

# Prospective Evaluation of Magnetic Resonance Imaging Guided In-bore Prostate Biopsy versus Systematic Transrectal Ultrasound Guided Prostate Biopsy in Biopsy Naïve Men with Elevated Prostate Specific Antigen

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## Abbreviations and Acronyms

FOV = field of view  
MR = magnetic resonance  
MRI = MR imaging  
PCa = prostate cancer  
PSA = prostate specific antigen  
START = Standards of Reporting for MRI-Targeted Biopsy Studies  
TE = echo time  
TR = repetition time  
TRUS = transrectal ultrasound

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**Purpose:** Magnetic resonance imaging guided biopsy is increasingly performed to diagnose prostate cancer. However, there is a lack of well controlled, prospective trials to support this treatment method. We prospectively compared magnetic resonance imaging guided in-bore biopsy with standard systematic transrectal ultrasound guided biopsy in biopsy naïve men with increased prostate specific antigen.

**Materials and Methods:** We performed a prospective study in 132 biopsy naïve men with increased prostate specific antigen (greater than 4 ng/ml). After 3 Tesla functional multiparametric magnetic resonance imaging patients were referred for magnetic resonance imaging guided in-bore biopsy of prostate lesions (maximum 3) followed by standard systematic transrectal ultrasound guided biopsy (12 cores). We analyzed the detection rates of prostate cancer and significant prostate cancer (greater than 5 mm total cancer length or any Gleason pattern greater than 3).

**Results:** A total of 128 patients with a mean  $\pm$  SD age of  $66.1 \pm 8.1$  years met all study requirements. Median prostate specific antigen was 6.7 ng/ml (IQR 5.1–9.0). Transrectal ultrasound and magnetic resonance imaging guided biopsies provided the same 53.1% detection rate, including 79.4% and 85.3%, respectively, for significant prostate cancer. Magnetic resonance imaging and transrectal ultrasound guided biopsies missed 7.8% and 9.4% of clinically significant prostate cancers, respectively. Magnetic resonance imaging biopsy required significantly fewer cores and revealed a higher percent of cancer involvement per biopsy core (each  $p < 0.01$ ). Combining the 2 methods provided a 60.9% detection rate with an 82.1% rate for significant prostate cancer.

**Conclusions:** Magnetic resonance imaging guided in-bore and systematic transrectal ultrasound guided biopsies achieved equally high detection rates in biopsy naïve patients with increased prostate specific antigen. Magnetic resonance imaging guided in-bore biopsies required significantly fewer cores and revealed a significantly higher percent of cancer involvement per biopsy core.

**Key Words:** prostate, prostatic neoplasms, biopsy, magnetic resonance imaging, ultrasonography

PROSTATE cancer is the malignancy with the highest incidence in Western countries.<sup>1</sup> However, the mortality rate of PCa is low, reflecting the broad spectrum of disease ranging from indolent low risk to aggressive high risk cancers.

PCa diagnosis is classically based on digital rectal examination, PSA testing, TRUS and systematic TRUS biopsy. Widespread PSA screening has led to an increased incidence of PCa diagnosis in addition to a shift toward earlier stages of detected cancer.<sup>2</sup> Nevertheless, the overall benefit of PSA screening is still controversial due to considerable over diagnosis and overtreatment.<sup>3</sup>

The growing availability of prostate MRI, different functional imaging modalities and increased standardization have improved the role of prostate MRI for detecting, localizing and staging PCa.<sup>4</sup> The important next step is to further investigate targeted biopsies of detected index lesions,<sup>5</sup> which are associated with Gleason upgrade.<sup>6–8</sup> High PCa detection rates were previously reported using MRI guided in-bore biopsy,<sup>9</sup> which has mainly been performed in patients with increased PSA and prior negative TRUS biopsies.

A few groups previously explored this area and reported that prostate MRI combined with targeted biopsies in biopsy naïve patients achieved a higher detection rate than standard TRUS biopsy.<sup>10–12</sup> We prospectively compared MRI guided in-bore biopsy with standard TRUS guided biopsy in biopsy naïve patients with increased PSA.

## MATERIALS AND METHODS

### Patient Population

Our institutional review board approved this prospective study and written informed consent was obtained from all patients. The study was registered with [ClinicalTrials.gov](http://ClinicalTrials.gov) (NCT01553838) and the design was described previously.<sup>13</sup> The main study inclusion criterion was increased PSA greater than 4.0 ng/ml. Exclusion criteria were PCa, prior prostate biopsy and/or contraindications to MRI or biopsy. The study accrued patients from November 2011 to October 2013.

Initially all patients underwent 3 Tesla functional multiparametric MRI of the prostate. The MR protocol was designed according to the recommendations of the European Consensus Meeting on the standardization of prostate MRI.<sup>14</sup> All prostate MRIs were analyzed according to ESUR (European Society of Urogenital Radiology) guidelines.<sup>15</sup> In all patients targeted MR guided in-bore biopsy of up to 3 of the most suspicious lesions was performed in addition to standard 12-core TRUS biopsy. Histological results of all cores were analyzed. Biopsy results were reported according to START criteria.<sup>16</sup>

### Magnetic Resonance Imaging

**Protocol.** MRI was performed on a 3 Tesla Magnetom® Trio MR scanner using a 6-channel phased array body

coil in accordance with the detection protocol of the ESUR guidelines.<sup>15</sup> To suppress peristalsis patients received 20 mg butylscopolamine (Buscopan®) intravenously and intramuscularly. If there were contraindications, patients received 1 mg glucagon hydrochloride (GlucaGen®) by intramuscular injection.

For anatomical imaging T2-weighted turbo-spin echo sequences were acquired in the 3 standard orthogonal planes, including axial (TR 10,630 milliseconds, TE 117 milliseconds, FOV 12.8 cm and voxel size  $0.5 \times 0.5 \times 3.0$  mm). T1-weighted turbo-spin echo images were acquired in the axial plane (TR 650 milliseconds, TE 13 milliseconds, FOV 30 cm and voxel size  $1.3 \times 0.9 \times 5.0$  mm).

Additionally, 2 functional imaging modalities were performed. Diffusion weighted imaging was done using a single shot spin-echo echo planar sequence (TR 4,600 milliseconds, TE 90 milliseconds, FOV 20.4 cm and voxel size  $1.5 \times 1.5 \times 3.0$  mm) with 5 b-values (0, 250, 500, 750 and 1,000 seconds per mm<sup>2</sup>). Apparent diffusion coefficient maps were calculated by the scanner software. Dynamic contrast enhanced MRI was performed with a volume interpolated gradient echo sequence (TR 5.26 milliseconds, TE 1.76 milliseconds, FOV 19.2 cm, voxel size  $1.5 \times 1.5 \times 3.0$  mm, scan time 5:05 minutes and temporal resolution 10 seconds). The contrast medium used was gadoteric acid (Dotarem®) at a dose of 0.2 mmol/kg body weight with an injection rate of 3 ml per second. Total scan time was approximately 33 minutes.

**Analysis.** The complete MRI data set was analyzed by 2 urologists with at least 4 years of experience with prostate MRI. For each patient up to 3 lesions, including the most suspicious lesions, were defined and described using a 27-region localization scheme.<sup>14</sup> To characterize lesions we calculated the PI-RADS (Prostate Imaging Reporting and Data System) score from the sum of the scores of each sequence (T2-weighted, diffusion weighted and dynamic contrast enhanced MRI).<sup>15</sup>

### Biopsy Procedures

All patients received 500 mg levofloxacin (Tavanic, Sanofi-Aventis, Frankfurt, Germany) as a prophylactic oral antibiotic. Coagulation levels and blood platelets were assessed before biopsy.

Ultrasound guided periprostatic nerve block (10 ml 1% lidocaine) was applied by a urologist. An experienced urologist then performed targeted MRI guided in-bore biopsies transrectally using a DynaTRIM portable biopsy device and corresponding DynaCAD software (Invivo, Gainesville, Florida). T2-weighted HASTE (half-Fourier acquisition single shot turbo spin-echo) images were acquired in the sagittal and axial planes for biopsy planning and lesion localization. Two tissue samples of each selected lesion were obtained with a MR compatible 18 gauge needle biopsy gun (Invivo).

After the targeted biopsy standardized systematic TRUS guided biopsy was performed by an experienced urologist blinded to the MRI report. In line with German national guidelines for prostate cancer<sup>17</sup> and the American Urological Association<sup>18</sup> 12 systematic biopsy cores were taken per patient with an 18 gauge, fully automatic

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