COMPARISON OF SINGLE DOSE AND THREE DAY CIPROFLOXACIN PROPHYLAXIS REGIMEN FOR TRANSRECTAL ULTRASOUND GUIDED PROSTATE BIOPSY

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ABSTRACT

Background: Prostate cancer incidence is rising leading to a major health problem globally. Infectious complications in TRUS guided prostate biopsy are very common without antibiotic prophylaxis. **Objective:** To compare the effect of single dose and three day ciprofloxacin prophylaxis regimen for prevention of urinary tract infection after prostatic biopsy. **Methodology:** This randomized controlled trial involved 130 patients with Prostate cancer which were randomly allocated into 2 groups. Group-A received two ciprofloxacin 500 mg tablets stat while Group-B received 3 days has of ciprofloxacin treatment. Patients were followed up to 5 days to observe any symptoms of UTI. Written informed consent was taken from all the patients. The data was entered and analyzed using SPSS version 19. **Results:** The mean age of the patients was 56.84 ± 7.28 years. The mean age of the patients in Group-A was 56.44 ± 7.10 years while in Group-B it was 57.23 ± 7.50 years. However, there was no statistically significant difference between groups in terms of age. On follow up at 5 days, 11 patients has UTI. The rate of presence of UTI was similar across different age groups and treatment regimens. Treatment with one-day antibiotic prophylaxis resulted in UTI in 6(9,2%) associated with in comparison to three days' antibiotic treatment, where 5 (7.6%) has UTI. (P=0.64) **Conclusion:** The incidence of UTI with one-day antibiotic prophylaxis with ciprofloxacin was comparable to three antibiotic treatments in patients who are candidates for TRUS guided biopsy.
Key Words: TRUS, UTI, prophylaxis

INTRODUCTION

Prostate cancer is one of the most common non skin related malignancy developed world specifically and developing world generally.[1] TRUS guided prostate biopsy is routinely performed in patients with palpably and ultrasonically abnormal prostate glands and sometimes bacteremia and bacteriuria.[2] Asymptomatic bacteriuria, urinary tract infection, and sepsis are the common complications seen following prostatic biopsy.[3] The American Urological Association (AUA) recommends fluoroquinolones as the antibiotic of choice.[4] There is a significant increase in infectious complications following prostate biopsy in recent reports.[6] The main reason of this increase is the emerging pattern of fluoroquinolone-resistant bacteria and the lack of a standardized antimicrobial for prophylaxis in patients undergoing prostate biopsy.[7,8,9,10,11] The objective of this study was to compare the effect of single dose and three day ciprofloxacin prophylaxis regimen for prevention of urinary tract infection after Transrectal Ultrasound (TRUS) guided prostate biopsy.

METHODOLOGY

It was a randomized controlled trial conducted at Department of Urology, Services Hospital, Lahore from 25th March 2013 to 24th September 2016. Sample size of 130 with 65 in each group was estimated using 5% level of significance and power of 80%.

Patients with age 50 to 80 years, with a suspicion of CA prostate (DRE reveals hard, irregular prostate) were included in our study. Patients with ongoing infection as suggested by fever temp >99 F, WBC >10,000, use of antibiotics in last 2 weeks prior to biopsy, patients with bleeding disorder (INR >1.5), patients on anticoagulants, and patients with Platelet count <150,000/mm3 were excluded from study.

All patients who met inclusion criteria, attending Urology Department of Services Hospital Lahore were enrolled in this study. After approval of Ethical Review Committee patients were explained about research protocol and informed written consent was obtained. Patients were divided in groups A and B according to random number table as single block. At enrollment in group A, preoperative dose consisting of two ciprofloxacin 500 mg tablets stat 2 hours before prostate biopsy was given was given. Patients in group B, received three days of ciprofloxacin treatment. (One dose two hours before the procedure and continued for next two days at a dose of 500 mg

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BD tablets per day. All the patients were followed for 5 days for presence of UTI measured by urine complete and CBC. All parameters were entered in the patient proforma.

Data was analyzed on SPSS (Statistical package for social sciences) version 19.0. Two groups were compared for presence of UTI. Mean and standard deviation has been calculated for quantitative variables like age. Two groups were compared for incidence of UTI on chi-square test. P-value of less than or equal to 0.05 was considered as significant. Data was stratified for age, presence of CA Prostate on biopsy, H/O Diabetes Mellitus, presence of urinary obstruction to deal with effect modifiers. Post stratification chi-square Test was applied.

RESULTS

Total number of patients in this randomized control trial were 130 with mean age of 56.84±7.28 years. In Group A, mean age of the patients was 56.44±7.10 years while in Group-B it was 57.23±7.50 years.(P=0.4) Overall 11 out of 130 patients developed UTI. 6 (9.2%) patients were in group A, while 5(7.6%) patients in Group B who developed UTI.

Table I: Comparison of Frequency of UTI between the Two Study Groups (n=130)

Study Groups	UTI Yes	UTI No	Total	P Value
Group-A	6(69.2%)	59 (90.7%)	65 (100%)	
Group-B	5 (7.6%)	60 (92.3%)	65 (100%)	0.640
Total	11 (8.46%)	119 (91.53%)	130 (100%)	

Table II: Comparison of Frequency of UTI between the Two Study Groups across Ca Prostate Status and DM status (n=130)

Ca Prostate	Study Groups	UTI Yes	UTI No	Total	P value
Yes	Group-A	2(7.40%)	11(40.34%)	13 (100%)	
	Group-B	2(7.40%)	12 (44.44%)	14 (100%)	0.727
	Total	4 (14.81%)	23 (85.18%)	27 (100%)	
No	Group-A	4 (7.6%)	48 (92.30%)	52 (100%)	
	Group-B	3 (5.88%)	48 (96%)	51 (100%)	0.399
	Total	7 (5.8%)	96 (94.17%)	103 (100%)	
Diabetes Mellitus					
Yes	Group-A	2 (14.28)	1 (7.14%)	3	
	Group-B	1 (7.14%)	10 (71.42%)	11	0.786
	Total	3 (21.42%)	11 (78.57%)	14 (100%)	
No	Group-A	4 (3.44%)	58 (50%)	62	
	Group-B	4 (3.44%)	50 (43.10%)	54	0.718
	Total	8 (6.89%)	108(93.10%)	116 (100%)	

There was no significant difference between groups in baseline characteristics. Out of 130 patients 27 have Ca Prostate on biopsy, out of these 2(7.40%) in Group A and 2(7.40%) in Group B has UTI. (P=0.7) (Table II)

14 patients were diagnosed as case of Diabetes Mellitus. In these patients 3(21.42%) presented with UTI, two in group A and one in group B (P=0.7) (Table II)

DISCUSSION

The most common non skin related malignancy in United States is prostate cancer.[8] TRUS guided prostate biopsy is routinely performed in patients with suspicious nodule on digital rectal examination. The infection-related complications following prostate biopsy include asymptomatic bacteriuria, urinary tract infection, and sepsis. Bacteremia and bacteriuria occur in 16% and 44% of cases, respectively.[9,10,11]

The use of prophylactic antibiotics decreases the incidence of infectious events in trans rectal prostatic biopsy. A Randomized control trial conducted by Kapoor DA et al comprised 537 patients who received oral ciprofloxacin or placebo before trans rectal needle biopsy showed that there was a significant difference in the incidence of UTI between two groups.[16] In another randomized controlled trial of 231 patients comparing placebo, single dose of ciprofloxacin and tinidazole, and the same combination twice a day for 3 days, the incidence of all infectious complications, and specifically UTI, was significantly lower in both antimicrobial groups. According to level of evidence there is consensus for prophylaxis in transrectal prostatic biopsy.[13,14]

Single dose antibiotic prophylaxis has been shown to be effective in reducing incidence of UTI after TRUS guided prostate biopsy. On long term follow up multiple studies are available internationally and nationally on the efficacy of single dose antibiotic prophylaxis. Among these prophylactic methods, antibiotic prophylaxis has been the standard method of preventing infectious complications. The use of Fluoroquinolones as the primary prophylactic agent is traditionally used owing to their excellent prostatic penetration. These antibiotics provides a good coverage against the key pathogens implicated in infections after prostate biopsy.[15]

We included 130 patients with Prostate cancer in this randomized control trial which were randomly divided into two groups. Group-A received One preoperative dose consisting of two ciprofloxacin 500 mg tablets stat 2 h before prostate biopsy while

Group-B received three days of ciprofloxacin treatment.(One dose two hours before the procedure and continued for next two days at a dose of 500 mg twice a day per day). The results of our study closely matches with that of Campeggi A et al there was no significant difference between groups except for a larger prostate volume in group B (median 45.5 vs 40.5 mL).[16]

The results of our study showed that single dose antibiotic prophylaxis is as good as three day antibiotic prophylaxis in prevention of incidence of UTI among patients undergoing TRUS guided prostate biopsy. Our study however was restricted to the efficacy of quinolones only and we didn't study the role of other antibiotics. However, our study provides basis for future studies to evaluate the role of antibiotics other than quinolones.

CONCLUSION

Single dose antibiotic prophylaxis with oral ciprofloxacin is as good as three day antibiotic prophylaxis in prevention of urinary tract infection among patients undergoing TRUS guided prostate biopsy.

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