

Successes and challenges in developing a magnetic resonance imaging-transrectal ultrasound machine fusion prostate biopsy service

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ABSTRACT

Prostate magnetic resonance imaging (MRI) is an integral part of the diagnostic pathway in patients with suspected prostate cancer. Patients with positive findings on MRI require targeted biopsy for histopathologic diagnosis, and machine fusion biopsy is emerging as an accurate and reliable technique for diagnosis; however, access to this service is lacking across Canada. Over the past three years, our institution has developed a successful MRI-transrectal ultrasound (US) machine fusion prostate biopsy program. The purpose of this article is to discuss operational and clinical aspects of the service, and how we've overcome challenges in implementation. We describe the technique and diagnostic yield of machine fusion biopsy at our institution, including the subset of patients undergoing concurrent systematic biopsy. Challenges in establishing this program have included having

KEY MESSAGES

- The increasing use of prostate MRI requires access to an accurate and precise method of targeted prostate biopsy.
- Machine fusion prostate biopsy provides accurate results, but takes longer to perform, requires more healthcare resources, and continuous quality assurance.
- This article presents several challenges and successful initiatives in developing an efficient machine fusion prostate biopsy service.

sufficient workforce, screening patients at high risk of post-biopsy urosepsis, implementing transperineal biopsy, and a growing waitlist. An avenue for future improvement is a formal radiology-pathology correlation process. The goal of our machine fusion prostate biopsy program is to provide early and accurate diagnoses of MRI findings, thereby enabling optimal treatment plans and ultimately improved patient outcomes.

INTRODUCTION

Prostate MRI has transformed the diagnostic pathway of men with suspected prostate cancer.¹ MRI results in a higher detection rate of clinically significant prostate cancer (csPCa)² and is the standard of care in men with suspected prostate cancer in European,³ American⁴ and Canadian⁵ guidelines. For patients with positive findings on MRI, there is a need for accurate biopsy for histopathological analysis. Some studies have shown that MRI-transrectal US (TRUS) machine fusion biopsy outperforms cognitive biopsy⁶ and traditional systematic biopsy⁷ in diagnosing csPCa, including two randomized controlled trials.^{8,9} However, a recent meta-analysis of comparative studies showed no difference in detection of csPCa between cognitive and machine fusion biopsy.¹⁰ In addition, universal access to MRI-TRUS machine fusion prostate biopsy is lacking.

Our institution implemented an MRI-TRUS machine fusion prostate biopsy program in September 2022. To date, the service has biopsied over 400 patients and 500 lesions, of which approximately 60% have yielded csPCa (International Society of Urological Pathology (ISUP) grade group ≥ 2).¹¹ This service has become a valuable tool in diagnosing patients with suspected prostate cancer. In this article, we discuss operational and clinical aspects of the service, including the technique, diagnostic yield, challenges with implementation, and future avenues to further improve the service.

PROCUREMENT

Procurement and implementation of our MRI-TRUS machine fusion biopsy system was a collaborative effort from a team of urologists, radiologists, and information technologist specialists, including a project manager.¹² The project manager coordinated multidisciplinary stakeholders through regular governance and working sessions, and liaised between industry and diagnostic imaging information systems on the infrastructure, integration, and readiness to program launch. The project manager supported workflow design and process optimization, as well as equipment installation, testing, and clinical validation to ensure the system was safe, functional, and fit for clinical practice.

Funding for the equipment was largely provided by generous donors to our hospital foundation.¹³ In the preliminary phase, we explored various systems and evaluated their advantages and disadvantages. We also solicited feedback from users at other centers performing machine fusion prostate biopsy. Following evaluation of different systems, the Uronav-DynaCAD system (Philips) was selected. A BK3000 US machine (BK Medical, Burlington, MA, USA) was also purchased as a shared resource between the departments of Urology and Diagnostic Radiology for prostate biopsy.

MRI AND FUSION BIOPSY TECHNIQUE

At our institution, prostate MRIs are performed on 1.5T (Siemens Magnetom Sola) and 3T (Siemens Magnetom Vida) magnets. MR imaging protocols are compliant with the American College of Radiology Prostate Imaging Reporting and Data System (PI-RADS) v2.1¹⁴ technical specifications. In 2023, our institution switched to a biparametric MRI (bpMRI) protocol, reserving dynamic contrast-enhanced images for patients with pelvic hardware which may degrade image quality, such as a hip arthroplasty.¹⁵ Patients with a PI-RADS 3 lesion in the peripheral zone are recalled for dynamic contrast-enhanced images. This practice is similar to elsewhere¹⁶ and carries several advantages, including quicker MRI examination times, substantially fewer contrast injections, and reduced healthcare costs. A study from our institution showed that only 6.6% of patients required being recalled for contrast-enhanced sequences.¹⁵ Other studies have shown that bpMRI has no adverse impact on diagnostic performance^{17, 18} or yield at subsequent targeted biopsy¹⁹.

As compared to systematic prostate biopsy or targeted biopsy with cognitive fusion, machine fusion prostate biopsies require more preparation, take longer to perform, and require more personnel. Prior to biopsy, each patient's MRI is reviewed for image quality and appropriateness of biopsy. The prostate gland and each target for biopsy is segmented by a radiologist on axial T2-weighted images using the DynaCAD software. The axial T2-weighted images, MRI-segmented prostate volume, and segmented regions of interest are uploaded to the DynaCAD workstation. This process takes approximately 15-20 minutes per patient, and must be done prior to the procedure. At present, we book 12 patients per day in 40-minute slots, with a 30-minute lunch break.

During the procedure, a registered nurse (RN), biopsy operator, and medical radiation technologist (MRT) are present. Using the US machine, the operator acquires a transverse cine series of the prostate, which is sent to the DynaCAD workstation. The MRT segments the prostate gland from the US images; the two segmented volumes (US and MRI) are then registered in a nonrigid fashion by the DynaCAD software. The segmentation and registration process takes approximately 10-15 minutes, during which the operator performs a diagnostic TRUS, applies local anesthetic, and performs a systematic biopsy, if indicated. Once completed, the registration process is reviewed for accuracy, and minor corrections are applied. Thereafter, a minimum of four 18-gauge

cores are obtained of each target identified on MRI.¹¹ Patients are typically well enough to be discharged without any specific observation period.

YIELD OF MACHINE FUSION TARGETED BIOPSY

At our center, prostate MRIs are reported by eight board-certified, fellowship-trained abdominal radiologists in accordance with the American College of Radiology PI-RADS v2.1.¹⁴ At present, approximately 190 MRIs are reported by each radiologist per year. The number of biopsies positive for clinically significant prostate cancer (defined as ISUP Grade Group ≥ 2 (GG ≥ 2), or Gleason ≥ 7) was evaluated in a recent study¹¹ and is summarized in Table 1 alongside results from other recent studies.²⁰⁻²² As in other studies, our results show progressively increasing positive predictive values (PPV) with increased PI-RADS score, and a similar PPV for PI-RADS 5 lesions. However, the PPV of PI-RADS 3 lesions is much higher at our institution, with 95% confidence intervals which overlap with PI-RADS 4. The PPV of PI-RADS 4 lesions is also higher than other studies,^{21, 22} but similar to a recent systematic review and meta-analysis.²⁰ The prevalence of disease (as estimated by the row of PPV for PI-RADS 3-5 lesions) at our institution is much higher than elsewhere.

There are a few possible reasons why our diagnostic yield differs from the literature.¹¹ At our institution, referrals for prostate MRI and biopsy are only accepted from urologists; selection bias can arise from urologists referring only the highest-risk patients. Our patient population may also be presenting with later-stage disease, as approximately 20% of our population lack a primary care physician and may not be undergoing screening for prostate cancer with serum prostate-specific antigen (PSA).⁵ However, our cohort's PSA and PSA density levels are comparable to other studies (Table 2). Shown in Table 3 is breakdown of PSA density values per PI-RADS score and fusion biopsy results. A third of PI-RADS 3 lesions with PSA density < 0.10 ng/mL² corresponded to csPCa; others have found this proportion to be less than one in five.²³ Another possibility is that our group of radiologists is under-calling disease, which would elevate the PPV at the sake of decreased negative predictive value (NPV). We plan to investigate the NPV and other diagnostic performance characteristics of prostate MRI at our institution, to compare with published benchmarks.²⁰

YIELD OF SYSTEMATIC BIOPSY

An area of uncertainty with targeted machine fusion prostate biopsy is whether patients should undergo concurrent systematic biopsy. The 2020 European guidelines 'strongly recommend' concurrent systematic and targeted biopsy in biopsy-naïve men, and 'weakly recommend' only targeted biopsy in patients with previous negative biopsy.³ The 2023 American Urological Association guidelines state that systematic biopsy is optional in patients who are biopsy-naïve or underwent prior negative biopsy.⁴ The 2022 Canadian Urological Association guidelines recommend systematic biopsy in all biopsy-naïve

patients with positive MRI requiring targeted fusion biopsy but make no specific recommendation regarding patients with prior negative systematic biopsy.⁵

Our institutional policy is to offer systematic biopsy to all biopsy-naïve patients and patients with a negative systematic biopsy that was over one year ago. A shared decision is made during the consent process. In our experience, the decision to perform systematic biopsy requires consideration of several factors, including whether the patient is biopsy-naïve, the interval from previous biopsy if not biopsy naïve, the size, location, and number of lesions for targeted biopsy, the risk of post-biopsy sepsis, and patient and referring urologist wishes.

As of April 2025, we have performed systematic biopsy in 142/372 (38.2%) biopsy-naïve and previous biopsy-negative patients. The yield of systematic biopsy is outlined in Table 4. There have been 9/142 (6.3%) patients in whom csPCa was found at systematic biopsy with either ciPCa or benign results from the targeted fusion biopsy; prior studies have shown similar rates of 10/240 (4.1%)²⁴ and 123/2103 (5.8%).²⁵ A recent randomized trial compared the yield of targeted biopsy alone vs. targeted plus systematic biopsy.²⁶ The cohort without systematic biopsy had 50% fewer GG1 cancers, but 27% fewer GG \geq 2 cancers were identified.²⁶ Although these results were not statistically significant, they could be considered clinically significant.⁴

Our approach is to continue offering systematic biopsy; however, this remains an area of ongoing investigation, with different recommendations from various associations.

CHALLENGES

Challenge 1: Personal shortage and remuneration

A challenge with TRUS-MRI machine fusion targeted prostate biopsy is that it requires more resources, including three staff members (biopsy operator, RN, and MRT). At our institution, the procedures are performed in an interventional radiology (IR) suite due to space and patient flow constraints elsewhere. The RN and MRT are drafted from the IR staffing pool and have been trained in machine fusion prostate biopsies. Similar to elsewhere,²⁷ our institution has experienced significant shortages in the MRT workforce. At our institution, approximately 14.5 full-time equivalents (FTEs) in the MRT pool provide daily coverage at two hospitals for 6 interventional body and neuroradiology suites, a hybrid operating room, and 5 cardiac catheterization labs. During the first two years of our machine fusion prostate biopsy program, the MRT pool was typically 2-3 FTEs short, and MRT training days for the prostate fusion program were repeatedly cancelled to provide coverage elsewhere. Because of the MRT shortage, we required two operators to perform the fusion biopsies: one to perform the biopsy, and the other to perform the segmentation and registration process. This approach is inefficient from both a scheduling and cost-recovery perspective, as there was no fee code to cover the software operator. Over the past year, MRT staffing has improved, and machine fusion

biopsies are now performed with only one operator. We have submitted a new fee code application to the public insurer to address the added time taken to perform a TRUS-MRI machine fusion prostate biopsy, as well as a transperineal (TP) machine fusion prostate biopsy (discussed below).

Challenge 2: Transperineal biopsy

The purchase order for our machine fusion prostate biopsy program included equipment to perform TP biopsies, including a stepper and floor-mounted stand (Kosarek 2018); the PrecisionPoint® Transperineal Access system does not yet have government approval to facilitate a freehand technique. The TP approach to prostate biopsies is reportedly beneficial because of low rates of post-biopsy sepsis even without antibiotic prophylaxis.^{28, 29} However, there were several obstacles in implementing this service.

First, TP biopsies require procurement of a suitable bed; this was a challenge at our institution and required borrowing a Skytron 6702 Hercules surgical table and Allen Medical Yellofins stirrups from Perioperative Services. Second, patient throughput was slow. During an initial 2-day trial of TP fusion biopsies, where two operators performed five TP fusion biopsies each day, procedure times took an average of 95 minutes, as compared to 40 minutes for TRUS biopsies. Conscious sedation was also provided for TP biopsies due to patient pain, which required another 90 minutes of post-procedure monitoring and recovery. Although some institutions perform TP prostate biopsies under general anesthesia, this requires even more time and healthcare resources, including added costs.^{30, 31}

Other logistical challenges with TP prostate biopsies include a single endocavity biplane ultrasound transducer that must be cleaned between patients, a single UroNav compatible ultrasound machine that is shared with the Urology department, the personnel shortage described previously, and a growing patient waitlist, which further compounded the issue of decreased throughput.

Three recent randomized controlled trials provide level I evidence that TP biopsies without antibiotic prophylaxis have similar infection rates as TRUS-guided biopsies with antibiotic prophylaxis.³²⁻³⁴ As such, the added value of the TP approach has been questioned, as it is more time consuming, adds complexity and material costs, is more painful, and often requires conscious sedation and post-procedural recovery. However, there are other compelling studies of very low rates of infection in transperineal biopsies with and without antibiotic prophylaxis^{29, 35} and there is a general trend towards a TP approach for prostate biopsy.

Since launching our fusion biopsy program, we have enhanced our capacity to transition to a TP approach by hiring an operator with fellowship training in TP prostate biopsies and supporting another operator to do hands-on training at another institution. However, capital equipment expenditures on a lithotomy bed / stirrups and a dedicated US machine with additional transducers are essential for this program to become viable.

Increased access to and resources devoted to monitored recovery beds are also required. The decision to pursue a TR or a TP biopsy approach should balance both clinical (e.g. trained personnel, fusion biopsy waitlists) and logistical factors (e.g. access to equipment and recovery space) to optimize patient outcomes. At present, we have chosen to pursue a TR fusion biopsy approach to optimize the service provided to our patients and referring urologists.

Challenge 3: Antibiotic prophylaxis

Prior to initiating the MRI-TRUS fusion prostate biopsy program, a regional guidance on prostate biopsy technique was established in 2020 by a multidisciplinary group of urologists, radiologists, and an Infectious Diseases specialist on recommended antibiotic prophylaxis. This guidance recommended screening patients for risk factors of post-biopsy sepsis, such as diabetes or immunosuppression. However, screening patients at the time of biopsy is problematic, as patients who screen positive require intramuscular administration of *Tobramycin* and the procedure must be delayed by one hour for the antibiotic to take effect. This resulted in unanticipated delays with machine fusion prostate biopsies.

To eliminate these delays, a nurse now screens each patient undergoing fusion prostate biopsy by telephone a few days prior to their biopsy. The nurse asks the patient about any risk factors, and if the patient screens positive, the patient is scheduled to arrive one hour before their biopsy for additional antibiotic prophylaxis. This change has substantially improved the efficiency and flow of the machine fusion prostate biopsy program. Shown in Figure 1 is the patient pathway for antibiotic prophylaxis and screening of high-risk patients at our institution. To our knowledge, there have been four patients (<1%) biopsied in our machine fusion program that were complicated by urosepsis. We are currently conducting a research study seeking to capture all instances of post-biopsy urosepsis in patients who underwent systematic and/or machine fusion prostate biopsy at our institution, and comparing the sepsis rate before and after introduction of screening for patients at high risk.

Challenge 4: Increased demand and waitlist

The use of prostate MRI is rapidly increasing, and this has led to increased demand for TRUS-MRI fusion biopsy. In their 2022 recommendations on prostate cancer screening and early diagnosis, the CUA guidelines advocate for prostate MRI in men considered at elevated risk of csPCa who are either biopsy-naïve or have undergone prior negative TRUS-guided systematic biopsy.⁵ Together with the acquisition of multiple new MRI scanners capable of performing prostate MRI, this change in clinical practice has dramatically increased the volume of prostate MRIs performed at our institution (Figure 2), which has subsequently led to increased demand for machine fusion biopsy.

At present, our waitlist has increased to approximately 160 patients awaiting machine fusion biopsy. In response to increasing demand, we have increased the number of fusion biopsy days, which began at one day per month and is now three days per month. We have also begun diverting machine fusion biopsy requests to be performed with cognitive fusion if the lesion is large (greater than 2.5 – 3.0 cm) and easily accessible. Cognitive fusion biopsies are booked with one of the three machine fusion biopsy operators at our institution. Another potential method to decrease demand is to ensure appropriateness of prostate MRI and fusion biopsy requests. CUA guidelines acknowledge that MRI is a limited resource, and prostate MRI should only be performed in patients when there is intent for curative management, and not in instances where the diagnosis of csPCa is unambiguous.⁵

Challenge 5: Quality improvement and rad-path correlation

A major benefit to the machine fusion biopsy program is the feedback provided to radiologists reporting prostate MRI at our institution and elsewhere in the province. To enable this feedback, we copy the reporting radiologist to the pathology report of every fusion biopsy. Another benefit of having radiologists as operators is that it requires re-review of a patient's prostate MRI; on rare occasion there is a discrepant interpretation which can be flagged for quality improvement (Figure 3) or discussed amongst the team to avoid biopsy (Figure 4). This is particularly important for prostate MRIs performed at other institutions, where the reporting radiologist may not be a fellowship-trained subspecialist, and private clinics in our region, which do not always conform to PI-RADS v2.1 technical and reporting guidelines.¹⁴

Although the yield of our machine fusion prostate biopsy program is high, occasionally biopsy results are discordant with MRI findings. A potential improvement in the future is to implement a formal radiology-pathology correlation process, similar to what is done in breast imaging. With every breast biopsy, the histopathology results are formally reviewed by the radiologist who conducted the biopsy. When imaging findings and pathology results are deemed discordant, an action plan is triggered; this may include repeat biopsy, further imaging, and/or discussion at multidisciplinary tumour board. A similar process could be done with prostate biopsy.^{36, 37} Discordant findings can also be used for peer learning and education.^{38, 39}

FUTURE DIRECTIONS

There are several future goals with our TRUS-MRI machine fusion prostate biopsy program. We are conducting two research studies, one evaluating the rates of urosepsis, and another evaluating the NPV of prostate MRI at our institution. We are monitoring the increased requisitions for prostate MRI, and the impact on wait times for other MRI examinations. Given the increased demand for machine fusion prostate biopsy, we are considering establishing criteria with the urologists regarding which patients are best

suited for machine vs. cognitive fusion, as well as concurrent systematic biopsy. At present, our TP biopsy approach is on hold to maximize throughput, however, this may change in the future based on the outcome of our local study on sepsis rates, as well as other studies and guidelines. As mentioned above, a potential future improvement is to implement a formal radiology-pathology correlation process, to establish a closed feedback loop between histopathology results, reporting radiologists and urologists.

CONCLUSIONS

Implementation of a TRUS-MRI machine fusion prostate biopsy program has improved the diagnostic pathway of patients with suspected prostate cancer in Nova Scotia, and assisted urologists in managing these patients. We have addressed some early challenges, such as having MRTs trained and available to perform the segmentation and registration process and having a nurse screen patients for risk factors of urosepsis. Implementation of a bpMRI protocol has increased efficiency and access to MRI. However, some issues and challenges remain. Meeting the high demand for this service is a challenge and requires monitoring of wait times. We are presently evaluating the rates of urosepsis and NPV of prostate MRI at our institution. Given the added healthcare resources and reduced efficiency of TP machine fusion biopsy, its role at our institution is unclear. It is hoped that with implementation of the machine fusion biopsy prostate program, patients receive early and accurate histopathological diagnoses of positive MRI findings, which will in turn lead to optimal treatment plans and improved patient outcomes.

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FIGURES AND TABLES

Figure 1. Antibiotic prophylaxis and screening pathway to identify patients at high risk of post-biopsy sepsis. MRI: magnetic resonance imaging. TRU: transrectal ultrasound.

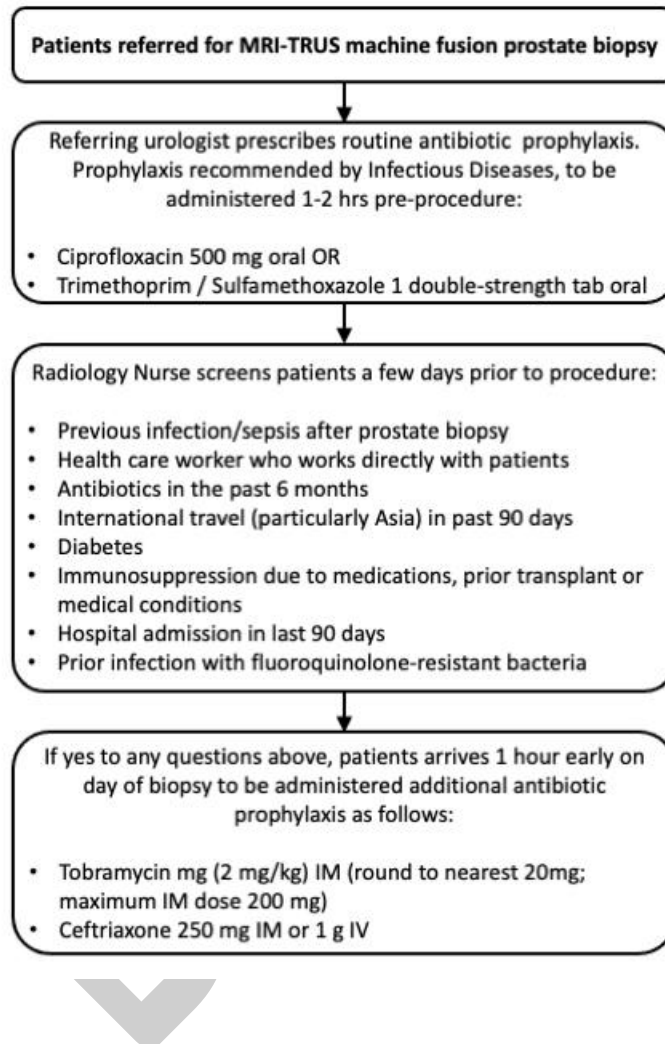


Figure 2. Annual number of prostate magnetic resonance imaging performed at our institution, 2017–2025. The number in 2025 is effective to November 14, 2025.

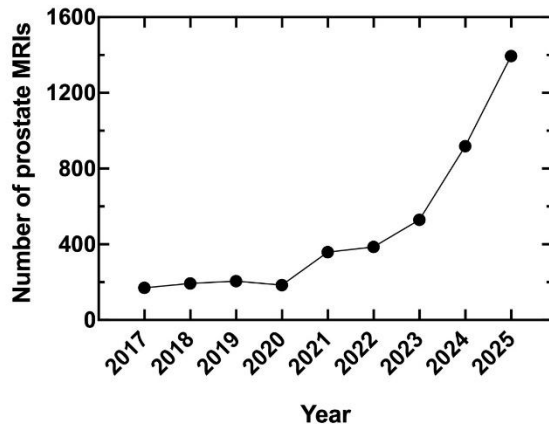


Figure 3. Example of a false-positive Prostate Imaging Reporting & Data System (PI-RADS) 4 lesion at prostate magnetic resonance image (MRI). A 73-year-old patient with a history of rising prostate-specific antigen (PSA, 19.03 ng/mL) and elevated PSA density (0 a.27 ng/mL²) underwent prostate MRI. (a) Axial and (b) coronal T2-weighted images show a triangular-shaped lesion in the posterior midline aspect of the mid gland. (c) Axial high b-value (b=1400) image and (d) corresponding apparent diffusion coefficient map show mild restricted diffusion. On more superior images of the prostate, this lesion was continuous with the central zone and surrounded the ejaculatory ducts at the verumontanum, and is consistent with normal central zone. The lesion was reported as high suspicion (PI-RADS 4) and targeted with machine fusion biopsy. Pathology showed normal prostatic parenchyma with a small focus of prostatic intraepithelial neoplasia.

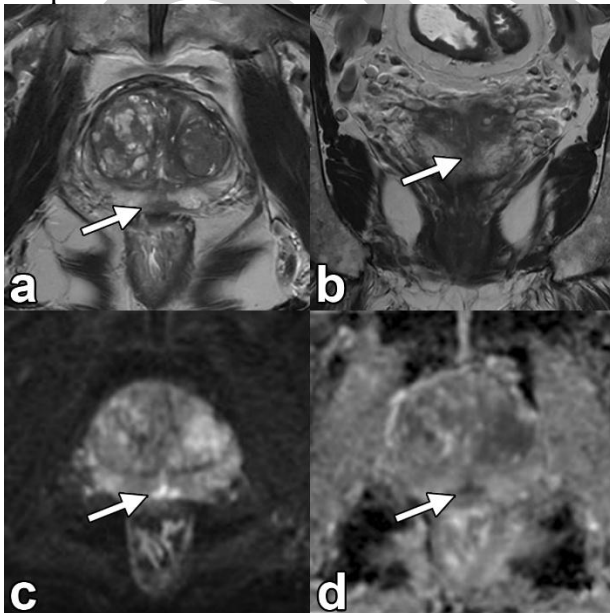


Figure 4. Example of discordant interpretation of prostate magnetic resonance image (MRI) from another institution. A 59-year-old patient with elevated prostate-specific antigen (5.4 ng/mL) underwent prostate MRI at another institution. (a) Axial T2-weighted image shows a subcentimeter lesion with T2-hyperintense signal. (b) There was hypoenhancement on axial dynamic-enhanced contrast-enhanced images. (c) Axial high b-value (b=1400) image and (d) corresponding apparent diffusion coefficient map show no restricted diffusion. The lesion was reported as high suspicion (Prostate Imaging Reporting & Data System [PI-RADS] 4) but was considered a PI-RADS 1 lesion on consensus reinterpretation by two radiologists, and the request for targeted fusion biopsy was declined.

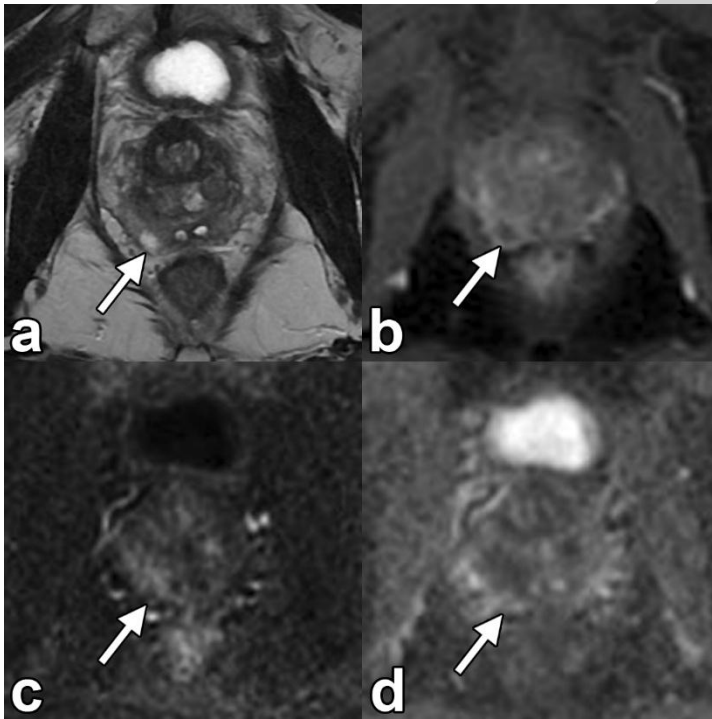


Table 1. Comparison of positive predictive values for clinically significant prostate cancer in targeted biopsy following prostate MRI*				
	Westphalen et al^{22**}	Schieda et al^{21†}	Oerther et al²⁰	Our institution¹¹
Year of study	2021	2024	2024	2025
Study design	26 Institutions, retrospective	Single institution, retrospective	Systematic review and meta-analysis	Single institution, retrospective
PI-RADS 3	15% (95% CI, 11, 19)	16% (95% CI, 12, 20)	16% (95% CI, 13, 20)	44% (95% CI, 33, 56)
PI-RADS 4	39% (95% CI, 34, 45)	35% (95% CI, 32, 38)	49% (95% CI, 46, 53)	51% (95% CI, 44, 57)
PI-RADS 5	72% (95% CI, 66, 77)	56% (95% CI, 53, 59)	74% (95% CI, 70, 78)	74% (95% CI, 68, 80)
PI-RADS 3–5	35% (95% CI, 27, 43)	40% (95% CI, 38, 41)	35% (95% CI, 33, 37)	59% (95% CI, 55, 64)

*Clinically significant prostate cancer is defined as International Society of Urological Pathology (ISUP) grade group ≥ 2 (Gleason score ≥ 7). Data correspond from September 2022 to April 2025.¹¹ **PI-RADS v2.0; combination of cognitive and machine fusion targeted biopsy; positive predictive values estimated using logistic regression to account for differences across imaging centers and the possibility of multiple lesions per patient. †Combination of cognitive and machine fusion targeted biopsy, and multiparametric and biparametric prostate MRI. CI: confidence interval; MRI: magnetic resonance imaging; PI-RADS: Prostate Imaging Reporting & Data System.

Table 2. Comparison of mean PSA values	
	Our institution ^{11*}
PI-RADS 3 PSA	10.8±8.5
PI-RADS 4 PSA	9.2±5.7
PI-RADS 5 PSA	10.4±5.9
PI-RADS 3–5 PSA	9.9±6.3 ^{**}
PI-RADS 3 PSA density	0.19±0.13
PI-RADS 4 PSA density	0.18±0.12
PI-RADS 5 PSA density	0.22±0.14
PI-RADS 3–5 PSA density	0.20±0.13 [†]

*Data are presented on a per-lesion basis in ng/mL (PSA) or ng/mL² (PSA density). Data correspond from September 2022 to April 2025.¹¹ **Previous studies found similar values for PI-RADS 3–5 PSA, as follows: Schieda et al,²¹ 10.3±7.9 and 10.9±3.6 (for multiparametric and biparametric MRI, respectively); Oerther et al,²⁰ 9.8 (7.9–13.1).
[†]Previous study found similar values for PI-RADS 3-5 PSA density, as follows: Schieda et al,²¹ 0.22±0.19 and 0.22±0.04 (for multiparametric and biparametric MRI, respectively). MRI: magnetic resonance imaging; PI-RADS: Prostate Imaging Reporting & Data System; PSA: prostate-specific antigen.

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PSA density	PI-RADS 3, ciPCa or benign	PI-RADS 3, csPCa	PI-RADS 4, ciPCa or benign	PI-RADS 4, csPCa	PI-RADS 5, ciPCa or benign	PI-RADS 5, csPCa
<0.10 ng/mL ²	66.7 (12)	33.3 (6)	60.3 (35)	39.7 (23)	48.6 (18)	51.4 (19)
0.10–0.15 ng/mL ²	75.0 (9)	25.0 (3)	49.3 (33)	50.7 (34)	34.3 (12)	65.7 (23)
≥0.15 ng/mL ²	45.2 (19)	54.8 (23)	44.1 (52)	55.9 (66)	17.6 (25)	82.4 (117)
Total	55.6 (40)	44.4 (32)	49.4 (120)	50.6 (123)	25.7 (55)	74.3 (159)

*Values in each cell correspond to percentage of lesions with the same PI-RADS score and PSA density; values in parentheses correspond to number of lesions (sample size). Data correspond from September 2022 to April 2025.¹¹ csPCa: clinically significant prostate cancer, International Society of Urological Pathology (ISUP) grade group ≥ 2, Gleason ≥7; ciPCa: clinically insignificant prostate cancer, ISUP grade group 1, Gleason <7; PI-RADS: Prostate Imaging Reporting & Data System; PSA: prostate-specific antigen.

Table 4. Yield of systematic biopsy in patients undergoing TRUS-MRI machine fusion targeted biopsy*					
		Systematic biopsy result			
		csPCa	ciPCa	Benign	Total
Fusion biopsy result	csPCa	69	15	8	92
	ciPCa	6	7	2	15
	Benign	3	9	23	35
	Total	78	31	33	142

*Data correspond from September 2022 to April 2025. csPCa: clinically significant prostate cancer, International Society of Urological Pathology (ISUP) grade group ≥ 2 , Gleason ≥ 7 ; ciPCa: clinically insignificant prostate cancer, ISUP grade group 1, Gleason < 7 ; MRI: magnetic resonance imaging; TRUs: transrectal ultrasound.

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