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Rate and characteristics of infection after transrectal prostate biopsy: a retrospective observational study

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ABSTRACT

Objectives: The aim of this study was to assess the incidence of infection after transrectal prostate biopsy (TRbx). Secondary objectives were to describe infection characteristics, antibiotic resistance patterns, ICD-10 coding, and costs.

Methods: TRbx carried out at the hospitals of Ängelholm and Helsingborg, Scania, Sweden, between October 2017 and March 2019, were identified based on the NOMESCO Classification of Surgical Procedures code for TRbx, TKE00. All patients received per oral antibiotic prophylaxis, usually 750 mg ciprofloxacin at biopsy. Other preventative measures were not used. Medical care within 30 days of the biopsy was evaluated through a manual retrospective medical chart review. Data on patient and infection characteristics were collected. The costs of infections causing hospitalization were estimated.

Results: After 36 (5.4%) of 670 biopsies, the patient developed post-biopsy infection within 30 days after TRbx. Twenty-six patients (3.9%) required hospitalization for an average of 6 days, at an estimated direct cost of USD 9174 (EUR 8031) per patient. Nine patients (1.3%) had a complicated infection leading to intensive care, multiple hospitalizations or emergency department visits. The inpatient care episodes for the 26 hospitalized patients were categorized with 15 different ICD-codes. In 6 episodes no ICD-code related to infection was used.

Conclusions: In this study, we found an infection rate of 5.4% after TRbx; 3.9% of the patients were hospitalized for a post-TRbx infection and 1.3% had complicated infections. A specific ICD code for post-TRbx infections would facilitate evaluation and monitoring of this common, costly, and sometimes serious complication.

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Introduction

Prostate cancer (PC) is one of the most common cancers, with an estimated 1.28 million new cases worldwide in 2018 [1]. PC is mainly diagnosed and sometimes monitored with repeated prostate biopsies, resulting in approximately 3.8 million biopsies annually in the US and Europe [2,3]. Prostate biopsies are most commonly performed transrectally (TRbx), using a tru-cut biopsy needle to puncture the prostate [4]. The procedure may cause infection by transferring colonic bacteria with the biopsy needle, or by exacerbating an ongoing urinary tract infection. [4–6]. The reported incidence of infection after TRbx is 0.1–13.8% [3,4]. Infections range in severity from mild urinary tract infections to potentially fatal sepsis [6] and are the most common cause of hospitalization after TRbx [7].

Fluoroquinolones (e.g. ciprofloxacin) are generally used for antibiotic prophylaxis in TRbx owing to their broad coverage and high penetration of the prostate [8], although currently questioned because of side effects such as aortic aneurysm [9]. A single dose is often used, but prolonged prophylaxis is

recommended for patients with known risk factors for infection [10]. Other preventive measures include rectal cleansing [11,12] and targeted antibiotic prophylaxis based on a pre-biopsy rectal culture [13,14]. Rectal cleansing with povidone-iodine is reported to significantly reduce infection rates, but is an uncomfortable and user-dependent procedure [11,12].

Despite the use of these preventative measures, the incidence of post-TRbx infections is rising [3,7,15,16]. For instance, a study of over 75,000 patients showed an increase in infections from 0.6% to 3.6% between 1996 and 2005 [7]. The observed rise of infection rates is to a large part caused by the increasing antibiotic resistance among colonic bacteria; in 2015 it was estimated that 42% of post-TRbx infections in the US were caused by fluoroquinolone resistant bacteria [17]. However, because of the wide range in reported infection rates and varying definitions of infection, it is challenging to compare results across studies and over time.

In this study, the primary aim was to evaluate the rate of post-TRbx infections. Secondary aims were to evaluate the

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severity, treatment, characteristics, and costs of post-Trbx infections. We used a rigorous method based on a medical chart review to identify post-TRbx infections at two hospitals serving a geographically defined population. As ICD-10 codes [18] are the basis for register-based studies, we also evaluated what codes were used following TRbx infections.

Materials and methods

TRbx identification

We included all transrectal prostate biopsies between October 2017 and March 2019 at two Swedish hospitals serving a geographically defined population of about 300,000 people (Helsingborg and Ängelholm hospitals). We set the time of 18 months inclusion prior to study start, as we estimated that this would yield around 650 patients, which would be adequate for calculating the rate of post-biopsy infections with a reasonable statistical precision. The biopsies were identified through the electronic medical record by a search for the NOMESCO Classification of Surgical Procedures (NCSP) code TKE00 in the Melior medical record system. A qualified medical secretary conducted the search providing a defined list of patients who underwent prostate biopsies at the two hospitals. We did not include biopsies carried out by private practitioners, which we estimate to have been around 150 during the study period. We only had access to the hospital charts in Region Skåne and not data from general practitioners or company health care journals. No analytical methods were applied to account for potential missed cases from these sources.

Outcomes

The primary outcome measure was clinical infection after TRbx. Clinical infection was defined as fever ($\geq 38^{\circ}\text{C}$) or a positive blood or urine culture within 30 days of TRbx, in combination with manual chart review with clinical suspicion of the infection arising from the urinary tract.

Urinary tract symptoms without fever ($\geq 38^{\circ}\text{C}$) or a positive culture alone were not considered as infection. Likewise were infections with other primary focuses such as airways or bowel were excluded. We did not use antibiotic prescriptions as an indication of infection. Furthermore, emergency department (ED) visits and hospital admissions for other reasons than infection were excluded. Sepsis was defined as sequential organ failure assessment (SOFA) score ≥ 2 [19]. Patients with infection were further divided into three categories based on severity: (1) patients not requiring hospitalization (2) patients requiring hospitalization who recovered at their first admission (3) patients with complicated infections requiring intensive care unit (ICU) treatment, repeated hospitalizations or repeated ER visits for recurring infection after hospital discharge. Secondary outcome measures were infections leading to hospital admission, infections leading to admission to an ICU, infection characteristics, antibiotic resistance patterns and clinical path of patients with infection, as well as ICD-10 codes [18] used for hospitalized patients.

Patient data

The following information was retrieved from the medical charts for each patient: date and hospital for TRbx, age, prostate volume, PSA value, biopsy result (cancer or no cancer), comorbidity (heart failure, cardiac arrhythmias, previous heart attack, chronic obstructive pulmonary disease, or kidney failure; evaluated based on diagnoses and medical treatments/prescriptions), immunosuppressing treatment, number of previous TRbx, previous infection after TRbx, and type and duration of antibiotic prophylaxis. A randomized controlled study of antibiotic prophylaxis with either single-dose 750 mg Ciprofloxacin or 800/160 mg Trimethoprim/sulfamethoxazole was ongoing at both hospitals during the studied time period; 93 of the included patients were included in the present study. As the antibiotic prophylaxis was blinded in the randomized study, it is unknown for these 93 patients.

Infection data based on ICD-10 codes

Data on inpatient care, bacterial resistance patterns in blood and urine cultures, ICD-10 codes at discharge, and deaths within 30 days after biopsy were collected in the medical chart review. Multiple ICD-10 codes were used for some of the inpatient episodes. Infection-related codes are presented if present. Primary codes are reported for discharges without infection-related codes.

Cost analysis

The cost of inpatient care was based on the average daily costs for health care-associated infections in Region Skåne, Sweden (12,544 SEK in 2015) [20]. The cost was adjusted for inflation (6.7% between 2015 and 2019) and converted to USD (8.75 SEK/USD) and to EUR (10.00 SEK/EUR), resulting in a daily inpatient care cost of USD 1529 or EUR 1338. We did not calculate indirect costs such as loss of work days or need for home care.

Statistics

Continuous data are reported as median and range. Categorical data are reported as numbers and percentages and 95% confidence intervals.

Ethics

This study was approved by the Swedish Ethical Review Authority (dnr 2019-00712). Owing to the study design patient consent was waived.

Results

Patient characteristics

Six-hundred-seventy (670) TRbx procedures in 566 men were identified by the NCSP code TKE00 (Figure 1). Median age at the time of biopsy was 69 years, median prostate volume

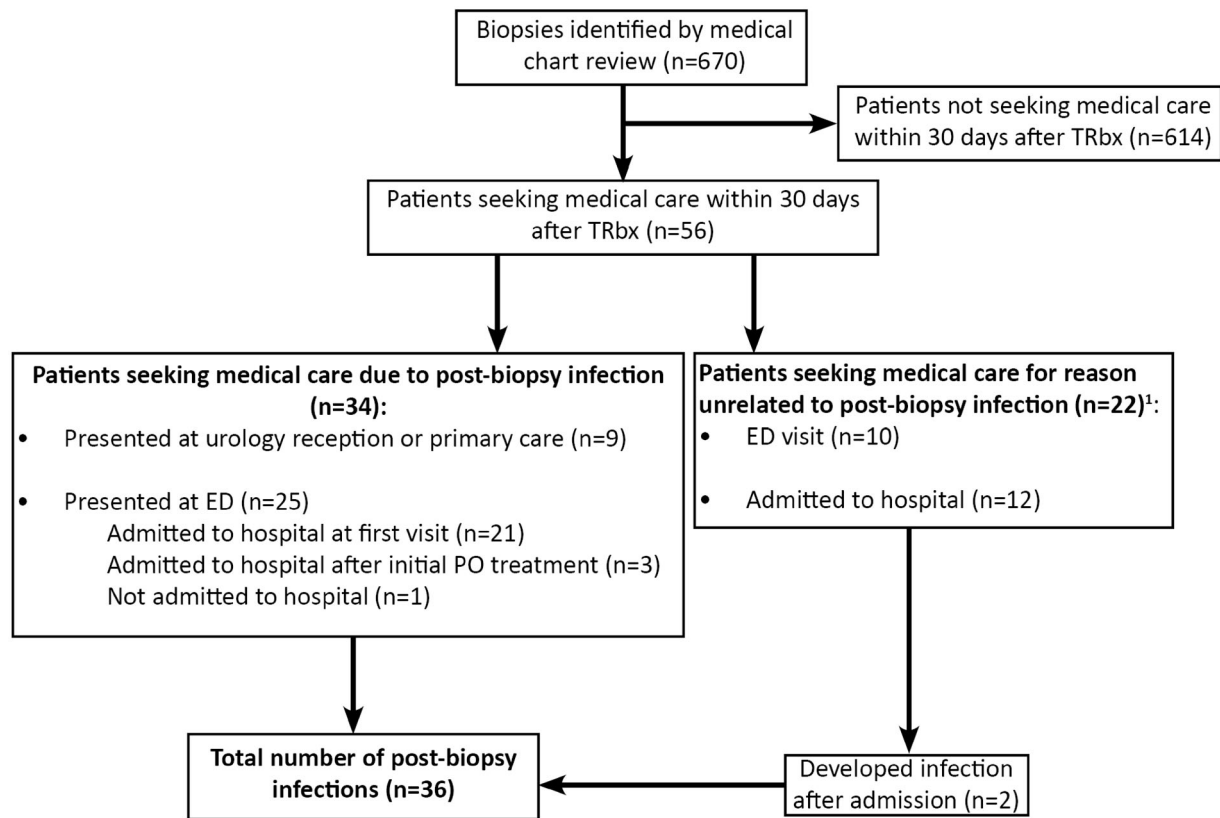


Figure 1. Identification of patients with infection after biopsy. Data on primary care visits for reasons unrelated to post-biopsy infection was not collected. ED: emergency department; PO: per oral; TRbx: transrectal prostate biopsy.

was 44 cm³, and median PSA level 7 µg/l (Table 1). Cancer was present in 60% of the biopsies. Twelve of the patients had previously developed an infection following a prostate biopsy. All these 12 patients received extended prophylaxis; one of them had a new infection.

Rate of post-biopsy infections

Fifty-six TRbx procedures (8.4%) led to the patient seeking medical care within 30 days. We found a total number of 36 infection episodes after TRbx (5.4% of the 670 TRbx procedures), of whom 26 (3.9%) were admitted to hospital. Nine patients came with infectious symptoms to the urology outpatient clinic or to primary care, and were thereafter managed in outpatient care. Twenty-six patients were hospitalized; details are described in figure 1.

Antibiotic prophylaxis

The type and duration of antibiotic prophylaxis are shown Supplementary Table 1. Most patients (77%; $n = 516$) received antibiotic prophylaxis on the day of the biopsy only. The Swedish guidelines recommend a single dose of Ciprofloxacin (750 mg) at the time of biopsy in patients without risk factors for post-TRbx infection, such as previous post-biopsy infection, diabetes, or catheterization [21]. The infection rates for patients who received 1-day antibiotic prophylaxis (single or two doses) and those who received prolonged prophylaxis (≥ 2 days) were similar (Supplementary Table 1). Targeted

antibiotic treatment was given to the 3% of patients who had a positive urine culture prior to TRbx.

Infection characteristics

Median antibiotic treatment time was 12.5 days, ranging from 5 to 63 days (Table 2; Supplementary Figure 1). Median time between biopsy and first ED visit was 2 days (0–11 days). Twenty-six patients were admitted to hospital for a median of 5 days (2–14 days, Table 2). Five of them fulfilled sepsis criteria (SOFA-score ≥ 2) and one required ICU treatment. Four patients were readmitted because of recurring infection and 2 patients had repeated ED visits after hospitalization for the same reason. No patients died because of a confirmed post-biopsy infection, but one elderly patient was found dead at home 12 days after biopsy with unknown cause of death.

Bacterial cultures in infected patients

Positive bacterial cultures were found in 28 of 36 patients with a post-biopsy infection (Table 3), of which 26 had a positive urine culture and 9 had a positive blood culture. *Escherichia coli* (*E. coli*) was by far the most common pathogen and was found in 23 of 28 cultures (82.1%). Other detected bacteria included *Klebsiella pneumoniae*, *Citrobacter koseri*, *Enterobacter cloacae* and *Enterococcus faecalis*. Fourteen (61%) of the *E. coli* cultures were Ciprofloxacin resistant. Trimethoprim/sulfamethoxazole resistant *E. coli*

Table 1. Patient characteristics and potential risk factors.

	Total	No infection	Infection
Total, <i>n</i>	670	634	36
Helsingborg ^a	430	409	21
Ängelholm ^b	240	225	15
Age, median years (range)	69 (42–91)	69 (42–90)	68 (52–91)
Prostate size, median cm ^c (range)	44 (11–190)	44 (11–190)	51 (17–127)
PSA, median µg/l (range)	7.0 (0.3–2037)	7.0 (0.3–2037)	7.0 (3.6–375)
Pathology diagnosis, <i>n</i> (%)			
No cancer	269 (40%)	253 (40%)	16 (44%)
Cancer	401 (60%)	381 (60%)	20 (56%)
Diabetes, <i>n</i> (%)	78 (12%)	68 (11%)	10 (28%)
Immunosuppression ^c , <i>n</i> (%)	28 (4.2%)	27 (4.3%)	1 (2.8%)
Hypertension, <i>n</i> (%)	274 (41%)	257 (40%)	17 (47%)
Other significant comorbidity ^d , <i>n</i> (%)	156 (23%)	141 (22%)	15 (42%)
Previously biopsied, <i>n</i> (%)	257 (39%)	242 (38%)	15 (43%)

^aBiopsies were obtained using Mermaid Medial M-biopsy 18 Gauge 25 cm tru-cut biopsy needles with Möller Medial Blue Biopsy Gun RRG-1000. BK ultrasound with single-use biopsy guide on transducer.

^bBiopsies were obtained using Argon medical 18 Gauge 25 cm Pro-Mag tru-cut biopsy needle with Argon medical Pro-Mag Ultra Automatic Biopsy Instrument. BK ultrasound with single-use biopsy guide on transducer.

^cMore than 5 mg prednisolone or equivalent.

^dHeart failure, cardiac arrhythmias, previous heart attack, chronic obstructive pulmonary disease, or kidney failure.

Table 2. Infection characteristics.

Characteristics	Outcome
Number of patients with post biopsy infections, <i>n</i> (% of total patients; 95% CI)	36 (5.4%; 3.7–7.1%)
Patients not hospitalized, <i>n</i> (% of total with infections; 95% CI)	10 (28%; 13–42%)
Patients hospitalized once, <i>n</i> (% of total with infections; 95% CI)	17 (47%; 31–64%)
Patients hospitalized and requiring multiple hospitalizations/ED visits, <i>n</i> (% of total with infections; 95% CI)	9 (25%; 11–39%)
Admitted to hospital after initial PO antibiotic treatment, <i>n</i> (% of total with infections; 95% CI)	3 (8.3%; 0–17.4%)
Developed infection while hospitalized, <i>n</i> (% of total with infections; 95% CI)	2 (5.6%; 0–13%)
Total patients hospitalized with infection, <i>n</i> (% of total patients; 95% CI)	26 (3.9%; 2.4–5.3%)
Hospitalized within 48 h of TRbx, <i>n</i> (% of hospitalized patients; 95% CI)	15 (58%; 39–77%)
Hospitalized within 7 days of TRbx, <i>n</i> (% of hospitalized patients; 95% CI)	24 (92%; 82–100%)
Duration of hospitalization, median days (range)	5 (2–14 ^a)
Duration of hospitalization, mean days (used in economic calculations)	6
Peak CRP, ^b median (range)	164 (9.4–442)
Antibiotic treatment duration, ^c median days (range)	12.5 (5–63)
Required IV antibiotics, <i>n</i> (% of total with infections; 95% CI)	24 (67%; 51–82%)
Treatment duration, median days (range)	4 (2–12)
SOFA score ≥ 2 , <i>n</i> (% of total with infections; 95% CI)	5 (14%; 2.6–25%)
ICU treatment, <i>n</i> (% of total with infections; 95% CI)	1 (2.8%; 0–8.1%)
Deaths due to post-biopsy infection, <i>n</i> (% of total with infections)	0 ^d (0%)

^aThe patient hospitalized for 14 days was treated for stroke and dyspnea in addition to post-biopsy infection.

^bThe venous CRP was not continuously measured for one patient and for this reason the low range value is likely an underestimation.

^cTreatments received at the ED or hospital and including available data from the primary care.

^dOne elderly patient not classified as having a post-biopsy infection was found dead at home 12 days after biopsy. Cause of death unknown.

ED: emergency department; CRP: c-reactive protein; IV: intravenous; PO: per oral; SOFA: sequential organ failure assessment; ICU: intensive care unit; 95%CI: 95% confidence intervals.

Table 3. Bacteria found in blood and urine cultures.

Bacteria	Any positive culture (<i>n</i> = 28)	Urine culture (<i>n</i> = 26)	Blood culture (<i>n</i> = 9)
<i>E. coli</i>	23	21	8
Ciprofloxacin resistant	14	12	5
TMP-SMX resistant	9	8	1
ESBL	3	3	0
<i>Klebsiella pneumoniae</i>	3	3	1
<i>Citrobacter koseri</i>	1	1	0
<i>Enterobacter cloacae</i> and <i>enterococcus faecalis</i>	1	1	0

TMP-SMX: Trimethoprim/sulfamethoxazole; ESBL: extended spectrum beta-lactamase.

were found in 9 cultures and extended spectrum beta lactamase (ESBL) carrying *E. coli* in 3 cultures (Table 3).

Costs of post-TRbx infections

Cost analysis was performed for hospitalizations only. With a daily inpatient cost for health care-associated infections of USD 1529 (EUR 1338) and an average hospital stay of 6 days, total direct cost is estimated to USD 9174 (EUR 8031) per

hospitalization. The additional hospital cost of infection per each performed TRbx is thus estimated to USD 358 (EUR 313) for a hospitalization rate of 3.9%.

ICD-10 coding

Of the 26 inpatient episodes, 20 (77%) had an infection-related code at discharge (Table 4; Supplementary Table 2).

Table 4. List of ICD-10 codes at hospital discharge given to patients with post-biopsy infection at the first hospitalization.

Type of code	Patients (n)	ICD-10 code	Description
Sepsis, total	5		
Sepsis	2	A41.5	Sepsis due to other Gram-negative organisms
Sepsis	2	A41.9	Sepsis, unspecified organism
Sepsis	1	R65.1	Sepsis, severe, as a result of disease classified elsewhere
Infection, total ^a	15		
Infection	3	N10	Acute tubulo-interstitial nephritis
Infection	7	N39.0	Urinary tract infection, site not specified
Infection	1	N41.0	Acute prostatitis
Infection	1	N45.9	Orchitis, epididymitis and epididymo-orchitis without abscess
Infection	2	T81.4	Infection following a procedure, not elsewhere classified
Infection	1	R50.9	Fever, unspecified
Unspecified, total	1		
Unspecified	1	T81.8 + Y83.8	Other complications of procedures, not elsewhere classified + Other surgical procedures
Cancer, total	2		
Cancer	1	C61	Malignant neoplasm of prostate
Cancer	1	C23	Malignant neoplasm of gallbladder
Internal medicine, total	3		
Internal medicine	1	I50.9	Heart failure, unspecified
Internal medicine	1	I63.9	Cerebral infarction, unspecified
Internal medicine	1	I26.0	Pulmonary embolism with mention of acute cor pulmonale
Total number	26		

^aNot including sepsis.

One infection-related ICD-10 code at discharge per patient is presented when applicable. If an infection-related code was not given then the primary ICD-10 code is presented here. (All patients who were readmitted to hospitals within Region Skåne received an infection-related code at readmission that is not presented here, please see [supplementary table 2](#).)

Six (23%) of the inpatient episodes that according to the medical chart review were related to a post-biopsy infection, were not labeled with an infection-related ICD-10 code at discharge. Five (19%) of these patients suffered from synchronous diseases such as stroke, heart failure or pulmonary embolism. In the remaining one case (4%) a non-infectious code attempting to describe TRbx infection was used.

Discussion

The overall risk of post-biopsy infection was 5.4%; 3.9% of the patients were admitted to hospital for the infection and 0.7% developed sepsis. Four patients were hospitalized multiple times and two had repeated ED visits for recurrent infection after discharge from hospital. Furthermore, three of the four patients sent home after an initial ED visit were later hospitalized due to failure of PO antibiotic treatment. Our results are similar to a previous report of sepsis after prostate biopsy [22], although comparisons are complicated by varying definitions of post-biopsy infection and sepsis. Hospitalization may be a better outcome measure since it is strongly associated with severe illness, costs and the healthcare resource utilization.

The infection rate after TRbx is increasing [7,15,16]. A study by Lundström et al. showed a 1% hospital admission for post-biopsy infection in Sweden between 2006 and 2011 [23], considerably lower than the 3.9% found in the present study. Moreover, another recent Scandinavian study, with a similar design as the present study, reported a 6.1% rate of hospital admissions for infection [24]. These studies indicate that the risk of hospitalization for post-TRbx infections may have increased significantly over the past ten years. The rising infection rates are at least partially a consequence of increasing antibiotic resistance [17]. According to the Public Health Agency of Sweden, 12.8% of *E. coli* in blood cultures

in Scania from 2014 were resistant and 0.9% intermediately sensitive to ciprofloxacin [25]. The proportion of ciprofloxacin-resistant cultures remained relatively stable during the study period, having risen to 13.3% in 2017. Our results show that nearly two thirds (60.9%) of *E. coli* cultured from patients with post-TRbx were resistant to Ciprofloxacin, the most commonly used antibiotic for prophylaxis.

In a recent meta-analysis of healthcare costs related to prostate biopsy, the average cost of an infection was estimated to USD 8672–19,100 [26]. In our calculation we used an average inpatient cost of USD 1529 (EUR 1338)/day and a mean hospitalization duration of 6 days, rendering a mean direct cost per hospitalization episode of USD 9174 (EUR 8031). With a hospitalization rate of 3.9% we estimate the average excess cost of infection to be USD 358 (EUR 313) for every patient undergoing a standard TRbx. However, this cost is likely to be an underestimation as we did not account for indirect costs such as sick leave, loss of work days, or care after hospital discharge.

Population-based studies commonly use ICD codes to identify patients with post-biopsy infection. The codes used include acute cystitis (N30.0), urinary tract infection (N39.0), and acute prostatitis (N41.0) [7,23,27,28]. In the current study, 23% of the inpatient episodes for a post-TRbx infection did not receive an infection-related code at discharge. The results imply that the infection rate may be underestimated in studies relying solely on ICD-10 [18]. An ICD code for post prostate biopsy infection would facilitate future studies and monitoring of post-biopsy infections.

A limitation of this study is that we only had access to the hospital charts in Region Skåne and not data from general or private practitioners. Some post-biopsy infections may thus have been missed if patients were treated at hospitals outside Region Skåne, or were culture negative and treated in primary care without any note about the infection in the Region Skåne hospital charts. We used a definition of post-

TRbx infections that we believe is sensitive for capturing clinical infections, but it may limit the comparability of our results with those from other studies. Furthermore, the time limit for a post-biopsy infection was defined as up to 30 days after TRbx, a limit commonly used in other studies [7,24]. Here, all admissions to the ward occurred within 11 days, yet some patients developed urinary tract infections more than 20 days after biopsy, all successfully treated by per oral antibiotics. We raise the question if all these infections were truly related to the TRbx. Additionally, the study was not population-based as only biopsies taken at the hospitals were included. Finally, antimicrobial resistance (AMR) is still relatively low in the study area, with 12.8–13.1% of *E. coli* resistant to ciprofloxacin [24], and our results may not be applicable for centres where AMR is much more common (AMR vary from 8.4% to 90.2% worldwide [29]).

In conclusion, post-biopsy infections (in a low AMR situation) occurred in 5.4% of men after TRbx, of which most (3.9%) were hospitalized with infection and some (1.3%) had a complicated infection. The hospital cost of these infections was estimated to USD 9174 (EUR 8031) per hospitalization. These increasingly common infections may thus not only have severe consequences for the affected patients, but are also be difficult to treat, resource-demanding and costly. A specific ICD-code for infection after prostate biopsy would facilitate monitoring of this iatrogenic complication.

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Disclosure statement

AF is listed as an inventor in patents of a novel biopsy needle aiming to reduce infection complications in TRbx and also the founder of Saga Surgical AB, a company owning the patent rights. Other authors have nothing to disclose.

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