

Comparative Study of Bisacodyl Suppository Plus Antibiotics versus Antibiotics Alone in the Prevention of Postprostate Biopsy Infection

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Abstract

Aims: The purpose of this study is to determine whether bisacodyl rectal suppository can reduce infective complications postprostate biopsy. **Patients, Materials and Methods:** This was a comparative cross-sectional study done at the urology unit of a tertiary hospital over 12 months. A sample size of 56 was determined using Fisher's formula. Both groups had tablets of ciprofloxacin 500 mg and metronidazole 400 mg at induction of anaesthesia and continued for three days postbiopsy at a dose of 500 mg twice daily and 400 mg thrice daily, respectively. In addition to antibiotics, those in Group 1 had 20 mg of bisacodyl (Dulcolax) suppositories given at night, starting two days before the procedure. The patients underwent digitally guided 10-core transrectal prostate biopsy on an outpatient basis. Blood and urine samples were taken for full blood count and urine culture, respectively, before surgery and three days after the biopsy. Statistical analysis was performed using the SPSS version 21.0. The level of significance was set at $P < 0.05$. **Results:** The mean age was 69.64 ± 9.31 with a range of 52–90 years. The peak age distribution was 70–79. In Group 1, two patients had urosepsis, one patient had urinary tract infection (UTI), and seven patients had bacteriuria, while in Group 2, four patients had urosepsis, four patients had UTI, and ten patients had bacteriuria. **Conclusions:** The addition of bisacodyl rectal suppository to antibiotics reduced the frequency of infective complications following prostate biopsy. The observed difference, however, was not statistically significant.

Keywords: Bisacodyl suppository, postprostate biopsy infection, prostate biopsy

INTRODUCTION

Prostate cancer represents the second-most common malignancy in males.^[1] In 2012, about 1.1 million men worldwide were diagnosed with prostate cancer, accounting for 15% of cancers in men.^[2] A Nigerian study had put the hospital incidence and annual death rate at 127/100,000 and 20,000, respectively.^[3]

Transrectal ultrasound (TRUS)-guided prostate biopsy is one of the most commonly performed procedures by urologists and remains the gold standard technique for prostate cancer diagnosis.^[4,5] In my environment, however, a digitally guided prostate biopsy is still widely practiced due to the nonavailability of TRUS probes in many centers. Prostate biopsy is indicated in men with raised serum levels of prostate-specific antigen (PSA), an abnormal digital

rectal examination (DRE) or elevated PSA, and abnormal DRE.^[5] The decision to perform prostate biopsy should take into consideration the patient's overall health, comorbidities, life expectancy, and level of anxiety.^[5]

Biopsy of the prostate is usually well tolerated, with a low risk of major complications.^[4] Complications resulting from a biopsy can be infective or noninfective, with infection

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occurring in up to 60% of cases.^[6] Mortality, though very rare, has been reported following prostate biopsy, and most deaths reported are due to septic shock.^[7] Therefore, effort should be made to prevent infection following a prostate biopsy. Attempts to mitigate the infective complications include the use of bowel/rectal preparations and use of preprocedural antibiotics. Opinions differ among urologists on whether or not to perform bowel preparation before prostate biopsy.^[8] Again among those that practice bowel preparation, the methods vary.^[8] Methods of bowel preparations include rectal enema (saline, soap, or povidone-iodine) as well as the use of bisacodyl suppository.

The effect of bowel preparation on infection reduction in patients undergoing prostate biopsy is variable. To address the role of an enema in preventing infection, a study had analyzed many variables, including bacteriuria, bacteremia, and organisms, cultured from biopsy needles in a randomized study of men.^[9] In this study, bacteremia was reported in 4% of patients given an enema compared to 28% of patients who had no enema. The authors concluded that asymptomatic bacteremia may be significantly minimized by a prebiopsy enema independent of antibiotic administration.^[9]

Other studies showed that 38%–76% of prostate biopsies developed bacteremia, while only 17%–19% of patients developed bacteremia when povidone-iodine enema was administered.^[9,10] Huang *et al.* concluded in their work that bowel preparation had a statistically significant impact on the infection rate after prostate biopsy.^[8] Apart from the above methods of bowel preparations, Jeon *et al.* evaluated the use of bisacodyl prebiopsy rectal preparation and observed that this preparation could reduce transrectal biopsy infective complications.^[11] Despite the observations above, many large centers have abandoned the use of cleansing enema citing a lack of data supporting its usage, patient cost, and inconveniences.^[12]

Infection (urosepsis) can be life-threatening even in otherwise healthy men. With the rising prevalence of antibiotic-resistant bacteria, rates of sepsis despite standard antibiotic prophylaxis have been growing.^[13] Apart from the threat to life which infection poses to these mostly elderly patients, infective complications will further increase the cost of the procedure. The purpose of this study, therefore, is to determine whether bisacodyl rectal suppository can reduce infective complications postprostate biopsy.

PATIENTS, MATERIALS AND METHODS

This was a comparative cross-sectional study done at the urology unit of a tertiary hospital, over 12 months (January 2019–December 2019). A sample size of 56 was determined using Fisher's formula.^[14] Inclusion criteria were elevated PSA level >4 ng/mL, abnormal DRE, or a combination of elevated PSA and abnormal DRE. Excluded from the study were patients with urinary tract infection (UTI) or suspected prostatitis, diabetics with poor glycaemic control, those

with acquired immunodeficiency syndrome, those with hypersensitivity to ciprofloxacin, and patients on a urethral catheter. All patients included in the study had prebiopsy negative urine culture results and normal total and differential white blood cell counts.

Ethical approval was obtained from the ethics committee of our institution, and written informed consent was obtained from each patient.

The patients were randomly assigned to two groups. Those in Group 1 had 20 mg of bisacodyl (Dulcolax) suppositories given at night, starting two days before the procedure in addition to antibiotics (tablet ciprofloxacin [ciprotab] 500 mg and tablet metronidazole [Jugyl] 400 mg commenced at an hour before the procedure). Those in Group 2 were given tablets of ciprofloxacin (ciprotab) 500 mg and metronidazole (Jugyl) 400 mg 1hr before the procedure. Tablet ciprofloxacin 500 mg twice daily and tablet metronidazole 400 mg three times a day were continued for three days in both Group 2.

The patients underwent digitally guided 10-core transrectal prostate biopsy on an outpatient basis. The procedures were performed by a single urologist with the patient in the left lateral position under a low-dose saddle block.^[15]

Blood and urine samples were taken for full blood count and urine culture, respectively, three days after the biopsy. During the outpatient visit on the third day after the biopsy, a clean catch mid-stream urine sample was collected and sent to the microbiology laboratory within 30 min. The samples were inoculated on blood agar for colony counting and MacConkey agar for cultural characteristics. Antimicrobial susceptibility testing was done on Mueller–Hinton agar according to Clinical Laboratory Standard Institute.^[16] Patients were classified as positive for infective complications if there was leukocytosis (total white cell count >12,000/mm³ on full blood count), positive urine culture ($\geq 10^5$ colony-forming units per ml) with symptoms (UTI) or without symptoms (asymptomatic bacteriuria), and systemic inflammatory response syndrome with positive urine culture (urosepsis).^[17,18] Data obtained from the study were analyzed using the IBM SPSS Statistics for Windows, Version 21.0. (Armonk, NY: IBM Corp). The mean differences between continuous variables were compared using an independent Student's *t*-test. Associations between categorical variables were tested using Fischer's exact test. The level of significance was set at $P < 0.05$.

RESULTS

The mean age was 69.64 ± 9.31 with a range of 52–90 years. The age distribution of the participants is shown in Figure 1. The peak age distribution was 70–79 accounting for 23 (41.07%) of the total patient.

A comparison of the mean for age, prostate volume, and PSA between the two groups showed no statistically significant difference [Table 1].

In Group 1, two patients, one patient, and seven patients had urosepsis, UTI, and asymptomatic bacteriuria, respectively, while in Group 2, four patients, four patients, and ten patients had urosepsis, UTI, and asymptomatic bacteriuria respectively [Table 2]. The difference in infection rates between the groups was, however, not statistically significant.

DISCUSSION

Urologists have employed several approaches in an attempt to reduce prostate biopsy-related infections. Among these, approaches are the use of prophylactic antibiotics and preprocedure bowel preparation. While most urologists agree on the use of prophylactic antibiotics for prostate biopsy, the same cannot be said for the adoption of bowel preparation. Opinions vary among urologists on whether or not to perform prebiopsy bowel preparation.^[7]

The mean age of participants in this study was 69.64 ± 9.31, and the peak age range was 70–79. This is not surprising since prostate cancer is a disease of the aging male population. This distribution is similar to that reported by other studies in our subregion.^[19,20]

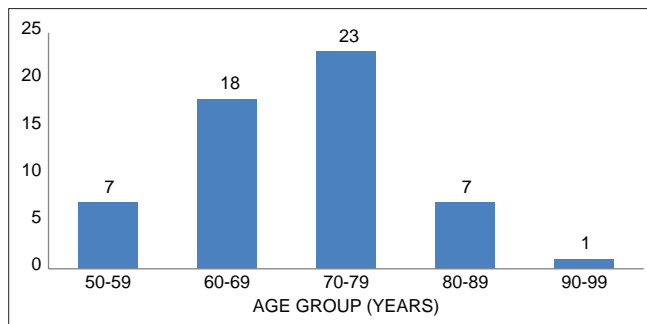


Figure 1: Bar chart showing the distribution of age groups among study participants (*n* = 56)

Table 1: Independent sample *t*-test showing the level of comparison between the test and control groups

Variable	Control group (<i>n</i> =28)	Test group (<i>n</i> =28)	<i>t</i>	<i>P</i>
Age (years)	69.10±8.76	70.17±9.95	-0.427	0.670
PSA (ng/ml)	89.036±88.47	82.81±76.89	0.280	0.779
Prostate volume (ml)	108.54±64.81	109.84±66.64	-0.074	0.941

PSA: Prostate-specific antigen

The indicators of infective complications in this study were urosepsis (systemic inflammatory response syndrome with positive urine culture), UTI (positive urine culture with clinical symptoms of dysuria, urgency, and suprapubic pain), and asymptomatic bacteriuria (positive culture in the absence of symptoms). Fewer infections were recorded in Group 1 compared to Group 2, but the difference between the two groups was surprisingly not statistically significant [Table 2]. This may be traceable to the relatively small sample size. This finding is in contrast to an observation by Jeon *et al.* that demonstrated that bisacodyl rectal suppository reduces infective complications following prostate biopsy.^[11] Similar to the current study, Zaytoun *et al.* compared the use of enema and antibiotics with the use of antibiotics alone, and concluded that there was no significant statistical difference in the incidence of infection or sepsis between the two groups.^[21] Again, Carey and Korman compared the use of preprocedural antibiotics alone with preprocedure enema and antibiotics. They concluded that ultrasound-guided prostate biopsy accompanied by quinolone antibiotics prophylaxis remains a relatively safe procedure and that enema before biopsy provides no clinically significant outcome advantage, and potentially increases patient cost and discomfort.^[22]

The prevalence of significant infection (UTI and urosepsis) requiring treatment in this study was 19.6%, while the overall prevalence (including asymptomatic bacteriuria) was 50%. This rate of biopsy-related infection is higher than 3.8% reported by Mbaeri *et al.*^[19] and comparable to 49.19% reported by Ugwumba *et al.*^[23] both in our subregion. It must, however, be stated that direct comparison of infection rates following prostate biopsy among various studies is difficult due to the fact that different hospitals/urologists have different biopsy protocols as well as different definitions for infection. To buttress this point in the study by Mbaeri *et al.*,^[19] rectal washout was done for all prostate biopsy cases, but postbiopsy urine cultures were not done for all cases, therefore, asymptomatic bacteriuria was not documented. Again in the study by Ugwumba *et al.*, it was not stated in their methods whether any form of bowel preparation was done. The authors also did not do postbiopsy urine cultures for all the participants and therefore did not report asymptomatic bacteriuria.

All patients that developed infective complications in this study belonged to either Clavien–Dindo Class 1 (bacteriuria) or 2 (urosepsis and UTI). Those that developed UTI and urosepsis were effectively treated with oral antibiotics on an outpatient

Table 2: Fischer’s exact test analysis showing the level of association in presence of postbiopsy infection between Group 1 and Group 2

Variable	Group 2 (<i>n</i> =28), <i>n</i> (%)	Group 1 (<i>n</i> =28), <i>n</i> (%)	Clavien-Dindo class	χ^2	<i>P</i>
Urosepsis	4 (14.29)	2 (7.14)	2	0.746	0.388
UTI	4 (14.29)	1 (3.57)	2	1.976	0.160
Bacteriuria	10 (35.71)	7 (25.0)	1	0.383	0.760
Prevalence	18 (64.28)	10 (35.71)			

UTI: Urinary tract infection

basis except for one patient from Group 2 that was admitted to the emergency department and treated with intravenous antibiotics. Those that had asymptomatic bacteriuria were not treated. Postbiopsy-related infections such as acute prostatitis, prostatic abscess, and epididymorchitis were not observed in this study. This may be attributed to the fact that patients with risk factors that can predispose to the above infections, such as uncontrolled diabetes, UTIs, and indwelling urethral catheters, were excluded from this study.

CONCLUSIONS

The addition of bisacodyl rectal suppository to antibiotics reduced the frequency of infective complications following prostate biopsy. The observed difference, however, was not statistically significant. Further studies with a larger sample size will be required to validate this.

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Conflicts of interest

There are no conflicts of interest.

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