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Results of Targeted Biopsy in Men with Magnetic Resonance Imaging Lesions Classified Equivocal, Likely or Highly Likely to Be Clinically Significant Prostate Cancer

Wulphert Venderink[a,*], *Annemarijke van Luijtelaar*[a], *Joyce G.R. Bomers*[a], *Marloes van der Leest*[a], *Christina Hulsbergen-van de Kaa*[b], *Jelle O. Barentsz*[a], *J.P. Michiel Sedelaar*[c], *Jurgen J. Fütterer*[a]

[a] *Department of Radiology and Nuclear Medicine, Radboud University Medical Center, Nijmegen, The Netherlands;* [b] *Department of Pathology, Radboud University Medical Center, Nijmegen, The Netherlands;* [c] *Department of Urology, Radboud University Medical Center, Nijmegen, The Netherlands*

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Abstract

Background: The Prostate Imaging Reporting and Data System (PI-RADS) is the most commonly used scoring system in prostate magnetic resonance imaging (MRI). One of the available techniques to target suspicious lesions is direct in-bore MRI-guided biopsy (MRGB).
Objective: To report on the experience and results of MRGB in a large cohort of patients with lesions classified as equivocal (PI-RADS 3), likely (PI-RADS 4), or highly likely (PI-RADS 5) to be clinically significant (cs) prostate cancer (PCa).
Design, setting, and participants: We retrospectively included 1057 patients having MRGB, between January 2012 and September 2016, of lesions classified as PI-RADS $\geq$ 3 on multiparametric MRI. Biopsy-naïve patients, patients with prior negative systematic transrectal ultrasound-guided biopsy, and patients in active surveillance were included.
Outcome measurements and statistical analysis: The primary outcome measurement is the detection rate of csPCa. Descriptive statistics and chi-square tests were used to calculate the differences in proportions. We considered a Gleason score of $\geq$3 + 4 as csPCa.
Results and limitations: PCa was diagnosed in 35% (55/156), 60% (223/373), and 91% (479/528), and csPCa in 17% (26/156), 34% (128/373), and 67% (352/528) of patients with PI-RADS 3, 4, and 5 lesions, respectively. Follow-up of patients with negative biopsy findings resulted in csPCa in 1.7% (5/300) after a median period of 41 (interquartile range 25–50) mo. The evaluation of prostate-specific antigen density (PSAD) to predict csPCa resulted in 42% of patients with a PI-RADS 3 lesion who could avoid biopsy in case a PSAD of $\geq$ 0.15 ng/ml/ml would be used. In 6% (95% confidence interval, 2–15), csPCa would then be missed. The study is limited because of its retrospective character.
Conclusions: MRGB in lesions scored PI-RADS $\geq$ 3 yields high detection rates of csPCa in daily clinical practice in cases with previous negative biopsy.
Patient summary: In daily clinical practice, direct in-bore magnetic resonance imaging-guided biopsy of suspicious lesions reported according to the Prostate Imaging Reporting and Data System yields high detection rates of clinically significant prostate cancer.

* Corresponding author. Department of Radiology and Nuclear Medicine, Radboud University Medical Center, P.O. Box 9101, 6500 HB Nijmegen, The Netherlands. Tel.: +31 0 24 361 8766; fax: +31 0 24 354 0866.
E-mail address: Wulphert.Venderink@radboudumc.nl (W. Venderink).

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1. Introduction

The role of magnetic resonance imaging (MRI) in the detection and localization of prostate cancer (PCa) rose after the introduction of multiple functional MRI parameters that were added to anatomical MRI approximately a decade ago [1–3]. Despite the high performance of this multiparametric (mp) MRI, systematic 10–12 core transrectal ultrasound-guided (TRUS) prostate biopsy is still the standard used to detect PCa [4].

To improve the diagnostic quality of prostate mpMRI and to simplify and standardize radiology reports, the European Society of Urogenital Radiology introduced in 2012 the first version of the Prostate Imaging Reporting and Data System (PI-RADS v1) [5]. Very recently, a new version (PI-RADS v2) was introduced [6].

Both version 1 and version 2 of PI-RADS are scoring systems based on a five-point Likert scale. Following the imaging characteristics of a lesion on the different MRI parameters, an overall score is given to a lesion to predict its chance of being clinically significant (cs) PCa. The chance of being csPCa, for example, is highly likely in case a PI-RADS score of 5 is given, whereas the chance is likely at a score of 4 and equivocal in PI-RADS 3 lesions.

After a PI-RADS assessment category is assigned to a lesion, the lesion has to be biopsied on a targeted way to confirm the diagnosis. One way to target such a lesion is by performing direct in-bore MRI-guided biopsy (MRGB).

Despite much research in PI-RADS classification and different prostate biopsy approaches, a broad evaluation of the implication of PI-RADS in large cohorts of patients who have undergone MRGB is not performed yet. Therefore, the main aim of our study is to outline MRGB findings in patients with differing levels of suspicion at mpMRI and to demonstrate follow-up of patients with negative biopsy findings despite a positive mpMRI. Further, we will examine the ability of prostate-specific antigen density (PSAD) to predict biopsy outcome, the implication location has on PCa detection, and the meaning of detecting lesions next to the index lesion.

We will address these issues based on our MRGB results since 2012 in men with lesions classified as PI-RADS 3, 4, or 5.

2. Patients and methods

This retrospective study with prospectively collected data was approved by our institutional review board with a waiver of written informed consent (2016-2739).

2.1. Patients

All patients having MRGB and prior mpMRI in our institution between January 2012 and September 2016 were identified. Patients with prior targeted biopsy, prior treatment of the prostate, or biopsy-proven PCa $\geq$ 3 + 4 Gleason score (GS) were excluded from our study (Fig. 1). Patients included in this study did not participate in other trials of our institution.

2.2. Multiparametric MRI

Multiparametric MRI was performed on a 3.0 T MR scanner (Skyra, Siemens Healthcare, Erlangen, Germany) with a pelvic phased-array coil. Owing to the large time span in which patients were included, there is a slight variation in mpMRI technical specifications, although it always met the PI-RADS criteria.

Multiparametric MRI images were interpreted by six radiologists with a varying range of experience in prostate MR reading (2–20 yr). All images were scored according to PI-RADS v1 or v2. In all patients, next to the PI-RADS score, PSAD is also measured. PSAD is calculated by dividing PSA blood level by the volume of the prostate; hereby, high PSA blood levels, for example, are corrected for large prostate volumes.

2.3. MRI-guided biopsy

During MRGB, performed in a separate session, patients were placed in the prone position with an MR-compatible needle guide rectally

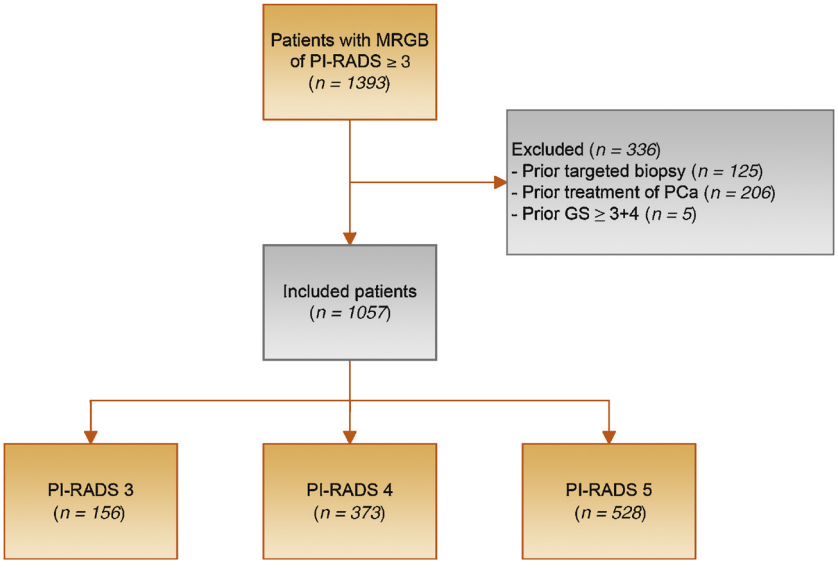

Fig. 1 – Patient flow chart. MRGB = magnetic resonance imaging guided prostate biopsy; PI-RADS = Prostate Imaging Reporting and Data System; PCa = prostate cancer; GS = Gleason score.

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