

# An observational study to monitor the efficacy and tolerability of levofloxacin 500 mg once daily for treatment of chronic bacterial prostatitis in Saudi Arabia

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## Abstract

**Introduction:** Chronic prostatitis is a common urological problem in men <50-year-old. Untypical uropathogens and an intact blood prostate barrier cause difficulty in using antibiotics to treat the infection.

**Patients and Methods:** In this open-label, observational study, levofloxacin 500 mg was given once daily for 28 days for treatment of chronic prostatitis. The primary efficacy measurement was the disappearance of all pre-treatment symptoms. Efficacy analysis is based on the per protocol population (PPP), all other analyses use the intent to treat (ITT) population.

**Results:** The ITT included 154 men and the PPP included 151 (results are for the ITT unless otherwise indicated). Mean age was  $42 \pm 9$  years, common concomitant conditions were diabetes mellitus (7%) and hypertension (5%). All symptoms decreased at day 28. Notably, the rate of dysuria decreased from 86.1% to 10.6%, painful ejaculation from 71% to 2.6% and perineal discomfort from 60.3% to 7.3%. A cure of condition was identified in 58.9%. No treatment failures were reported. Physician-reported adherence to study medication was 96.8%.

**Conclusion:** Levofloxacin appears to be an effective antibiotic for treating symptoms of chronic bacterial prostatitis. Levofloxacin was well-tolerated in this population.

**Key Words:** Chronic bacterial prostatitis, genito urinary infections, levofloxacin

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## INTRODUCTION

Chronic prostatitis is the most common urological condition in men under 50 years of age. According to the National Institutes of Health, prostatitis is classified as acute bacterial prostatitis (category I), chronic bacterial prostatitis (CBP) (category II), chronic pelvic pain

syndrome (category III) and asymptomatic inflammatory prostatitis (category IV). Category II is defined clinically as recurrent urinary tract infection caused by bacteria localized to the prostate between episodes of infection.<sup>[1]</sup>

There are differences of opinion about the treatment of men with bacteria localized to the prostate when the causative bacteria are not typical uropathogens.<sup>[2]</sup> These atypical uropathogens include Gram-positive bacteria and anaerobes. Gram-positive bacteria, such as coagulase negative staphylococci, can be present in prostatitis. The mainstay of treatment for category II prostatitis is antibiotics. Because the “blood prostate” barrier is intact in men with chronic prostatitis, antibiotics with a high pKa and high lipid solubility represent optimal treatment. Classes of antibiotics with these features include the sulfas,

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macrolides tetracyclines and quinolones which are the most commonly used antibiotic in prostatitis.

Antimicrobial agents have a clinical benefit in men with CBP. The objective of this observational study, therefore, was to evaluate the use of levofloxacin 500 mg given once daily for 28 days on reducing symptoms of chronic prostatitis.

## PATIENTS AND METHODS

This was an open-label, observational study which was conducted in 20 clinical sites in Saudi Arabia.

Men who were eligible for the study received levofloxacin 500 mg once daily orally which was prescribed by the attending physician in the setting of routine medical management of CBP. The implementation of any supplemental treatments was at the discretion of the attending physician. Concomitant medications were permitted.

Eligible for the study were men 18 years of age or older with a clinical diagnosis of chronic prostatitis with clinical signs and symptoms of prostatitis including a soft, tender prostate without noticeable nodularity. The presence of one or more of the following symptoms was necessary for study enrollment: Dysuria, suprapubic discomfort, painful ejaculation, low back pain, perineal discomfort, urinary frequency, urinary urgency, urinary hesitancy, decreased urinary stream, urinary retention, pain on digital examination, perineal tenderness and fever or chills. Additional eligibility requirements were a history of chronic prostatitis, defined as symptomatic prostatitis, a leucocyturia with  $\geq 10$  white blood cell/high-power field (WBC/HPF)  $\times 400$  and laboratory evidence of prostatitis. The main exclusion criteria were: Parenteral therapy for the treatment of CBP, a transurethral prostatectomy within the previous 6 months, any concomitant medication affecting bladder or prostate function and known prostatic carcinoma.

Study participants were assessed at baseline and again at day 28 for clinical symptoms of CBP.

The primary objective of the study was to assess the clinical response to levofloxacin in terms of cure, defined as the disappearance of all pre-treatment symptoms. Secondary objectives were to evaluate the microbiological efficacy, defined as eradication rate based on microbiologically evaluable participants 1 month after treatment with levofloxacin. The per protocol population (PPP) is used to assess the primary objective and the intent to treat (ITT) is used for the assessment of all other objectives and measured variables. Collected data were analyzed using mean, median, standard deviation and range for continuous parameters and counts and percentages for categorical parameters.

## RESULTS

### Participants

In total, 160 men were enrolled in the study. Of these, six did not fully meet the inclusion criteria and were excluded from any data analysis. The infringements of inclusion criteria were age  $< 18$  or age not recorded (four participants) and weight  $< 40$  kg or weight not recorded (two participants). Three patients were lost to follow-up and hence did not complete the study protocol. The ITT comprised 154 patients and the PPP 151.

Participant average age was  $42 \pm 9$  years (range, 20-67 years). Concomitant medical conditions were present in 40 of 154 participants (26%). The most common condition was diabetes mellitus (7%) followed by hypertension (5%) and infertility (3%). Similarly, 43% of the study population was taking concomitant medications. The most commonly taken medications were alfuzosin (5%), ciprofloxacin (4%) and bisoprolol (3%).

The most common symptoms of CBP at study enrollment were: Dysuria, 87% (134/154); pain on digital examination, 77% (118/154); and urinary frequency, 74% (114 of 154 men). At the time of enrollment, 79% of participants (122/154) had leucocyturia  $\geq 10$  WBC/HPF. More detailed laboratory results are presented in the Table 1.

All participants received levofloxacin 500 mg and five participants were prescribed antibiotics in addition to the study agent.

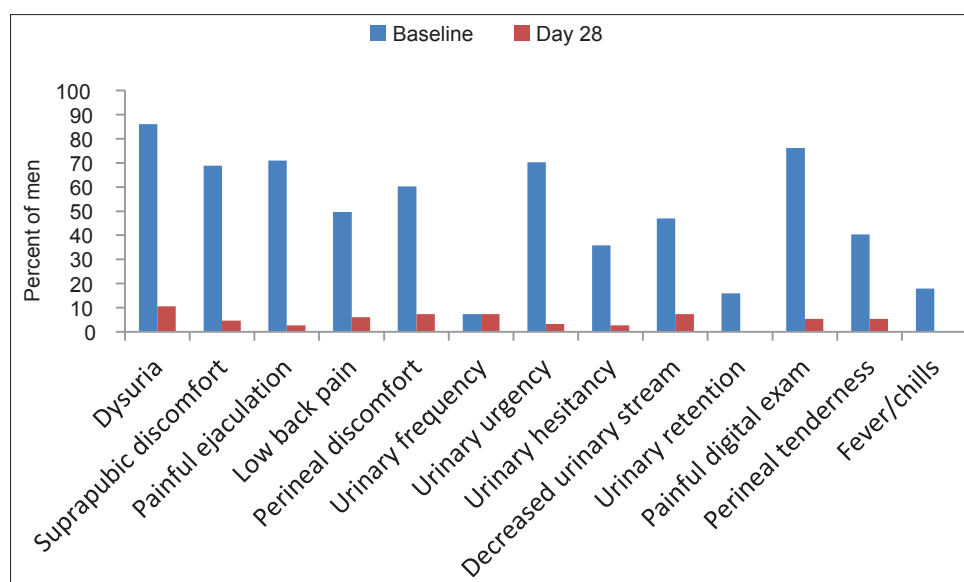
### Treatment efficacy

Based on the PPP, the cure rate was 58.9% (89 of 151 patients) (95% confidence interval: 58.9-66.5%). The rate of participants with an improvement in symptoms was 38.4% (58 of 151). A decrease in the rate of all symptoms was observed [Figure 1]. The most commonly assessed symptoms at day 28 were dysuria at 10.6% and perineal discomfort, urinary frequency and decreased urinary stream each reported at a rate of 7.3%.

**Table 1: Laboratory analyses at baseline and day 28 (N=154)**

Laboratory test	Baseline %	Day 28%
Leucocyturia $\geq 10$ WBC/HPF	81	19
VB2		
Sterile	37	96
Non-sterile	63	4
VB3		
VB3 or EPS specimen has $> 10^3$ bacterial count and is different from organism in VB2	58	31
VB3 or EPS specimen has $10 \times$ bacterial count of VB2	42	38

WBC: White blood cell, HPF: High-power field, VB2: Voided bladder 2, VB3: Voided bladder 3, EPS: Expressed prostatic secretion



**Figure 1:** A comparison of symptoms of chronic bacterial prostatitis reported at baseline and at day 28 after treatment with levofloxacin 500 mg once daily ( $N = 151$ )

### Laboratory analyses

At day 28 the most common symptom found to be positive was leucocyturia  $\geq 10$  WBC/HPF at a rate of 16% (25 of 154). Complete results of laboratory analyses are presented in Table I.

### Tolerability

Participant adherence to the study medication was very good at the physician-rated rate of 96.8%. Three patients were lost to follow-up and were considered as study drop-outs.

At day 28, physicians assessed 64% of participants as being in an excellent state of health, 23% as being in a very good state and 6% as being in a fairly effective state of health.

There were no adverse events reported.

### CONCLUSIONS

The results of this study indicate the efficacy of levofloxacin as used to treat men with CBP. The rate of cure of symptoms was approximately 58.9%. Physicians rated the tolerability of levofloxacin as high for 76% of the study participants. The

results of this observational study suggest that levofloxacin is an effective antibiotic for the treatment of CBP. The cure rate of almost 59% is somewhat less than rates previously reported.<sup>[3]</sup> Nevertheless, physicians in this study assessed the efficacy of levofloxacin as excellent to fairly effective for 94% of the men participating in the study.

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