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Patient Experience of Systematic Versus Fusion Prostate Biopsies

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Abstract

Background: The magnetic resonance imaging/ultrasound fusion-guided biopsy (FBx) technique has gained popularity in prostate cancer (PCa) diagnostics, but little is known about its effect on patient experience.

Objective: To evaluate pain, discomfort and other non-infectious complications in PCa patients undergoing either systematic 12-core transrectal ultrasound-guided biopsy (SBx) or FBx and patient willingness to undergo rebiopsy.

Design, setting, and participants: A prospective trial of 262 male patients, 203 of whom underwent transrectal SBx and 59 FBx at Helsinki University Hospital in 2015–2016. Patients completed two questionnaires immediately after and at 30 d after biopsy.

Outcome measurements and statistical analyses: Patients reported pain and discomfort on a numeric rating scale (NRS; 0–10) immediately after biopsy. At 30 d, discomfort was measured on a scale ranging from 1 (no inconvenience) to 4 (maximal inconvenience). Other symptoms were reported dichotomously (yes/no) in both questionnaires. Mann-Whitney *U*, Pearson's χ^2 , and logistic regression tests were used.

Results and limitations: For the SBx and FBx groups the median number of cores per patient was 12 and three, respectively. At 30 d, a higher proportion of patients in the SBx group had experienced pain than in the FBx group (70/203 [34%] vs 12/59 [20%]; $p = 0.043$), whereas there was no difference in the median discomfort scores. Hematuria was less common in the FBx group (26/59 [44%] vs 140/203 [69%]; $p < 0.001$). Patients willing to undergo rebiopsy immediately post-biopsy reported lower median NRS (3.0 [interquartile range 2.0–5.0] vs 5.0 [4.3–6.0]; $p < 0.001$) and discomfort scores (4.0 [2.0–6.0] vs 7.0 [5.0–8.0]; $p < 0.001$) than those unwilling. At 30 d, less discomfort (2.0 [interquartile range 1.0–2.0] vs 2.0 [2.0–3.0]; $p = 0.008$) and fever (6/195 [3.1%] vs 6/28 [22%]; $p = 0.001$) were experienced by patients willing to undergo rebiopsy. The nonrandomized design was a limitation.

Conclusions: FBx is associated with less pain and hematuria than SBx during the 30-d interval after biopsy.

Patient summary: Magnetic resonance imaging (MRI)-targeted prostate biopsy is associated with less pain, discomfort, and blood in the urine compared to the standard ultrasound-guided procedure. Performing MRI-targeted procedures may reduce biopsy-related complications and promote adherence to recommended repeat biopsy for patients on active surveillance for prostate cancer.

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1. Introduction

The increasing use of systematic transrectal ultrasound (TRUS)-guided prostate biopsy (Bx) in men with no symptoms or signs of prostate cancer (PCa) has led to a rise in the reported incidence of low-risk PCa, which seldom develops into a lethal cancer [1,2]. The call to reduce unnecessary treatments and their side effects for low-risk PCa has led to the use of active surveillance (AS) [3]. Current AS protocols rely on repeated Bxs (rebiopsies) to detect possible PCa reclassification or true progression that would warrant definitive treatment [4]. However, Bxs may cause pain, discomfort, and complications [5]. TRUS-guided Bxs may cause discomfort and pain to such a degree that the willingness of patients to undergo rebiopsy may be compromised [6–9]. Bleeding complications such as hematuria and hematospermia occur in up to 50% of Bxs [5]. Infections occur more frequently because of to increasing bacterial resistance to antibiotics [5]. Some patient-related factors, such as age, have been associated with patients' adverse experiences of Bx [5,10]. The current practice of TRUS-guided Bx is a balance between timely diagnostic accuracy and harm to the patient [6,8,11]. The administration of local anesthetic before Bx reduces pain during the procedure and is therefore recommended [6,8,12]. A numeric rating scale (NRS) that ranges from 0 to 10 has hitherto been found to be the most convenient tool to grade and evaluate pain immediately after Bx procedures [8,13].

Magnetic resonance imaging (MRI) targeting of Bxs with fusion techniques (FBx) has drawn increasing attention among urologists concerned about overdiagnosis and inaccuracies in PCa diagnostics, as FBx has been shown to detect more clinically significant PCa using fewer biopsy cores compared to systematic 12-core Bx (SBx) [14–16]. However, 12-core SBx is not associated with more pain or complications than ten-core or six-core SBx [11,17,18]. Moreover, symptoms and signs such as excessive hematuria are a problem after Bx in approximately half of cases, and also when anticoagulant medication such as warfarin is administered [5]. It is therefore unclear whether the use of FBx may diminish pain, discomfort, and other biopsy-related complications [19,20].

The aims of this study were (1) to determine possible differences in patient-reported pain, discomfort, and other noninfectious complications between patients undergoing either SBx or FBx and (2) to assess the willingness of patients to undergo rebiopsy. Possible explanatory factors for differences between the groups were also investigated.

2. Patients and methods

A prospective trial was conducted at the Department of Urology of Helsinki University Hospital from January 2015 to February 2016 to evaluate the incidence of fluoroquinolone-resistant bacteria in prebiopsy rectal swabs and associated infectious and other complications (NCT02140502). Here we present a subanalysis of that study cohort focusing on patient-reported incidences of noninfectious complications. The analysis comprised 262 consecutive patients aged <80 yr and

referred for Bx because of suspicion of PCa for elevated prostate-specific antigen (PSA) or abnormal digital rectal examination findings or both. Of these, 203 patients underwent SBx and 59 patients underwent FBx. The characteristics of the study population are presented in Table 1. Both biopsy techniques involved a transrectal approach using an 18G needle under ultrasound guidance. The choice of Bx procedure was at the discretion of the urologist, but in general the indication for FBx was a previous negative SBx finding when suspicion for PCa remained (elevated PSA) or surveillance Bx on AS. The MRI scanner used was a 3.0-T Philips Achieva instrument. The image slices were 3.0-mm thick and included T2-weighted imaging, diffusion-weighted imaging with apparent diffusion coefficient mapping, and dynamic contrast enhancement. The European Society of Urogenital Radiology guidelines were followed for imaging and MRI interpretation [21]. MRI-TRUS FBx was performed using a software-guided real-time navigation system (UroNav; Philips Healthcare, Best, The Netherlands) [14].

All patients received a 10-ml injection of 1% lidocaine under ultrasound guidance for periprostatic nerve block before Bx [22]. Ciprofloxacin (750 mg orally) was routinely administered as antimicrobial prophylaxis 1 h before Bx. Phosphomycin (3 g orally) was used 2 h before Bx instead of ciprofloxacin when a patient had experienced hypersensitivity reactions to fluoroquinolones or had been travelling to countries with a higher risk of extended-spectrum betalactamase-producing bacteria strains [23]. After informed consent was obtained, patients were asked to complete two questionnaires (Supplementary material). These questionnaires were originally developed for and used in the ProtecT trial [24]. The questionnaires were then adapted for the PRECISION trial [25]. We used a version translated into Finnish. The first questionnaire measured pain and discomfort immediately after Bx using an NRS and a numeric representation of the visual analog scale (VAS), with 0 denoting “no pain” and 10 indicating “worst imaginable pain”. Discomfort scores similarly ranged from 0 to 10. At 30 d after Bx, patients were asked to complete and return a second questionnaire, which asked whether they had experienced any fever, hematuria, rectal bleeding, hematospermia, pain, or discomfort during that period of time. In addition, patients were asked to grade these symptoms on a scale from 1 to 4, with 1 denoting no inconvenience and 4 denoting maximal inconvenience. Patients were also asked how reluctant they would be to undergo another biopsy in the future (scale from 1 to 4; no reluctance to maximal reluctance). For statistical analyses, answer scores of 1 and 2 (no or minor reluctance) were considered as “willing to undergo rebiopsy” and answer scores of

Table 1 – Patient characteristics

	FBx group (n = 59)	SBx group (n = 203)
Mean age, yr (\pm standard deviation)	68 (\pm 7.6)	68 (\pm 6.8)
Median number of cores, n (IQR)	3 (2–7)	12
Comorbidities, n (%)		
No comorbidities	14 (24)	51 (25)
Diabetes	11 (19)	31 (15)
Chronic renal failure	1 (2)	1 (0)
Liver disease	0 (0)	0 (0)
Cancer, other than prostate	2 (3)	4 (2)
Unspecified illnesses	28 (47)	102 (50)
Data missing	3 (5)	14 (7)
Number of biopsies before the study, n (%)		
0	11 (19)	142 (70)
1	28 (47)	33 (16)
2	14 (24)	15 (7)
3	2 (3)	7 (3)
4	3 (5)	6 (3)
5	1 (2)	0 (0)

FBx = fusion prostate biopsy; SBx = systematic prostate biopsy; IQR = interquartile range.

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