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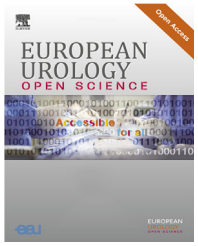

Prostate Cancer

Office-based Magnetic Resonance Imaging–guided Transperineal Prostate Biopsy Without Antibiotic Prophylaxis: A Real-world Clinical Utility Study

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Abstract

Background and objective: Advances in for magnetic resonance imaging (MRI)-guided transperineal biopsy (TPBx) techniques have facilitated outpatient prostate biopsies under local anaesthesia to lower postbiopsy infection rates. However, there is debate regarding antibiotic prophylaxis because of concerns regarding antibiotic resistance and interactions. Our objective was to assess the transition from office-based transrectal biopsy to TPBx performed under local anaesthesia without antibiotic prophylaxis despite potential risk factors for infectious complications.

Methods: We conducted a prospective assessment of 665 men undergoing office-based MRI-guided TPBx. The primary outcome was the rate of urosepsis or febrile urinary tract infections requiring hospitalisation and/or antibiotics within 2 wk after biopsy. Secondary outcomes included patient-reported procedure tolerability and the prostate cancer detection rate.

Key findings and limitations: TPBx using a median of nine cores per patient (range 4–15) detected prostate cancer in 534/665 men (80%). Only four men (0.6%) were hospitalised for suspected postbiopsy infection; no patient experienced urosepsis. The TPBx procedure was well tolerated, with low pain scores (median Visual Analogue Scale score of 2, interquartile range [IQR] 1–3) and positive patient ratings (median rating 1 [no problem], IQR 1–2). Limitations include the single-centre analysis and lack of randomisation for antibiotic prophylaxis.

Conclusions and clinical implications: An office-based TPBx strategy under local anaesthesia without antibiotic prophylaxis is well tolerated and has a very low risk of side effects. This approach should be considered as the standard of care. Further studies may determine if a subgroup of predisposed men could benefit from antibiotic prophylaxis.

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Patient summary: For prostate biopsy the sampling needle can be inserted through the rectum or through the perineum, which is the skin between the rectum and the scrotum. Our study confirms that in everyday clinical practice, prostate biopsy via the perineum can be carried out under local anaesthetic and without routine use of antibiotics because of its lower risk of infection. Patients reported low pain scores and positive ratings for the overall experience.

1. Introduction

Transrectal biopsy (TRBx) has been the standard approach for office-based prostate biopsy in outpatient clinics because of the anatomic location of the prostate gland and the feasibility of the procedure. However, TRBx necessitates the use of antibiotic prophylaxis because the biopsy needle passes through the rectal wall multiple times, with potential for inoculation of rectal bacteria. Despite antibiotic prophylaxis, up to 5–7% of men undergoing TRBx may develop postbiopsy infection and sepsis requiring hospitalisation and additional intravenous antibiotics [1–3]. This high TRBx-related morbidity represents a major burden for health care systems and urology departments. Furthermore, because the worldwide prevalence of antibiotic-resistant bacteria in the rectal flora is increasing and the number of effective antibiotics is declining [4,5], a transperineal biopsy (TPBx) route has been proposed as a strategy to reduce biopsy-related infections [6]. For TPBx, all cores are obtained via puncture of the disinfected perineal skin, and because neither the rectal wall nor the urinary tract is penetrated, it is considered an aseptic procedure with lower infection risk [4,7]. Consequently, TPBx has been more widely adopted and is now recommended in the European Association of Urology (EAU) guidelines as a preferred alternative to TRBx [8]. However, there is debate on whether to use antibiotic prophylaxis for the procedure because of concerns regarding antibiotic resistance and drug interactions, especially for men with known risk factors for postbiopsy infection such as an indwelling catheter, a history of urinary tract infection (UTI), and/or diabetes and obesity. Furthermore, some centres still use general anaesthesia for TPBx, making it less suitable for routine clinical practice. However, recent technological advances have facilitated TPBx under local anaesthesia in the outpatient setting, with good patient tolerance reported [9]. Consequently, our department decided to switch from antibiotic-dependent TRBx to antibiotic-free TPBx for all men undergoing magnetic resonance imaging (MRI)-guided prostate biopsy. The aim of this study was to evaluate our first-year real-world clinical experience with office-based TPBx under local anaesthesia in the outpatient clinic without any antibiotic prophylaxis despite potential risk factors for postbiopsy complications. We assessed the rate of postbiopsy infection, patient-reported scores for the overall experience and tolerability, and prostate cancer (PCa) detection rates.

2. Patients and methods

This prospective study included consecutive men registered in our institutional review board–approved database who underwent office-based MRI-transrectal ultrasound (TRUS) fusion-guided prostate TPBx in the outpatient clinic from May 2022 to May 2023. All men provided written informed consent and no antibiotic prophylaxis was used, even for men with risk factors for postbiopsy infection such as an indwelling catheter, a prior post-TRBx infection, or recent antibiotic use. The men were either biopsy-naïve with clinical suspicion of PCa, had prior negative biopsies requiring repeat biopsy, or were on active surveillance requiring a protocol-based staging biopsy. Prebiopsy MRI was performed and the scans were analysed by experienced prostate MRI physicians according to Prostate Imaging-Reporting and Data System (PI-RADS) version 2.1 criteria [10]. All men were graded on a 5-point scale (PI-RADS score) according to their likelihood of having significant PCa (sPCa). The cohort was divided into three MRI suspicion categories: low (PI-RADS $\leq$2), equivocal (PI-RADS 3), and high (PI-RADS $\geq$4). Men without suspicious lesions were assigned an overall PI-RADS score of 1.

2.1. Biopsy procedure

All procedures were performed by one of three experienced senior operators using an MRI-TRUS fusion software platform (Koelis Trinity®, Meylan, France or UroNav® 3.0, Invivo International, Best, The Netherlands). There was no formal training before the switch from TRBx to TPBx other than phantom and software training following a required TPBx software upgrade, as the operators had prior TPBx experience from brachytherapy and ProACT balloon placement. Therefore, no learning curve analysis was conducted.

Patients were placed in the lithotomy position in the outpatient procedural room, with the scrotum fixed with a pair of single-use underwear cut to reveal the perineum. The perineal skin was disinfected twice (chlorhexidine-alcohol 0.5%) and infiltrated with 10 ml of 1% lidocaine on both sides of the midline. A TRUS probe with a longitudinal mini-grid was inserted into the rectum and a periprostatic block was applied to both sides of the prostate using 10 ml of 1% lidocaine. MRI and live ultrasound images were merged using software registration for targeted biopsies. A coaxial needle (17G; 10 cm) was used to puncture the perineal skin and guide an 18G biopsy needle. In most cases, the coaxial needle was repositioned to sample the contralateral prostate half. For men with MRI-suspicious lesions (PI-RADS 3–5), a minimum of four targeted cores per lesion were sampled. Systematic biopsies were performed in men with unilateral MRI foci (five contralateral cores) and in men with negative MRI findings (10 cores, five from each prostate half) according to the standard institutional protocol. Men with a suspicious lesion crossing the midline involving both prostate halves only underwent targeted biopsies. The biopsy samples were marked and potted separately and for assessment by experienced uropathologists according to the International Society of Urological Pathology consensus recommendations on grade group (GG) [11]. Significant PCa (sPCa) was

defined as GG ≥2. The last 100 consecutive patients rated their pain and experience with TPBx using a questionnaire completed immediately after the procedure.

2.2. Outcome measures

The primary endpoint was the rate of urosepsis or febrile UTI requiring postbiopsy in-house observation and/or antibiotics within 2 wk after biopsy. Secondary endpoints included other biopsy-related medical assistance, patient-reported tolerability (patient experience and procedural pain), and the PCa detection rate. All patients were given oral and written instructions to contact our department for in-house clinical evaluation in case of adverse events and/or fever ≥38.0 °C after biopsy. Clinical information, including urine and blood culture results and treatment plans, was collected from all men requiring clinical evaluation, and decisions on the need for hospitalisation were at the discretion of the treating physician. Sepsis was defined as infection and organ dysfunction according to the Sequential Organ Failure Assessment instrument [12] as recommended by the Danish national guidelines [13]. Suspicions for UTI included the onset of symptoms such as dysuria, pollakisuria, suprapubic pain or discomfort, and/or fever ≥38.0 °C after biopsy.

2.3. Statistical analysis

The patient characteristics were summarised using descriptive statistics. Results for continuous variables (age, prostate-specific antigen [PSA] level, PSA density, and prostate volume) were stratified by biopsy results and compared using a Wilcoxon rank-sum test. Fisher's exact test was used to compare clinical T stage on digital rectal examination between nonpalpable and palpable tumour groups. A χ^2 analysis was conducted to determine the association between the prebiopsy MRI suspicion score and positive biopsy results. Median values for patient-reported ratings for their procedural experience were stratified by perception of pain on application of local anaesthetic and during biopsy sampling. Overall pain was reported by patients using the Visual Analog Scale (score from 0 to 10). Finally, the patients rated their overall opinion on undergoing TPBx using a Likert scale ranging from 1 (no problem) to 5 (worst possible experience).

Rates of urosepsis or UTI after TPBx are expressed as the frequency and proportion and were compared with previously reported rates following TRBx.

Statistical significance was set at $p < 0.05$ and analyses were performed using SPSS version 28.0 (IBM, Armonk, NY, USA).

3. Results

From May 17, 2022, to May 16, 2023, a total of 681 men underwent TPBx at our institution and were prospectively enrolled in the institutional database. Of these, 16 patients were excluded for various reasons, as detailed in Figure 1. The final study population consisted of 665 men with a median age of 67 yr (interquartile range [IQR] 61–71) and median PSA of 8.3 ng/ml (IQR 6–14). The baseline clinical characteristics of the cohort are listed in Table 1. TPBx detected any PCa in 80% of the patients (n = 534/665) and sPCa in 64% (n = 425/665). Higher MRI suspicion scores were associated with a higher sPCa detection rate (Fig. 2). Most men were biopsy-naïve (74%; n = 490/665) and scheduled for TPBx because of either positive MRI findings (PI-RADS ≥4) or PSA density ≥0.15 ng/ml/cm^3. The remaining patients were either on active surveillance (22%; n = 147/665) or had prior negative biopsies but persistent clinical suspicion of PCa warranting repeat biopsy (4%; n = 28/665).

Systematic biopsies were performed in 74% of the patients (n = 495/665), with the majority (80%; n = 398/495) undergoing five-core contralateral systematic biopsies in addition to targeted biopsies of unilateral MRI-suspicious foci. The median number of cores per patient was nine (range from four to 15).

Overall, six men (0.9%) underwent postbiopsy in-house clinical evaluation because of suspicion of biopsy-related adverse events. In terms of the primary endpoint, four of these six men (0.6%; n = 4/665) were hospitalised and

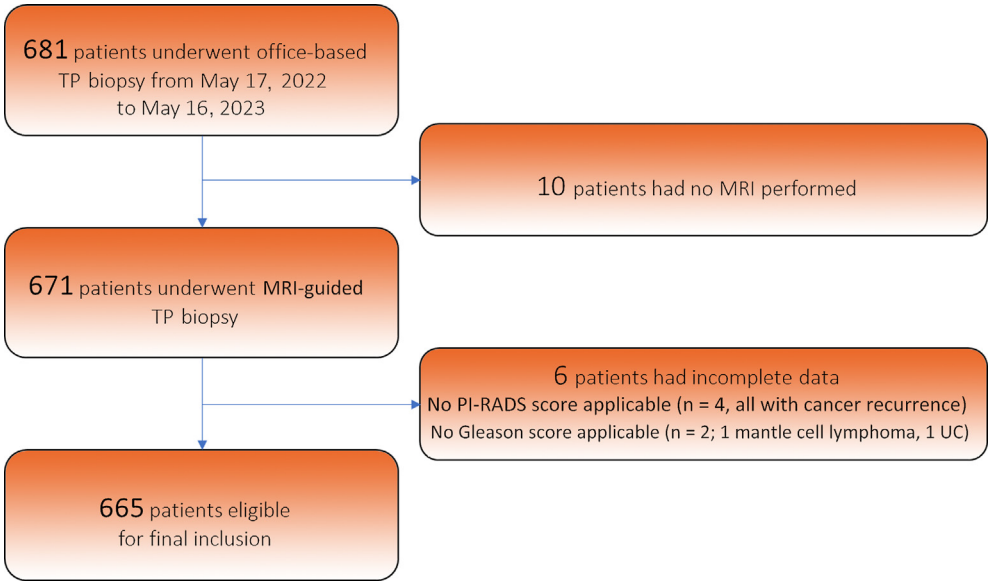

Fig. 1 – Flowchart of the study population. MRI = magnetic resonance imaging; PI-RADS = Prostate Imaging-Reporting and Data System; TP = transperineal; UC = urothelial carcinoma.

Table 1 – Patient characteristics

Parameter	Overall (n = 665)	No PCa (n = 131)	Insignificant PCa (n = 109)	Significant PCa (n = 425)	p value[a]
Median age, yr (IQR)	67 (61–71)	64 (58–69)	66 (61–71)	68 (63–72)	<0.001
Median PSA, ng/ml (IQR)	8.3 (5.6–14.1)	8,6 (5.6–14.3)	7.2 (4.9–10.7)	8.9 (5.8–16.0)	0.004
Median PV, cm^3 (IQR)	45 (34–65)	56 (38–83)	47 (38–73)	42 (32–56)	<0.001
Median PSAD, ng/ml/cm^3 (IQR)	0.18 (0.12–0.28)	0.16 (0.10–0.21)	0.15 (0.09–0.21)	0.21 (0.14–0.37)	<0.001
cT stage on DRE, n (%)					<0.001
Nonpalpable tumor (cTx–1c)	464 (70)	114 (87)	98 (90)	252 (59)	
Palpable tumor (cT2–3)	201 (30	17 (13)	11 (10)	173 (41)	
PI-RADS score, n (%)					<0.001[b]
1–2 (low suspicion)	90 (14)	54 (41)	26 (24)	10 (2)	
3 (equivocal)	40 (6)	21 (16)	7 (6)	12 (3)	
4–5 (high suspicion)	535 (80)	56 (43)	76 (70)	403 (95)	

DRE = digital rectal examination; IQR = interquartile range; PCa = prostate cancer; PI-RADS = Prostate Imaging-Reporting and Data System; PSA = prostate-specific antigen; PSAD = PSA density; PV = prostate volume.
[a] Significant PCa versus no PCa and insignificant PCa.
[b] Fisher's exact test for comparison of pooled scores for nonsuspicious versus suspicious findings on magnetic resonance imaging.

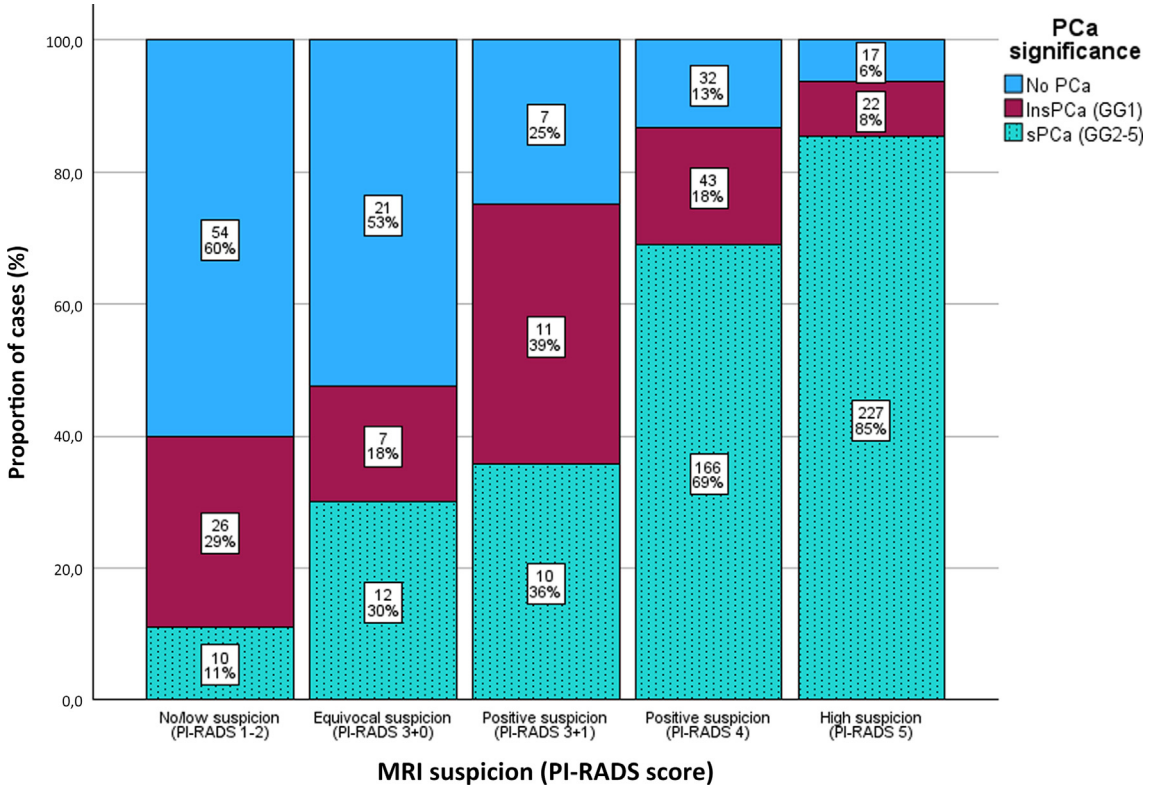

Fig. 2 – Magnetic resonance imaging (MRI) suspicion by biopsy outcome for the 665 patients who underwent transperineal prostate biopsy. GG = grade group; PCa = prostate cancer; InsPCa = insignificant PCA; sPCa = significant PCa; PI-RADS = Prostate Imaging-Reporting and Data System.

started on antibiotics because of suspicion of postbiopsy infection (fever ≥38.0 °C). The remaining two men had a systemic reaction related to the procedure (vasovagal) or to application of local anaesthetic (mild systemic reaction) requiring brief in-house observation after their biopsies. None of the four hospitalised men developed urosepsis (0%) and all were discharged after 1–2 d with oral antibiotics and a final diagnosis of febrile UTI. Interestingly, retrospective review confirmed that three of the four men (75%) also had a UTI in the period up to the TPBx procedure, including one man with prebiopsy urinary retention requiring intermittent catheterisation. The remaining man had no risk factors other than obesity. Two of the men had positive urine cultures (one with *Escherichia coli* and one with *Enterobacter cloacae*); none had positive blood cultures.

The TPBx procedure was well tolerated, with a median pain VAS score of 2 (IQR 1–3) for all steps and a patient-reported median rating of 1 (no problem; IQR 1–2) for the overall biopsy experience (Fig. 3). The procedure duration was not formally recorded but was typically <30 min.

4. Discussion

We present our 1st year clinical experience after switching from antibiotic-dependent TRBx to antibiotic-independent

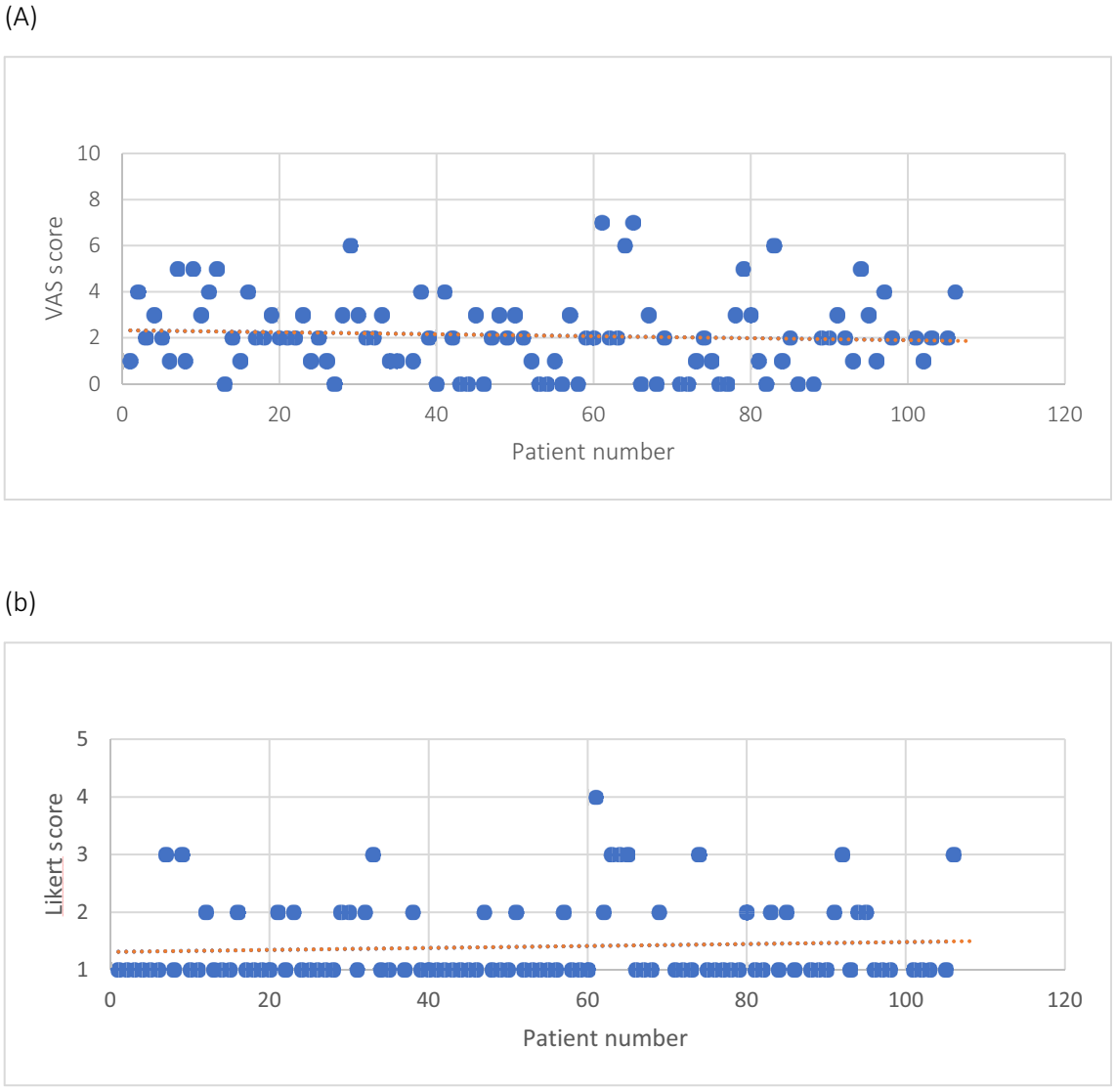

Fig. 3 – Patient-reported scores for pain and the overall biopsy experience. (A) Patient-reported perception of procedural pain using Visual Analog Scale (VAS) scores from 0 (no pain) to 10 (worst pain). (B) Patient ratings for the overall transperineal biopsy experience using a Likert scale ranging from 1 (no problem) to 5 (worst possible experience).

TPBx. Our data form a large, real-world cohort demonstrate that office-based MRI-guided TPBx is possible without antibiotic prophylaxis, despite possible risk factors such as prior UTI, an indwelling catheter, or diabetes. Overall, we found very low rates of postbiopsy infection requiring in-house observation and treatment for febrile UTI (0.6%) or urosepsis (0%). This is remarkably lower than our historical annual admission rate of 5–7% for post-TRBx infection despite antibiotic prophylaxis [1]. Our findings are in alignment with previous studies comparing TRBx and TPBx that showed very low UTI and sepsis rates for TPBx [4,7]. A retrospective analysis of 4233 biopsy cases by Tops et al. [14] revealed that TPBx was associated with no bacteraemia or hospitalisation within 7 d and a significantly lower infection rate in comparison to TRBx (odds ratio 0.29). Interestingly, in contrast to studies using antibiotic prophylaxis, our study showed the same low infection and sepsis rates without antibiotics. The antibiotic-independent TPBx approach is also supported by a recent meta-analysis by Basourakos et al. [15] comparing TPBx with and without antibiotics. The authors found no significant difference in the sepsis rate (0.05% vs 0.13%; $p = 0.2$) or overall infection rate (1.35% vs 1.22%; $p = 0.8$) between the groups. However, in a subgroup of men with a low to moderate number of biopsy cores as in our study, there was a small but significant difference in the overall infection rate favouring antibiotic use (0.55% vs 1.22%; $p < 0.01$). Nevertheless, the absolute difference was <1% and there was no difference in the sepsis rate between the groups. Furthermore, most "no-antibiotic" studies included in the review (71%; 10/14) were retrospective, which possibly introduced unknown selection bias because of the exclusion of men with known infection risks. In the NORAPP trial reported by Jacewicz et al. [16], 555 men undergoing office-based TPBx were randomised 1:1 to biopsy with or without antibiotic prophylaxis. There were no hospitalisations or sepsis

cases in either group. However, there was a small, non-significant absolute increase in the UTI rate for the group without antibiotic prophylaxis (0.36% vs 1.09%; $p = 0.316$). The number needed to treat to avoid one infection was 137. Interestingly, the recent ProBE-PC trial [17] found no difference in infection rate (2.6% vs 2.7%) in a cohort of 763 men randomised to TRBx with antibiotics or TPBx with no antibiotics. No patients had sepsis and only three (0.4%) patients were admitted for observation, as in our study. Notably, unlike our study, these previous studies either excluded men with known high-risk features for postbiopsy infection or used antibiotic prophylaxis for selected cases. Therefore, our study reinforces prior findings of very low sepsis and infection rates following office-based TPBx under local anaesthesia without antibiotic prophylaxis and validates this outcome in a real-world setting that involves prospectively obtained data for a cohort including men with possible known or unknown prebiopsy risk factors for infection.

Switching from office-based TRBx to TPBx without antibiotics can significantly reduce the major burden of postbiopsy admissions and nearly eliminate the use of antibiotic prophylaxis, reducing its contribution to antibiotic resistance and potential drug interactions. This strategy was recently endorsed by the EAU Young Academic Urologists Prostate Cancer Working Party [18]. Importantly, our study also shows that the procedure was well tolerated, with only mild levels of discomfort on the pain VAS scale, in line with previous studies [19].

4.1. Limitations

Our study has several limitations that need to be highlighted. First, because we completely switched from TRBx to TPBx without any transition period, we could not include concurrent data from TRBx procedures as a direct comparator. However, according to solid historical data from the past decade, we know that the admission rate following TRBx was consistently ten times higher (5–7%) [1] than our current result of 0.6% for febrile UTI following TPBx. Thus, our low admission rate following TPBx is reassuring and we expect that the TPBx strategy will reduce patient harms and costs. Second, no patient developed urosepsis; however, because our current practice is to initially hospitalise all febrile men with clinical suspicion of postbiopsy infection and start intravenous antibiotics for at least 24 h during the observation period despite no clinical evidence of sepsis, we cannot determine whether urosepsis would have occurred without this intensive initial treatment. Third, we did not formally record potential prebiopsy medical comorbidities, history of prior UTI, or urinary retention requiring cauterisation, all of which are known risk factors for postbiopsy infection. Instead, in consultation with the microbiology department, we chose to let all men undergo TPBx without antibiotic prophylaxis but with ongoing monitoring of possible postbiopsy side effects to facilitate early intervention in case of an increase in events in certain risk groups. Notably, three of the four men hospitalised for febrile UTI had a history of UTI. However, the admission rate of 0.6% is very low and it is uncertain whether antibiotic prophylaxis would have prevented these UTIs. Finally, the median number of cores sampled per patient in our study was moderate, and an increase in the number of cores in situations where needed could influence both adverse events and pain tolerability, making it less suitable as an office-based intervention without antibiotics.

5. Conclusions

In conclusion, we believe that an office-based TPBx strategy under local anaesthesia without routine use of antibiotics is well tolerated with a very low risk of side effects and should be considered the standard of care [9,18]. However, future studies are needed to address whether a small proportion of predisposed men could potentially benefit from antibiotic prophylaxis.

Author contributions: Lars Boesen had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Boesen, Nørgaard, Bisbjerg, Løgager.
Acquisition of data: Boesen, Nørgaard, Bisbjerg, Løgager, Al-Hamadani, Sjölin.
Analysis and interpretation of data: Boesen, Nørgaard, Bisbjerg, Løgager.
Drafting of the manuscript: Boesen, Nørgaard, Bisbjerg, Løgager.
Critical revision of the manuscript for important intellectual content: Boesen, Nørgaard, Bisbjerg, Løgager, Al-Hamadani, Sjölin.
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