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Comparison of IV versus oral ciprofloxacin for prevention of acute bacterial prostatitis during ultrasound-guided transrectal prostate biopsy

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ABSTRACT

Background: Trans-rectal prostate biopsy is commonly used for the diagnosis of prostate cancer; this procedure is associated with infective complications like acute bacterial prostatitis. There is evidence that antibiotic prophylaxis decreases infective events after trans-rectal prostate biopsy, but different regimens are used.

Aim: The purpose of the current study is to compare the effect of oral Ciprofloxacin and intravenous (IV) Ciprofloxacin in the prevention of acute bacterial prostatitis during ultrasound-guided transrectal prostate biopsy.

Methods: In the current prospective, open-label, randomized, controlled trial, a total of 307 patients with indications for transrectal prostate biopsy were randomized into two groups. These patients received either oral or IV ciprofloxacin before a transrectal needle biopsy of the prostate. All patients underwent ultrasound-guided transrectal prostate biopsy. 3 days after the biopsy, infectious complications including acute bacterial prostatitis were compared between the two groups.

Results: 132 IV ciprofloxacin patients and 137 Oral ciprofloxacin patients have participated in the final analysis. Comparing the two groups, demographic and medical baseline data was similar ($P<0.05$). The rate of acute bacterial prostatitis in IV and Oral patients was 5.3 % (7/132) and 21.16 % (29/137), respectively ($P=0.0001$). Also in both groups, all infected patients had bacteriuria, Pyuria, Hematuria, Leukocytosis, fever, and Lower urinary tract symptoms.

Conclusions: Single-dose IV ciprofloxacin significantly reduced acute bacterial prostatitis after biopsy compared with oral ciprofloxacin in patients undergoing transrectal prostatic biopsy. Further study of these observed findings with larger patient numbers is indicated.

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INTRODUCTION

Prostate cancer is the most prevalent non-skin malignancy among men in developed communities and due to aging populations in these communities, the incidence of this cancer has been increasing. In addition, despite the remarkable advances in the diagnosis and treatment of prostate cancer, it is considered the second leading cause of cancer-related deaths in men of these communities (1-3). Many cases of prostate cancer in progressive stages of diseases do not have symptoms, are not detectable in early stages, and remain subclinical (4). So, the use of screening tests for early cancer detection and treatment is of utmost importance. The current screening tests for prostate cancer include prostate-specific antigen (PSA) and digital rectal examination (DRE) (5, 6). These screening tests may in some cases lead to a biopsy, which is done through transrectal ultrasonography. Transrectal ultrasound-guided biopsy is a standard procedure for histological diagnosis of prostate cancer and is considered the most reliable method in confirmation of prostate cancer, which is done 800,000 biopsies annually in the USA (7-9).

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It is noticeable that transrectal ultrasound-guided biopsy has some complications and the most common is infectious complication. This infection complications rate from prostate biopsy in previous studies has been estimated at 0.1% to 7% (10-12). Other studies have shown that infections and hospital admissions after transrectal prostate biopsy, have increased at alarming rates during the last decade (13, 14). Some infectious complications from prostate biopsy include fever, urinary tract infection, epididymal-orchitis, sepsis, and acute bacterial prostatitis (10, 12).

Acute bacterial prostatitis is an acute infection of the prostate gland that causes pelvic pain and urinary tract symptoms and also may lead to systemic symptoms such as fever chills, nausea, emesis, and malaise. Although the exact incidence of this infection is not clear, almost 10 % of all cases of prostatitis is included. Many cases of acute bacterial prostatitis is community acquired, however, some cases may occur after procedures such as transrectal prostate biopsy (15).

Antibiotic prophylaxis before transrectal ultrasound-guided prostate biopsy had been shown to reduce the infection rate significantly, however, there is no agreement on the choices of antibacterial agents, administration route, and treatment course, so more investigations is needed in this area to be the basis for clinical practice. Some investigations demonstrated that Antibiotic prophylaxis significantly reduces the incidence of bacteremia after biopsy, but others did not show significant reduction (16). Also, a recent review revealed that, currently there is no standard for the use of antibiotics prophylaxis in ultrasound-guided transrectal prostate biopsies (17).

A variety of antimicrobial agents have been used in needle biopsy prophylaxis. Oral quinolones have a broad spectrum of antibacterial activity, including most aerobic microorganisms residing in the bowel. Important characteristics of ciprofloxacin such as appropriate oral bioavailability, long half-life and high concentrations in the urine and prostate tissue introduce it as a logical candidate for prophylaxis in patients undergoing transrectal needle biopsy of the prostate. Ciprofloxacin has permanent antibiotic effects that suppresses the growth of bacteria within 2 to 6 hours (14, 18).

To date, there have been no prospective, randomized, controlled trial comparing the antimicrobial prophylaxis of IV versus Oral Ciprofloxacin in reducing the rate of infection, specifically the rates of acute bacterial prostatitis after transrectal needle biopsy of the prostate. The purpose of this study was to determine the effect of single-dose of IV versus Oral Ciprofloxacin antimicrobial prophylaxis in the prevention of acute bacterial prostatitis in Iranian patients undergoing transrectal needle biopsy of the prostate.

METHODS

Study Design and Patients

This was a prospective, open-label, randomized, and controlled trial conducted at Urologic Clinic of Baqiyatallah Hospital from 1 March 2014 to 1 March 2015. Male patients with age of 20-80 years old who were candidate for Transrectal ultrasound guided prostate biopsy were eligible for enrollment in the study.

The inclusion criteria were as PSA > 4 ng/ml, positive result by digital rectal examination, or radiographic examination as suspected prostate cancer. The patients who meet one of the inclusion criteria were requested to sign the written informed consent for participating in study and then a complete history and physical examination for each patient were documented.

The exclusion criteria were as; history of allergy to ciprofloxacin, pre-procedure fever, pre-procedure bacteriuria, history of valvular heart disease, gastrointestinal disease, epilepsy, coagulation disorders, disease causing low immunity, abnormal liver or renal function, receiving antibiotic(s) within 1 week of the needle biopsy, history of endoscopic manipulation of the urinary tract within 7 days of study enrollment and any condition that the investigator considered to potentially increase the patients risk or interfere the test results.

Data Collection

Urine and blood specimens were obtained before needle biopsy of the prostate for routine urinalysis, urine culture, hematologic, coagulation, and biochemistry laboratory tests.

Patient's demographic data, and baseline clinical data including serum PSA, diabetes mellitus, valvular heart disease, artificial prosthesis, immunosuppressive consumption, recent use of antibiotics (less than 1 month), recent catheterization, recent hospitalization, history of prostatitis, history of previous prostate biopsy, urine analysis, urine culture and prostate size based on ultrasonic examination were collected. Also, some questions designed to determine the patient's risk of prior fluoroquinolone exposure such as previous cystoscopy, recent antibiotic intake and hospital admission in the year before the biopsy.

Study Procedures, Test Drugs and Dosage Regimen

A total of 307 patients were included in the study, and were allocated in a 1:1 ratio to oral (Tab. Ciprofloxacin 500 mg oral 30-60 minute before biopsy) or IV treatment (Vial Ciprofloxacin 400 mg intravenous immediately before biopsy) groups according to random numbers table. A single oral / IV dose of ciprofloxacin (either 500 mg or 400 mg) were given to each patient before the biopsy.

All patients had a cleansing enema before the biopsy. For Biopsy, Patients had lithotomy position and surgeon got 10 biopsies including 6 medial and 4 lateral samples. Before insertion of ultrasonic probe, 50cc of Gel Lidocaine 1% and povidone iodine was instilled rectally.

After biopsy, prostate was packed for 3 minutes from rectum and also all patients received oral Ciprofloxacin (500 mg BID) for 3 days.

Acute Bacterial Prostatitis Evaluation

Patients were followed up on day 3 after the biopsy and the laboratory measurements, patient evaluation, and observation were performed. At this follow-up, all patients were evaluated for acute bacterial prostatitis and adverse events including fever; body temperature more 38 °C, severe lower urinary tract symptoms; positive urine culture and symptoms of UTI, bacteriuria; positive urine culture on the morning of the third day after the biopsy, hematuria (RBC>2-5), Pyuria (WBC>5), Leukocytosis (WBC>5000).

Statistical Analysis

All data were analyzed by SSPS software, version 17.0 (SPSS,

Inc., Chicago, IL, USA). For comparing the qualitative and quantitative parameters between the two groups, chi-square test and independent t-test was used, respectively. Normal distributions of quantitative parameters were proved by the Kolmogorov-Smirnov test. The results are expressed as a mean± standard deviation (SD), and frequency (percent). A *p* value of <0.05 was taken to mean that statistical significance had been reached.

Ethical Consideration

This trial followed the principles of the Declaration of Helsinki and was approved by the Medical Ethics Review Board of Baqiyatallah University of Medical Sciences. All information about the patients was kept fully confidential, and all information will be released as a group without patients' name. Study patients did not incur any costs and the study protocol did not have any harm to patients. Written informed consent was obtained from volunteers and details and purpose of the study were disclosed.

RESULTS

In this prospective, open-label, randomized, and controlled trial 307 adult men met prescreening criteria and were enrolled. 35 men were excluded because of fault in clinical and laboratory data, two men withdrew after consent and enrollment, and one man was excluded from the analysis because of a consent error, leaving N = 38 men (figure-1).

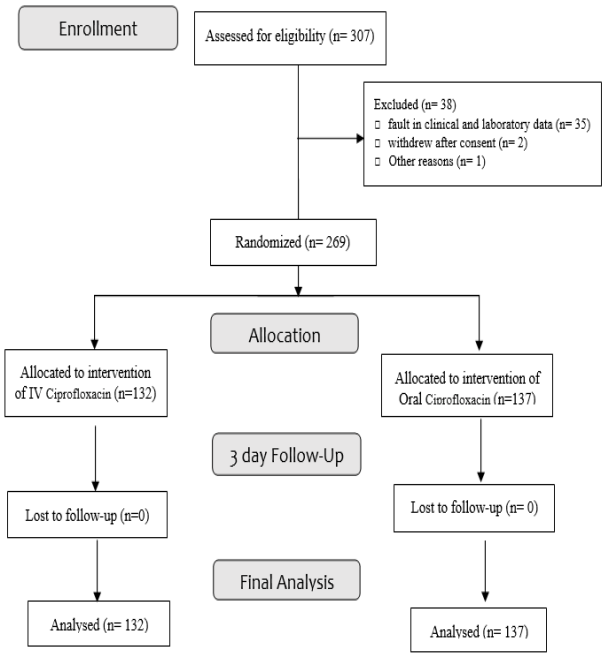

Figure 1: Flowchart of Patients' Distribution in Two Groups

Finally, there were 269 evaluable patients, 132 patients in the IV Ciprofloxacin group, with a mean age of 63.3 years (range 38 to 79), and 137 patients in the Oral Ciprofloxacin group, with a mean age of 65.1 years (range 35 to 80). There was no statistically significant difference between the two groups for all patients' demographic and basic clinical data (Table-1). Clinical data before biopsy indicated that no patients has acute bacterial prostatitis in any groups.

Table 1: Patients' Demographic and Baseline Clinical Data in Both Groups

	IV Ciprofloxacin group (n=132)	Oral Ciprofloxacin group (n=137)	P value
Age (year)	63.3±14.2	65.1±13.9	0.382
BMI (Kg/m2)	25.3±4.2	25.1±3.8	0.682
Mean prostate size (^{cc})	36.2 ±5.2	31.6±4.5	0.0001
Diabetes Mellitus, n%	11 (8.3%)	15 (10.9%)	0.470
Positive DRE, n%	48 (36.4%)	46 (33.6%)	0.630
PSA (ng/dl)	7.4±3.1	6.9±2.8	0.166
acute bacterial prostatitis, n%	0	0	-

DRE: digital rectal examination; **PSA**: prostate specific antigen, **Notes**: no difference between two groups for other clinical indicators including body temperature, heart rate, respiratory rate, blood pressure, etc. before biopsy.

The infectious complication rates in oral and IV Ciprofloxacin groups were compared (Table-2). Acute bacterial prostatitis, bacteriuria, Pyuria, Hematuria, Leukocytosis, fever and Lower urinary tract symptoms was less frequent in the IV Ciprofloxacin group, which the differences between two groups were significant (P<0.001).

The overall rate of post biopsy acute bacterial prostatitis in IV Ciprofloxacin group was 5.3 % (7/132), which all of them had bacteriuria, Pyuria, Hematuria, Leukocytosis, fever and Lower urinary tract symptoms.

The overall rate of post biopsy acute bacterial prostatitis in Oral Ciprofloxacin group was 21.16 % (29/137), which all of them had bacteriuria, Pyuria, Hematuria, Leukocytosis, fever and Lower urinary tract symptoms.

Also, no drug-related adverse events observed in either group.

Table 2: Comparison of Post-biopsy Infectious Complications Between Two Groups

	Acute bacterial prostatitis (%)	bacteriuria	Pyuria	Hematuria	Leukocytosis	Lower urinary tract symptoms	fever
IV Ciprofloxacin group (n=132)	7 (5.3%)	7 (5.3%)	7 (5.3%)	7 (5.3%)	7 (5.3%)	7 (5.3%)	7 (5.3%)
Oral Ciprofloxacin group (n=137)	29 (21.16%)	29 (21.16%)	29 (21.16%)	29 (21.16%)	29 (21.16%)	29 (21.16%)	29 (21.16%)
P value	0.0001	0.0001	0.0001	0.0001	0.0001	0.0001	0.0001

DISCUSSION

One of the most prevalent risks of transrectal prostate biopsies is infectious complications (11, 16). The proposed mechanism of infection involves the biopsy needle passing through the rectal mucosa with fecal contamination seeding the bladder and

vasculature, rather than the bladder being the origin (19). To prevent these infections broad spectrum antibiotics with or without bowel preparation have been used (12, 17). The American Urological Association provides a Best Practice Policy Statement on Urologic Surgery and Antimicrobial Prophylaxis, in which recommends use of a fluoroquinolone as a first line for prophylaxis in transrectal prostate biopsy (20). Although most of urologists used antimicrobial prophylaxis in this regard, but so far, few studies conducted to confirmation the usefulness of antimicrobial prophylaxis.

The current clinical trial demonstrated a remarkable clinical benefit from using single dose of ciprofloxacin, as antimicrobial prophylaxis, in the performance of transrectal needle biopsy of the prostate. In present study, the rate of post biopsy acute bacterial prostatitis in the IV Ciprofloxacin group was significantly lower than in the oral Ciprofloxacin group, 5.3% versus 21.16% (P=0.0001), respectively. This effect may be related to correct use of Ciprofloxacin in proper time, proper serum level of Ciprofloxacin in shorter time, better quality of injectable form of Ciprofloxacin in IV form. There is no previous clinical trials that compare the route of Ciprofloxacin as a prophylactic antibiotics in trans-rectal prostate biopsy.

By the way, there is some previous studies that using different antimicrobial prophylaxis in the efficiency of transrectal needle biopsy of the prostate. In a study conducted by Roach et al., patients who received oral ciprofloxacin had significantly lower rates of bacteremia compared to patients who received intravenous gentamicin (21). Cam et al. showed no difference in morbidity between oral and systematic antibiotics (22). The results of a study in China by Qiao et al., represented that levofloxacin, in comparison to clinically routine prophylactic regimens consisting of Cefotiam, Ciprofloxacin, Cefmetazole for 3 consecutive days in the prevention of infectious complications of ultrasound-guided transrectal prostate biopsy, demonstrated the similar effect in preventing infective complications, with lower cost and economic advantage for levofloxacin (23). In a meta-analysis, Zani et al. have demonstrated no significant difference between the administration routes, whether systemic or oral, in reduction of infection complications of ultrasound-guided transrectal prostate biopsy (24). But in our clinical trial, IV route for administration of ciprofloxacin as a prophylactic antibiotic in trans-rectal prostate biopsy are inferior to Oral route.

In current trial, regarding elimination of the effect of confounding factors on the results, the baseline variable like age and PSA were similar in both groups and there were not any significant differences between groups regarding these factors (P=0.382, P=0.166, respectively). Also, it has been suggested that various comorbidities like diabetes, do place the patient at increased risk for infectious complications after transrectal prostate biopsy (14, 25). The presence of diabetes in IV and Oral Ciprofloxacin treated patients was 8.3% and 10.9%, respectively and was not statistically significant (p=0. 470).

The present trial assessed the most important complication of biopsy including; bacteriuria, Pyuria (WBC>5), Hematuria (RBC>2-5), Leukocytosis (WBC>5000), fever (>38.5 0C) and Lower urinary tract symptoms. These complications were observed in all patients with acute bacterial prostatitis in both groups that is higher than previous reported total complication rate in similar studies. In Desmond et al. study, 2.1% total complication rate (eg, fever, hematuria) were reported among 580 male patients who received 1 to 3 days of ciprofloxacin prophylaxis around the time of ultrasound-guided transrectal prostate biopsy (26). A retrospective review of 4439 ultrasound-guided transrectal prostate biopsies revealed 0.1 % symptomatic Urinary tract infections in patients receiving an 8-dose ciprofloxacin (500 mg twice daily) as prophylaxis regimen (27). As such, the Enlund and Varenhorst represented approximately 1.2% infection rate in ultrasound-guided transrectal prostate biopsies (28). Djulbegovic et al. reported 1.4% acute bacterial prostatitis in patients who received 3 days oral Ciprofloxacin (4). In another study conducted by Kapoor et al., in 1998, incidence of symptoms of a urinary tract infection and bacteriuria was 3% in patients received ciprofloxacin orally for 3 days (10). These variety in rate of infection complication may be related to differences between quality of medications in different countries, different type of uropathogens, improper use of medications, different techniques of prostate biopsy, different resistance to quinolones, race and diets of people in different countries.

Beside the lack of placebo or no treatment group in current clinical trial, there is some other limitations to mention. We did not check single dose regimen versus the multiple doses, durations of therapy (1-day and 3-day regimen), Ciprofloxacin in comparison with other medications, the effect of other techniques like rectal cleansing with povidone-iodine, using disposable needle, prebiopsy enema, fluoroquinolone resistance rate, hospitalization rate, some other endpoints like bacteremia, urosepsis, and cost benefit ratio of antibacterial agents. So considering these parameters, larger study population is needed to complete and confirm current findings.

There is no doubt now that antibiotics decrease infective complications but regimens of prophylactic antibiotics is still an issue of debate in urology. Based on our experience in practice, fluoroquinolones is the most common choice for prophylactic antibiotics that selected by Iranian urologists. To our knowledge, this is the first clinical trial in Iran in this area.

CONCLUSION

Our study showed that use of IV Ciprofloxacin for prophylaxis before transrectal ultrasound guided prostate biopsy is more effective than oral form. Single-dose IV ciprofloxacin more reduced post procedure acute bacterial prostatitis compared with oral Ciprofloxacin in patients undergoing transrectal prostatic biopsy. Also, current findings revealed that routine antimicrobial prophylaxis is useful and necessary during transrectal needle biopsy of the prostate and in this regards a single pre-procedure dose of IV ciprofloxacin is more recommended.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest that could be perceived as prejudicing the impartiality of the research reported.

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