

Original Article

Ofloxacin prophylaxis can reduce bacteriuria in patients with sterile urine who underwent extracorporeal shockwave lithotripsy (ESWL) for treatment of upper urinary tract stone: a randomized controlled trial

Tri Hanprasertpong¹, Tasanee Klinhom², Nidtaya Teskumjon², Darunee Boongthong², Wattanachai Ungjaroenwathna¹

¹Division of Urology, Department of Surgery, ²Department of Nursing, Sunpasitthiprasong Hospital, Ubon Ratchathani, Thailand

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Abstract

Objective: Urinary tract infections (UTI) are a serious complication in patients undergoing extracorporeal shock wave lithotripsy (ESWL). While antibiotic prophylaxis has proven beneficial in various surgical procedures, this study aimed to evaluate its benefits in ESWL patients with sterile urine.

Materials and Methods: This double-blind, randomized clinical trial was conducted in patients with upper urinary tract stones admitted for ESWL at Sunpasitthiprasong Hospital, Thailand. Patients were randomly assigned to receive either ofloxacin (200 mg) or placebo one hour before ESWL. The incidence of UTI, bacteriuria, pyuria, and patient characteristics including gender, age, underlying conditions, and stone location were assessed in both groups.

Results: Data were collected from a total of 598 patients who were admitted for ESWL between 2008 and 2015. No cases of UTI were observed, and the incidence of pyuria did not differ significantly between the two groups ($p = 0.399$). However, bacteriuria was found in 11 patients, with 2 (0.60%) in the antibiotic group ($n = 310$) and 9 (3.10%) in the placebo group ($n = 286$), showing a statistically significant difference ($p = 0.023$).

Conclusions: Ofloxacin prophylaxis in sterile urine ESWL patients showed a benefit in reducing the incidence of bacteriuria but incidence of UTI and pyuria showed no change.

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Corresponding author: Wattanachai Ungjaroenwathna

Address: Division of Urology, Department of Surgery, Sunpasitthiprasong Hospital, Ubon Ratchathani 34000, Thailand

E-mail: wattanachaiu@yahoo.com

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Introduction

Extracorporeal shockwave lithotripsy (ESWL) is a minimally invasive procedure that uses shock waves to break down stones in the upper urinary tract. Compared to percutaneous nephrolithotomy (PCNL) and retrograde intrarenal surgery (RIRS), ESWL results in shorter hospital stays, quicker treatment times, and fewer complications.¹

Standard laboratory tests for bacteriuria and pyuria are used to confirm the presence of a urinary tract infection (UTI) in patients with clinical symptoms suggestive of a UTI, such as increased urinary frequency or urgency, hematuria, dysuria, suprapubic pain, fever, chills, severe pain, or sepsis.^{2,3} UTI are a significant complication following urological procedures, including ESWL. UTI involves the colonization of the urinary system by uropathogenic bacteria, leading to different degrees of inflammatory response. Common clinical symptoms of UTI can involve organs, pyuria and bacteriuria. UTIs can be present in ESWL patients who have kidney injury and vascular disruption, which may allow bacteria in the urine or stone to enter the bloodstream and also cause a significant rise in intrapelvic pressure during shockwave treatment.⁴ The use of routine prophylactic antibiotics in ESWL remains a topic of debate. Several studies, including randomized controlled trials, have shown no benefit from using prophylactic antibiotics in patients who do not have a preoperative UTI or infection-related stones.⁵

Canadian Urological Association (CUA) guidelines suggest that antibiotic prophylaxis for ESWL does not significantly reduce the risk of UTI and fever in patients undergoing ESWL, but should be considered in patients at high risk of infectious complications.⁶ The American Urological Association (AUA) guidelines recommend that noninvasive procedures such as shock wave lithotripsy do not require antimicrobial prophylaxis if the pre-procedural urine microscopy shows as negative for infection.⁷ The European Association of Urology (EAU) guidelines on urological infections state that for patients undergoing ESWL who have no evidence of bacteriuria, no prophylaxis recommended.⁸

This study aimed to assess the benefits of antibiotic prophylaxis in patients with sterile urine undergoing ESWL. The primary objective was to

determine the incidence of UTI, which included bacteriuria, pyuria, and clinically diagnosed UTI. The secondary objective focused on the identification of risk factors that may predispose patients to develop UTI after ESWL.

Material and Methods

This study was a randomized, double-blind, and parallel clinical trial with a 1:1 allocation ratio. The trial received approval from the Ethics Committee of Sunpasitthiprasong Hospital, Ubon Ratchathani, Thailand (ECSPS: 017/2551). All procedures were conducted in accordance with good clinical practice guidelines and the Declaration of Helsinki. Written informed consent was obtained from all participants before enrollment.

Between September 2008 and June 2015, patients with upper urinary tract stone diagnosed by plain film kidney, ureter and bladder (KUB) with ultrasonography of kidney, intravenous pyelography (IVP) or computer tomography (CT scan) with negative urine culture before ESWL (no growth/sterile) with planned ESWL in Sunpasitthiprasong Hospital were invited to participate in this study. Inclusion criteria were: (1) patients aged 18 years or older, and (2) patients with opaque kidney stones less than 2 cm or opaque ureteric stones less than 1 cm. Exclusion criteria were: (1) immunocompromised patients (e.g., those with liver cirrhosis, HIV, or on immunosuppressive therapy), (2) pregnant or breastfeeding women, (3) patients without a double J stent, ureteric catheter, Foley catheter, or nephrostomy tube, (4) patients with known allergies to quinolones, (5) patients who had received antibiotics within four weeks prior to ESWL, and (6) those with prosthetic devices such as valvular heart prostheses.

Patient characteristics including gender, age, underlying medical conditions, and stone location were recorded. Preoperative evaluation included a thorough assessment of clinical symptoms and signs, laboratory tests (complete blood count, blood chemistry, urinalysis, and urine culture), chest X-ray, and a plain KUB film.

All participants were admitted to the hospital one day before until one day after undergoing ESWL. Ward nurses used a random number list and sealed envelope technique to assign patients to either the experimental group (receiving ofloxacin 200 mg) or the placebo group. Ofloxacin (200

mg) or placebo was administered to patients one hour before ESWL.

All ESWL procedures were performed using the SIMENS Lithostar MODULARIS machine. For renal calculi, the energy protocol involved delivering 3,000-3,500 shockwaves at a rate of 90 per minute (maximum energy level 2.5). For ureteric calculi, 3,500-4,000 shockwaves were delivered at the same rate, but with a maximum energy level of 3.0.

One day after ESWL, urine samples were collected from patients for urinalysis and urine culture. The incidence of UTI, bacteriuria (any bacterial growth), pyuria, and clinical UTI was assessed in both groups. At the one month follow up, UTI symptoms, stone-passing history, and plain KUB imaging were evaluated. Additionally, any risk factors that predisposed patients to UTI following ESWL were explored.

The primary aim of the study was to assess the efficacy of prophylactic antibiotics in reducing post-ESWL bacteriuria, pyuria, and UTI. The sample size calculation adhered to a 1:1 allocation ratio. Based on an alpha value of 0.05 and a beta value of 0.2, with expected bacteriuria rates of 2.00% in the prophylaxis group and 7.00% in the untreated group⁹, a minimum of 269 patients per group was required to detect a statistically significant difference. After application of continuity correction, the sample size was adjusted to 308 patients per group. The authors used 320 patients per group to take potential dropout into consideration.

Simple randomization was used to allocate patients to the experimental (ofloxacin 200 mg)

or placebo group. A coordinating nurse then re-arranged the sequence of paper sheets and packed each into sealed envelopes to ensure blinding. Ofloxacin (200 mg) or placebo was administered in a double-blind, randomized manner, one hour before ESWL. Only the ward nurses were aware of the assignment through the sealed-envelope technique, while the authors, surgeons, scrub nurses, technicians, and participants remained blinded.

Data were analyzed using SPSS version 25th, with statistical tests including chi-square, independent t-tests, and multivariate logistic regression. A p-value of <0.05 was considered statistically significant

Results

Six hundred and forty patients were initially enrolled onto this study, with a total of 598 patients being included in the study. The cut off dates were between 2008 and 2015. Of these, 312 patients were assigned to the experimental group, and 286 patients were assigned to the control group. The demographic data are presented in Table 1, with no statistically significant differences observed between the two groups. Pyuria in the pre-ESWL urine analysis was identified in 38.10% of patients in the experimental group and 31.80% in the control group ($p = 0.106$). After ESWL, pyuria was present in 46.80% of the experimental group and 43.40% of the control group ($p = 0.655$), again showing no significant difference.

None of the patients in either group developed clinical signs of a UTI the day after ESWL or at the one-month follow-up. Post-ESWL

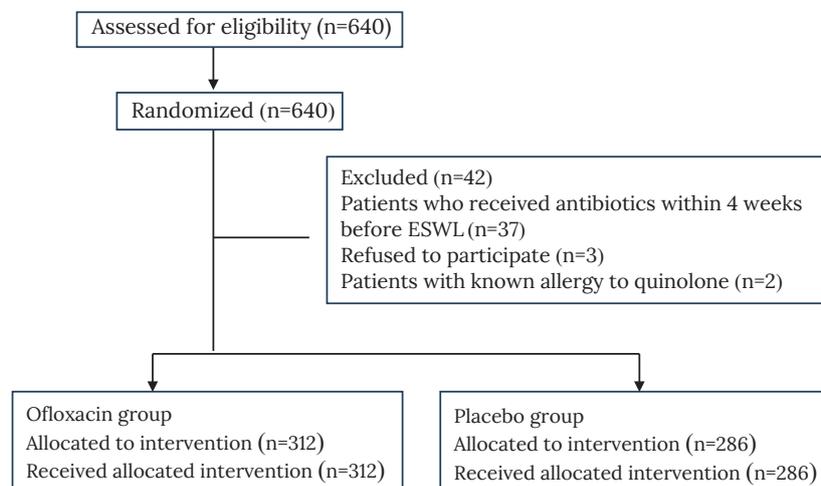


Figure 1. Participant flow

bacteriuria was detected in fewer patients in the experimental group (2 patients) compared to the control group (9 patients), and this difference was statistically significant ($p = 0.023$). Only one patient in the experimental group developed a hypertensive disorder. The bacteria identified

in urine samples were either *Escherichia coli* or *Proteus* spp. However, there was no significant difference between the two groups in terms of bacteriuria with pyuria. Further details are shown in Table 2 and Table 3.

Table 1. Demographic data in ofloxacin and placebo group

	Ofloxacin Group (n=312)	Placebo Group (n=286)	P-value
Male gender n (%)	248 (79.50)	232 (81.10)	0.616
Age [years] mean (SD)	50.40 (12.14)	52.58 (11.37)	0.459
Underlying disease n (%)	40 (12.90)	33 (11.50)	0.099
Renal calculi n (%)	290 (93.60)	265 (92.70)	0.652
Pre-ESWL pyuria n (%)	119 (38.10)	91 (31.80)	0.106
Co-morbidity n (%)			0.099
DM	0(0.00)	4 (1.40)	
HT	10 (3.20)	17 (5.90)	
Gout	0 (0.00)	1 (0.30)	
Asthma/COPD	1 (0.30)	2 (0.70)	
≥ 2 underlying diseases	14 (4.50)	9 (3.10)	

ESWL = extracorporeal shock wave lithotripsy, DM = diabetes mellitus, HT = hypertension, COPD = chronic pulmonary obstructive disease

Table 2. Urine culture and urine analysis results on post-ESWL day 1

	Ofloxacin Group (n=312)	Placebo Group (n=286)	P-value
Bacteriuria n (%)	2(0.60)	9 (3.10)	0.023
Post-ESWL pyuria n (%)	146 (46.80)	124 (43.40)	0.712
Bacteriuria with pyuria n (%)	1 (50.00)	5 (55.60)	0.655

ESWL = extracorporeal shock wave lithotripsy, DM = diabetes mellitus, HT = hypertension, COPD = chronic pulmonary obstructive disease

Table 3. Bacteriuria on post-ESWL day 1

No	Groups	Genders	Age years	Underlying diseases	Stone location	Pre-operative pyuria	Post-operative pyuria	Type of bacteriuria
1	Placebo	Male	68	None	Kidney	No	Yes	<i>E. coli</i>
2	Ofloxacin	Male	54	None	Kidney	No	Yes	<i>E. coli</i>
3	Placebo	Female	55	None	Kidney	Yes	No	<i>E. coli</i>
4	Placebo	Male	59	None	Ureter	Yes	Yes	<i>E. coli</i>
5	Placebo	Male	68	None	Kidney	Yes	Yes	<i>E. coli</i>
6	Placebo	Female	65	None	Kidney	Yes	No	<i>Proteus</i>
7	Placebo	Male	76	None	Kidney	Yes	Yes	<i>E. coli</i>
8	Ofloxacin	Male	54	Hypertension	Kidney	No	No	<i>E. coli</i>
9	Placebo	Male	49	None	Kidney	Yes	Yes	<i>Proteus</i>
10	Placebo	Male	53	None	Kidney	No	No	<i>Proteus</i>
11	Placebo	Male	38	None	Kidney	No	No	<i>E. coli</i>

ESWL = extracorporeal shock wave lithotripsy

Discussion

Shafi et al studied the impact of antibiotic prophylaxis on the prevention of UTI in patients with sterile urine before extracorporeal shock wave lithotripsy and found that incidence of bacteriuria was 10.13% and 13.01% in the treatment and control groups, respectively. The incidence of bacteriuria after ESWL was generally low in patients and the use of antibiotic prophylaxis resulted in no significant difference with regard to the reduction of the incidence of bacteriuria after ESWL.¹⁰ In a prospective cohort study by Moreno et al, urine culture was positive in 8.50% of patients 7 days after ESWL, 2.10% of these patients being symptomatic and the rest asymptomatic. They also found that elderly patients were more at risk of bacteriuria after ESWL, hence more at risk of possible infectious complications.¹¹ Therefore, it is evident that antibiotic prophylaxis before ESWL is not necessary in patients without risk factors and with negative urine culture.¹²⁻¹⁵

In the present study, the incident of bacteriuria was 0.60% in the ofloxacin group and 3.10% in the placebo group, the results being statistically significantly difference ($p = 0.023$). However, no significant difference was found in the incidence of UTI with regard to pyuria ($p = 0.655$). The lower incidence of bacteriuria when compared to other studies is most likely because one of the inclusion criteria was sterile urine. In some studies the term negative bacteriuria was used when the mean growth of bacteria in the urine of patients was less than 10^5 bacterial colonies per milliliter.⁹⁻¹³ The cause of post-ESWL day 1 bacteriuria could be explained by some patients having an infected stone, and the reporting of the different pathogens for stone or renal pelvic urine or urinary bladder urine in the same patients could be misleading. The incidence of bacteria in the stone or renal pelvic urine or urinary bladder urine did not always show a correlation in nephrolithiasis patients.^{16,17}

The focus of this study was on the short term results during the admission period, specifically bacteriuria, pyuria, and clinical UTI post-ESWL on the day after ESWL and then one month after ESWL. The authors were not able to explore any risk factors that predisposed patients to UTI following ESWL as there was no evidence of the complete pattern of UTI in any participants. There was no evidence of any UTI in this study which

might be a result of the inclusion of only inclusion immune-competent individuals. Approximately 50.00% of participants with bacteriuria, also had pyuria. The tests used for bacteriuria, pyuria, and clinical UTI may not be the most sensitive tests for the detection of UTI.

In clinical practice, some urologists just give routine oral antibiotic prophylaxis in ESWL patients as results of urine culture may be delayed for at least 24 hours. However, in this study the urine samples were tested before the ESWL so there was the assurance that the antibiotic prophylaxis in ESWL was not necessary for uncomplicated patients who had sterile urine. Antibiotic prophylaxis should be considered in immunocompromised patients because bacteriuria is more likely to emerge after ESWL. All relevant evidence needs to be considered, balancing benefit and harm, to ensure the best outcome for the patient.

The authors suggest that in immunocompetent urolithiasis patients who have sterile urine who are scheduled to undergo ESWL there is no need for antibiotic prophylaxis. However, in immunocompromised urolithiasis patients, urinary catheterized patients and patients with prosthetic devices prophylaxis needs to be considered.

Conclusion

The use of ofloxacin prophylaxis in sterile urine ESWL patients showed benefits in reducing the incidence of bacteriuria but did not affect UTI or pyuria rates. In immunocompetent patients, prophylaxis is largely unnecessary.

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Conflict of Interest

The authors declare no conflict of interest.

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