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# Not All Multiparametric Magnetic Resonance Imaging–targeted Biopsies Are Equal: The Impact of the Type of Approach and Operator Expertise on the Detection of Clinically Significant Prostate Cancer

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## Abstract

**Background:** The extensive use of multiparametric magnetic resonance imaging (mpMRI) has led to an even more widespread use of different targeted biopsy techniques and approaches. The best way of performing targeted biopsies and the effect of operator expertise have still to be defined.

**Objective:** To compare the rate of detection of clinically significant prostate cancer (csPCa) of different mpMRI targeted approaches and to assess the role of operator expertise in the detection of csPCa.

**Design, setting, and participants:** We included 244 consecutive patients who underwent both 12-core transrectal ultrasound (TRUS) biopsy and mpMRI targeted biopsy with either a cognitive biopsy (CB) or fusion biopsy (FB) approach during the same session between 2013 and 2016 at a single tertiary referral centre.

**Intervention:** All men underwent 1.5-T mpMRI with an endorectal coil. All biopsies were performed by three operators as their first cases of targeted biopsy. Lesions with a Prostate Imaging Recording and Data System (PI-RADS) v.2 score of  $\geq 3$  detected at mpMRI were targeted.

**Outcome measurements and statistical analysis:** csPCa was defined as disease with a Gleason score at biopsy of  $\geq 7$ . Operator expertise was coded as the progressive number of targeted biopsies performed by each physician. Multivariable logistic regression analyses (MVA) were used to assess the association between the targeted biopsy technique (FB vs CB) and operator expertise for detection of csPCa. Covariates consisted of prostate-specific antigen, prostate volume, PI-RADS v.2 (3 vs  $>3$ ), number of targeted cores per MRI lesion, and digital rectal examination (negative vs positive). The same analyses were performed for patients undergoing FB only after accounting for the FB approach (transrectal vs transperineal). A lowess smoothing weighted function was used to graphically assess the effect of operator expertise on the probability of detecting csPCa, after accounting for all confounders.

**Results and limitations:** Overall, 157 patients (64%) underwent FB and 87 (36%) underwent CB. The overall csPCa detection rate was 58% for FB and 45% for CB ( $p = 0.07$ ). A significantly higher rate of csPCa detection in targeted samples was observed for FB compared to CB (57% vs 36%;  $p = 0.002$ ). On MVA, FB and operator expertise were significantly associated with a higher probability of csPCa detection in targeted samples (odds ratio [OR] 2.4 and 1.7, respectively; both  $p \leq 0.03$ ). When the same analyses were repeated for patients undergoing FB, operator expertise remained an independent predictor of csPCa detection (OR 1.9;  $p = 0.004$ ). An increase in the probability of detecting csPCa with the number of procedures performed was observed after accounting for all confounders.

**Conclusions:** We demonstrated that FB had higher detection rate than CB for csPCa. Moreover, operator expertise was significantly associated with higher detection rates for csPCa.

**Patient summary:** When different targeted biopsy techniques were compared, fusion biopsy provided a higher detection rate compared to cognitive biopsy for clinically significant prostate cancer (csPCa). Moreover, we found that operator expertise was an important predictor of the detection of csPCa, regardless of the procedure used.

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## 1. Introduction

Currently available guidelines suggest a 12-core transrectal ultrasound (TRUS)-guided prostate random biopsy as the standard of care for the initial diagnosis of prostate cancer (PCa) [1]. However, misdiagnosis of clinically significant PCa (csPCa), histologic upgrading at radical prostatectomy, and overdiagnosis of clinically insignificant PCa are major drawbacks of this method [2–5]. In order to improve the PCa diagnostic pathway, multiparametric magnetic resonance imaging (mpMRI) of the prostate has the ability to identify csPCa lesions accurately [6,7]. In this context, recent studies have provided evidence of higher diagnostic accuracy of mpMRI in detecting csPCa when compared to TRUS-guided random biopsy in both the initial and repeat biopsy settings [8–10]. This has led to a trend towards greater use of targeted biopsy (TB) with a consequent reduction in overdiagnosis and overtreatment of clinically insignificant disease [11–13]. However, to date discordant data have been reported regarding the optimal technique (cognitive mpMRI/TRUS biopsy [CB] vs fusion mpMRI/TRUS biopsy [FB] vs in-bore mpMRI-guided biopsy) and approach (transrectal [TR] vs transperineal [TP]) for TB of the prostate [14–16]. For this reason, the best method for targeting mpMRI-detected suspicious lesions is still under debate [14,15,17–19]. Moreover, it is likely that besides the approach used, other operator-dependent variables such as physician expertise in TB can influence the performance characteristics. However, the impact of operator expertise on detection of csPCa has not been properly tested yet [20–22]. This is key, since the learning curve may influence the TB diagnostic performance and ultimately impact on correct patient management. To address these gaps, we compared the rate of csPCa detection for different TB approaches (visually registered TB, cognitive approach; TR and TP software-registered TB, fusion approach) and assessed the role of operator expertise in the detection of csPCa at a single tertiary referral centre.

## 2. Patients and methods

### 2.1. Study population

The study cohort consisted of 244 consecutive assessable patients who underwent mpMRI of the prostate with subsequent TB (FB or CB) and concomitant systematic biopsy in a single tertiary referral centre between January 2013 and December 2016. Data were prospectively collected from the first case performed.

### 2.2. mpMRI

All patients underwent a 1.5-T mpMRI study (Achieva and Achieva dStream; Philips Medical Systems, Best, The Netherlands) with a phased-array surface coil and an endorectal coil (BPX-15; Bayer Medical Care, Indianola, PA, USA). According to the European Society of Urogenital Radiology guidelines [6], the imaging protocol consisted of multiplanar T2-weighted images, diffusion-weighted imaging (with long  $b$  value and apparent diffusion coefficient map), dynamic contrast-enhanced MRI, and T1-weighted images with fat suppression. For patients who had previously received one or more sets of biopsies, all mpMRI scans were

performed at least 4 wk after prostate biopsy, and precontrast T1-weighted images were recorded to rule out postbiopsy hemorrhagic artifacts. The mpMRI images were scored and reported according to Prostate Imaging Reporting and Data System (PI-RADS) v.2 [23] by three radiologists with at least 8 yr of experience in prostate mpMRI. Imaged lesions with a PI-RADS score of  $\geq 3$  were considered suspicious for PCa and were thus targeted.

### 2.3. Prostate biopsy technique and histopathology examination

Lesions visualized on mpMRI as suspicious for PCa were submitted to TB using either a software registration (FB) or a visual registration (CB) approach. Each patient also underwent a standard 12-core random biopsy during the same session, in accordance with current guidelines [1]. TRUS was performed using a Flex Focus 500 machine with a biplanar transducer (BK Medical, Herlev, Denmark). CBs and FBs were carried out by three urologists, each of whom had performed at least 200 prostate biopsies but were naïve for TB techniques. Each operator performed TB using one specific approach (operators 1, 2, and 3 performed CB, TR FB, and TP FB, respectively) regardless of any preferences. Operators 1, 2, and 3 performed 87, 70, and 87 TBs, respectively. Every biopsy was performed using an 18-gauge needle and a biopsy gun providing a specimen size of 18–22 mm using a TR approach only for CBs and either a TR or a TP approach for FBs.

For the FB technique, the patient's data and prostate mpMRI images were first entered into the BioJet fusion system (D&K Technologies, Barum, Germany) [24]. Then segmentation and contouring of the prostate and the suspicious lesion were performed by the urologist under the supervision of an experienced radiologist. For the TP approach, a standard brachytherapy grid with 5-mm spacing was also used. Technical data and use of the BioJet fusion system have previously been described [25]. The decision on the type of TB approach used was left to the discretion of each treating physician, regardless of the characteristics of the individual patient and the lesion being targeted. All prostate biopsy specimens were analyzed by two dedicated uropathologists.

### 2.4. Variable definition

Complete clinical data consisting of age at biopsy, prostate-specific antigen (PSA) values (ng/ml), digital rectal examination (DRE; negative vs positive), prostate volume defined at TRUS (ml), PI-RADS score (3 vs  $>3$ ), biopsy technique (FB vs CB), biopsy approach (TR vs TP), number of target cores per MRI lesion, and previous biopsy (none vs prior negative biopsy) were available for all patients.

Operator expertise was coded as the progressive number of TBs performed by each physician. Each physician started from his own first TB case.

### 2.5. Outcomes

The study endpoint was comparison of the rate of csPCa detection for different TB techniques (FB vs CB) and approaches (TR vs TP) and to assess the role of operator expertise in csPCa detection in contemporary patients with a positive mpMRI. csPCa was defined as disease with a Gleason score at biopsy of  $\geq 7$ .

### 2.6. Statistical analysis

Our statistical analysis consisted of four steps. First, the median and interquartile range and the frequency and proportion were reported for continuous and categorical variables, respectively. A Mann-Whitney  $U$  test and a  $\chi^2$  test were applied to assess the statistical significance of differences in medians and proportions, respectively.

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