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Effectiveness of fosfomycin-based antimicrobial prophylaxis for transrectal ultrasound-guided prostate biopsy: A Korean multicenter study

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Purpose: Recent studies have highlighted increasing infectious complications due to fluoroquinolone (FQ)-resistant organisms in men undergoing transrectal ultrasound-guided prostate biopsy (TRUSPB). This study investigated whether fosfomycin (FM)-based antibiotic prophylaxis reduces infections after TRUSPB and identified risk factors for infective complications.

Materials and Methods: A multicenter study was conducted in the Republic of Korea from January 2018 to December 2021. Patients undergoing prostate biopsy with FQ or FM-based prophylaxis were included. The primary outcome was the post-biopsy infectious complication rate after FQ (group 1) or FM-based antibiotic prophylaxis with FM alone (group 2) or FQ and FM (group 3). Risk factors for infectious complications after TRUSPB were secondary outcomes.

Results: Patients (n=2,595) undergoing prostate biopsy were divided into three groups according to the type of prophylactic antibiotics. Group 1 (n=417) received FQ before TRUSPB. Group 2 (n=795) received FM only and group 3 (n=1,383) received FM and FQ before TRUSPB. The overall post-biopsy infectious complication rate was 1.27%. The infectious complication rates were 2.4%, 1.9%, and 0.5% in groups 1, 2, and 3, respectively (p=0.002). In multivariable analysis, predictors of post-biopsy infectious complications included an association with health care utilization (adjusted odds ratio [OR], 4.66; 95% confidence interval [CI], 1.74–12.4; p=0.002) and combination antibiotic prophylaxis (FQ and FM) (adjusted OR, 0.26; 95% CI, 0.09–0.69; p=0.007).

Conclusions: In comparison with monotherapy with FM or FQ, combination antibiotic prophylaxis (FQ and FM) showed a lower rate of infectious complications after TRUSPB. Utilization of health care was an independent risk factor for infectious complications after TRUSPB.

Keywords: Biopsy; Fluoroquinolones; Fosfomycin; Infection; Prostate

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INTRODUCTION

With the increasing incidence of prostate cancer, transrectal ultrasound-guided prostate biopsy (TRUSPB) is being more commonly used as a diagnostic procedure. In general, TRUSPB is considered as a safe procedure with minor complications such as pain, hematuria, and rectal bleeding [1-3]. Despite the rare incidence of infectious complications after TRUSPB, when complications occur, they can be life-threatening. According to a review article, the post-biopsy infection rate after TRUSPB is 5%–7%, and the rate of more severe infections requiring treatment on hospital admission is 1%–3% of prostate biopsies [4].

With increasing antibiotic-resistant bacterial infections, particularly high fluoroquinolone (FQ) resistance in the Republic of Korea [5,6], alternative antimicrobial prophylaxis is required to prevent post-TRUSPB-related infections. Owing to its good permeability into prostate tissue and lower resistance rate [7], FM trometamol has emerged as an alternative to FQ for the prophylaxis of post-biopsy infectious complications. Although the efficacy of FM compared with FQ has been demonstrated [8], a combination of FM and FQ remains to be investigated.

A previous study examined the efficacy of a combined regimen of FM and FQ as prophylactic antibiotics compared with FQ alone for TRUSPB at a single center in the Republic of Korea [9]. This retrospective study was conducted with patients from seven different institutions located in the Republic of Korea. The purpose of this study was to determine the efficacy of FM-based prophylaxis compared with FQ alone for TRUSPB and to identify risk factors for infectious complications after TRUSPB.

MATERIALS AND METHODS

1. Data collection

This retrospective multicenter study was performed between January 2018 and December 2021 with patients from seven institutions located in the Republic of Korea. A total of 2,595 patients were enrolled and divided into three groups according to the type of prophylactic antibiotics. In group 1 (n=417), FQ alone was administered before TRUSPB. In group 2 (n=795), only osfomycin was given. In group 3 (n=1,383), FQ and FM were administered before TRUSPB. The primary outcome of the three groups was the infectious complication rate within 1 month after TRUSPB. Risk factors for infectious complications after TRUSPB were secondary outcomes.

Before biopsy, an enema was performed for most patients undergoing TRUSPB (group 1, 100%; group 2, 87%; group 3, 100%). Intrarectal povidone-iodine cleansing (povidone-iodine 10% solution) was performed before biopsy.

An inquiry was conducted to assess the patients' characteristics including age, serum prostate-specific antigen (PSA), prostate volume, utilization of health care (as defined in the next paragraph), diabetes mellitus, surgical history, prostatitis, urinary tract infection (UTI), and antibiotic exposure (FQ or others) within 6 months, as well as previous prostate biopsy history (within 1 year) before TRUSPB. Periprocedural data were also collected, which included the number of biopsy cores, type of prophylactic antibiotics, period of antibiotic use, local anesthetic use, post-procedural infectious complications, and pathological results.

In this study, "health care utilization" was defined as follows: patients under specialized nursing care at home or in a long-term care setting such as a nursing home; patients who had been hospitalized for more than 2 days and discharged from the hospital within 90 days; patients with an indwelling urethral catheter; patients who had undergone an invasive urinary procedure; and outpatients undergoing hemodialysis or intravenous chemotherapy within 30 days of prostate biopsy [10].

Through an inquiry on specific complications after TRUSPB, we determined whether patients undergoing TRUSPB had infectious complications, a history of acute urinary retention, or hematuria. To investigate biopsy-related events, 30 days after the procedure was set as the time limit for the assessment of infectious complications after TRUSPB. Infectious complications consisted of hospitalization due to infection, fever, febrile UTI, afebrile UTI, bacteremia, and sepsis or systemic inflammatory response syndrome (SIRS). Inpatients with infection underwent blood and urine tests to detect pathogens and determine antibiotic sensitivity.

The study protocol was reviewed and approved by the Institutional Review Board of Chonnam National University Hwasun Hospital (approval number: CNUHH-2021-059). The study was conducted following the Declaration of Helsinki and the Ethical Guidelines for Clinical Studies.

2. Statistical methods

Statistical analyses were performed using SPSS software version 26.0 (SPSS Inc.). Mean values and standard deviations are reported for continuous variables, and categorical variables are reported as frequencies (%). One-way analysis of variance (ANOVA) and chi-square test were conducted to assess the association between the covariate distribution and infectious complications. Multivariate logistic regression

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Table 1. General characteristics of patients

Variable	Group 1 (FQ; n=417)	Group 2 (FM; n=795)	Group 3 (FQ+FM; n=1,383)	p-value
Age (y)	68.8, 9.2[a]	68.3, 9.2[b]	70.1, 8.5	0.001[c]
PSA (logarithmic transformed)	2.18, 1.19	2.30, 1.02	2.23, 1.25	0.222[c]
Prostate volume	40.5, 20.8[d]	46.2, 20.5	45.1, 23.8	0.001[c]
Health care utilization	53 (12.7)	10 (1.3)	66 (4.8)	0.001[e]
Health care workers	13 (3.1)	2 (0.3)	67 (4.8)	0.001[e]
Travel within 4 weeks	6 (1.4)	0 (0.0)	2 (0.1)	0.001[e]
Diabetes mellitus	64 (15.3)	133 (16.7)	311 (22.5)	0.001[e]
Previous operation history within 6 months	22 (5.3)	8 (1.0)	53 (3.8)	0.001[e]
Previous prostatitis history within 6 months	11 (2.6)	8 (1.0)	26 (1.9)	0.098[e]
Previous UTI history within 6 months	6 (1.4)	8 (1.0)	15 (1.1)	0.782[e]
Previous prostate biopsy within 12 months	13 (3.1)	12 (1.5)	51 (3.7)	0.014[e]
Previous antibiotic exposure within 6 months				0.001[e]
Other than quinolone	48 (11.5)	30 (22.2)	57 (42.2)	
Quinolone	0 (0.0)	23 (2.9)	20 (1.4)	
Local anesthetic use	47 (11.3)	322 (40.5)	105 (7.6)	0.001[e]
Rectal cleansing using povidone-Iodine	417 (100.0)	672 (84.5)	1,383 (100.0)	0.001[e]
Enema	417 (100.0)	692 (87.0)	1,383 (100.0)	0.001[e]
Prostate biopsy specialist				0.001[e]
Urologist	111 (26.6)	782 (98.4)	541 (39.1)	
Radiologist	306 (73.4)	13 (1.6)	842 (60.9)	
Biopsy core number ≥12	148 (35.5)	625 (78.6)	484 (35.0)	0.001[e]
Pathology				0.006[e]
BPH	259 (62.1)	437 (55.0)	736 (53.2)	
Cancer	158 (37.9)	358 (45.0)	647 (46.8)	
Overall infectious complication within 4 weeks	10 (2.4)	15 (1.9)	8 (0.5)	0.002[e]
Fever	10 (2.4)	14 (1.8)	7 (0.5)	0.002[e]
Febrile UTI	8 (1.9)	12 (1.5)	7 (0.5)	0.013[e]
Afebrile UTI	0 (0.0)	1 (0.1)	1 (0.1)	0.752[e]
Bacteremia	4 (1.0)	5 (0.6)	3 (0.2)	0.104[e]
Sepsis or SIRS	1 (0.2)	4 (0.5)	2 (0.1)	0.297[e]

Values are presented as mean, standard deviation or number (%).
FQ, fluoroquinolone; FM, fosfomycin; PSA, prostate-specific antigen; BPH, benign prostatic hyperplasia; UTI, urinary tract infection; SIRS, systemic inflammatory response syndrome.
[a,b]:Significantly different from group 3.
[c]:One-way analysis of variance.
[d]:Significantly different from groups 2 and 3.
[e]:Chi-square test.

(stepwise backward procedure) was performed to identify factors influencing infectious complications. Statistical significance was set at $p<0.05$ for all analyses.

RESULTS

A total of 2,595 patients undergoing TRUSPB at seven different institutions were retrospectively evaluated. According to the antibiotics used, the patients were assigned to three groups: FQ (group 1, n=417), FM (group 2, n=795), and FM and FQ (group 3, n=1,383). The antibiotics were administered for 1 or 2 days, including the day of the biopsy.

As shown in Table 1, the overall post-prostate biopsy infectious complication rate was 1.27%. The infectious complication rates were 2.4%, 1.9%, and 0.5% in groups 1, 2, and 3, respectively. The incidence of diabetes mellitus was higher in group 3 than in groups 1 and 2 (22.5% [n=311] vs. 15.3% [n=64] and 16.7% [n=133], respectively; $p<0.001$). Previous antibiotic exposure within 6 months was also more common in groups 2 and 3 than in group 1 ($p<0.001$).

As shown in Table 2, multivariable analysis identified health care utilization (adjusted odds ratio [aOR], 4.66; 95%

Table 2. Univariable and multivariable analysis of clinical parameters affecting infectious complications after prostate biopsy

Univariable logistic regression		
Variable	Unadjusted OR (95% CI)	p-value
Age	0.97 (0.93–1.01)	0.176
PSA	0.94 (0.68–1.29)	0.727
Prostate volume	1.00 (0.98–1.01)	0.967
Health care utilization	4.57 (1.85–11.3)	0.001
Health care workers	0.98 (0.13–7.33)	0.991
Travel within 4 weeks	Not estimable	0.999
Diabetes mellitus	1.15 (0.49–2.68)	0.742
Previous operation history within 6 months	3.21 (0.95–107)	0.059
Previous prostatitis history within 6 months	1.84 (0.24–13.8)	0.550
Previous UTI history within 6 months	2.92 (0.38–22.1)	0.300
Previous prostate biopsy within 12 months	Not estimable	0.999
Previous antibiotic exposure within 6 months (reference: none)		0.031
Other than quinolone	2.80 (0.97–8.16)	0.058
Quinolone	4.48 (1.03–19.5)	0.046
Local anesthetic use	2.05 (0.96–4.37)	0.061
Rectal cleansing using povidone-Iodine	0.34 (0.11–0.98)	0.047
Enema	1.28 (0.17–9.50)	0.806
Prostate biopsy specialist; urologist	1.35 (0.65–2.78)	0.410
Biopsy core number ≥12 (n, %)	1.78 (0.87–3.67)	0.114
Pathology; prostate cancer	0.95 (0.47–1.93)	0.903
Prophylactic antibiotics (reference: FQ)		0.003
FM	0.78 (0.34–1.75)	0.553
FM+FQ	0.21 (0.08–0.55)	0.001
Multivariable logistic regression		
Variable	Adjusted OR (95% CI)	p-value
Health care utilization	4.66 (1.74–12.4)	0.002
Prophylactic antibiotics (reference:FQ)		0.004
FM	1.08 (0.45–2.59)	0.860
FM+FQ	0.26 (0.09–0.69)	0.007

FQ, fluoroquinolone; FM, fosfomycin; OR, odds ratio; CI, confidence interval; PSA, prostate-specific antigen; UTI, urinary tract infection.

confidence interval [CI], 1.74–12.4; p=0.002) and combination antibiotic prophylaxis (FQ and FM; aOR, 0.26; 95% CI, 0.09–0.69; p=0.007) as predictors of post-biopsy infectious complications.

Table 3 shows detailed information for patients with infectious complications. This information included the patient group; type of infectious complications, such as acute prostatitis, bacteremia, SIRS, and sepsis; results of urine and blood culture; FQ resistance; and extended-spectrum beta-lactamase (ESBL) positivity.

DISCUSSION

A retrospective multicenter study in the Republic of Korea showed that infectious complications were reduced with a combined regimen of FM and FQ compared with FQ alone after TRUSPB. This study was extended from a single retrospective study conducted in the same country to investigate the efficacy of a combination of FM and FQ for antibiotic prophylaxis before TRUSPB [9]. Our results showed that health care utilization and a combination of FM and FQ were predictors of post-biopsy infectious complications.

As shown in Table 1, the incidence of diabetes mellitus was higher in group 3 (FQ and FM) than in group 1 (FQ alone) and group 2 (FM alone) (22.5% [n=311] vs. 15.3% [n=64] and 16.7% [n=133], respectively; p<0.001). In addition, previous antibiotic exposure within 6 months was also more common in groups 2 and 3 than in group 1 (p<0.001). Taken together, the results suggest that patients with a high risk of infection due to diabetes mellitus and previous exposure to antibiotics within 6 months may consider FM-based antibiotic prophylaxis instead of FQ alone to reduce possible infectious complications after TRUSPB.

With the increasing prevalence of FQ-resistant *Esch-*

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Table 3. Culture results of patients with infectious complications

Case	Group	Type of infectious complication	Urine culture	Blood culture	FQ resistance	ESBL positivity
1	1	AP, bacteremia	No growth	*Escherichia coli*	Yes	Yes
2	1	Sepsis	*Escherichia coli*	*Escherichia coli*	Yes	Yes
3	1	AP, bacteremia	No growth	*Escherichia coli*	Yes	No
4	1	AP, bacteremia	*Citrobacter freundii*	*Citrobacter freundii*	No	No
5	1	AP	*Escherichia coli*	No growth	No	No
6	2	Sepsis	*Klebsiella* spp.	No growth	Yes	Yes
7	2	AP	*Escherichia coli*	No growth	No	No
8	2	AP, bacteremia	No growth	*Klebsiella* spp.	No	No
9	2	AP	*Escherichia coli*	No growth	Yes	Yes
10	2	AP, bacteremia	No growth	*Klebsiella* spp.	No	No
11	2	AP	*Klebsiella* spp.	No growth	No	No
12	2	AP, SIRS	*Klebsiella* spp.	No growth	Yes	Yes
13	2	Sepsis	*Klebsiella* spp.	*Klebsiella* spp.	No	No
14	2	AP	*Escherichia coli*	No growth	Yes	Yes
15	2	AP, bacteremia	No growth	*Klebsiella* spp.	No	No
16	3	AP, SIRS	*Escherichia coli*	No growth	Yes	No
17	3	Sepsis	No growth	*Staphylococcus aureus*	Yes	NR
18	3	AP	*Escherichia coli*	No growth	No	No
19	3	AP	*Escherichia coli*	No growth	NR	NR
20	3	AP, bacteremia	No growth	*Escherichia coli*	Yes	No
21	3	AP, bacteremia	*Escherichia coli*	*Escherichia coli*	Yes	Yes

Group 1=FQ; Group 2=FM; Group 3=FQ+FM.
FQ, fluoroquinolone; ESBL, extended-spectrum beta-lactamase; NR, not reported; AP, acute prostatitis; SIRS, systemic inflammatory response syndrome; FM, fosfomycin.

erichia coli, there is an increased need for an alternative prophylaxis to FQ before TRUSPB [7], which is stated in the 2017 American Urological Association guidelines. FM trometamol has emerged as an alternative prophylactic antibiotic to FQ for TRUSPB owing to its effective penetration into prostatic tissue, less *E. coli* resistance, and ease of oral use with fewer adverse effects [11-14].

Although several studies examining the effectiveness of FM compared with FQ showed that the use of FM alone would be an attractive alternative to FQ as prophylaxis for TRUSPB [11-14], this was not the case in the Republic of Korea. However, a combination of FM and FQ was observed to be effective in reducing post-biopsy infections [9], which may be attributed to regional differences in the antibiotic resistance pattern [6].

According to a study that examined the drug susceptibility profiles of ESBL-producing bacteria in a single center in the Republic of Korea, *E. coli* was more susceptible than *Klebsiella* to FM [10]. In addition, ciprofloxacin, levofloxacin, trimethoprim-sulfamethoxazole, and ampicillin-clavulanate appeared to be the least active against pathogens [10].

As shown in Table 3, patients in group 2 who received FM alone showed susceptibility to *Klebsiella* spp. Although FM has a very low minimum inhibitory concentration (MIC $\leq$ 4 μg/mL) against uropathogens, some antibiotic-resistant strains might exist [15]. This may explain the greater effectiveness of a combination of FM and FQ compared with FM alone or FQ alone in reducing post-biopsy infections.

To the best of our knowledge, thus far, two studies have compared FQ monotherapy with a combination of FM and FQ. One of them was carried out in the Republic of Korea, which revealed the clinical efficacy of a combined regimen of FM and FQ in reducing overall infectious complications [9]. The other study focused on the incidence of sepsis within 1 month after TRUSPB in Canada, which also showed that the use of FM and FQ together was more effective than FQ alone in decreasing sepsis [16].

Following a study that evaluated the efficacy of a combined regimen of FM and FQ as prophylaxis for TRUSPB in a single center in the Republic of Korea, this multicenter study was designed to investigate the effectiveness of FM-based antimicrobial prophylaxis for TRUSPB [9]. A total of 2,595 patients from seven tertiary hospitals located in the Republic of Korea were enrolled, and the data were retrospectively analyzed. One-way ANOVA and chi-square tests revealed that the use of FM and FQ together rather than

FM alone was more effective in reducing the infectious complication rate.

Because of its retrospective design, this study had several limitations. First, there was an imbalance in patient characteristics. In particular, the rate of well-known reported risk factors such as health care utilization and diabetes mellitus could not be controlled. Because FM-based antibiotic prophylaxis was used for the patients with high rates of diabetes mellitus in group 3, diabetes mellitus may have been excluded from the risk factors.

Second, there was inconsistency in several factors such as who performed the biopsy and whether pre-biopsy rectal cleansing was done. In general, those who performed biopsies were either urologists or radiologists; thus, biopsy skill may have been uneven among the seven different institutions. In the case of rectal cleansing using povidone-iodine, most of the providers who performed the biopsy did rectal cleansing just before the biopsy (group 1, 100%; group 2, 87%; group 3, 100%).

Regarding the use of antibiotics, there were inconsistencies in the time of use, the number of doses, the route of administration, and the kind of antibiotics used by hospitals, which may have affected the study results. Depending on the institutions, patients received antibiotics for only 1 day (the day before biopsy or the day of biopsy) or for 2 days (the day of biopsy and the day before or after). The route of administration of FQ could be either oral or intravenous because of equivalent serum drug concentrations of oral and intravenous FQ. The kind of FQ used in the study differed by hospital. Because the use of levofloxacin is restricted in the Republic of Korea, only one institution used levofloxacin and the other six institutions used ciprofloxacin. To reduce the bias related to antibiotics use, a prospective randomized trial that controls the use of antibiotics such as the timing of antibiotic administration (e.g., the night before biopsy or the morning of the procedure), the number of doses (1 or 2 doses of antibiotics), the route of administration (oral or intravenous), and the kind of antibiotics (ciprofloxacin or levofloxacin) should be carried out.

CONCLUSIONS

The results of this multicenter retrospective study of the efficacy of prophylactic antibiotics showed that co-administration of FM and FQ was associated with reduced post-biopsy infectious complications. Although post-biopsy infections are rare, the use of appropriate antibiotics according to the regional antibiotic resistance pattern is crucial if antibiotic prophylaxis is to reduce the incidence of infectious complications, especially life-threatening urosepsis. To confirm the clinical efficacy of FM-based antibiotics, further research is needed.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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AUTHORS' CONTRIBUTIONS

Research conception and design: Seung IL Jung. Data acquisition: Seung Il Jung, Eu Chang Hwang, Tae-Hyoung Kim, Sangrak Bae, Jung-Sik Huh, Seung-Ju Lee, Hong Chung, and Hoon Choi. Statistical analysis: Eu Chang Hwang. Data analysis and interpretation: Eu Chang Hwang and Seung Il Jung. Drafting of the manuscript: Do Gyeong Lim. Critical revision of the manuscript: Do Gyeong Lim and Seung Il Jung. Administrative, technical, or material support: Seung Il Jung. Supervision: Seung Il Jung. Approval of the final manuscript: all authors.

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