

Clinical Evaluation of Ofloxacin in Symptomatic Lower Urinary Tract Infection

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Abstract

This study was aimed to evaluate the clinical effectiveness and safety of ofloxacin in the treatment of symptomatic lower urinary tract infection in female patients. The study was conducted at Department of Obstetrics and Gynecology, Songklanagarind Hospital, during March 1 to September 30, 1986. We treated 40 female patients, diagnosed as symptomatic lower urinary tract infection by urine culture and antibody-coated bacteria test, with ofloxacin in the dosage of 200 mg. daily for 3 days. All patients returned to follow up 7-14 days after the treatment. The relief of clinical symptoms was shown in 38 out of 40 patients. Bacterial eradication was 31 in 33 patients. No adverse drug reaction was reported. In our study, ofloxacin has shown to be a useful antibacterial agent in the treatment of symptomatic lower urinary tract infection in terms of high effectiveness, convenience and safety.

เรื่องย่อ

การศึกษาประสิทธิผลของ ofloxacin ในการรักษาโรคติดเชื้อทางเดินปัสสาวะส่วนล่างชนิดมี อาการ

สมทิศ สุทธิจุมรูณ พ.บ., วีระพล จันทร์ดียิ่ง พ.บ.

หน่วยโรคติดเชื้อ ภาควิชาสูติศาสตร์และนรีเวชวิทยา คณะแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์ วิทยาเขตใหญ่ สงขลา 90112

วารสารโรคติดเชื้อและยาต้านจุลชีพ 2531; 5: 184-186.

การศึกษานี้มีจุดมุ่งหมายเพื่อประเมินประสิทธิผลและความปลอดภัยของยาโอฟลอกซาซิน ในการรักษาหญิงที่เป็นทางเดินปัสสาวะส่วนล่างอักเสบ ที่ภาควิชาสูติศาสตร์-นรีเวชวิทยา โรงพยาบาล สงขลานครินทร์ ตั้งแต่วันที่ 1 มีนาคมถึงวันที่ 30 กันยายน พ.ศ. 2529 ผู้ป่วย 40 รายได้รับยาโอฟลอกซาซิน วันละ 200 มก. เป็นเวลา 3 วัน หลังการรักษา 7-14 วันอาการดีขึ้น 38 ใน 40 ราย แบคทีเรียถูกกำจัดไป 31 ใน 33 ราย ผู้ป่วยไม่เกิดผลข้างเคียงจากยา

INTRODUCTION

Quinolones were introduced in the treatment of urinary tract infection in 1963,¹ nalidixic acid being the first compound of this series to be reported. Since then some hundred other quinolone derivatives have been synthesized and studied but at the moment less than twenty of them are either investigated or marketable.

Ofloxacin is a new pyridonecarboxylic acid deri-

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vative showing very interesting features in comparison to the newest compounds of the same group. In fact ofloxacin seems to have a broad spectrum and strong bactericidal activity together with a low appearance rate of natural resistances and high effectiveness in various infections of different apparatus (in fact the drug achieves high concentrations in blood and urine).¹

Among adult women, acute uncomplicated urinary tract infection is the most common of all bacterial infections. In the past, most women with acute uncomplicated urinary tract infection had been treated with antimicrobial agent, multiple daily-dose re-

gimen for a period of 1 to 2 weeks. Such therapy has yielded a success rate of 85% but some of the commonly employed agents cause side effects (drug rash, vaginal candidiasis and diarrhea) in more than 30% of the patients.² Short course antibacterial agent offers the possible advantages of increased patient compliance, reduced risk of drug toxic reaction, reduced alteration of the gastrointestinal and vaginal flora, and reduced cost.^{3,4} Since urinary tract infection is very common and ofloxacin is recently available, we had the opportunity to study the efficacy and tolerability of ofloxacin, in the treatment of this infection.

PATIENTS AND METHODS

Ambulatory, nonpregnant women between the ages of 22 to 51 years with acute, uncomplicated lower urinary tract infection, seen at Songklanagarind Hospital, Songkla, were eligible for entrance into the study. All patients accepted, had symptoms of frequency, dysuria and suprapubic pain with documented pyuria (10 WBCs or more per high-power field) and presence of bacteria in the spun, unstained urinary sediment (more than 20 organisms per high-power field). Patients were excluded if they had symptoms of acute toxicity with temperature higher than 38°C; had flank pain; had history of cardiac, hepatic or renal disease; were pregnant or nursing; were previously treated by antimicrobial within 7 days; and on pelvic examination shown to have genital tract infection. Clean-voided midstream urine culture was performed and those who had positive antibody-coated bacteria testing (suggesting upper urinary tract infection) were excluded. Patients then were assigned to receive ofloxacin (100 mg) two tablets daily for 3 days.

For purposes of analysis, patients with documented pyuria (10 WBCs or more per high-power field) and significant bacteriuria (100,000 colonies or more per milliliter of urine) were diagnosed as having true bacterial infection. Patients without significant bacteriuria were diagnosed as having acute urethral syndrome. Repeated urine cultures were obtained 7-14 days after the treatment. The parameters of evaluation were clinical outcome (scored as healed, improved, not modified/worsened), efficacy (scored as good = sterile urine after treatment, poor = 100,000 colonies or more after treatment). Side effects and toxicity were identified by questioning of symptoms and laboratory tests (complete blood count, BUN, creatinine, SGOT, SGPT) were performed on every patient at each visit.

Detection of antibody-coated bacteria

The presence of antibody-coated bacteria in urine sediments were detected by the method previously described by Harding and co-workers.⁵ In

brief, one drop of washed urine sediments was fixed on a glass slide and was incubated with one drop of 1:5 goat fluorescein-conjugated antihuman gammaglobulin (Behringwerke AG, Germany) at 37°C for 30 minutes. Later, washed slides were examined for fluorescence under oil immersion objectives (Reichert Fluorescence Illuminator, Model "Binolux 3"). The criteria used for positive test is noting of at least five uniformly fluorescing bacterial cells. The positive and negative controls were included in each test. Antibody-coated bacteria test was used in this study to exclude upper urinary tract infection. False negative rate was 5% as reported by Thomas et al.⁶

RESULTS

Forty-two patients were diagnosed as symptomatic lower urinary tract infection by urinalysis, the symptoms were shown in Table 1, the bacteriological results and antibody-coated bacteria test were shown in Table 2.

After treatment, the clinical outcome and efficacy were shown in Table 3.

Adverse reaction

No gastrointestinal tract disturbances such as; stomach discomfort, heart burn, nausea, vomiting and abdominal pain or hypersensitivities to ofloxacin such as; eruption, itching and lip swelling were recorded.

Laboratory tests — complete blood count, BUN, creatinine, SGOT, SGPT were not significantly changed.

Table 1 Subjective symptoms of 42 patients before treatment.

Symptoms	No. (42)
Dysuria	31/42
Frequency of urination	35/42
Suprapubic pain	20/42

Table 2 Bacteriological and antibody-coated bacteria test results

Bacteria	No. of patients (42)	
	ACB negative	ACB positive
<i>E. coli</i>	21	2
Staph. coagulase negative	7	—
<i>S. saprophyticus</i>	5	—
No growth	7	—
Total	40	2

Table 3 Clinical outcome and efficacy of ofloxacin in therapy of lower urinary tract infection.

		No.
Clinical outcome	Healed	38
	Improved	—
	Not modified/worsened	2
Clinical outcome	= 95%	
Efficacy	Good	31
	Poor	2
Efficacy	= 93.9%	

DISCUSSION

Of forty-two patients, two patients were excluded because of positive antibody-coated bacteria test as mentioned above. Although the antibody-coated bacteria test had been unavailable in general practice, we used this test to exclude upper urinary tract infections. In the group of negative antibody-coated bacteria test (lower urinary tract infection), *E. coli* was the most common bacteria isolated from urine culture, followed by *Staph. coagulase negative* and *S. saprophyticus* (Table 2). In general, uncomplicated lower urinary tract infection responds to low doses and short course antimicrobial therapy³ which is our study, the bacteria were eradicated in 31 out of 33 patients (93.9%) after treatment. The bacteria were found with the persistence of clinical symptoms (Table 3) in only 2 of 33 patients.

Many antibiotics (ampicillin, sulfonamides, tetracycline, penicillin, cephalosporins, nitrofurantoin, aminoglycosides) achieved cure rate of approximately 80-85 per cent.^{2,3} However, the quinolone compound, ofloxacin was more effective and might be of more benefit than conventional therapy because of patient's compliance. Short course regimen of ofloxacin (5 days) achieved good results in lower urinary tract infection.⁷

Nevertheless, after completion of therapy and follow up cultures, if the bacteriuria was not eradicated the patients should be evaluated for the other underlying causes; urethral stenosis, incomplete emptying of bladder, the anatomical defects or other pathogenic organisms.

In the group of negative urine culture (acute urethral syndrome), Stamm et al.,^{3,8,9} Tolkoﬀ-Rubin et al.¹⁰ demonstrated the usefulness of antimicrobial

therapy, which in our study all seven patients were relieved of clinical symptoms. No adverse drug reaction or abnormal laboratory tests were reported.

CONCLUSION

In our study, ofloxacin has shown to be a useful antibacterial agent in the treatment of lower urinary tract infection in terms of high effectiveness, convenience and safety similar to other studies.^{11,12}

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