



Safety of Single-Dose Oral Cefaclor Prophylaxis in Transperineal Prostate Biopsy

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Purpose: Transperineal prostate biopsy is essential for diagnosing prostate cancer; however, infection remains a clinically significant issue. We evaluated the safety and outcome of a single, prophylactic oral dose of cefaclor 500mg during transperineal prostate biopsy.

Patients and Methods: This retrospective observational study included 127 patients who underwent transperineal prostate biopsy for suspected prostate cancer at our institution between April 2024 and October 2025. Biopsies were performed transperineally under spinal anesthesia. Cefaclor 500 mg was administered orally 30 minutes pre-operatively as a prophylactic antibiotic. We collected information on laboratory data, medication history, comorbidities, frailty, and infection risk for analysis.

Results: Among 127 patients, 73 (57.8%) were classified as prefrail or frail and 27 (21.2%) were identified as at risk of infection. The median initial prostate-specific antigen level was 9.92 ng/mL (interquartile range, 6.55–17.3 ng/mL). Fifty patients (39.3%) with polypharmacy and seventy-one (55.9%) with multimorbidity were noted. All patients were discharged after a 2-day hospital stay. Complications were observed in 36 patients (28.3%). Grade 1 and grade 2 Clavien–Dindo complications occurred in 33 patients (25.9%) and 3 patients (2.3%; urinary retention in 2 patients, fever in 1), respectively. One patient (0.7%) developed a urinary tract infection and underwent additional oral antibiotic therapy. No cases of rehospitalization or sepsis occurred. Among patients who underwent biopsy, 90 (70.8%) tested positive for cancer.

Conclusion: Single-dose oral cefaclor prophylaxis in TPB appears to be safe, with no serious post-procedural infections observed. Its effectiveness in frail or high-risk patients requires confirmation in future large prospective studies.

Keywords: antibiotics, infection, sepsis, transperineal prostate biopsy

Introduction

Prostate biopsy is an essential procedure for diagnosing prostate cancer, but infection, particularly sepsis, remains a clinically serious complication.¹ Biopsy methods include transrectal or transperineal approaches, with transperineal prostate biopsy (TPB) considered to carry a lower risk of infection. The European Association of Urology guidelines recommend the transperineal approach.^{2,3} TPB has been reported to not require the use of prophylactic antibiotics,^{4,5} but other reports indicate an increased risk of infection with this procedure.⁶ Prophylactic antibiotics may be effective for some patients, such as those with high-risk, frailty, polypharmacy, or multimorbidity.^{7–11} Because infection can progress to severe sepsis with potentially fatal consequences, the choice to forgo antibiotics should be carefully considered. In fact, both the European Association of Urology and Japanese guidelines do not recommend omitting antibiotics; however, they also do not specify clear recommended agents or routes of administration.^{12,13} However, due to the high safety of transperineal biopsy, outpatient day surgery has become more common in recent years, increasing the need for simpler and more appropriate prophylactic antibiotic administration.^{14–16}

Traditionally, prophylactic antimicrobial agents, primarily consisting of fluoroquinolones and aminoglycosides, have been widely administered during prostate biopsies.⁶ However, the global increase in resistant bacteria, including those resistant to fluoroquinolones, has become a significant concern in recent years, necessitating careful selection of these agents.^{12,17} In Japan, increasing fluoroquinolone resistance among common uropathogens has been recognized as



a growing problem.¹⁸ Cephalosporins may be used as an alternative, and the efficacy of intravenous first-generation cephalosporins as prophylactic antibiotics has been reported.¹⁹ However, there are few reports of simpler oral administration; evidence for single-dose oral cephalosporins with clearly defined numbers, dosages, and administration routes remains limited.

Therefore, this study aimed to evaluate the safety of a single oral dose of cefaclor 500 mg, a second-generation cephalosporin, for prophylaxis in TPB.

Materials and Methods

This was a retrospective observational study. We identified male patients who underwent prostate biopsy at our institution between April 2024 and October 2025 for suspected prostate cancer. We defined suspected prostate cancer as either a prostate-specific antigen level of 4 ng/mL or higher, or magnetic resonance imaging findings corresponding to Prostate Imaging Reporting and Data System version 2.1 category 3 or higher. Biopsies were performed transperineally after spinal anesthesia was administered and skin cleansing with povidone-iodine. For patients with imaging findings who provided consent, magnetic resonance imaging–transrectal ultrasound fusion biopsy was performed using the three-dimensional navigation system Trinity Perine (Koelis, Meylan, France). All patients received 500 mg of cefaclor orally 30 minutes before the procedure, prophylactically. Before protocol standardization, prophylactic antibiotics were administered at the attending physician's discretion, including oral levofloxacin or multiple-dose intravenous cefazolin. During the transition period, 82 patients received heterogeneous antibiotic regimens and were excluded. In addition, one patient was already taking antibiotics, three patients were undergoing other surgeries simultaneously, and four patients for whom data acquisition was complex were excluded.

Patient background data at admission were retrospectively recorded. These data included age, body mass index, prostate volume measured using transrectal ultrasonography, prostate-specific antigen level, oral medications, comorbidities, frailty, presence of a high risk of infection, digital rectal examination findings, surgery time, number of biopsies, post-biopsy complications, number of cancer positive findings, length of hospital stay, and number of rehospitalizations within 2 months after biopsy. Post-biopsy complications were assessed during hospitalization and for up to 4 weeks after the procedure, with a focus on early infectious complications. Infectious events were defined as febrile episodes or urinary tract infections requiring additional antibiotic treatment or hospitalization. Rehospitalization was defined as any hospital admission for any reason, including infectious and non-infectious causes, during the follow-up period. Frailty was assessed using the Frailty Screening Index.^{20,21} Patients were considered at high risk of infection if they had a prostate volume of ≥ 75 mL, diabetes, steroid dosing, voiding dysfunction (indicated by an International Prostate Symptom Score of ≥ 20 points, maximum urinary flow rate of ≤ 12 mL/second, or residual volume of ≥ 100 mL), or were in a state of immune deficiency. Amongst others, complications such as hematuria, wound pain, urinary retention, and fever that arose after the biopsy were noted. Infection risk was determined using the criteria for high risk listed in the Essential Japanese guidelines for the prevention of perioperative infections in the urological field.^{13,22}

Fisher's exact test was used to compare complication rates. A P-value < 0.05 was considered statistically significant. All statistical analyses were performed using the software JMP Pro version 18 (SAS Institute Inc., Cary, NC, USA).

This study was conducted at a single center in accordance with the guidelines of the Declaration of Helsinki and approved by the institutional review board of Kishiwada Tokushukai Hospital (approval number 24–24). With the approval of the institutional review board, informed consent was obtained using an opt-out method.

Results

Among 217 patients who underwent TPB at our facility, we included in this study the data for 127 patients who received oral cefaclor 500 mg as prophylaxis during the study period and for whom data acquisition was possible (Table 1). The median age was 74 years, and the median body mass index was 22.9 kg/m². Among the patients, 49 were classified as prefrail and 24 as frail. The median baseline prostate-specific antigen level was 9.92 ng/mL. The median number of oral medications was four, and the median number of comorbidities was three. Fifty patients were currently administered five or more medications. Comorbidities included hypertension, heart failure, ischemic heart disease, cerebrovascular disease, respiratory diseases, such as chronic obstructive pulmonary disease, chronic kidney disease, neurodegenerative diseases,

Table 1 Patient Characteristics All Continuous Variables are Expressed as Median (IQR).

Characteristics	All (n=127)
Age, year	74(69–77)
Body mass index, kg/m ²	22.9(21.0–25.1)
Frailty status, n (%)	
Robust	53(42.0)
Pre-frail	49(38.8)
Frail	24(19.0)
Initial PSA, ng/mL	9.92(6.55–17.3)
Palpable induration on digital rectal examination, n (%)	18(14.1)
PV(TURS), mL	41.9(32.7–63.1)
Oral medication, n	4(2–6)
Comorbidities, n	3(2–4)
Risk of infection, n (%)	27(21.2)
Prostate volume >75 mL	11(8.6)
Diabetes	14(11.0)
Steroids dosing	0(0)
Voiding dysfunction	8(6.2)
Immune-deficiency status	0(0)
MRI PIRADS v2.1, n (%)*	
1	14(11.6)
2	2(1.6)
3	28(23.3)
4	42(35.0)
5	34(28.3)

Note: *Excluding Patients Who Have Not Undergone Magnetic Resonance Imaging (MRI).

and diabetes. Seventy-one patients had three or more comorbidities. Data on factors associated with risk of infection after biopsy (presence of severe benign prostatic hyperplasia or urinary retention, diabetes, steroid use, and immune deficiency) are also shown in Table 1.

The surgical outcomes are shown in Table 2: 82 patients (64.5%) had 15 biopsy cores, seven patients (5.5%) had 16 or more, and 32 patients (29.9%) had 12 or fewer, without a target biopsy. The duration of hospital stay was 2 days for all

Table 2 Outcomes All Continuous Variables are Expressed as Median (IQR).

Outcome	All
Surgery time, minutes	9(7–11)
Number of biopsy cores, n	15(12–15)
Target biopsy performed, n (%)	98(77.1)
Hospital stay, day	2(2–2)
Complications present, n (%)	36(28.3)
Clavien-Dindo classification, n (%)	
Grade 1	33(25.9)
Grade 2	3(2.3)
Type of complication, n (%)*	
Hematuria	30(23.6)
Wound pain	1(0.7)

(Continued)

Table 2 (Continued).

Outcome	All
General fatigue	1(0.7)
Urinary retention	3(2.3)
Fever	1(0.7)
Headache	1(0.7)
Hematochezia	2(1.5)
Hypotension related to vagal reflex	3(2.3)
Postoperative urinary tract infection, n (%)	1(0.7)
Postoperative sepsis/septic shock, n (%)	0(0)
Rehospitalization, n (%)	0(0)
Cancer positive, n (%)	90(70.8)
Gleason score, n (%)	
No malignancy	37(29.2)
6	24(18.9)
7	29(22.8)
8	29(22.8)
9	5(3.9)
10	3(2.4)

Note: *With Overlap.

patients. Complications were observed in 36 patients. According to the Clavien–Dindo classification, grade 1 complications occurred in 33 patients and grade 2 complications in 3 patients (urinary retention in 2 patients, fever in 1). One patient developed a urinary tract infection and underwent oral treatment with amoxicillin hydrate and potassium clavulanate, but did not require rehospitalization. This patient was treated at another hospital and, because no urine culture tests were performed, no culture results were available. Ninety patients tested positive for cancer. No significant difference in the incidence of complications, including infections, was observed between patients either only with frailty or at high risk of infection and those without these factors (25% [21/84] vs 35.7% [15/42]; $p = 0.20$). Patients with both frailty and high-risk features tended to have a higher incidence of infection (6.25% [1/16] vs 0% [0/111]; $p < 0.01$). Given the small number of events, this finding should be regarded as exploratory. Additionally, all patients who developed the infection had polypharmacy and multimorbidity.

Discussion

The findings of this study indicate that no serious infections occurred when a single dose of oral antibiotic was administered, even with a minimal dose. Therefore, prophylaxis with oral cefaclor may be safe in standard TPB. To our knowledge, reports on prophylaxis with oral cefaclor alone in TPB are limited, and our findings add new insights to the current evidence.

Past reports indicate a low risk of infectious complications with TPB, ranging from 0.11% to 2.6% under antibiotic prophylaxis,^{2,5,6,23,24} the infection rate in this study demonstrated comparable safety. However, debate persists regarding the optimal antimicrobial prophylaxis strategy in TPB: Although some reports indicate that TPB can be safely performed without antimicrobial prophylaxis,^{4,5,23,24} Jacewicz et al²⁵ reported that TPB without antibiotic prophylaxis showed a slightly increased incidence of urinary tract infections, although the difference failed to reach statistical significance (0.36% vs 1.09%; $p = 0.31$). Furthermore, Basourakos et al⁶ reported that use of antibiotics reduced infection rates (67/12,140 [0.55%] vs 58/4,772 [1.22%]; $p < 0.01$) and that infection risk increased when the number of biopsy cores exceeded 25 (2.64% vs 0.55%; $p < 0.01$). A multicenter study conducted in Japan reported that among 602 patients who received Tazobactam and piperacillin as prophylactic antibiotics and underwent prostate biopsy, only 6 patients developed urinary tract infections. Additionally, all of those patients had at least one of the following risk factors: prostate

volume of 75 mL or more, diabetes, steroid administration, voiding dysfunction, or immunodeficiency.¹¹ Therefore, these factors are considered high-risk factors for prostate biopsy in Japanese guidelines.²² These findings suggest that antibiotic administration may still contribute to reducing infection risk in patients with specific risk factors.^{6,25} Abundant evidence indicates that, in low-risk patients, the omission of antibiotic administration should be considered in transperineal prostate biopsy from the perspective of the risk of antibiotic-resistant bacteria and appropriate antibiotic use, and reports that exclude such high-risk patients are occasionally seen.^{4,5,25} Therefore, in high-risk patients, it is necessary to consider each case carefully.

Interestingly, the cohort of the present study included a high proportion of patients (104 patients, 81.8%) who were generally at high risk of complications, such as infection, including patients with frailty, polypharmacy, and multimorbidity.^{7–10} The incidence of infections after biopsy was extremely low with a single oral dose of cefaclor, a second-generation cephalosporin; no cases of sepsis were observed. This finding suggests that a single dose of oral cefaclor as prophylaxis may be a safe and well-tolerated option, even in populations at generally high risk of infection. The present findings also suggested similar safety and efficacy in high-risk patients, as defined by Japanese guidelines. However, the present findings suggest that the tendency for infection to occur is high in patients both with frailty and a high risk of infection. However, the limited number of cases prevented statistical confirmation. These results suggest that assessing frailty and stratifying risk of infection may be useful supplementary indicators for determining the appropriateness of antimicrobial prophylaxis. Validation through future prospective studies is anticipated.

Many past studies involved the use of fluoroquinolones or aminoglycosides.⁶ This policy, once recommended, is no longer advised due to the issue of increasing bacterial resistance to fluoroquinolones. The use of alternatives, such as cephalosporins, aminoglycosides, and fosfomycin, is now proposed.^{3,12,17,26,27} Considering that the primary causative organisms of infections following TPB are skin flora and urinary tract-derived bacteria, Tohi et al reported that a single case of *Escherichia coli* and one case of *Acinetobacter baumannii*/*Staphylococcus epidermidis* were detected in cultures from infected patients who received a single prophylactic dose of intravenous cefazolin shortly before TPB.²⁸ Furthermore, Koguchi et al²⁹ reported that cefaclor demonstrated excellent efficacy, even in patients with urinary tract infections who exhibited in vitro resistance to cefazolin or levofloxacin. From a microbiological standpoint, cefaclor provides adequate coverage against the most likely causative organisms of post-TPB infections. With good absorption (bioavailability) and a time to peak plasma concentration of 30 to 60 minutes, oral administration of cefaclor for preventing infection during TPB is considered a practical choice from a pharmacokinetic standpoint.³⁰ Although the present study was conducted in a different clinical context, given the increasing implementation of outpatient TPB, single-dose oral regimens may still offer valuable insights regarding convenience, cost-effectiveness, and patient satisfaction.^{14–16} Cefaclor is classified in the Watch group under the World Health Organization's AWaRe Classification Database,³¹ necessitating caution for appropriate use. The low incidence of serious infectious complications suggests that single-dose oral cefaclor prophylaxis may be a reasonable option for TPB, consistent with antimicrobial stewardship principles. For patients at low risk, narrow-spectrum first-generation cephalosporins administered orally or even no antibiotic prophylaxis warrants consideration, highlighting a strong need for such prospective trials.

Some limitations warrant mention. First, the retrospective, single-center study design prevents completely ruling out the effects of selection or information bias. Second, the limited sample of 127 cases and low number of events prevented the performance of multivariate analysis of infection risk factors or comparisons with other regimens. While this is an important limitation of our study, one of the study objectives was to emphasize the need to identify true risk factors for which prophylactic antibiotics are useful against infection, a serious complication of transperineal prostate biopsy. Validation through future large-scale prospective studies is anticipated. Despite these limitations, the findings of this study provide significant, real-world clinical data demonstrating the safety of a single dose of oral cefaclor for preventing infection after TPB.

To conclude, a single dose of oral cefaclor prophylaxis in TPB appears to be a safe and practical option, as no serious post-procedural infections were observed in this cohort. However, the effectiveness of this approach in frail or high-risk populations could not be directly assessed in this study and warrants further investigation in large prospective studies.

Data Sharing Statement

Data are available upon reasonable request. Access will be granted only after proper institutional approvals have been obtained.

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Disclosure

The authors declare no conflicts of interest in this work.

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