and calculating the B value of 1,500 in equipment that allowed such action (MagnetomAera).
- T1-weighted axial 3 mm thickness imaging after the injection of 0.1 mmol/kg of the gadolinium-based contrast agent (Dotarem; Guerbet®) by an injection pump with an injection rate of 3 ml/s. The total acquisition time of the sequence was at least 5 minutes.

All patients received an antispasmodic agent (scopolamine butylbromide) intravenously and immediately prior to the examination.

## Prostate biopsies

All patients underwent COG-BX to obtain typically 1–4 fragments of the lesions classified as PI-RADS 3,4 or 5. After targeted biopsy, SYS-BX was performed to obtain fragments of 12–14 regions comprising the base, midgland and apex of the prostate. See results for details on number of fragments obtained in suspicious lesions for each PI-RADS category. Fragments of the transition zone were obtained when the prostate volume was greater than 50 cm<sup>3</sup> or in those patients who had a previous biopsy. All biopsies were performed under general venous anaesthesia and lasted between 15 and 20 min using fentanyl citrate (50 mcg), midazolam (1–3 mg) and propofol (50–200 mg). Targeted biopsies were performed through cognitive fusion of M-MRI and transrectal prostate ultrasonography (COG-BX). In patients who had an M-MRI with low suspicion for PCa (PI-RADS 1 and 2), only systematic biopsies were performed.

All the biopsies were performed by the same radiologist.

## Clinical data

Age, recent serum PSA level, previous prostate biopsy history, race, family history and prostate volume were obtained from each patient. The PSA density was calculated by dividing the total PSA by the prostate volume obtained in the M-MRI.

## Image analysis

All images were analysed in a single session by a single radiologist and classified according to PI-RADS version 2 criteria on the following bases. The low-suspicion images for CSPCa were grouped into PI-RADS 1 and 2. The remaining images were interpreted as indeterminate suspicion, moderate suspicion or high suspicion of CSPCa and classified as PI-RADS 3, 4 or 5, respectively. The imaging findings used in the study were the same as those provided in the reports provided to the patients.

CSPCa was defined as adenocarcinoma > GG1. Grading was performed by a single experienced urologic pathologist (10-year experience in urologic pathology) and all cases were classified using the criteria from the 2014 International Society of Urological Pathology (ISUP) Consensus Conference on Gleason Grading of Prostatic Carcinoma [15].

This study was approved by the Institutional Ethics Committee of the Faculty of Medicine, Federal University of Bahia (Number: 3.709.229).

## Results

Clinical and demographic data of patients are available in Table 1. The detection rates stratified by PI-RADS scores are detailed in Table 2 (for all patients) and Table 3 (for patients with no previous biopsy).

Patients with no suspicious MRI findings (PI-RADS 1–2) were all submitted to SYS-BX and the detection rate of adenocarcinoma of any grade, >GG1 and GG4/5 was 25/73

**Table 1.** Clinical and demographic data among subgroups stratified by PIRADS.

	n	Age (mean ± SD)	PSA serum levels (ng/mL) (mean ± SD)	PSA density (mean ± SD)
PI-RADS 1/2 (biopsy naïve)	42	59.5 ± 8.0	4.76 ± 2.54	0.09 ± 0.07
PI-RADS 1/2 (with previous biopsy)	31	60.6 ± 7.5	5.24 ± 2.14	0.10 ± 0.08
PI-RADS 3 (biopsy naïve)	45	61.9 ± 7.9	4.23 ± 2.88	0.09 ± 0.05
PI-RADS 3 (with previous biopsy)	17	62.2 ± 6.2	6.91 ± 3.55	0.13 ± 0.07
PI-RADS 4 (biopsy naïve)	126	64.9 ± 9.0	4.91 ± 2.60	0.13 ± 0.09
PI-RADS 4 (with previous biopsy)	60	66.9 ± 7.3	8.37 ± 10.77	0.19 ± 0.28
PI-RADS 5 (biopsy naïve)	36	67.4 ± 9.2	18.00 ± 58.60	0.33 ± 0.63
PI-RADS 5 (with previous biopsy)	9	68.4 ± 8.6	17.30 ± 52.55	0.31 ± 0.57

**Table 2.** Detection rate among targeted and systematic samples based on PI-RADS assignment. All patients included.

	Any cancer n/N (%)			Cancer > GG1 n/N (%)			Cancer > GG2 n/N (%)		
	Combined	TB	SB	Combined	TB	SB	Combined	TB	SB
PI-RADS 1/2	–	–	25/73 (34)	–	–	10/73 (14)	–	–	5/73 (7)
PI-RADS 3	27/62 (44)	19/62 (31)	26/62 (42)	9/62 (15)	7/62 (11)	8/62 (13)	3/62 (5)	3/62 (5)	2/62 (3)
PI-RADS 4	145/186 (78)	120/186 (65)	137/186 (74)	97/186 (52)	77/186 (41)	70/186 (38)	44/186 (24)	31/186 (17)	36/186 (19)
PI-RADS 5	44/45 (98)	44/45 (98)	35/45 (78)	35/45 (78)	30/45 (67)	24/45 (53)	29/45 (64)	24/45 (53)	16/45 (36)
All	216/293 (74)	183/293 (62)	223/366 (61)	112/293 (48)	114/293 (39)	112/366 (31)	76/293 (26)	48/293 (16)	52/366 (14)

Combined: grade based on highest grade in all samples (systematic and all targeted biopsies including lesions with lower PI-RADS assignments), TB (grade found in targeted biopsy of the highest PI-RADS lesion assigned) and SB (highest grade among systematic biopsies).

**Table 3.** Detection rate among targeted and systematic samples based on PI-RADS assignment. Only patients with no previous prostate biopsy included.

	Any cancer n/N (%)			Cancer > GG1 n/N (%)			Cancer > GG2 n/N (%)		
	Combined	TB	SB	Combined	TB	SB	Combined	TB	SB
PI-RADS 1/2	–	–	14/42 (33)	–	–	7/42 (17)	–	–	2/42 (5)
PI-RADS 3	22/45 (49)	16/45 (36)	21/45 (47)	7/45 (16)	6/45 (13)	6/45 (13)	2/45 (4)	1/45 (2)	2/45 (4)
PI-RADS 4	109/126 (87)	92/126 (73)	103/126 (82)	77/126 (61)	58/126 (46)	58/126 (46)	30/126 (24)	24/126 (19)	29/126 (23)
PI-RADS 5	35/36 (97)	35/36 (97)	29/36 (81)	28/36 (78)	24/36 (67)	20/36 (56)	23/36 (64)	19/36 (53)	14/36 (39)
All	166/207 (80)	143/207 (69)	167/249 (67)	112/207 (54)	88/207 (43)	91/249 (37)	55/162 (34)	44/207 (21)	47/249 (19)

Combined: grade based on highest grade in all samples (systematic and all targeted biopsies including lesions with lower PI-RADS assignments), TB (grade found in targeted biopsy of the highest PI-RADS lesion assigned) and SB (highest grade among systematic biopsies).

(34%), 10/73 (14%) and 2/73 (3%), respectively. Adenocarcinoma of any grade was detected in 27/62 (44%), 145/186 (78%) and 44/45 (98%) of the patients assigned as PI-RADS 3, 4 and 5 based on the highest PI-RADS lesions found at MRI. Adenocarcinoma > GG1 were detected in 9/62 (15%), 97/186 (52%) and 35/45 (78%) of patients with PI-RADS 3, 4 and 5 lesions. Adenocarcinoma > GG2 was detected in 3/62 (5%), 44/186 (24%) and 29/45 (64%) of patients with PI-RADS 3, 4 and 5 lesions, respectively.

Similar findings were observed for patients with no previous biopsy (Table 3). The detection rate in patients with no suspicious MRI findings (PI-RADS 1–2) for adenocarcinoma of any grade, >GG1 and >GG2 was 14/42 (33%), 7/42 (17%) and 2/42 (5%), respectively. Adenocarcinoma of any grade was detected in 22/45 (49%), 106/126 (87%) and 35/36 (97%) of the patients assigned as PI-RADS 3, 4 and 5 based on the highest PI-RADS lesions found at MRI. Adenocarcinoma > GG1 were detected in 7/45 (16%), 77/126 (61%) and 28/36 (78%) of patients with PI-RADS 3, 4 and 5 lesions. Adenocarcinoma > GG2 was detected in 2/45 (4%), 30/126 (24%) and 23/36 (64%) of patients with PI-RADS 3, 4 and 5 lesions, respectively.

We performed multivariate analysis to test whether any clinical data could predict PI-RADS 1/2 patients who would receive an adenocarcinoma > GG1 diagnosis. PSA levels, PSA

density, clinical history of prostate cancer or age could not predict positive biopsy cases.

For all PIRADS 3 lesions, the mean ± SD of number of fragments obtained was 2.9 ± 1.6 and number of fragments was 1, 2–3 or >3 in 3%, 79% and 19%, respectively. For all PIRADS 4 lesions, the mean ± SD of number of fragments obtained was 3.0 ± 1.1 and number of fragments was 1, 2–3 or >3 in 0, 81% and 19%, respectively. For all PIRADS 5 lesions, the mean ± SD of number of fragments obtained was 5.6 ± 4.2 and number of fragments was 1, 2–3 or >3 in 0, 58% and 42%, respectively. The rate of clinically significant adenocarcinoma did not differ for lesions with 2–3 versus 4 or more fragments obtained in targeted biopsies.

The data on how many cases would be missed if only a targeted or a systematic approach was used alone is detailed in Table 4 (for all patients) and Table 5 (for patients with no previous biopsy). Considering the combined targeted and systematic biopsy approach as the gold standard, targeted biopsy improved the diagnosis of cancer in 8% of patients, while systematic biopsies added 15% more cancer cases in the series (adenocarcinoma of any grade). For clinically significant cancer (>GG1), targeted biopsies improved the diagnosis in 28% while systematic biopsies added 19% more cancer cases in the series. For higher grade cancers (GG4/GG5), targeted biopsies improved the diagnosis in 50% of

**Table 4.** How many cases would be missed if only one approach was used (including all cases with focal lesions, PI-RADS  $\geq$  3).

MRI findings	Any cancer		
	Only targeted n/N (%) would miss	Only Systematic n/N (%) would miss	Total of cases missed by combined TB or SB findings
PI-RADS 3	8/27 (30)	1/27 (4)	27
PI-RADS 4	25/145 (17)	8/145 (6)	145
PI-RADS 5	0/44 (0)	9/44 (20)	44
All cases (with focal lesions)	33/213 (15)	18/213 (8)	213
	Cancer > GG1		
	Only targeted n/N (%) would miss	Only Systematic n/N (%) would miss	Total of cases missed by combined TB or SB findings
PI-RADS 3	2/9 (22)	1/9 (11)	9
PI-RADS 4	20/97 (21)	27/97 (28)	97
PI-RADS 5	5/35 (14)	11/35 (31)	35
All cases (with focal lesions)	27/141 (19)	39/141 (28)	141
	Cancer > GG2		
	Only targeted n/N (%) would miss	Only Systematic n/N (%) would miss	Total of cases missed by combined TB or SB findings
PI-RADS 3	1/2 (50)	1/2 (50)	2
PI-RADS 4	13/44 (30)	8/44 (18)	21
PI-RADS 5	5*/29 (17)	13/29 (49)	18
All cases (with focal lesions)	19/75 (25)	22/75 (29)	41

\*One additional case would be diagnosed only by targeted biopsy of lower PI-RADS lesions.

**Table 5.** How many cases would be missed if only one approach was used (including all cases with focal lesions, PI-RADS  $\geq$  3). Only patients without previous biopsy included.

MRI findings	Any cancer		
	Only targeted n/N (%) would miss:	Only Systematic n/N (%) would miss	Total of cases missed by combined TB or SB findings
PI-RADS 3	6/22 (27)	0/22 (5)	22
PI-RADS 4	17/109 (16)	6/109 (6)	109
PI-RADS 5	1/35 (3)	6/35 (17)	35
All cases (with focal lesions)	24/166 (14)	13/166 (8)	166
	Cancer > GG1		
	Only targeted n/N (%) would miss:	Only Systematic n/N (%) would miss:	Total of cases missed by combined TB or SB findings
PI-RADS 3	1/7 (14)	1/7 (14)	7
PI-RADS 4	19/77 (25)	19/77 (25)	77
PI-RADS 5	4/28 (14)	8/28 (29)	28
All cases (with focal lesions)	24/112 (21)	28/112 (25)	112
	Cancer > GG2		
	Only targeted n/N (%) would miss:	Only Systematic n/N (%) would miss:	Total of cases missed by combined TB or SB findings
PI-RADS 3	1/2 (50)	0/2 (0)	2
PI-RADS 4	7/30 (23)	4/30 (13)	11
PI-RADS 5	4*/23 (17)	9/23 (39)	17
All cases (with focal lesions)	12/55 (22)	13/55 (24)	41

\*One additional case would be diagnosed only by targeted biopsy of lower PI-RADS lesions.

cases while systematic biopsies added 22% more cancer cases in the series. In only one case (PI-RADS 5), a high-grade tumour (GG5) was diagnosed by only targeted biopsies from a lower PI-RADS lesion.

Detailed analysis stratified by PI-RADS score shows in which extent cases would have been missed by each approach. Targeted biopsies seem suboptimal for PI-RADS 4 lesions and to detect higher grade adenocarcinoma (39% of all cases would be missed). In contrast, systematic biopsies missed significant cancer at a higher rate among PI-RADS 5 patients: 31% would not have had a > GG1 cancer diagnosed by such an approach, while 50% would not have had a diagnosis of GG4/5 cancer.

## Discussion

In this series, clinically significant prostate cancer (defined as > GG1) was diagnosed in 14%, 15%, 52% and 78% of

patients with PI-RADS 1/2, 3, 4 and 5 findings (all patients included). In a recent comparable study from the Netherlands, the rates of > GG1 cancer in PI-RADS 3, 4 and 5 patients were 25%, 51% and 72%, respectively [10]. In that study, systematic and targeted biopsies improved the diagnosis of > GG1 cancer in 13% and 10% of cases, respectively [10]. In our experience, targeted biopsies improved the detection of clinically significant cancer in 28% of patients, while systematic sampling showed a 19% improvement.

In our series, patients with PI-RADS 1/2 findings had rates of adenocarcinoma of any grade, > GG1 and > GG2 of 34%, 14% and 7%, respectively. The rates of adenocarcinoma of any grade, > GG1 and > GG2 in biopsy-naïve patients were 33%, 17% and 5%. These findings are similar to those from three centres (United Kingdom, Germany and Australia), where the rates of cancer in biopsy-naïve PI-RADS 1/2 patients were 35–49% for cancer of any grade, 15–28% for cancer > GG1 and 3–7% for > GG2 [16]. Such a high rate of

clinically significant cancer in prostates without suspicious lesions at MRI indicates that systematic biopsy should still be considered in this group of patients with a clinical or laboratory indication of prostate biopsy.

In our series, the overall rates of adenocarcinoma of any grade, >GG1 and >GG2 in patients with PI-RADS 3 lesions were 44%, 15% and 3%, respectively. Among biopsy-naïve patients with PI-RADS 3 lesions, the rates of adenocarcinoma of any grade, >GG1 and >GG2 were 49%, 16% and 4%, respectively. In other centres, the reported rates of tumours of any grade are 48–60%, those of >GG1 tumours are 27–32%, and those of tumours with a Gleason score >GG2 are 5–9%. By contrast, in the biopsy-naïve subgroup, PI-RADS4 patients had rates of adenocarcinoma of any grade, >GG1 and >GG2 of 87%, 61% and 17%, respectively. PI-RADS5 patients had rates of 97%, 78% and 50% in our study. In other centres, the combined rates of PI-RADS4/5 in biopsy-naïve patients were 75–90% for any grade and 59–79% for >GG1 and 24–41% for >GG2 [13]. The rates of cancer of any grade and CSPCa diagnoses are also comparable with the PROMIS study [1].

In a multicentre study, the additional value of a biopsy was estimated for both the targeted and systematic strategies. Targeted biopsies improved the rate of diagnosis of adenocarcinoma of any grade by 3% in PI-RADS3 patients and by 8% in PI-RADS 4/5 patients. Systematic biopsies improved the diagnosis of adenocarcinoma of any grade in 18% of PI-RADS3 patients and 15% of PI-RADS 4/5 [16]. In the same multicentre study, targeted biopsies improved the rate of diagnosis of adenocarcinoma >GG1 by 3% in PI-RADS3 patients and by 10% in PI-RADS 4/5 patients. Systematic biopsies improved the diagnosis of adenocarcinoma >GG1 by 9% in PI-RADS3 patients and by 12% in PI-RADS 4/5 patients [16].

In our series, the rates of additional cases of adenocarcinoma >GG1 detected only by targeted biopsy were 11%, 28% and 31% for patients with PI-RADS 3,4 and 5 lesions, respectively. The rate of additional cases of adenocarcinoma >GG1 detected only by systematic biopsy was 22%, 21% and 14% for patients with PI-RADS 3,4 and 5 lesions, respectively (Table 4). Among biopsy naïve patients, adenocarcinoma >GG1 was detected only by targeted biopsies in 14%, 25% and 29% for patients with PI-RADS 3,4, and 5 lesions. Conversely, adenocarcinoma >GG1 was detected only by systematic biopsies in 14%, 25% and 14% for patients with PI-RADS 3,4, and 5 lesions. This is a higher additional value when compared to large multicentre prospective studies that estimated additional detection rates for detection adenocarcinoma >GG1 of 5.2% for systematic biopsies and 7.0–7.6% for MRI-guided biopsies [11, 12].

In our series and among all patients, the rate of additional cases of adenocarcinoma >GG1 detected by targeted biopsy was 11%, 28% and 31% in PI-RADS 3,4 and 5 patients, respectively. The rate of additional cases of adenocarcinoma >GG1 detected by systematic biopsy was 22%, 21% and 14% in PI-RADS 3,4 and 5 patients, respectively (Table 3). Among biopsy-naïve patients, the rate of additional cases of adenocarcinoma >GG1 detected by targeted

biopsy was 14%, 25% and 29% in PI-RADS 3, 4 and 5 patients, respectively. The rate of additional cases of adenocarcinoma >GG1 detected by systematic biopsy was 14%, 25% and 14% in PI-RADS 3,4 and 5 patients, respectively (Table 4). Our findings suggest a stronger benefit of the combined strategy of targeted and systematic biopsies than the findings of previous studies regarding the detection of clinically significant cancer in biopsy-naïve patients.

In a recent large study enrolling 2103 men conducted by the National Cancer Institute, Bethesda, United States, the combination of systematic biopsies permitted detection of 6% more adenocarcinomas >GG1 when compared to MRI-targeted lesions alone. Adoption of MRI and guided biopsies allowed 10% more diagnoses of adenocarcinoma, 29% of which were grade >GG2 [17].

The goal of this work is to describe the performance of an MRI-targeted cognitive fusion biopsy for prostate cancer in an outpatient, nonacademic institution using a 1.5 Tesla scanner for comparison with systematic biopsy in the same patient. The results mirror those of the international experience except for a higher additive value of the combination of systematic and targeted biopsies. The limitations of this study include its retrospective nature, which reflects the experience of a single institution. Most suspicious lesions in this study were sampled with 2 or 3 fragments from PI-RADS3, 4 or 5 areas. Data from recent studies suggest that additional fragments of suspicious lesions may improve the detection rate of clinically significant cancer thus overcoming the issue of potential sampling error [18–20]. We could not compare our results with subsequent prostatectomy findings, saturation biopsies or re-biopsies during follow up. The M-MRI images were analysed, and the biopsies conducted by a single radiologist.

We report the experience of an outpatient imaging clinic with high volume of MRI-scans and biopsies. Our approach seems to be suitable for small and medium volume centers where not uncommonly one physician interprets MRI-images and performs biopsies. Cognitive fusion is a feasible technique to obtain targeted biopsies, but it requires experience in imaging interpretation. It is based on cognitive (visual) appraisal of the location of the suspicious lesion seen on the different MRI images on Transrectal Ultrasound (TRUS) without any additional equipment. Successful cognitive fusion will rely on familiarity with prostate anatomy (and spatial cognition) on ultrasonography. We do not use dedicated hardware and algorithm-based fusion software. A recent comparison of cognitive fusion with MRI guided in-bore approach showed similar performances for the detection of clinically significant prostate cancer [21]. In a meta-analysis by Wegelin and colleagues, the detection rate of clinically significant cancer was not different when MRI guided in-bore, software assisted fusion or cognitive fusion approaches were compared [22].

Cognitive fusion biopsy avoids additional capital investment or training with unfamiliar equipment or software. The procedure is based on reviewing the lesion on M-MRI and anatomical knowledge to target the biopsy needle at the suspected prostate area. This strategy is less expensive and time-consuming and, consequently, may be more comfortable for patients, and perhaps more cost-efficient. It is

common sense that the accuracy of cognitive fusion biopsy largely depends on the experience and cognitive skills of the operating practitioner. Cognitive fusion may have a higher likelihood for sampling errors in the distal apex and base or lateral edges of the prostate due to the anatomical variation between axial M-MRI and image-acquisition during TRUS [23].

Although there are limitations of the study, it does reflect the use of the methods in a real-world situation. The lack of patient follow-up of negative biopsies or patients who opted for active surveillance and the lack of correlation with prostatectomy findings are also limitations of the study.

## Conclusion

The use of MRI prior to biopsy in our series increased the detection of CSPCa by 28% among patients with focal lesions, and focal lesions were present in 293/366 (80%) of all patients. Clinically significant cancer in men without suspicious lesions at MRI was diagnosed in 14% of all cases and indicated that a systematic biopsy should not be abolished in this group of patients. In addition, systematic biopsies improve the detection of CSPCa and higher-grade adenocarcinomas and, therefore, should be combined with MRI-targeted biopsies. Our findings suggest a stronger benefit of the combined strategy of targeted and systematic biopsies in biopsy-naïve patients. In the described scenario (outpatient, nonacademic institution, using 1.5T scanning and cognitive fusion biopsy), MRI improves the diagnosis of CSPCa, and systematic biopsies should not be abandoned either in patients with benign findings or in those with focal lesions on MRI.

## Disclosure statement

No potential conflict of interest was reported by the author(s).

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