SCANDINAVIAN JOURNAL OF UROLOGY
2021, VOL. 55, NO. 6, 434–440
https://doi.org/10.1080/21681805.2021.1981995

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ARTICLE

Diagnostic outcomes from transrectal and transperineal prostate biopsies – experiences from a Swedish tertiary care Centre

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ABSTRACT

Objective: The aim of this study was to compare diagnostic and infectious outcomes between MRI-guided transrectal (TR) and transperineal (TP) prostate biopsies, in order to evaluate implementation of local-anaesthesia TP biopsies in a Swedish university hospital setting.

Methods: In this non-randomized observational study, we recruited 105 patients who underwent TR or TP software-based MRI-ultrasound fusion prostate biopsies between April and August 2020. Information on outcome and covariates were obtained from hospital records. We compared detection rates of overall prostate cancer (PCa) and clinically significant PCa (≥ISUP2) between the two groups using simple and multivariable-adjusted analyses. As a secondary outcome, we descriptively compared infection-related outcomes between the two groups.

Results: Of the total population, 72 patients underwent TR and 33 patients underwent TP biopsies. Biopsies were positive for PCa in 50 (69.4%) patients of the TR group and 23 (69.7%) patients of the TP group. Clinically significant cancer was found in 28 (38.9%) patients of the TR group and 10 (30.3%) patients of the TP group. Simple and multivariable-adjusted analyses did not indicate any statistically significant difference between groups. Post-biopsy infection was diagnosed in one patient (3%) of the TP group and eight patients (11.1%) in the TR group, conforming to previous reports of low infection rates after TP biopsies.

Conclusions: Our results conform to data suggesting that the transition from TR to TP MRI-guided biopsies is feasible and safe, maintaining a high diagnostic quality while possibly reducing the risk of infection-related complications.

ARTICLE HISTORY
Received 18 March 2021
Revised 7 September 2021
Accepted 13 September 2021

KEYWORDS
Prostate cancer; prostate biopsy; transperineal; MRI-guided; fusion biopsy; infection

Introduction

Multiparametric magnetic resonance imaging (mpMRI) of the prostate has received a prominent position in prostate cancer (PCa) diagnostics [1] and is now recommended for initial diagnostics in most men with suspected PCa in national and international guidelines [2,3]. Targeted biopsies based on MRI have been shown to reduce overdiagnosis of clinically insignificant PCa as well as to increase detection of clinically significant PCa (csPCa) [4].

The reduced number of biopsies required have further been suggested to possibly reduce the risk of post-biopsy infection, but clear evidence of this is lacking [5]. Biopsy-related infections [6–10] and emerging fluoroquinolone resistant *E. coli* [11] thus remain disturbing concerns, particularly in the context of increasing numbers of PCa assessments in an ageing population.

The transperineal (TP) biopsy approach has been introduced to improve the safety of prostate biopsies. Systematic reviews suggest a reduced risk for infections when applying the TP approach rather than the transrectal (TR) approach, albeit possibly at the prize of greater patient discomfort [5,12]. Detection rates of csPCa with transperineal biopsies (TPBx), compared to transrectal biopsies (TRBx), in MRI-positive patients have been observed to be similar [13] or possibly even higher [14]. This presents MRI-targeted TPBx as an attractive alternative in prostate cancer work-up, possibly combining high sensitivity with reduced risk of infection.

The aim of this observational study was to evaluate the implementation of TPBx in a Swedish tertiary care urologic centre with extensive previous experience in TR MRI-ultrasound (US) fusion biopsies, by comparing diagnostic and infection-related outcomes in patients undergoing MRI-US fusion TR and TP biopsies.

Methods

Ethical statement

The study was approved by the regional ethical review board in Uppsala, Sweden (Ref. 2019–00286; 2010/005).

Study aim

The primary aim of this study was to investigate the possible impact of MRI-US fusion biopsy route (transrectal [TR] vs. transperineal [TP]) on the detection rate of csPC, defined as International Society of Urological Pathology (ISUP) grade

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≥2) [15], in order to evaluate introduction of the TP biopsy method at a Swedish tertiary urological referral centre. As a secondary aim, we descriptively evaluated the impact of biopsy method on post-biopsy infection rates.

Study population

Between 30 April and 31 August 2020, performing of TP prostate biopsies was implemented at the Department of Urology, Örebro University Hospital, Örebro, Sweden. Since 2018, TR MRI-US fusion biopsies constitute the primary diagnostic procedure in PCa work-up at the department. In the standardized work-up of suspected PCa at the department, all men under age 75 years and displaying PSA-values <100 ng/mL are automatically referred to an MRI. If this includes the finding of lesions classified as Prostate Imaging Reporting and Data System (PI-RADS) 4–5, or PI-RADS 3 in combination with high PSA-density (>0.15 ng/mL^2), patients are scheduled for fusion biopsies. Other clinical routes leading up to fusion biopsies include patients in active monitoring for PCa, or patients with persistent suspicion of prostate cancer despite previous negative biopsies, who in the context of clinical routine have undergone an MRI displaying suspect pathological lesions.

The source population of this study was all men, regardless of prior route, who underwent MRI-US fusion biopsies at the department during the study period. From the basis of this population, we recruited $n = 106$ participants for this non-randomized observational study. Patients were at the time of inclusion, in connection to the biopsy procedure, provided oral and written study information before agreeing to participate. A flow-chart describing the study population, as well as the clinical routes to MRI-US fusion biopsies (i.e. study eligibility) is available in Figure 1.

The source population included patients referred for primary evaluation of suspected prostate cancer, most commonly due to elevated prostate specific antigen (PSA) level (≥3 ng/mL), as well as prostate cancer patients in active monitoring and patients with remaining clinical suspicion of csPCa despite previous negative biopsies.

Allocation of participants to TR or TP biopsies was not randomized, but was determined by clinical decision-making. Patients with previous post-biopsy infection were, if possible, generally considered as candidates for TP biopsies.

bpMRI

Biparametric MRI (bpMRI) [16] was performed according to local clinical routine and in conformity with European Society of Urogenital Radiology (ESUR) recommendations [17]. Unlike conventional mpMRI, which utilizes multiple MRI sequences to better characterize lesions, this abbreviated examination protocol does not include dynamic contrast enhancement, which shortens the examination time and may reduce the number of adverse events. Although still a matter of some scientific debate, evidence suggests the diagnostic performance of bpMRI to be comparable with that of mpMRI [16]. Examinations were performed at the Department of Radiology, Örebro University Hospital for county inhabitants, and at the referring hospital for patients living in adjacent regions. Interpretation and grading of all MRI images was performed according to Prostate Imaging Reporting and Data System Version 2 (PI-RADS v2) [18] by one of three designated radiologists at Örebro University Hospital. Reports included location and PI-RADS score (1–5) of suspected lesions, as well as prostate volume.

Clinical procedure

TR and TP MRI-US fusion biopsies were performed using the KOELIS Urostation and Trinity systems (KOELIS Inc., Princeton, NJ), respectively. These systems utilize so-called elastic software-based MRI-US fusion, superimposing and adapting the MRI image, including suspected lesions, to the US image [19], thus enabling the investigator to visualize and target suspected lesions. Biopsies were performed according to clinical routine by any one out of three designated urologists experienced in TR MRI-US fusion biopsies (TRBx). TRBx were performed with the patient in left lateral position, after US guided periprostatic injection of 5 mL 10 mg/mL Carbocain bilaterally. If lesions were present in only one lobe, only unilateral periprostatic infiltration of 5 mL was used. TP biopsies (TPBx) were performed in lithotomy position, after perineal infiltration of 20 mL 10 mg/mL Carbocain subcutaneously, as well as periprostatic local infiltration in the same manner as for TRBx. The total time required (from patient entry to patient exit) for the TPBx procedure was some 35–40 min, compared to some 20 min for TRBx.

All patients, regardless of biopsy method, underwent 2–4 biopsies per suspected lesion, based on clinician's assessment. Systematic biopsies were performed only on selected patients based on clinical indications according to national guidelines [3].

According to clinical routine, a urine culture was performed prior to biopsies on all patients. If positive, an appropriate course of antibiotic treatment was prescribed prior to biopsies. Based on clinical decision, patients deemed at high risk of procedure-related infection were prescribed a prolonged prophylactic antibiotic course following biopsies, despite absent signs of bacteriuria. This was not systematically determined according to study-specific criteria, but subject to individual clinical decisions by the responsible urologist according to clinical routine. All other patients received a standard single dose of oral fluoroquinolone prophylaxis of Ciprofloxacin 750 mg prior to biopsies in conformity with national guidelines and clinical routine.

Biopsy specimens were diagnostically evaluated at the Department of Pathology, Örebro University hospital, according to standard clinical routine. Reports included findings of cancer, as well as grade according to the Gleason and ISUP systems.

Outcome measures and characteristics

We used hospital records to obtain information on age, PSA-level, previous history of prostate cancer, and indication for biopsies, as well as various other characteristics.

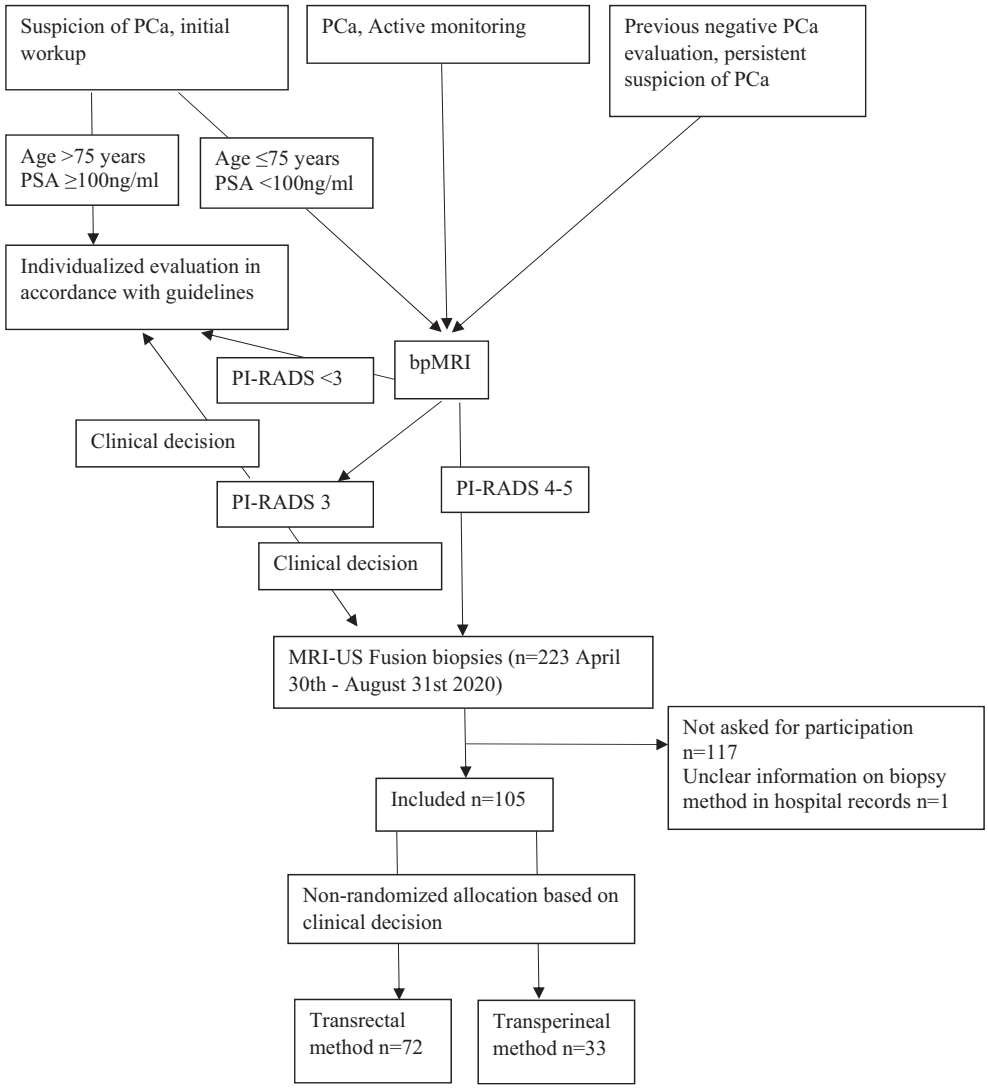

Figure 1. Flow-chart: Study population and clinical routes leading up to MR-US fusion biopsies.

Estimated prostate volume, number, location, size, and PI-RADS score of suspected lesions were obtained from radiologist's reports. PSA-density was calculated from the most recent PSA-value and MRI-estimated prostate volume. Biopsy method, number of biopsies and clinical tumor stage (cT) from digital rectal examination were obtained from biopsy protocols. The presence of cancer and cancer grade (Gleason/ISUP) were obtained from pathology reports.

In order to evaluate baseline characteristics possibly impacting the risk of infection, information on previous infections after urological procedures, presence of urinary catheter or intermittent self-catheterization, immunosuppressant drugs (such as corticosteroids or antirheumatic drugs), a recorded diagnosis of type 2-diabetes, positive urine culture and type of prophylaxis/antibiotic regimen were obtained from hospital records. Development of urinary tract infection (UTI) and hospitalization within 30 days of biopsies were assessed using hospital and prescription records. As definition of infection, we used any patient who, based on hospital records, received treatment for a urinary tract infection, whether based only on clinical assessment or verified by positive urine culture. As definition of hospitalization, we used any reported hospitalization within 30 days of biopsies.

Statistical analysis

We performed statistical analyses in IBM SPSS Statistics version 25 (IBM Corp., Armonk, NY). In order to evaluate differences between groups, we used standard non-parametric tests for continuous variables, and Chi-squared Test for proportions. Descriptive statistical measures included frequencies, medians, ranges, and percentages.

In order to estimate the impact of biopsy strategy (TR vs. TP) on the detection rate of csPCa, adjusted for cofactors possibly influencing the likelihood of positive finding, we estimated unadjusted and multivariable adjusted odds-ratios (ORs) and 95% confidence intervals (95% CIs) for the association between biopsy type and finding of csPCa using logistic regression. Covariates were chosen based on clinical rationale, and the final model included biopsy method (categorical), age (years, continuous), PSA density (categorical; <0.1 ng/mL^2, $0.1-<0.15$ ng/mL^2, ≥ 0.15 ng/mL^2), number of

Table 1. Characteristics of $N = 105$ men undergoing MRI-US fusion prostate biopsies between May and August 2020, by biopsy route (transrectal or transperineal).

	Transrectal biopsies ($N = 72$)	Transperineal biopsies ($N = 33$)	p-value
Age (years)			
Median (min–max)	66 (49–81)	68 (46–79)	0.11[a]
PSA (ng/mL)			
Median (min–max)	6.7 (0.74–47.0)	6.0 (1.9–29.0)	0.98[a]
Prostate volume (mL, MRI estimated)			
Median (min–max)	43 (12–280)	40 (22–115)	0.81[a]
PSA density (ng/mL^2)			
Median (min–max)	0.15 (0.04–1.07)	0.16 (0.05–0.40)	0.66[a]
Biopsy naive, *N* (%)	36 (50.0)	16 (48.5)	0.89[b]
Indication for biopsies, *N* (%)			
Primary evaluation	36 (50.0)	15 (45.5)	0.65[b]
Active monitoring	22 (30.6)	13 (39.4)	
Suspicion of cancer despite previous negative biopsies	14 (19.4)	5 (15.1)	
No. of MRI lesions, *N* (%)			
1	46 (63.9)	14 (42.4)	0.12[b]
2	20 (27.8)	15 (45.5)	
3	6 (8.3)	4 (12.1)	
Highest PI-RADS score, *N* (%)			
2	1 (1.4)	0 (0)	0.92[b]
3	20 (27.8)	9 (27.3)	
4	28 (38.9)	13 (39.4)	
5	23 (31.9)	11 (33.3)	
Size largest MRI lesion (mm)			
Median (min–max)	13 (3–48)	13 (4–30)	0.76[a]
No. of biopsies			
Median (min–max)	4 (3–12)	5 (3–8)	0.87[a]
Positive finding of prostate cancer in biopsies, *N* (%)	50 (69.4)	23 (69.7)	0.97[b]
Finding of clinically significant cancer ($\geq$ISUP2[c]), *N* (%)	28 (38.9)	10 (30.3)	0.40[b]

[a]*p*-value from Mann-Whitney U-test.
[b]*p*-value from Chi-squared test.
[c]One case of IDC included as clinically significant tumor.

biopsies (categorical; $\leq$3, 4–6, >6), highest PI-RADS score (categorical $\leq$3, 4, 5), and indication for biopsies (categorical; primary evaluation, active monitoring, and persistent suspicion of cancer despite previous negative biopsies). We defined statistical significance as $p < 0.05$ and 95% confidence intervals not including 1.00.

Results

From $n = 106$ recruited participants, we excluded one due to unclear information on biopsy method, rendering $n = 105$ participants eligible for evaluation. Characteristics of patients by biopsy method are available in Table 1. Median age at time of biopsy was 66 years for the transrectal (TR) group, and 68 years for the transperineal (TP) group. Median PSA was 6.7 ng/mL for the former, and 6.0 ng/mL for the latter (range = 0.74–47.0 ng/mL and 1.9–29.0 ng/mL). Median MRI-estimated prostate volume was 43 mL and 40 mL, respectively. PSA density was similar in both groups (0.15 ng/mL^2 and 0.16 ng/mL^2, range = 0.04–1.07 ng/mL^2 and 0.05–0.40 ng/mL^2). There were no statistically significant differences between the groups regarding age, PSA, prostate volume and PSA-density (Table 1).

A similar proportion of participants ($n = 36$, 50.0% in the TR group and $n = 16$, 45.5% in the TP group) underwent biopsies due to primary evaluation of suspected PCa. Consequently, half of the participants in both groups were biopsy naïve. The proportion who underwent biopsies as part of active monitoring was slightly higher in the TP group (39.4% compared to 30.6%), and the proportion undergoing biopsies due to persistent suspicion of cancer was consequently slightly lower (15.1% compared to 19.4%). Proportions of previous PCa, previous biopsy and indication for biopsy did not differ with statistical significance over groups (Table 1).

Although not statistically significant, the proportion with more than one suspect prostatic MRI lesion was higher in the TP group ($n = 19$, 57.6%, compared to $n = 26$, 36.1%). Distribution of highest PI-RADS score (defined as the highest PI-RADS score of any MRI lesion in one individual), size of largest MRI lesion, and number of biopsies taken did not differ significantly between the two groups (Table 1). The total number of biopsies taken was primarily determined by the number of MRI lesions; the median number of biopsies was four for participants with one lesion, six for those with two lesions, and seven for those with three lesions (Kruskal-Wallis Test $p < 0.01$, data not shown).

Biopsies were positive for prostate cancer in $n = 73$ participants; $n = 50$ (69.4%) of the TR group and $n = 23$ (69.7%) of the TP group, with no statistically significant difference (Table 1). Clinically significant cancer, defined as $\geq$ ISUP2 but also including one case of intraductal carcinoma (IDC), was present in $n = 28$ (38.9%) of the TR group and $n = 10$ (30.3%) of the TP group, with no statistical difference (Chi-squared test $p = 0.40$, see Table 1).

Tumor characteristics are displayed in Table 2. The distribution of ISUP and Gleason sum gravitated slightly towards higher scores in the TR group, but with no statistically significant difference (Chi-squared test $p = 0.51$ and $p = 0.76$, respectively). The proportion of reported $\geq$ cT2 was likewise higher in the TR group ($n = 12$, 24.0%) compared to the TP group ($n = 3$, 13.0%), but rectal examination at the time of

Table 2. Tumor characteristics among men with biopsies positive for prostate cancer ($N = 73$), by biopsy route (transrectal or transperineal).

	Transrectal biopsies ($N = 50$) N (%)[a]	Transperineal biopsies ($N = 23$) N (%)	p[b]
ISUP			
1	22 (44.9)	13 (56.5)	0.51
2	14 (28.6)	6 (26.1)	
3	4 (8.2)	3 (13,)	
4	3 (6.1)	0 (0)	
5	6 (12.2)	1 (4.3)	
Gleason sum			
3 + 3	22 (44.0)	13 (56.5)	0.76
3 + 4	14 (28.0)	6 (26.1)	
4 + 3	4 (8.0)	3 (13.0)	
4 + 4	1 (2.0)	0 (0)	
3 + 5	2 (4.0)	0 (0)	
4 + 5	5 (10.0)	1 (4.3)	
5 + 4	1 (2.0)	0 (0)	
IDC	1 (2.0)	0 (0)	
cT-stage			
cT1	37 (74.0)	16 (69.6)	0.09
cT2	11 (22.0)	3 (13.0)	
cT3	1 (2.0)	0 (0)	
cTx	1 (2.0)	4 (17.4)	

[a]Percentages of ISUP counted on $N = 49$ due to one case of IDC not classified.
[b]p-value from Chi-squared Test.

biopsies was more often not performed in the TP group (17.4% compared to 2.0%). The reported reason in several of these cases was abstinence from rectal examination in order to avoid faecal perineal contamination. Positive finding of cancer in biopsies from the anterior part of the prostate did not differ between groups (TR, $n = 18$, 25.0% vs. TP, $n = 8$, 24.3%, Chi-squared Test, $p = 0.93$, data not shown), neither did the proportion with anteriorly located MRI lesions ($n = 27$, 37.5% vs. $n = 11$, 33.3%, Chi-squared test, $p = 0.68$, data not shown).

In simple logistic regression analyses, only PI-RADS score (PI-RADS 5 vs. $\leq$3, OR [95%]: 5.62 [1.74–18.17], $p < 0.01$) and number of biopsies taken (4–6 vs. $\leq$3, OR [95%]: 3.17 [1.06–9.49], $p < 0.04$) were independently associated with finding of csPCa on the 0.05 alpha-level, while PSA density, age, and indication for biopsy were not (Table 3). The estimated OR (95% CI) for the association between TP biopsies, compared to TR biopsies, csPCa was 0.68 (0.28–1.65), $p = 0.40$. In the multivariable model, only PI-RADS score remained an independent determinant of significant cancer (PI-RADS 5 vs. $\leq$3, OR [95% CI]: 5.02 [1.35–18.66], $p = 0.02$), while biopsy route remained not associated with finding of significant cancer (OR [95% CI]: 0.53 [0.19–1.48], $p = 0.23$). Adjusted and unadjusted ORs and 95% CIs for all covariates are presented in Table 3.

The proportion of participants with diabetes, urinary catheter, immunosuppressant drugs, and positive urine culture did not differ significantly between groups (Table 4). A slightly larger proportion of participants in the TP group had had previous UTI following urological procedures ($n = 6$ [18.2%] vs. $n = 5$ [6.9%], Chi-squared Test, $p = 0.08$), and a larger proportion of the same group received prolonged antibiotic prophylaxis, compared to the TR group ($n = 9$ [27.7%] vs. $n = 9$ [11.1%], Chi-squared Test, $p = 0.06$, Table 4). Of those with negative urine culture who received a prolonged prophylaxis, the majority (seven out of nine) were in the TP group, and the most common reason was a history of UTI (six out of nine). Within 30 days of biopsies, $n = 1$ patient (3%) in the TP group and $n = 8$ patients (11.1%) in the TR group were treated for an infection (Chi-squared Test, $p = 0.17$, Table 4). Among those who were treated for an infection, $n = 6$ form the TR group and the one patient from the TP group were also hospitalized ($p = 0.13$). While we did not systematically evaluate patient discomfort or presence of local complications such as hematoma, all patients were able to complete the procedure.

Discussion

In this non-randomized observational study of men undergoing MRI-US fusion biopsies of the prostate, we observed no difference in detection rates of PCa when comparing the transperineal (TP) and transrectal (TR) biopsy approach. Although not statistically significant, the observed proportion of detected csPCa was slightly smaller among men undergoing TP biopsies. The observed proportion of participants who developed UTI after the procedure was smaller in the TP group than in the TR group, but with few events and no statistically significant difference.

Systematic reviews evaluating the impact of biopsy route on detection rate of csPCa in MRI-guided biopsies have rendered conflicting results. One review [14], encompassing studies of software-based MRI-US fusion biopsies, as well as other techniques such as in-bore MRI-targeted biopsies, concluded that TP biopsies (TPBx) has a higher detection rate of csPCa than TR biopsies (TRBx). However, another review [13], limited to studies of software-based MRI-US fusion biopsies, did not find evidence supporting this difference. The authors attributed this inconsistency to stricter inclusion criteria in the latter study, and concluded that evidence did not support a difference in csPCa detection rate between TR and TP software-based MRI-US fusion biopsies. Our results, lacking clear evidence of difference in cancer detection rate between groups, overall conform to this report.

To our knowledge, only one study has compared the different biopsy routes in MRI-US software targeted fusion biopsies head-to-head in the same patients, reporting an increased csPCa detection rate, particularly for anterior tumors, in TPBx compared to TRBx [20]. Our data does not show any difference in detection rates of anterior PCa between biopsy routes.

Possible sources of confounding exist in the present study. Distribution of biopsy indication, for example, differed between the groups. This reflects the real-life clinical setting and non-randomized design of the study, and may underlie observations such as the statistically non-significant lower proportion of csPCa in the TP group. We aimed to address this using multivariable-adjusted analysis, which although rendering a lower magnitude OR estimate (i.e. further from 1.0) still retained CI encompassing 1.0, thus not indicating a statistically significant difference. Population characteristics such as biopsy indication should also be kept in mind when

Table 3. Unadjusted and multivariable adjusted ORs and 95% CIs for the association between biopsy method, as well as other covariates, and clinically significant cancer finding (≥ISUP2) in prostate biopsies among men undergoing evaluation for prostate cancer ($N = 105$).

			Unadjusted			Multivariable-adjusted[b]		
Variable	*N* population	*N* sign. tumors[a]	OR	(95% CI)	*p*-value	OR	(95% CI)	*p*-value
Biopsy method								
Transrectal	72	28	Ref.	—		Ref.	—	
Transperineal	33	10	0.68	(0.28–1.65)	0.40	0.53	(0.19–1.48)	0.23
Age (years)	—	—	1.03	(0.98–1.09)	0.26	1.03	(0.96–1.10)	0.44
PSA density category (ng/mL^2)								
<0.1	18	4	Ref.	—		Ref.	—	
0.1–<0.15	28	11	2.26	(0.59–8.70)	0.23	1.86	(0.40–8.62)	0.43
≥0.15	59	23	2.24	(0.65–7.64)	0.20	2.03	(0.50–8.17)	0.32
No. of biopsies, category								
≤3	24	5	Ref.	—		Ref.	—	
4–6	66	30	3.17	(1.06–9.49)	0.04[d]	2.99	(0.90–9.88)	0.07
>6	15	3	0.95	(0.19–4.72)	0.95	0.59	(0.10–3.49)	0.56
Highest PI-RADS score, category								
≤3[c]	30	5	Ref.	—		Ref.	—	
4	41	15	2.88	(0.91–9.12)	0.07	3.11	(0.92–10.51)	0.07
5	34	18	5.62	(1.74–18.17)	<0.01[d]	5.02	(1.35–18.66)	0.02[d]
Indication for biopsies								
Primary evaluation	51	20	Ref.	—		Ref.	—	
Active monitoring	35	12	0.81	(0.33–1.98)	0.64	0.89	(0.32–2.48)	0.83
Suspicion of cancer despite previous negative biopsies	19	6	0.72	(0.23–2.19)	0.56	0.71	(0.20–2.53)	0.59

[a]Defined as ≥ ISUP2 including one case of IDC.
[b]Adjusted for biopsy method (categorical), age (years, continuous), PSA density (categorical; <0.1 ng/mL^2, 0.1–<0.15 ng/mL^2, ≥0.15 ng/mL^2), number of biopsies (categorical; ≤3, 4–6, >6), highest PIRADS score (categorical ≤3, 4, 5), and indication for biopsies (categorical; primary evaluation, active monitoring, previous negative biopsies).
[c]Category includes one case of PIRADS 2.
[d]$p < 0.05$.

Table 4. Infection-related characteristics of men undergoing MRI-US fusion prostate biopsies ($N = 105$) between May and August 2020, by biopsy method (transrectal or transperineal approach).

	Transrectal biopsies ($N = 50$) *N* (%)	Transperineal biopsies ($N = 23$) *N* (%)	*p*[a]
Diabetes diagnosis	5 (6.9)	1 (3.0)	0.42
Urinary catheter/Intermittent self-catheterization	2 (2.8)	1 (3.0)	0.94
Immunosuppressant drugs	3 (4.2)	2 (6.1)	0.67
Previous UTI following urological procedure	5 (6.9)	6 (18.2)	0.08
Positive urine culture prior to biopsy	8 (11.1)	2 (6.1)	0.41
Prolonged antibiotic treatment in connection to biopsy*	9 (12.5)	9 (27.3)	0.06
UTI within 30 days of biopsy	8 (11.1)	1 (3.0)	0.17
Hospital admission within 30 days of biopsies	6 (8.3)	1 (3.0)	0.31

[a]Any treatment of longer duration than routine single dose antibiotic prophylaxis. Includes treatment due to positive urine culture as well as extended prophylaxis based on clinical assessment.
[b]*p*-value from Chi-squared Test.

comparing cancer detection rates in the present study with those of other populations.

TPBx may require more care giver resources, especially when performed under general anaesthesia [21]. When using only local anaesthesia, the up-front cost difference between biopsy routes decrease, and TPBx has been suggested even to represent an overall cost saving [22]. TPBx under local anaesthesia may, however, be associated with greater patient discomfort compared to TRBx [12]. While we did not evaluate patient experience or discomfort in an organized manner, all patients planned for TPBx were able to complete the procedure, suggesting some degree of tolerability, in agreement with previous reports [23].

As TPBx rarely causes post-biopsy infection [5], it may protect patients from potentially severe complications, while still retaining high diagnostic sensitivity. Although based on few observations, our observed small number of post-biopsy infections in the TP group arguably conforms to previous reports. It should be noted that the number of participants with previous procedure-related infections was higher in the TP group, as was consequently the number of participants receiving extended antibiotic prophylaxis. This reflects study's lack of randomization and use of real-life clinical data, with clinical selection of infection-prone patients to the TP group. A larger proportion of men receiving extended antibiotic prophylaxis may have influenced the low observed frequency of infections in the TP group. Using clinically determined, as opposed to only culture-verified, infections as outcome may further lead to misclassification (overestimation), but most likely non-differential. The observed frequency of infectious complications is in the higher end of the spectrum of previous reports [5]. This may be influenced by constitution of the study population (age and comorbidities), as well as definition of outcome measures and variation due to chance in a small population. In the one case of infection in the TP group, the patient, who had indeed received extended antibiotic prophylaxis due to the presence of biological aortic valve prosthesis, was in fact hospitalized due to haematuria, and put on antibiotic treatment on clinical suspicion of possible synchronous infection.

The strengths of the present study include the real-life clinical setting, enabling evaluation of a newly implemented method in the context of clinical practice. Conversely, the non-randomized composition of the study population and groups, with subsequent distribution of baseline characteristics and confounders, may bias results and warrants caution in interpretation and generalization of results. The population size limits power to detect small differences between groups, as well as differences in rare events such as post-biopsy infection.

In conclusion, our observations do not indicate a difference in csPCa detection rate between TR and TP MRI-US software fusion biopsies. This is consistent with previous reports. Refraining from far-reaching conclusions due to small numbers and non-randomized study design, our observations further conform to reports of a low infection rate following TPBx. Our data suggests that the transition from TR to TP fusion biopsies in a medical center with good knowledge of the prior method is feasible and safe.

Disclosure of interest

The authors report no conflicts of interest

Data availability statement

The present dataset is not publicly available, due to patient confidentiality issues, but is available from the corresponding author on reasonable request.

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