

## ORIGINAL ARTICLE

**Comparison of Single Versus Multiple Doses of Fluoroquinolone (Levofloxacin) for Prophylaxis in Prostate Biopsy**IQBAL NASIM<sup>1</sup>, FARAZ KHALID<sup>2</sup>, FARAZ BASHARAT KHAN<sup>3</sup>, AATIF HASSAN SHAIKH<sup>4</sup>, RAJAB ALI<sup>5</sup>, HIRA ANIS BUMBIA<sup>6</sup><sup>1</sup>Consultant Urologist, Murshid Hospital and Health Care Centre Karachi Pakistan<sup>2</sup>Senior Registrar Urology, Almana General Hospital Alhasa, Saudi Arabia<sup>3</sup>Senior Registrar Urology, Benazir Bhutto Hospital Rawalpindi Pakistan<sup>4</sup>Specialist Urologist, Mediclinic Airport Hospital Abudhabi<sup>5</sup>Assistant Professor Urology, Isra University Hospital Hyderabad Pakistan<sup>6</sup>Consultant Urologist, Dr Ziauddin Hospital Karachi PakistanCorresponding author: Iqbal Nasim, Email: [Iqbal.mallick@hotmail.com](mailto:Iqbal.mallick@hotmail.com)**ABSTRACT****Objective:** To assess the efficacy of Levofloxacin 500 mg orally for prophylaxis in transrectal prostate biopsy guided by ultrasonography compared to three dosages.**Study design:** A comparative study**Place and Duration:** this study was done in Murshid Hospital and Health Care Centre Karachi from September 2021 to September 2022**Methodology:** A total of 615 patients having the typical indications for prostate biopsy performed under transrectal ultrasonography guidance (increased PSA, abnormal digital rectal examination) were included in this study. Overall 425 patients were considered qualified for participation; using Graph Pad Prism 6.0, patients were assigned to one of two groups using random assignment, 205 individuals in Group A were given one oral dosage of 500 mg of levofloxacin 60 to 120 minutes before the procedure, Likewise, 220 patients in Group B received Levofloxacin (500 mg) once per 24 hours for two days before to the procedure as well as the day of it.**Results:** Patients in Group A were given orally a single dose of levofloxacin 500 mg there were 205 patients in this group. These individuals were diagnosed with diabetes mellitus (DM) at a rate of 43.9%, febrile urinary tract infections at a rate of 4.3%, and sepsis at a rate of 0.97%. In this group, 65.80cc, was the average prostate volume, and 90.17% were overweight. A total of 220 patients in group B who received orally three doses of levofloxacin 500 mg, with an average age of 67.45 years and a PSA mean of 21.26 ng/mL; 31.8% of patients had diabetes mellitus, & 4.45% had a febrile urinary tract infection (FUTI). In this group, no patients had sepsis, 75.61 cc was the mean prostate volume, and 72.74% of the patients were overweight, as in Group A.**Conclusion:** Because of how effective it is, a single dose of levofloxacin containing 500 milligrams is an excellent option for prophylaxis in patients who are going to have a transrectal prostate biopsy.**Keywords:** transrectal biopsy, floquinolone, prophylaxis**INTRODUCTION**

The most popular way to get prostate tissue for evaluation is through a transrectal ultrasound-guided (TRUS) biopsy. (1) Although complications are well known, TRUS biopsies are normally regarded as a well-tolerated outpatient treatment. (2) Antimicrobial prophylaxis is universally advised by current practice recommendations prior to a TRUS biopsy since it has been shown to greatly reduce the incidence of infectious complications following a biopsy. (3, 4) Despite this, infectious problems can still arise. Sepsis rates have been reported to range from 0.6 to 5.7% in recent investigations, (5, 6) and there is an indication that this incidence is rising. (7) The transrectal passage of the biopsy needle is most likely the cause of the post-biopsy infection's suggested pathogenesis. This technique makes it possible to directly inoculate the prostate, blood arteries, or urinary system with bacteria taken from the rectal mucosa. (8, 9) The preponderance of available information points to the presence of endogenous antimicrobial-resistant bacteria as a major contributor to the danger of developing infectious problems. (10) In men undergoing TRUS biopsy, endogenous fluoroquinolone-resistant bacteria were a risk factor for post-biopsy infection problems, according to Steensels et al. (11) It is possible that numerous circumstances, such as the use of antimicrobials or international travel prior to TRUS biopsy, may enhance the chance of acquiring endogenous bacteria that are resistant to antimicrobials. (12, 13) Other patients or procedure-related risk factors for sepsis after TRUS biopsy fall into these categories. Despite the investigation of patient co-morbidities, (14) the administration of an enema prior to the biopsy, as well as the number of cores collected during the procedure (15) Transrectal ultrasound-guided prostate biopsies are frequently used to diagnose prostate cancer, although there are risks and side effects associated with this technique. (16) Numerous patients have experienced adverse events, including local pain, bloody urine, hematospermia, painful

urination, rectal bleeding, orchitis, prostatitis, epididymitis, and sepsis; bacteriuria affects 20–50% of patients, fever and symptoms of the lower urinary tract affected 3–10% of patients, and sepsis occurs in 0.5–5% of patients (17) Antimicrobials lessen the side effects of infected biopsies. (18) Despite the presence of clinical guidelines and the fact that over a million prostate biopsies are conducted annually in the United States and Europe, there is no consensus on the antibiotic prophylaxis regimen that should be used in clinical practice. Enemas should be used prior to biopsy, but some studies challenge their value. (19) Antimicrobial prophylaxis is widely established, although there are various opinions on when to take medications, how long to take them, and how to give them. (20) The majority of research employ strategies ranging from prevention to the administration of antibiotics 1-3 days before the procedure. (21) In the current study, the main goal is to assess the efficacy of a single 500 mg oral dose of levofloxacin for prophylaxis in individuals having transrectal prostate biopsy guided by ultrasound versus three doses of the same medicine

**METHODOLOGY**

We studied at 615 patients who had the typical indications for prostate biopsy performed under transrectal ultrasonography guidance. Patients with febrile urinary tract infection a month prior, drug hypersensitivity, an indwelling catheter, lower urinary symptoms, acute urine retention and hematuria were excluded; 425 patients in all were considered qualified for participation; using Graph Pad Prism 6.0, patients were assigned to one of two groups using random assignment, 205 individuals in Group A were given one oral dosage of 500 mg of levofloxacin 60 to 120 minutes before to the procedure, Likewise, 220 patients in Group B received Levofloxacin (500 mg) once per 24 hours for two days before to the procedure as well as the day of it. Diabetes mellitus, body mass index and prostate volume were all assessed. The

primary outcome, taking into account our variables, compares the effectiveness of three doses to a single dosage. Before the transrectal biopsy day, all patients received an oral polyethylene glycol bowel preparation. The Aloka ultrasonography 6 with intracavitary transducer 5-10 MHz and needle biopsy yielding samples of 22 mm, was used to do the biopsy. After obtaining 12 cylinders, we used an EchoTip Skinny needle with a chiba tip size of 22 gauge to apply simple lidocaine for a local anaesthetic in the periprostatic plexus. All patients had urinalysis following the treatment, but only those who had a fever episode underwent a urine culture. A urinary tract febrile episode was characterized as having at least one urinary tract symptom and a fever of less than 38.0 degrees Celsius. Patients with this problem were hospitalized, and general, urine, and blood culture investigations were included in pre-clinical evaluation. IBM SPSS Statistics 19 correlated the variables using Fisher's exact test and Student's t-test.

**RESULT**

The 425 patients had an average age of 66.86 years, a 71.14 cc prostate volume, and a mean 22.13 ng/mL PSA ; they were stratified by BMI, with normal 19.00% weight , 54.76% overweight, 20.23% obesity grade I , and 5.95% obesity grade II ; thus, 80.92% of our patients were overweight or obese, and 36.90% had diabetes mellitus. Group A consisted of 205 patients who received a single dose of levofloxacin 500 mg orally. Of these patients, 43.9% had diabetes mellitus, 4.3% had a febrile urinary tract infection and two had sepsis (0.97%). In this sample, the average prostate volume was 65.80 cc, and 90.17% of the men were overweight. Similar to Group A 220 individuals in group B received three levofloxacin 500mg doses orally. In this group, 4.45% of patients had a febrile UTI, and 31.8% of patients had diabetes mellitus. There were no patients with sepsis, and the mean prostate volume was 75.61 cc. 72.74% of the patients were overweight. In both groups, the fluoroquinolone was modified in accordance with the antibiogram. The organism prevalent in urine culture was E. coli. At third week following the procedure, all patients are monitored, and those who experienced sepsis and a febrile infection received two more appointments at four and six weeks. The similarities between the two groups mean that there are no discernible differences in the complications (P = 0.66; Table 1); When patients were evaluated based on their BMI and risk of complications, there was no difference in either group when examining both groups when the analysis was done considering diabetes into account (As shown in Table 2).

Table 1: Comparison between the two groups

	Single dose	Multiple doses	p-value
Number	205	220	0.6
Age	66.2	67.4	0.2
PSA mean	23.0	21.2	0.5
DM	43.9	31.8	0.5
FUTI	4.30	4.45	
Volume	65.8	75.61	0.24
Sepsis	0.97	0	

FUTI: febrile urinary tract infection

Table 2: Types of infections and associated risk factors

Patient	Age	Type of infection	Blood culture	Risk factor
A	62	UTI+Sepsis	E.coli	Cardiovascular diseases and secondary neurological disorder
B	71	GUI+Sepsis	E.coli	Prostatitis, Lower urinary tract infection

GUI: UTI urinary infection

**DISCUSSION**

Each year, millions of men worldwide get prostate biopsies as part of the diagnostic process for finding prostate cancer.(22) Recent retrospective investigations carried out in Europe and the United States have both shown evidence of an apparent increase in the

occurrence of infectious complications following prostate biopsies. (23)When it comes to the detection of cancer, both the prostate biopsy and the prostate specific antigen have a low level of specificity. The initial prostate biopsy detection rate ranges from 22.8 to 42%. A diagnostic test should be as safe as possible if its positive detection rate is less than 50%. There is disagreement in the majority of facilities about the use of specific medications and prophylaxis, despite certain worldwide recommendations for antibiotic prophylaxis in BTRP. (24)From 1% to 6% of individuals who have a prostate biopsy have infectious side effects, such as temperature, UTI, acute prostatitis,&epididymitis. The patient's life may be in threat if they develop sepsis, which is one of the most serious adverse effects of BTRP. Fortunately, it only happens in 0.5–1% of BTRP patients. Studies on infection frequency range; the majority of hospitals indicate a hospitalization rate of 0-6.3%. 2.15 to 3.6% of the 72,500 biopsies carried out in UK hospitals resulted in readmission. (24)According to the Global Prevalence Study of Infections in Urology, hospitalization for febrile UTIs following BTRP has an incidence of 3.5% and 3.1%. (25)Park et al. found that there were only 0.3% of infections with rectal preparation and 6% without it (P 0.001).(24)

Despite no variation in fever or infection, a Cochrane study found that antibiotics with an enema reduced the incidence of bacteremia compared to antibiotics alone. Fluoroquinolone prophylaxis has been found to minimize infection complications in BTRP, according to several investigations. According to several studies, using fluoroquinolones significantly reduced the risk of infection problems (8% versus 25%)(24)Levofloxacin concentrations in prostate fragments acquired through transurethral resection were assessed, and it was shown that the quantities were sufficient for treating the majority of common pathogens effectively. (25) This proved the drug's great bioavailability. Additionally, they observed that an oral dose of 500 mg of levofloxacin was administered intravenously, and that the peak concentration was reached within the first hour. Peak plasma concentrations are reached in the same amount of time as with oral administration, which is between 30 and 60 minutes. Levofloxacin has a 6 to 8 hour half-life, allowing for daily dose. When we compared the increased risk of infection associated with one dosage of levofloxacin to that associated with three dosages, our research found that there was no discernible difference (P = 0.66). For microorganisms like E. coli, resistance rates tend to be rising in our country. The conventionally used first-line antimicrobials are becoming less effective. According to available data, fluoroquinolone resistance in E. coli is only 2.5% and trimethoprim-sulfamethoxazole resistance in the United States is relatively low (17%), which justifies the drug's use only in difficult UTIs or when the antibiogram indicates an advantage. Among our nation, the range of levofloxacin resistance among outpatients is wide (7.6-29.7%), with larger resistance rates seen in patients in hospital and those in ICU (40–66%).

We do not feel that diabetic patients should be given a prophylactic with a longer duration because, according to our research, there was no significant difference between administering one dose versus three doses to diabetic or obese patients. Diabetes mellitus and the use of steroids were found to be risk factors for infection complications in BTRP, according to a study that was reported in 2002 by Griffith et al. and involved 400 patients. The presence of levofloxacin resistance in faecal E. coli is an essential component for further investigation and analysis. According to the findings of one investigation, the appearance of levofloxacin-resistant faecal E. coli bacteria predicts a large rise in the infectious effects associated with BTRP risk. Few randomized trials have examined the use of rectal swab culture results for prophylactic antibiotic usage in BTRP to date. (25-27)

**CONCLUSION**

Levofloxacin 500mg in a single dose is a great choice for prophylaxis in patients who are having a transrectal prostate biopsy due to its ease of administration and reliability. A single

dose makes it easier for patients to adhere to preventive care and can reduce the expense of antibiotic medication, with a safety profile that is essentially comparable to three doses.

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