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Comparative Retrospective Assessment of the Effectiveness and Risk Factors of Fluoroquinolones, Cephalosporines, and Selective Antibiotic Prophylaxis for Transrectal Prostate Biopsy

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Keywords
Prostate biopsy · Antibiotics · Fluoroquinolones · Cephalosporines · Urinary tract infection · Sepsis

Abstract

Introduction: Despite increasing resistance of enterobacteria against fluoroquinolones (FLU), they are still widely used during transrectal prostate biopsy (TRPB). This study was designed to analyse infectious complications and risk factors between FLU, cephalosporines (CEPH) and selective other antibiotics (O-AB) used during TRPB. ***Methods:*** 664 patients were included retrospectively (152 FLU, 452 CEPH and 60 O-AB). Infectious complications were defined as fever >38.0°C, the in-house definition of complicated urinary tract infection (cUTI) (if all applied: fever >38.0°C, leucocytosis >11.000/µL and positive urine dipstick) or postinterventional bacteriuria. Hospitalisation rate, duration and comorbidities were also assessed. χ^2 and Fisher's exact test were used for group comparison. Multivariate regression analysis assessed the association of comorbidities with infectious complications. ***Results:*** FLU and CEPH were indifferent regarding infectious complications, however in the O-AB group significantly more common compared to FLU and CEPH (11.6, 13.3, 25%, $p < 0.05$). Duration of hospital stay in CEPH was significantly shorter compared to FLU and O-AB (4.1 vs. 6.3 vs. 8.2 days, $p < 0.05$). Arterial hypertension showed increased association with fever (OR 6.002 (1.178; 30.597) $p = 0.031$) and cUTI (OR 6.006 (1.207; 29.891) $p = 0.029$). ***Conclusion:*** Infectious complications were low and indifferent between FLU and CEPH but significantly more frequent in O-AB. Arterial hypertension was significantly associated with postinterventional fever and cUTI.

Introduction

The gold standard procedure for prostate cancer (PCa) detection is a 10- to 12-core prostate biopsy (PBx) performed either by a transrectal (TRPB) or perineal (TPPB)

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prostate biopsy [1, 2]. Although both methods are associated with low complication rates, EAU guidelines have most recently recommended TPPB over TRPB based on a recent meta-analysis [1]. However, TRPB is still widely used in an outpatient setting due to its uncomplicated practicability and overall positive long-term experience in the context of PCa diagnosis [1, 2]. In addition, TRPB can usually be performed under local anaesthesia whereas general anaesthesia is more often applied for TPPB.

During a prostate biopsy, the reduction of complications such as infectious complications is highly important and usually antibiotics are administered throughout the perioperative procedure of PBx [3, 4]. Overall, TRPB and TPPB are associated with low complication rates such as urinary tract infections, acute prostatitis and sepsis which occur in up to 2.16–3.6%, 1.1%, 0.6–1.7% of cases, respectively [5, 6]. Fluoroquinolones (FLU) have traditionally been used for TRPB due to their high accumulation in soft tissue such as the prostate [7], easy oral administration as well as efficacy against gram-negative and gram-positive bacteria [8]. However, the prevalence of quinolone-resistant enterobacteria (mostly *Escherichia coli*) has increased over the last decade [3]. Additionally, the use of FLU has been restricted due to toxicity and side effects by the US Food and Drug Administration and the European Medicine Association [9]. To account for these changes and restrictions, other antibiotic regimes such as cephalosporines (CEPH) have been implemented in clinical practice [3, 10]. Although several studies have investigated differences in antibiotic use during TRPB, data on direct comparison between FLU and CEPH and their incidence of infectious complications is scarce. In addition, data on infectious complications during TRPB in patients with selective other antibiotics, that did not receive FLU or CEPH due to positive urine culture with resistance against both or other contraindications, is scarce. This study aimed to evaluate the efficacy of FLU, CEPH and selective other antibiotic (O-AB) regimes with respect to clinically relevant co-morbidities.

Materials and Methods

Study Design and Population

We retrospectively investigated a total of 664 patients from July 2016 to July 2018, which underwent TRPB (systematic, magnet resonance imaging (MRI) targeted biopsy or combination of both) in the Department of Urology and Paediatric Urology at the University Hospital Mainz, Germany. Indication for TRPB was primary suspicion of PCa due to increased PSA levels according to current guidelines or active surveillance of low-risk PCa.

Data Extraction and Definition of Infectious Complications

Patient data was obtained from the digital patient files. Three types of infectious complications were defined. First, postoperative fever >38.0°C. Second, an in-house definition of complicated urinary tract infection (cUTI), which was positive if all three of the following parameters were applied: fever >38.0°C, leucocytosis >11.000/µL and positive urine dipstick, lastly postinterventional bacteriuria (in urine culture) in case of readmission [3–6]. Hospitalisation rate (within 30 days after prostate biopsy) and duration of hospital stay, oncological parameters (PSA level, Gleason score, number of biopsy cores, systematic vs. MRI targeted biopsy) as well as patient's comorbidities such as smoking, coronary heart disease, diabetes, hypertension, anticoagulation and secondary cancers were also documented.

Procedure of Prostate Biopsy

All prostate biopsies were performed in a transrectal approach with a high-end ultrasound device (Hi ViSiOn Ascendus by Hitachi Medical Systems, Tokyo, Japan). Urine cultures were taken before the procedure and in case of readmission to the hospital. Prior to TRPB, all patients received purgative medication and rectal disinfection in an equal manner. Periprostatic local anaesthesia with mepivacain 2% or analgosedation, Ketanest and Midazolam, at a dose of 25 mg/mL and 5 mg/mL, respectively, were typical options of anaesthesia. In the great majority of cases, at least 12 systemic biopsies were taken as recommended in current guidelines [1]. For MRI-targeted biopsies at least 2 extra cores were taken from each target lesion in addition to systematic 12-core biopsies. In some cases, saturation biopsies with 24 cores were taken, if MRI did not show any lesions with a PI-RADS score greater than 3 and previous biopsies were negative. Patients usually were supervised overnight. Readmission rate was assessed up to a time period of 30 days after TRPB.

Perioperative Antibiotic Prophylaxis

All patients received perioperative antibiotic prophylaxis as recommended for TRPB [1]. During the investigated time period (July 2016 to July 2018), the perioperative antibiotic regime was changed from monotherapy with FLU to CEPH as of May 2017. Patients in the FLU group received oral antibiotic monotherapy with Ciprofloxacin 500 mg twice/d or Levofloxacin 500 mg once/d 3 days prior and 3 days after TRPB. Patients in the CEPH group received a single application of 2 g ceftriaxone intravenously 1 h prior to TRPB and 200 mg cefpodoxime/cefixime twice/d over 3 days after TRPB. All other patients who were not eligible for the above-mentioned antibiotics received specific antibiotics depending on pre-operative urine culture which was applicable for the patient such as aminoglycosides, penicillins, tetracyclines, or sulfonamides. Similarly, in each case, we checked for contraindications, allergies or comorbidities that would allow the administration of the specific necessary antibiotic.

Statistical Analysis

For statistical analysis, χ^2 and Fisher's exact test were used. A multivariate logistic regression analysis was used to evaluate risk factors for primary endpoints. The level of significance was set at $p < 0.05$. IBM SPSS Statistics and GraphPad Prism 5 Project were used for statistical analysis and visualisation.

Table 1. Age, number of biopsy cores and iPSA in all three groups

	FLU (n = 152)	CEPH (n = 452)	O-AB (n = 60)
	median (IQR)	median (IQR)	median (IQR)
Age (a)	69 (63; 74.5)	68 (63; 74)	67.5 (59.25; 75)
Number of biopsy cores (n)	12 (12; 16)	13 (12; 16)	12 (12; 16)
iPSA (ng/mL)	7.85 (5.58; 14.25)	8.2 (5.6; 13)	8.47 (6.86; 20)

Number of biopsy cores differed significantly between FLU and CEPH (p = 0.0098) as well as CEPH and O-AB (p = 0.044). All other parameters did not differ significantly (p > 0.05). Statistical significancy was defined as p < 0.05. iPSA, initial prostate specific antigen; TRPB, transrectal prostate biopsy; FLU, fluoroquinolones; CEPH, cephalosporines; O-AB, selective other antibiotics.

Results

Baseline Characteristics

Overall, 664 patients were included in the study, of which 152 patients received a mono-antibiotic prophylaxis with FLU and 452 CEPH, and 60 patients received O-AB. Mean age as well as initial PSA was comparable between all groups (all p > 0.05) (shown in Table 1). However, number of biopsy cores differed significantly between FLU and CEPH (p = 0.0098) as well as CEPH and O-AB (p = 0.044) (shown in Table 1). PCa was detected in 379 of 664 patients. Predominantly, ISUP 1 (International Society of Urological Pathology [7, 8]) was detected in 137 patients, followed by ISUP 2 (97 patients), ISUP 3 (70 patients), ISUP 4 (38 patients) and ISUP 5 (37 patients) (Data not shown). In 26 Patients ASAP (atypical small acinar proliferation) or PIN (prostatic intraepithelial neoplasia) was detected.

Infectious Complications

Overall, 12 patients were readmitted with fever (1.81%), 11 with cUTI as defined above (1.66%) and 31 patients had a positive urine culture at readmission (4.67%). In the FLU group, only 1 patient (0.66%) was readmitted with cUTI and in 2 cases (1.32%) a positive urine culture was present after TRPB (shown in Fig. 1). In comparison 4 patients in the CEPH group (0.88%) had cUTI and 14 (3.10%) had a positive urine culture (shown in Fig. 1). In O-AB, 7 patients (11.67%) had fever, six (10%) cUTI and in 15 cases (25%) positive urine culture was detected after biopsy (shown in Fig. 1). Fisher's exact Test showed highly significant differences between the FLU and CEPH group in comparison to the O-AB group regarding all three clinical parameters, whereas no significant differences were present between the FLU and CEPH group.

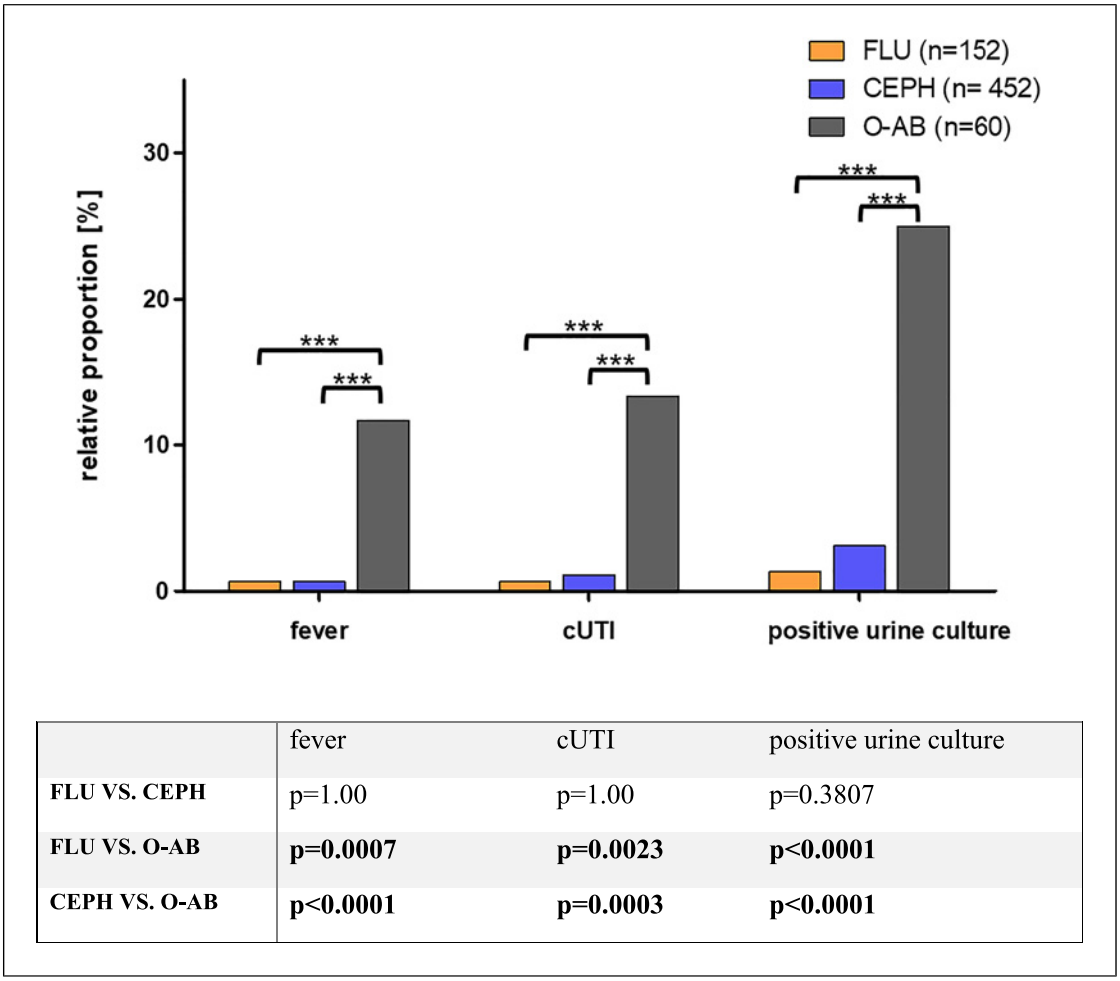
Prior to biopsy, patients in the O-AB group had bladder catheters (transurethral or suprapubic) significantly more often compared to FLU and CEPH (5 in FLU [3.29%], 6 in CEPH [1.33%] and 10 in O-AB [16.67%], p = 0.0015) (Data not shown). Consistently, patients in O-AB showed positive urine cultures significantly more often in advance of biopsy than FLU and CEPH (13 in FLU [8.55%], 52 in CEPH [11.50%] and 28 in O-AB [46.67%], p < 0.0001) (Data not shown).

Hospitalisation

Overall, 197 patients were hospitalised within 30 days after TRPB (46 in FLU [30.26%], 115 in CEPH [25.44%] and 36 in O-AB [60%]). Patients treated with O-AB were significantly more likely to be hospitalised (p < 0.001) compared to FLU and CEPH (shown in Fig. 2). The mean duration of hospitalisation in FLU was 6.28 days (SD 7.06), in CEPH 4.13 (SD 4.23) and in O-AB 8.21 (SD 5.94) (shown in Fig. 2). Compared to each other, duration of hospitalisation was significantly less in CEPH compared to FLU (p = 0.0187) and O-AB (p < 0.0001) (shown in Fig. 2).

Comparison of Comorbidities

Data on body mass index BMI and American Society of Anaesthesiologist's Score (ASA Score) were available for 85 patients in the FLU group, 233 patients in the CEPH group and 45 patients in the O-AB group. Only the BMI differed significantly between CEPH and O-AB (p < 0.01) (FLU 27.45, SD 3.74; CEPH 27.2, SD 3.78; O-AB 28.89, SD 4.61). The ASA Score, which is predictive of perioperative complications, did not differ between all groups (FLU 2.37, SD 0.61; CEPH 2.39, SD 0.58; O-AB 2.44, SD 0.76; p > 0.05) (data not shown). Sixty-three patients were former smokers, 51 patients had secondary malignancies, 68 had coronary heart disease, 103 had



	fever	cUTI	positive urine culture
FLU VS. CEPH	p=1.00	p=1.00	p=0.3807
FLU VS. O-AB	**p=0.0007**	**p=0.0023**	**p<0.0001**
CEPH VS. O-AB	**p<0.0001**	**p=0.0003**	**p<0.0001**

Fig. 1. Relative proportion of three endpoints (fever, cUTI, and positive urine culture after TRPB) compared between all three groups (FLU, CEPH, and O-AB). $p < 0.05$ was considered statistically significant. cUTI, complicated urinary tract infection; TRPB, transrectal prostate biopsy; FLU, fluoroquinolones; CEPH, cephalosporines; O-AB, selective other antibiotics.

diabetes, 374 had arterial hypertension, and 182 patients had anticoagulants in their medication (shown in Table 2).

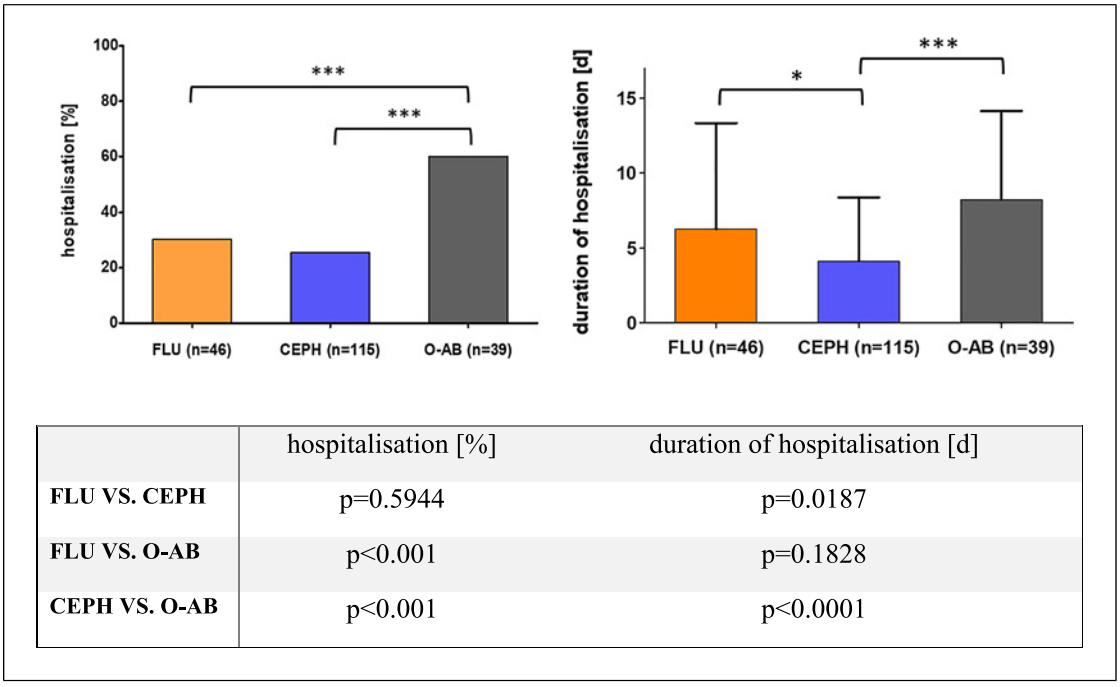
Multivariate Regression Analysis

In a multivariate regression analysis, we evaluated patient characteristics and comorbidities as potential risk factors regarding infectious complications after TRPB (shown in Table 3). Age and number of biopsy cores were not associated with an increased probability of infectious complications. However, among the other parameters tested, arterial hypertension was the only parameter with a significantly increased risk of fever and cUTI (shown in Table 3). All the other parameters were not associated with an increased risk of any of the three clinical parameters.

Discussion

Despite recent EAU recommendations in favour of TPPB, TRPB is still widely used due to its uncomplicated accessibility, low complication rates and established operating procedures. Since antibiotic prophylaxis is recommended during TRPB [4, 11, 12], we investigated the efficacy of standard-of-care antibiotic regimes in terms of infectious complications and multiple clinically relevant comorbidities. In this context, increasing resistances of enterobacteria (mostly *Escherichia coli*) against FLU led to increased use of CEPH as an alternative option in our department [9, 13].

In our study, we found a low incidence rate of infectious complications ranging around 1–2%, which is



	hospitalisation [%]	duration of hospitalisation [d]
FLU VS. CEPH	p=0.5944	p=0.0187
FLU VS. O-AB	p<0.001	p=0.1828
CEPH VS. O-AB	p<0.001	p<0.0001

Fig. 2. Comparison between antibiotic regimes regarding hospitalisation rate within 30 days after TRPB (left) and duration of hospitalisation in days (right). $p < 0.05$ was considered statistically significant. TRPB, transrectal prostate biopsy; FLU, fluoroquinolones; CEPH, cephalosporines; O-AB, selective other antibiotics.

Table 2. Comorbidities in all three antibiotic regimes with absolute and proportionate values to the total population

	FLU, *n* (%)	CEPH, *n* (%)	O-AB, *n* (%)
Smoking	17 (11.18)	31 (6.86)	15 (25)
Secondary malignancy	19 (12.5)	26 (5.75)	6 (10)
Coronary heart disease	21 (13.82)	40 (8.85)	7 (11.67)
Diabetes mellitus type 2	24 (15.79)	66 (14.6)	13 (21.67)
Arterial hypertension	79 (51.97)	253 (55.97)	42 (70)
Anticoagulants	38 (25)	123 (27.21)	21 (35)

FLU, fluoroquinolones; CEPH, cephalosporines; O-AB, selective other antibiotics.

comparable to data reported in international guidelines and other recent literature for TRPB [1, 5, 14–16]. Consistent with the results of Wenzel et al., [17] infectious complications were not more often when FLU was used in comparison to CEPH, despite increasing resistances against FLU. Conversely, there was no superior effect of CEPH compared to FLU. In line with a meta-analysis from nine randomised controlled trials [18], we did not observe a higher risk of infectious complications with an increasing number of prostate biopsy cores as the number of biopsy cores in the CEPH group was significantly higher than the other groups (shown in Table 1), and CEPH did not show more infectious complications than the other two groups (shown in Fig. 1). Interestingly, our study revealed that the O-AB group performed significantly worse in all three predefined infectious complications (shown in Fig. 1) despite equally balanced patient characteristics that are potentially predictive of inferior outcomes such as age or ASA Score. However, patients in the O-AB group more often had indwelling bladder catheters and positive urine cultures. This finding is especially interesting because the standard antibiotic regime often was replaced with a targeted antibiotic treatment in accordance with the urine culture taken. Previous study results already showed significantly more frequent

Table 3. Multivariate regression analysis of comorbidities in relation to fever, cUTI (in-house definition of complicated urinary tract infection) and positive urine culture

	Fever		cUTI		Positive urine culture	
	OR (95% CI)	*p* value	OR (95% CI)	*p* value	OR (95% CI)	*p* value
Age	1.006 (0.942; 1.074)	0.862	1.007 (0.942; 1.077}	0.831	1.012 (0.964; 1.062)	0.635
Number of biopsy cores	1.092 (0.936; 1.274)	0.263	1.043 (0.884; 1.231)	0.617	1.022 (0.917; 1.139)	0.696
Smoking	1.083 (0.257; 4.567)	0.913	1.301 (0.297; 5.692)	0.727	1.280 (0.471; 3.479)	0.628
Secondary malignancy	0.784 (0.129; 4.767)	0.792	0.797 (0.118; 5.368)	0.816	1.088 (0.334; 3.539)	0.888
Coronary heart disease	0.917 (0.144; 5.842)	0.927	1.140 (0.168; 7.711)	0.893	1.289 (0.401; 4.142)	0.671
Diabetes mellitus type 2	0.346 (0.067; 1.770)	0.202	0.124 (0.011; 1.465)	0.098	0.423 (0.138; 1.298)	0.132
Arterial hypertension	6.002 (1.177; 30.597)	**0.031**	6.006 (1.207; 29.891)	**0.029**	1.727 (0.682; 4.376)	0.249
Anticoagulants	0.589 (0.157; 2.212)	0.433	0.423 (0.099; 1.804)	0.245	1.268 (0.520; 3.089)	0.602

$p < 0.05$ was considered statistically significant. OR, odds ratio; CI, confidence interval.

bacterial colonisation of the urine in patients with a bladder catheter as well as more resistant bacterial spectra [19]. Therefore, it is not surprising that patients in the O-AB group had significantly more positive urine cultures before biopsy. Nevertheless, it is surprising that these patients showed significantly more infectious complications than the other two standard therapies, even with targeted antibiosis. It is known that patients with long-term indwelling catheters have a much broader and more resistant spectrum of bacteria in their urine. In addition, complete eradication of bacterial colonisation is often not possible due to the formation of a biofilm [20–22]. This could explain the increased number of patients with fever, cUTI and postoperative positive urine cultures in the O-AB group (shown in Fig. 1). To increase patient safety and reduce the risk of infectious complications in patients with indwelling catheters for TRPB, the bladder catheter could be changed shortly before the biopsy and a control urine culture could be analysed after completion of targeted antibiotics. Certainly, further research is warranted to better manage this patient group.

Another relevant result from our study is the fact that the O-AB group had a significantly higher hospitalisation rates compared to FLU and CEPH as well as a longer inpatient treatment time. This result cannot be explained by differences in peri-interventional management between the three groups since peri-interventional management was always similar (i.e., purgative measures, rectal disinfection, anaesthesia, discontinuing of blood thinners, number of biopsy cores). However, looking at the patient comorbidities, patient characteristics were indeed slightly different. In the O-AB group, patients had more often arterial hypertension, diabetes mellitus, a history of smoking, and anticoagulant medication. Therefore, a complicated and a longer duration of hospitalisation could explain these findings. Patients with higher perioperative risks due to multiple comorbidities are more often monitored in an inpatient setting [23, 24], which is to be expected. To further analyse the comorbidities, we performed a multivariate regression analysis which revealed that only arterial hypertension could be identified as an independent risk factor for fever and cUTI after TRPB. This is also supported by the study of Davidson et al., [25] which reported a correlation of arterial hypertension and acute respiratory infections. This finding is rather interesting because diabetes mellitus, which is commonly known to aggravate infections complications [26, 27], did not turn out to be a significant risk factor.

Our study has some limitations. Firstly, data acquisition was retrospective in a single centre setting with a relatively small study population, relative to the low number of complications in general. Secondly, there are no standardised definitions on relevant clinical endpoints for infectious complications. Therefore, it was our intention to find endpoints that are clinically meaningful in daily practice. However, this makes it difficult to compare our data with other study results. In addition, concomitant clinical characteristics, such as rectal/urethral bleeding or epididymitis or dysuria were not recorded, which also could have led to a higher readmission rate and longer inpatient treatment. Still, with the transition from TRPB to TPPB in which case some advocate no antibiotic prophylaxis at all, our main finding for increased infectious complications in patients treated with other antibiotics due to positive urine culture raises further questions on how to optimise peri-interventional treatment with these patients.

Conclusion

Infectious complications after TRPB are rare and CEPH did not show superior efficacy in terms of prevention of infectious complications. Interestingly, the use of selective antibiotic prophylaxis resulted in significantly worse clinical outcomes regarding infectious complications, hospitalisation rate and duration of hospitalisation. Also, arterial hypertension was an independent risk factor for developing fever and cUTI after TRPB.

Statement of Ethics

This study protocol was reviewed and approved by the Ethics Committee of the State Medical Association of Rhineland-Palatinate, approval number 2019-14231. Written informed consent was obtained from participants to participate in the study and for the use of their pseudonymised data.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

M.H.: conceptualisation, data curation, formal analysis, investigation, methodology, validation, visualisation, and writing – original draft. C.R.: data curation, formal analysis, and writing – review and editing. R.D., A.T., M.P.S., N.D.F., L.J.F., and G.D.: formal analysis and writing – review and editing. A.H.: methodology and writing – review and editing. I.T.: methodology, project administration, and writing – review and editing. M.P.B.: formal analysis, methodology, project administration, supervision, and writing – review and editing.

Data Availability Statement

Research data are not publicly available on legal or ethical grounds. Research data can be provided on request in pseudonymized form. Further enquiries can be directed to the corresponding author.

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