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ORIGINAL RESEARCH ARTICLE

Fluoroquinolone-resistant *Escherichia coli* among the rectal flora is the predominant risk factor for severe infection after transrectal ultrasound-guided prostate biopsy: a prospective observational study

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ABSTRACT

Background: Infection of the prostate gland following biopsy, usually with *Escherichia coli,* is a common complication, despite the use of antimicrobial prophylaxis. A fluoroquinolone (FQ) is commonly prescribed as prophylaxis. Worryingly, the rate of fluoroquinolone-resistant (FQ-R) *E. coli* species has been shown to be increasing.
Objective: This study aimed to identify risk factors associated with infection after transrectal ultrasound-guided prostate biopsy (TRUS-Bx).
Methods: This was a prospective study on patients undergoing TRUS-Bx in southeast Sweden. Prebiopsy rectal and urine cultures were obtained, and antimicrobial susceptibility and risk-group stratification were determined. Multivariate analyses were performed to identify independent risk factors for post-biopsy urinary tract infection (UTI) and FQ-R *E. coli* in the rectal flora.
Results: In all, 283 patients were included, of whom 18 (6.4%) developed post-TRUS-Bx UTIs. Of these, 10 (3.5%) had an UTI without systemic inflammatory response syndrome (SIRS) and 8 (2.8%) had a UTI with SIRS. Being in the medium- or high-risk groups of infectious complications was not an independent risk factor for UTI with SIRS after TRUS-Bx, but low-level FQ-resistance (minimum inhibitory concentration (MIC): 0.125–0.25 mg/L) or FQ-resistance (MIC > 0.5 mg/L) among *E. coli* in the faecal flora was. Risk for SIRS increased in parallel with increasing degrees of FQ-resistance. Significant risk factor for harbouring FQ-R *E. coli* was travelling outside Europe within the previous 12 months.
Conclusion: The predominant risk factor for UTI with SIRS after TRUS-Bx was FQ-R *E. coli* among the faecal flora. The difficulty in identifying this type of risk factor demonstrates a need for studies on the development of a general approach either with rectal swab culture for targeted prophylaxis, or prior rectal preparation with a bactericidal agent such as povidone-iodine before TRUS-Bx to reduce the risk of FQ-R *E. coli*-related infection.

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Introduction

Transrectal ultrasound-guided prostate biopsy (TRUS-Bx) is a common procedure used in the histologic diagnosis and active surveillance of prostatic carcinoma. TRUS-Bx is usually performed under local anaesthetic in the outpatient setting, and although generally considered a safe and well-tolerated procedure, complications are not uncommon. Urinary tract infection (UTI) after TRUS-Bx develops in 5% of patients in Sweden and bacteraemia or sepsis in 1.3% [1]. The main source of urological infection following biopsy is contamination and inoculation with rectal flora. Empirical antibiotic prophylaxis is used to reduce the risk of post-TRUS-Bx infection, usually in the form of a fluoroquinolone (FQ) such as ciprofloxacin at 500 mg to 750 mg due to its bioavailability and because it reaches high concentrations in the prostate gland, as well as its efficacy against a wide spectrum of gram-negative microorganisms [2].

Escherichia coli (E. coli) is the most common FQ-resistant (FQ-R) pathogen causing infection after TRUS-Bx. Several studies have shown that the risk of post-TRUS-Bx infection and the prevalence of FQ-R pathogens have increased over the last two decades [3–5]. It has been suggested that the increased rate of post-TRUS-Bx infection is a consequence of the increased prevalence of FQ-R. A probable association between risk of post-TRUS-Bx infection and the presence of FQ-R *Enterobacterales* in

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the rectal flora has been demonstrated [6, 7]. According to the European Committee on Antimicrobial Susceptibility Testing (EUCAST) guidelines, the breakpoints for ciprofloxacin in *Enterobacterales* isolates including *E. coli* are as follows: susceptible, MIC ≤ 0.25 mg/L; resistant, MIC > 0.5 mg/L [8]. There may be a specific FQ-R MIC breakpoint for *E. coli* that could identify men at risk for post-TRUS-Bx infection. Furthermore, it may be possible to identify risk factors for faecal colonization with FQ-R *E. coli* and thereby men who are at increased risk of associated UTIs after TRUS-Bx.

The aims of this study were as follows: (1) to identify risk factors associated with infection after TRUS-Bx; (2) to determine if the presence of FQ-R bacteria (even low-level resistant) in the rectal flora is a risk factor for developing post-TRUS-Bx infection; and (3) to determine whether risk factors for the presence of FQ-R bacteria in the faecal flora can be identified.

Materials and methods

Study design and setting

This study was a prospective observational study of a population of patients undergoing TRUS-Bx at two hospitals in south-east Sweden between 2012 and 2013. Patients scheduled for TRUS-Bx were invited to participate in the study. Patients who gave written informed consent were included. The only exclusion criterion was previous participation in the study. In all, 296 patients agreed to participate. Thirteen patients were excluded due to incomplete questionnaires or missing cultures, resulting in a total of 283 patients for evaluation.

Prophylaxis with 750 mg ciprofloxacin orally just before biopsy was considered the standard of care. Patients were asked about known risk factors for UTI after TRUS-Bx and risk factors for harbouring fluoroquinolone resistant (FQ-R) bacteria in the faecal flora (Supplementary Table 1). The examining physician ranked the patient as low, medium, or high risk for post-TRUS-Bx UTI using the following definitions: high risk = ongoing UTI or urinary catheter present; medium risk = previous UTI or catheter or bladder emptying problems; and low risk = none of the former (Supplementary Table 2). Patients considered by the responsible physician to have an increased risk for post-TRUS-Bx UTI could be given an antibiotic other than the standard prophylaxis in accordance with clinical routine.

Patients were asked to answer a questionnaire concerning complications 6 to 8 weeks after biopsy. If patients reported fever, hospitalization, UTI, or antibiotic treatment, we conducted a review of their medical records. Outcomes were defined as no infection, UTI without systemic inflammatory response syndrome (SIRS) (UTI with no systemic symptoms), or UTI with SIRS (Supplementary Table 3).

Microbiology techniques

A faecal sample was collected with a culture swab stick (ESwab 480CE, Copan, Brescia, Italy) in connection with digital examination of the prostate just prior to biopsy. The sample was collected from visible faeces on the glove. Sterile bactericide-free gel was used as lubricant.

The swabs were sent to the Clinical Microbiology Laboratory at Linköping University for analysis. The faecal sample was spread using the flocked ESwab on selective chromogenic UTI agars (Oxoid) containing 2 mg/L vancomycin, 15 mg/L amphotericin B, and 16 mg/L nalidixic acid to detect *Enterobacterales* with reduced susceptibility to quinolones and on chromogenic UTI antibiotic-free agar as a control. The species identification of isolates growing on antibiotic-free UTI medium was based on the colour of the colony on the UTI agar. Isolates of *Enterobacterales* growing on the selective media were further characterized at the species level using conventional typing methods and matrix-assisted laser desorption/ionisation time-of-flight mass spectrometry (MALDI-TOF MS). Susceptibility testing of the isolates growing on the selective agar to nalidixic acid and ciprofloxacin was performed using disc diffusion according to the manufacturer's instructions. The MICs of ciprofloxacin were determined by using Etest (BioMerieux). EUCAST's clinical breakpoints classify *E. coli* isolates as susceptible when the ciprofloxacin MIC ≤ 0.25 mg/L and resistant when the MIC > 0.5 mg/L. The *E. coli* isolates with a ciprofloxacin MIC of 0.5 mg/L are designated an area of technical uncertainty (ATU). The ATU is a warning to laboratory staff that there is uncertainty that needs to be addressed before reporting antimicrobial susceptibility testing results to clinical colleagues.

One objective of the study was to explore the clinical significance of low-level ciprofloxacin resistance among *E. coli* (a ciprofloxacin MIC above the epidemiological cutoff (ECOFF) of 0.06 mg/L but below the breakpoint for resistance of >0.5 mg/L) in this setting. Thus, ciprofloxacin MICs were divided into three categories: 'wild-type/susceptible', indicating a MIC ≤ 0.06 mg/L; resistant, indicating a MIC > 0.5 mg/L; and a new category, 'low-level resistant', for isolates with a ciprofloxacin MIC of 0.125–0.5 mg/L (Supplementary Table 4).

Ethics approval

The study was approved by the Linköping Regional Ethics Committee (2012/219-31 and 2015/68-32).

Statistical analysis

Descriptive analysis included percentages, means, and medians. Student's *t*-test, Chi-square test, or Fisher's exact test were used for univariate analyses to determine risk factors for FQ-R bacteria in the patient's faecal flora. Logistic regression model to investigate possible risk factors for UTI after TRUS-Bx. Associations were expressed as odds ratio (OR) for risk with 95% confidence intervals (CIs). A *P*-value < 0.05 was considered statistically significant. All statistical analyses were performed with SPSS 27.

Results

A total of 283 patients were included and subsequently ranked as being at a low (*n* = 189), intermediate (*n* = 79), or high (*n* =15)

risk for post-TRUS-Bx UTI. A total of 98% patients received FQ as prophylaxis before TRUS-Bx at varying dosages according to risk-group stratification (Table 1).

Infections and complications

Of the 283 included patients, 18 (6.4%) developed post-TRUS-Bx UTIs. Of this group, 10 (3.5%) had an UTI without SIRS and 8 (2.8%) had a UTI with SIRS. The distribution of post-TRUS-Bx UTI in each risk group was as follows: low risk = 7 (4%); medium-risk = 8 (10%); high-risk = 3 (20%). UTIs with SIRS were mainly seen in the low- and medium-risk groups, at 5 (63%) and 3 (38%) respectively, with an *E. coli* with reduced susceptibility to ciprofloxacin (Table 1 and Table 2).

Faecal cultures

Faecal cultures were performed prior to TRUS-Bx and *Enterobacterales* were isolated in cultures from 271 (96%) patients, whereof *E. coli* was found in 261 (92%) of the patients. A total of 46 (16%) patients had FQ non-wild-type *E. coli* among their rectal flora; within this group 30 (10.6%) carried low-level FQ-resistant *E. coli* and 16 (5.7 %) FQ-resistant *E. coli* (Table 2). Significant risk factor for harbouring *E. coli* resistant to ciprofloxacin was travelling outside Europe within the previous 12 months. Antibiotic treatment within the previous 12 months, UTI within the previous 12 months, and indwelling catheter within the previous 12 months were not found to be significant risk factors in this study (Table 3).

Risk factors for UTI following TRUS-Bx

While age and being rated as 'high-risk' increased the OR for UTI without SIRS significantly, with ORs of 1.09 (1.01–1.18) and 18.49 (1.63–209.56) respectively, the risk for UTI with SIRS was not affected by these factors. The presence of *E. coli* with low-level FQ-resistance or FQ-resistance among the faecal flora was the only significant risk factor for UTI with SIRS, with ORs of 12.5 (1.99–78.17) and 25.96 (3.98–169.21), respectively. The risk increased in parallel with increasing levels of resistance, since two of 237 with wild-type (0.8%), three of 30 with low-level resistance (10%), and three of 16 (19%) patients with resistant *E. coli* among their faecal flora developed UTI with SIRS (Table 3).

Discussion

In this study *E. coli* with reduced susceptibility to fluoroquinolones were frequently (16%) identified in the rectal flora of men prior to TRUS-Bx, and that severe infectious complications occur more frequently in men with such *E. coli* among their rectal flora. Others have previously reported similar results [9]. In our study, a significant risk factor for harbouring non-susceptible *E. coli* was travelling outside Europe within the previous 12 months. This result, at least to some extent, conforms with the study by Kalalahti et al., where travelling abroad within the previous 3 months was associated with an increased prevalence of *E. coli* with low-level resistance to ciprofloxacin in rectal swabs, while travelling within the previous 6 months was not.

Our results correlate well with the findings of other authors [10–15], suggesting the importance of the rectal bacterial flora and resistance to the administered prophylaxis. Although several studies have shown an association between the risk for post-TRUS-Bx UTI and the presence of ciprofloxacin-resistant *E. coli* in the rectal flora, the metric for resistance was not always defined or varied between studies [13, 14]. Eruz et al. used the Clinical and Laboratory Standards Institute (CLSI) breakpoints for resistance,

Table 1. Antibiotic prophylaxis before TRUS-Bx and incidence of urinary tract infection (UTI) after TRUS-Bx based on risk-group stratification (n = 283) at Linköping University Hospital, Sweden between 2012 and 2013.

	Risk-group stratification		
	Low risk[a] *N* = 189	Intermediate risk[b] *N* = 79	High risk[c] *N* = 15
Antibiotic prophylaxis			
Ciprofloxacin 750 mg	187 (99)	57 (72)	3 (20)
Ciprofloxacin 750 mg × 2	1 (1)	1 (1)	1 (7)
Ciprofloxacin 750 mg × 2 for 3 days	0	10 (13)	3 (20)
Ciprofloxacin 750 mg × 2 for 5 days	0	9 (11)	5 (33)
TMP-SMX 800 mg/160 mg × 2 for 10 days	0	0	2 (13)
Cefadroxil 500 mg × 3 for 7 days	0	1 (1)	2 (13)
Other	1 (1)	0	0
Infections	7 (4)	8 (10)	3 (20)
UTI without SIRS[d,e]	2 (1)	5 (6)	3 (20)
UTI with SIRS[e]	5 (3)	3 (4)	0 (0)

Data are presented as *n* (%).

Risk-group stratification: [a]low risk: no risk factors; [b]intermediate risk: patient history of UTI, history of indwelling catheter, urologist assesses that the patient has difficulties emptying the bladder completely; [c]high risk: indwelling catheter, ongoing UTI, bacteriuria/positive Nitur® test, ongoing antibiotic treatment for UTI.

Infections: [d]UTI without SIRS: patient has clinical symptoms of UTI (there must be either a positive urine culture or high clinical probability of UTI; examples of symptoms: urgency, painful micturition, suprapubic pain, pain over the kidneys, epididymitis); [e]UTI with SIRS: as above and at least two of the following: body temperature < 36 or > 38, heart rate > 90/min, respiratory rate > 20/min or PaO2 < 4 kPa, WBC < 4 × 10^9/L or > 12 × 10^9/L.

TMP-SMX: trimethoprim-sulfamethoxazole; SIRS: systemic inflammatory response syndrome; UTI: urinary tract infection.

Table 2. Risk factors for post-TRUS-Bx urinary tract infection (UTI) in 283 patients.

	No infection	UTI without SIRS[d,e]	OR (95% CI)	*P*	UTI with SIRS[e]	OR (95% CI)	*P*
***n* (%)**	265 (94)	10 (4)	-	-	8 (3)	-	-
Mean age (SD)	67 (±8)	73 (±7)	1.09 (1.01–1.18)	*0.02*	67 (±9)	1.01 (0.92–1.10)	*0.86*
Type 2 diabetes	20 (8)	1 (10)	1.36 (0.16–11.29)	*0.78*	1 (12)	1.75 (0.20–14.94)	*0.61*
Subjective impaired bladder emptying	122 (46)	7 (70)	2.73 (0.69–10.80)	*0.15*	4 (50)	1.17 (0.29–4.78)	*0.83*
Positive Nitur®-test	7 (3)	1 (10)	4.07 (0.45–36.75)	*0.21*	0 (0)	-	-
Objective impaired bladder emptying	86 (32)	7 (70)	4.86 (1.22–19.24)	*0.02*	1 (12)	0.30 (0.04–2.45)	*0.26*
Risk groups							
Low risk (reference)[a]	182 (69)	2 (20)	1	*1*	5 (63)	1	*1*
Intermediate risk[b]	71 (27)	5 (50)	3.48 (0.42–28.96)	0.25	3 (38)	5.25 (0.93–29.89)	*0.06*
High risk[c]	12 (5)	3 (30)	18.49 (1.63–209.56)	*0.02*	0 (0)	-	-
Pre-biopsy faecal culture							
FQ-susceptible *E. coli* (MIC ≤ 0.06) or no finding of *E. coli* (reference)	225 (85)	10 (100)	1	1	2 (25)	1	*1*
Low-level FQ-resistant (ciprofloxacin) *E. coli* (MIC = 0.125–0.5)	27 (10)	0 (0)	-	-	3 (38)	12.5 (1.99–78.17)	*0.01*
FQ-resistant (ciprofloxacin) *E. coli* (MIC > 0.5)	13 (5)	0 (0)	-	-	3 (38)	25.96 (3.98–169.21)	*<0.01*

Data are presented as *n* (%); $P < 0.05$ is considered statistically significant.

Risk-group stratification: [a]low risk: no risk factors; [b]intermediate risk: patient history of UTI, history of indwelling catheter, urologist assesses that the patient has difficulties emptying the bladder completely; [c]high risk: indwelling catheter, ongoing UTI, bacteriuria/positive Nitur® test, ongoing antibiotic treatment for UTI.

Infections: [d]UTI without SIRS: patient has clinical symptoms of UTI. There must be either a positive urine culture or high clinical probability of UTI. Examples of symptoms: urgency, painful micturition, suprapubic pain, pain over the kidneys, epididymitis; [e]UTI with SIRS: as above and at least two of the following: body temperature < 36 or > 38, heart rate > 90/min, respiratory rate > 20/min or PaO2 < 4 kPa, WBC < 4×10^9/L or > 12×10^9/L

OR: odds ratio; CI: confidence interval; SD: standard deviation; FQ: fluroquinolones (ciprofloxacin), SIRS: systemic inflammatory response syndrome, UTI: urinary tract infection.

Table 3. Risk factors for carrying fluoroquinolone resistant (FQR) *E. coli* (including low-level resistance) in faecal culture.

	Faecal culture			*P*[a]
	FQ-susceptible	FQ-low-level-resistance	FQ-resistance	
n (%)	237 (84)	30 (11)	16 (6)	-
Mean age (years)	67	68	66	0.66
History of urinary tract infection (UTI)	76 (32)	10 (33)	8 (50)	0.35
UTI within previous 12 months	29 (12)	1 (3)	2 (12)	0.26
Indwelling catheter within previous 12 months	30 (13)	5 (17)	2 (12)	0.64
Any antibiotic within previous 12 months	76 (32)	10 (33)	3 (19)	0.61
Antibiotic for UTI within previous 12 months	33 (14)	3 (10)	2 (12)	0.58
Travel outside Europe within previous 12 months	42 (18)	10 (33)	6 (37)	*<0.01*
Diabetes	16 (7)	6 (20)	0 (0)	*0.25*
Subjective impaired bladder emptying	109 (46)	17 (57)	7 (44)	0.44
Positive Nitur®-test	8 (3)	0 (0)	0 (0)	0.47
Objective impaired bladder emptying	80 (34)	10 (33)	4 (25)	0.66

Data are presented as *n* (%).

[a]The FQ-low-level-resistant and FQ-resistant groups have been merged for comparison with the FQ-susceptible group. Chi-square test, Fisher's exact test or *t*-test, as appropriate. $P < 0.05$ is considered statistically significant.

FQ-susceptible *E. coli*: MIC ≤ 0.06; FQ-low-level-resistant *E. coli*: MIC = 0.125–0.5 mg/L; FQ-resistant *E. coli*: MIC > 0.5 mg/L.

which at the time of publication of those studies was ≥ 4 mg/L. The current CLSI The Clinical and Laboratory Standards Institute (CLSI) breakpoint for ciprofloxacin resistance in *Enterobacterales*, including *E. coli*, is ≥ 1 mg/L, and concurs with the EUCAST breakpoint of > 0.5 mg/L used by others [10, 15].

Kalalahti et al. were the first to report an association between rectal *E. coli* with resistance above the ciprofloxacin ECOFF with post-TRUS-Bx infectious complications. To our knowledge, we are the first to corroborate their findings and to show increasing risk coinciding with increasing levels of resistance.

The rate of infectious complications after TRUS-Bx has been reported to be in the range of 1%–6% [1, 16–20]. The infection rate in this study is thus in the higher range, which may be since both UTI without SIRS and UTI with SIRS were included. Several studies have shown that the rate of infectious complications after TRUS-Bx is growing and is directly related to the increasing prevalence of FQ-resistant microorganisms [6, 10, 11, 13]. Some studies have shown that use of FQ in the last 6 months prior to TRUS-Bx independently predict the presence of FQ-resistant faecal organisms [21, 22]. Neither

we nor a Finnish study could confirm these results [9]. This may be explained by a power factor due to low use of FQ in our population, as a result of a campaign to reduce the use of FQ in general.

Age is a risk factor for infections in general. We found in this study that patients with UTI without SIRS were older than both the patients without infection complications and the patients who develop a UTI with SIRS. Our data did not show that age was as strong risk factor for serious infection as FQ-R *E. coli* in the faecal flora. Furthermore, we insert the bacteria via the biopsy needle, which means that even healthy and younger patients who usually have a resistance to avoid an infection are affected.

In this study, risk-group stratification mainly based on direct urogenital risk factors was used to predict the risk of post-biopsy infection. We showed that some patients who were assessed as low-risk had an increased risk of severe infectious complications after TRUS-Bx. In this group, increased incidence of *E. coli* with reduced susceptibility (low-level resistance) to ciprofloxacin was observed. Since the risk-group stratification for infectious complications did not identify these patients, they received standard antibiotic prophylaxis. Our data showed that low-level ciprofloxacin resistance among *E. coli* may be a risk factor to be added, to predict and counteract the risk of infectious complication after TRUS-Bx. The difficulties in determining adequate antibiotic prophylaxis before TRUS-Bx justify alternative methods such as povidone-iodine rectal cleansing and targeted antimicrobial prophylaxis based on rectal swab cultures prior to TRUS-Bx. Transperineal biopsy has gained popularity recently due to its lower rate of infection.

A limitation of our study is that we screened with nalidixic acid and may have missed plasmid resistance transfer. As this mechanism is not as common as mutational resistance in Sweden, however, this is probably of little significance. A further limitation of the study was that our analyses regarding risk factors for an infectious complication after TRUS-Bx were mainly based on direct urogenital risk factors. Another weakness is that the study period, 2012 to 2013, was some time ago. However, considering that FQ resistance has increased in Sweden since the study setting, our conclusions are reasonably equally significant. The strength of this study is that it was an observational study reflecting a typical clinical setting with meticulous risk-group stratification before deciding on antibiotic prophylaxis. Since a rectal swab was obtained just prior to TRUS-Bx, we were able to both evaluate risk factors and relate them to microbiologic data.

Sweden has a generally low level of antibiotic resistance [23], but despite this, our study shows that antibiotic resistance is the dominant risk factor for UTI with SIRS. This calls for further diagnostics such as culture from a rectal or faecal flora or rectal preparation with a bactericidal agent such as povidone-iodine before TRUS-Bx.

Conclusion

In this study, 3% of patients developed a severe urinary tract infection (UTI) after TRUS-Bx. The predominant risk factor for UTI with systemic inflammatory response syndrome (SIRS) after TRUS-Bx was *E. coli* with reduced susceptibility to fluoroquinolones in the faecal flora, and the risk increased in parallel with increasing levels of resistance. Antibiotic resistance is difficult to identify without pre-biopsy culture from a rectal swab, and therefore further studies are warranted to investigate if rectal preparation with a bactericidal agent such as povidone-iodine before TRUS-Bx may be used to reduce the risk of fluoroquinolone resistant pathogen infection even in countries with a generally low level of antibiotic resistance.

Disclosure statement

No potential conflicts of interest were reported by the authors.

Data availability statement

All relevant data may be found within the manuscript and its supplementary files.

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