Original Article

# Minimizing transrectal prostate biopsy-related infections; A prospective randomized trial of povidone-iodine intrarectal cleaning versus formalin needle disinfection

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## ABSTRACT

**Introduction:** Transrectal prostate biopsies are associated with post biopsy infection and sepsis. We compared the efficacy of povidone-iodine rectal disinfection versus formalin needle disinfection in preventing post biopsy infection among patients undergoing transrectal ultrasound-guided prostate biopsy.
**Methods:** Patients scheduled to undergo ultrasound-guided transrectal prostate biopsy ($n$ = 621) over 20 months were randomized into 2 groups to receive either povidone-iodine intrarectal disinfection or formalin disinfection of needle after each core. These were compared to assess which methodology better prevented postprocedure infection. Statistical analysis were used to identify independent factors promoting infections.
**Results:** Two hundred and ninety-eight patients from povidone-iodine intrarectal disinfection were compared with 300 from formalin needle disinfection group. Formalin needle disinfection was associated with significantly more infections ($P$ = 0.02). *Escherichia coli* was the dominant pathogen, with >50% of cases being quinolone resistant. Type of disinfection ($P$ = 0.002), BMI ($P$ = 0.001), chronic prostatitis ($P$ = 0.002), and diabetes mellitus ($P$ = 0.01) were independent predictors of infections. BMI at 28.95 kg/m$^2$ provided the best predictive cut-off point for infections, irrespective of method of disinfection. Area under the curve for all these parameters together was 0.91.
**Conclusions:** We conclude that along with oral cephalosporin prophylaxis, povidone-iodine intrarectal disinfection is a superior to formalin needle disinfection alone in preventing post biopsy infection. Patients with BMI >28.95 kg/m$^2$ should be considered at a higher risk for infections.

## INTRODUCTION

In the United States of America, more than one million prostate biopsies are performed annually. Therefore, a small percentage of adverse events postbiopsy can significantly impact a large portion of population's health. One of the most feared complications of transrectal ultrasound-guided prostate biopsy (TRUSPB) is postbiopsy infection and/or sepsis. In fact, infections after TRUSPB due to fluoroquinolone-resistant/extended-spectrum beta-lactamases (ESBL)-producing phenotype *Escherichia coli* are rising.[1,2] With the most common cause of hospitalization post-TRUSPB being

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infections, their financial burden on the healthcare system is enormous.[3-6]

Reported rates of infectious complications range from 0.1% to 7% and sepsis from 0.3% to 3.1%, sometimes associated with mortality.[7,8] Current evidence-based practice recommends the use of prophylactic antibiotics before TRUSPB, with the American Urological Association guidelines recommending a fluoroquinolone or first, second, or third-generation cephalosporin combined with an aminoglycoside.[3] Safe intraprocedural measures that complement the antibiotic prophylaxis are intrarectal povidone-iodine instillation or formalin needle disinfection after every core of the biopsy. Both are more effective at preventing postbiopsy infection than performing TRUSPB with antibiotic prophylaxis alone.[9,10] Although transperineal approach for prostate biopsy decreases risk of infection, for transrectal approach, literature evidence proving enhanced efficacy of povidone-iodine instillation versus formalin needle disinfection after every core of the biopsy is lacking. Accordingly, the objective of the present study was to comparatively and prospectively assess effectiveness of these two methods of infection prevention during TRUSPB.

## METHODS

### *Study design*

In a prospective randomized trial approved by the Larkin Community Hospital institutional review board (LCH-1-052019), six hundred and twenty-one consecutive patients scheduled for TRUSPB from a single urologist's practice between May 2019 and December 2020 were randomized into two groups, one receiving intrarectal instillation of commercially available 10% povidone-iodine and another undergoing 10% formalin needle cleansing after each biopsy coreas augmented prophylaxis.[11-14]

No patients received any prior bowel preparation. *A priori* power calculation determined that a total of 221 patients would be needed with 80% power to detect significant difference in the incidence of infections between these two techniques of disinfection. All patients were biopsied in the office by a single urologist having more than 15 years of experience doing prostate biopsies. To the best of our knowledge, this is the only study comparing these two methodologies in such a fashion.

### *Exclusion criteria*

Known allergy to povidone/iodine, ongoing immunosuppressive drugs, absent consent, lack of indication for biopsy after antibiotics therapy, MR fusion biopsy.

*Exclusion from statistical analysis after enrolment*

Prophylactic antibiotic sensitivity (2), postbiopsy Foley catheterization (6).

*Standard transrectal ultrasound-guided prostate biopsy procedure*

For formalin

All patients were placed in the left lateral decubitus position and received 2% lidocaine as periprostatic block through a side-firing transrectal ultrasound probe 10 min before the procedure. Patients underwent a 14-core biopsy protocol, including six parasagittal and six laterally targeted cores covering the base, mid-zones, apex, and two periurethral cores in the office setting using spring-loaded 18G BARD® MONOPTY® disposable core biopsy needle under ultrasonic guidance (Model Flex Focus 400®, BK medical systems). Ultrasound probes were processed by a trained medical assistant and brush washed along with enzymatic soap detergent (MAXIZYME®) as well as disinfected using wipes containing quaternary ammonium compounds and isopropyl alcohol (MICROKILL®) after every use. The biopsy needle adaptor for the needle along with the needle was disposed after each procedure.

### *Postbiopsy infection definitions*

1. UTI: Bacteriuria with leukocytes by microscopy within a week of procedure with signs of UTI (chills, dysuria, frequency, urgency, AND temperature <100.4 °F)
2. Bacteremia: Bacterial growth in blood culture
3. Sepsis: Systemic inflammatory response syndrome (presence of ≥2 of the following: Temperature ≥100.4°F or <96.8°F; tachycardia >90 beats/minute; tachypnea >20 breaths/minute or respiratory alkalosis paCO2 ≤32 mmHg; leukocytosis ≥12000 or leukopenia ≤4000 due to infection).[7,15]

*Randomization*

A computer-generated randomization sequence was used to allocate patients into two groups in a 1:1 ratio. This sequence was stored on a password-protected computer and accessed only at the time of biopsy.

Group F: Standard biopsy with needle disinfected by swirling in 10% formalin as per Issa *et al.* after every core.[13]

Group P: Intrarectal luminal instillation of 10 ml of 10% povidone-iodine for 10 min before standard biopsy procedure.

### *Study protocol*

Prebiopsy urine cultures were obtained from all patients. Culture-appropriate antibiotic therapy was initiated for infected patients defined as >50,000 colony-forming unit/mL of a single flora, even if asymptomatic. Biopsy was performed when culture was negative, provided indication for biopsy persisted. Anticoagulants were appropriately stopped. Blood sugar levels were controlled within normal limits before biopsy. Due to local bacterial susceptibility to cephalosporins and resistance to quinolones, our study patients were given single dose of oral cefuroxime 500 mg

once on the day of procedure.[16] Patients needing Foley catheterization after biopsy were excluded from the analysis, as catheterization could independently increase risk of infectious complications. The study's endpoint was development of signs and symptoms of infection, as previously defined, within a week of biopsy. Study assistants not directly associated with patient care and blinded to the type of intervention done (to eliminate detection bias) telephonically interviewed all patients regarding their symptoms along with daily temperature measurements, for 1 week. Within a week, symptomatic patients provided sample for urine culture, and oral nitrofurantoin 100 mg twice daily was initiated empirically. Further antibiotic course was dictated by urine culture results. Additional blood cultures were drawn whenever patients had temperatures ≥100.4°F. These patients were also admitted for extended-spectrum penicillin with β-lactamase inhibitor (piperacillin-tazobactam) antibiotics until afebrile.

### *Statistical analysis*

Normally distributed data are represented as mean ± standard deviation. Categorical data were analyzed by Chi-squared test ($\chi^2$). For dichotomous outcomes of infection, results were expressed as risk ratios (RRs) with 95% confidence intervals (CI). Binary logistic regression was performed to assess independent significant predictors for infectious complications. Receiver operating curve (ROC) determined predictive ability for infections with all significant factors taken together. ROC derived highest value of Youden index "J," defined as max (sensitivity + specificity-1), gave the best cut-off value for body mass index (BMI), where *c* ranges over all possible BMI values. [17,18] All statistical analysis was performed using SPSS v. 22.0 software (IMB, Chicago, IL, USA) and Jamovi,[19] and $P \leq 0.05$ was considered significant.

## RESULTS

Abnormal DRE ($n$ = 32, 5.5.3%), PIRADS-5 lesions with normal PSA ($n$ = 3, 0.5%), PSA > 4 ng/mL ($n$ = 497, 82%), and active surveillance biopsy ($n$ = 74, 12.2%) were indications for prostate biopsy. After excluding as per exclusion criteria, each group had 303 patients. In Group F, 2 did not receive the intended intervention and 3 were excluded from analysis after intervention due to retention of urine. In Group P, all received the desired intervention but three were eliminated from analysis after receiving the intended intervention due to retention of urine. Thus, resulting in 298 from the former and 300 from the latter is analyzed statistically. There was no attrition resulting from lack of follow-up [Figure 1].

There was no significant difference in the clinical and biochemical parameters between the two groups [Table 1]. Total duration of TRUSPB was not significantly different between the two groups ($P$ = 0.72). Infectious complications within a week of biopsy in the total study population were observed in 30 patients (5%), distributed as 23 (76.6%) and 7 (23.3%) in Group F and Group P, respectively. Patients in Group F were more than three times as likely to get infected (RR 3.3), $\chi^2$ (1, $n$ = 598) =5.1, $P$ = 0.02, as compared to Group P. Group F was observed to have a higher incidence of UTI + fever < 100.4°F ($P$ = 0.005) and of fever ≥100.4°F ($P$ = 0.03) as compared to Group P. This difference was statistically significant. Incidence of other infectious complications such as epididymo-orchitis ($P$ = 0.64) and acute prostatitis ($P$ = 0.99) was not statistically different between the two groups [Table 2a and Figure 2a]. There was no statistical difference in the time to report infections after biopsy, (Group F 2.2 days versus Group P 2.6 days; $P$ = 0.6).

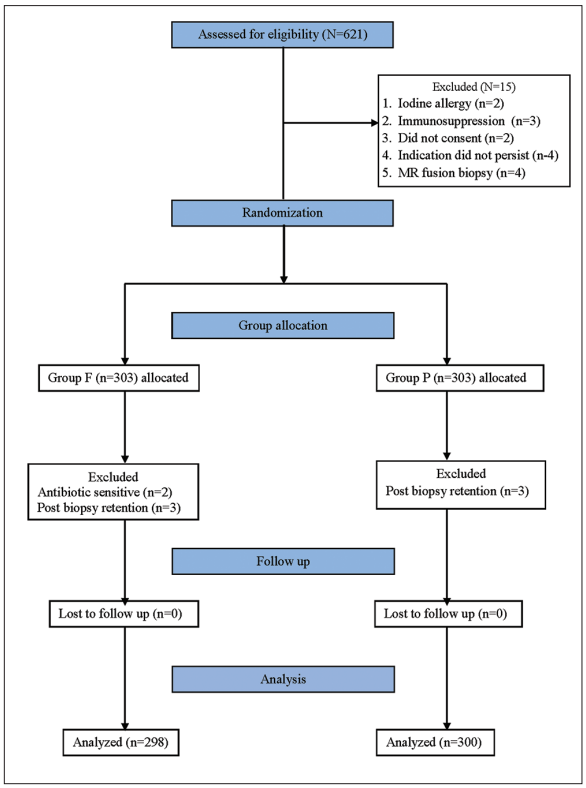


**Figure 1:** CONSORT flow diagram of the study. Group F, Needle disinfection with formalin; Group P, Povidone-iodine rectal disinfection

Twenty-two out of 30 symptomatic patients had bacterial growth on urine culture and six out of eight septic patients had positive blood cultures. *E. coli* was the dominant pathogen ($n$ = 17, 63%), followed by *Klebsiella pneumoniae* ($n$ = 4, 14.8%) and *Staphylococcus saprophyticus* ($n$ = 3, 11%), with *Enterococcus faecalis*, Proteus spp. and combined *E. coli* with *E. faecalis* comprising the rest. Quinolone resistance was observed in 17 cultures (63%) wherein *E. coli* and *K. pneumoniae* showed ≥ 50% resistance and 47% of *E. coli* were ESBL producing [Table 2b]. Discordant blood and urine cultures were seen in two patients in Group F. One grew *S. saprophyticus* in urine but *E. coli* in blood. Another had sterile urine, but blood culture grew *E. coli* + *E. faecalis* [Table 2b]. One patient in Group F with quinolone-resistant Klebsiella initially

**Table 1: Patient demographics and clinical data**

| Parameter | Student's *t*-test | | | | |
|---|---|---|---|---|---|
| | Group F (*n*=298) | Group P (*n*=300) | *t*-statistic (*t*) | *P* | 95% CI |
| Age | | | | | |
| Mean±SD | 64±3.3 | 63.5±4.9 | 1.65 | 0.09 | −0.11–1.2 |
| Median (IQR) | 64 (6) | 65 (8) | | | |
| BMI | | | | | |
| Mean±SD | 25.9±1.9 | 26.1±1.9 | 0.97 | 0.32 | −0.4–0.15 |
| Median (IQR) | 26.1 (2.8) | 26.3 (2.7) | | | |
| PSA | | | | | |
| Mean±SD | 7±1.9 | 7.3±2.5 | 1.81 | 0.07 | −0.7–0.02 |
| Median (IQR) | 6.7 (2.5) | 6.5 (3.7) | | | |
| Prostate weight | | | | | |
| Mean±SD | 42.5±11.3 | 43.1±11.7 | 0.69 | 0.48 | −2.51–1.2 |
| Median (IQR) | 40 (18) | 42 (20) | | | |
| **Parameter** | **Chi-square test** | | | | |
| | **Group F (*n*=298)** | **Group P (*n*=300)** | **$\chi^2$-statistic** | **df** | ***P*** |
| Hypertension | 34 | 38 | 0.22 | 1 | 0.63 |
| Charlson index | | | | | |
| 1 | 87 | 78 | 6.4 | 4 | 0.16 |
| 2 | 125 | 144 | | | |
| 3 | 33 | 42 | | | |
| 4 | 49 | 32 | | | |
| 5 | 4 | 4 | | | |
| DM | 18 | 14 | 0.55 | 1 | 0.45 |
| Chronic prostatitis | 6 | 3 | 1.1 | 1 | 0.30 |
| Anticoagulants | 16 | 20 | 0.44 | 1 | 0.50 |
| Recent Foley | 7 | 3 | 1.65 | 1 | 0.19 |
| UTI | 10 | 5 | 1.7 | 1 | 0.18 |
| Prior biopsy | 31 | 43 | 2.13 | 1 | 0.14 |
| Recent hospitalization | 6 | 11 | 1.47 | 1 | 0.22 |
| TURP | 4 | 2 | 0.6 | 1 | 0.40 |
| Antibiotics <3 m | 20 | 17 | 0.28 | 1 | 0.59 |
| Cancer detection | 57 | 51 | 0.6 | 1 | 0.43 |

df being 596 for all *t*-tests. Group F=Needle disinfection with formalin, Group P=Povidone-iodine rectal disinfection, UTI=Urinary tract infection, TURP=Transurethral resection of prostate, df=Degree of freedom, DM=Diabetes mellitus, BMI=Body mass index, PSA=Prostate specific antigen, SD=Standard deviation, IQR=Interquartile range, CI=Confidence interval

**Table 2: Rate of infections and detailed bacteriogram of positive cultures**

**a. Rates of infectious complications**

| Parameters | Total, *n* (%) | Group F, *n* (%) | Group P, *n* (%) | *t*-statistic (t) | df | *P* |
|---|---|---|---|---|---|---|
| Infective complications | 30 (5) | 23 (76.6) | 7 (23.3) | 5.1 | 1 | 0.02* |
| LUTS without fever | 104 (16.8) | 56 (53.8) | 48 (46) | 0.8 | 1 | 0.3 |
| UTI (chills, dysuria, frequency, urgency, temperature<100.4°F) | 15 (50) | 12 (80) | 3 (20) | | 1 | 0.005* |
| Septicemia | 8 (26.6) | 7 (87.5) | 1 (12.5) | 4.6 | 1 | 0.03* |
| Epididymitis/orchitis | 5 (16.6) | 3 (60) | 2 (40) | 0.2 | 1 | 0.64 |
| Acute prostatitis | 2 (6.6) | 1 (50)† | 1 (50) | 0.0 | 1 | 0.99 |

**b. Bacteriogram of all positive cultures**

| Bacteria | Total, *n* (%) | Positive urine culture, *n* (%) | Positive blood culture, *n* (%) | Fluoroquinolone resistance, *n* (%) |
|---|---|---|---|---|
| *E. coli* | 17 (63) | 14 (66.6) | 3 (50) | 14 (70) (*n*=8 ESBL positive) |
| *S. saprophyticus* | 3 (11.1) | 2 (9.5) | 1 (16.6) | 1 (33.3) |
| *E. faecalis* | 1 (3.7) | 1 (4.7) | 0 | 0 |
| *K. pneumoniae* | 4 (14.8) | 3 (14.2)‡ | 1 (16.6) | 2 (50) |
| *Proteus spp.* | 2 (6.6) | 2 (100) | 0 | 0 |
| *E. coli+E. faecalis* | 1 (3.7) | 0 | 1 (16.6) | E. coli (resistant) + Enterococcus sensitive) |
| Total | 28 | 22 | 6§ | 17 |

*Statistically significant values, †One patient needed admission due to fever>100.4°F and was analyzed in acute prostatitis as well as in group with fever>100.4°F, ‡Delayed hospitalization for late rise in fever (after 3 days of antibiotics), §Two patients in sepsis did not have any growth on blood culture. Group F=Needle disinfection with formalin, Group P=Povidone iodine rectal disinfection, UTI=Urinary tract infection, ESBL=Extended spectrum beta-lactamase, LUTS=Lower urinary tract symptoms, df=Degree of freedom, *E. coli=Escherichia coli, E. faecalis=Enterococcus faecalis, S. saprophyticus=Staphylococcus saprophyticus, K. pneumonia=Klebsiella pneumonia*

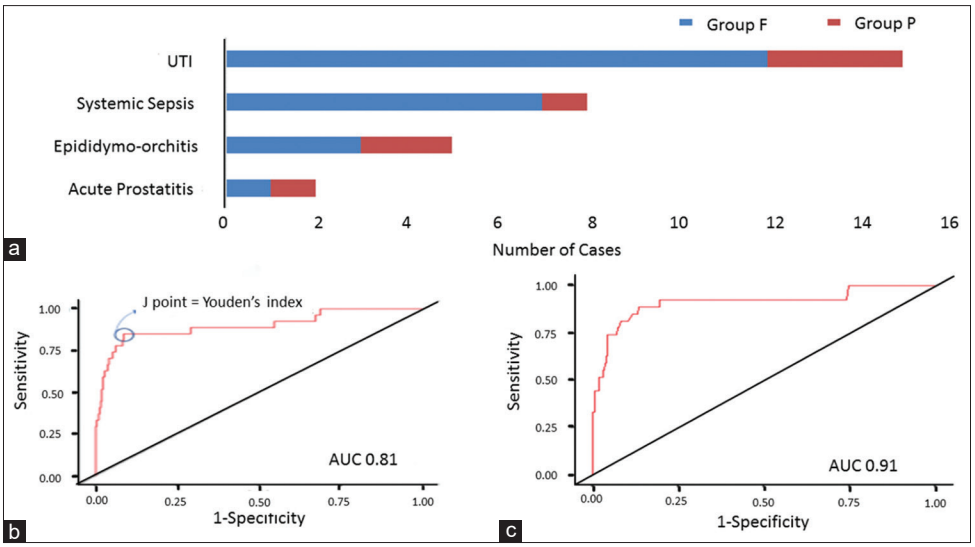


**Figure 2:** (a) Distribution of infective complications within Groups F and Group P. (b) Receiver operator curve to determine the Youden's index from body mass index data. (c) Receiver operator curve for all the significant predictors taken together. Group F, Needle disinfection with Formalin; Group P, Povidone-iodine rectal disinfection

responded to oral antibiotics, but after 3 days, developed fever >100.4°F necessitating admission [Table 2b]. A total of eight patients (1.3%) were hospitalized with sepsis, none in the intensive care unit.

Binary logistic regression was conducted based on an $\alpha$ of 0.05 to examine whether age, PSA, prostate weight, past urinary infection, hospitalization within a month before biopsy, prior history of prostate biopsy, prior transurethral resection of prostate (TURP), recent catheterization, hypertension, recent antibiotic usage, anticoagulants, type of disinfection used, diabetes mellitus (DM), prior biopsy-proven chronic prostatitis, and BMI had a significant effect on the odds of getting an infection postbiopsy. Number of cores taken during biopsy was not considered due to literature evidence of it not effecting the incidence of infection.[20] Variation inflation factors (VIFs) were calculated to detect the presence of multicollinearity between predictors. All predictors in the regression model had VIFs <10. McFadden's $R^2$ value of 0.41 indicated the model to be an excellent fit. The overall model was significant $\chi^{2[19]} = 90.25$, $P < 0.001$ with regression coefficients for DM being significant ($B = 2.5$, $P = 0.01$, odds ratio [OR]: 5.0, 95% confidence interval [CI]: 1.4–16.9). Povidone-iodine disinfection significantly decreased the odds of infection ($B = -2.4$, $P = 0.002$, OR: 0.18, 95% CI: 0.06–0.53). BMI and chronic prostatitis both had significant regression coefficients of ($B = 4.9$, $P = 0.001$ OR: 1.73, 95% CI: 1.4–2.1) and ($B = 3.3$, $P = 0.002$, OR: 22.3, 95% CI: 3–165), respectively [Table 3a]. Age, PSA, prior UTI/biopsy/catheterization/TURP/hospitalization, and Charlson index did not predispose to infections irrespective of disinfection method employed, $\chi^2$ (1, $N = 598$) = 0.157, $P = 0.69$. Type of disinfection did not show any statistical significance in the cancer detection rates $\chi^2$ (1, $n = 5$ 98) = 0.6, $P = 0.4$. A ROC was drawn to determine the Youden's index value, beyond which BMI was most significantly associated with infections irrespective of the method of sterilization [Figure 2b]. Youden's index for BMI was 28.95 kg/m$^2$ with area under curve (AUC) of 0.81. The predictive value of the combination of all significant predictors of infections was evaluated by constructing a ROC curve which had AUC of 0.91 [Table 3b and Figure 2c].

**Table 3: Binary logistic regression and AUC curves for predictors of infections**

**a. Entire cohort Binary logistic regression**

| Predictor | SEM | *P* | OR | 95% CI | |
|---|---|---|---|---|---|
| | | | | Lower | Upper |
| BMI | 0.11 | 0.001 | 1.73 | 1.39 | 2.16 |
| Chronic prostatitis | 1.02 | 0.002 | 22.3 | 3.0 | 165 |
| DM | 0.62 | 0.01 | 5.0 | 1.47 | 16.9 |
| Disinfection method | 0.53 | 0.002 | 0.18 | 0.06 | 0.53 |

**b. AUC for each predictor**

| Parameters | AUC |
|---|---|
| BMI (*P*<0.001) | 0.81 |
| Chronic prostatitis (*P*<0.001) | 0.59 |
| DM (*P*=0.03) | 0.58 |
| Type of disinfection (*P*=0.03) | 0.61 |
| BMI, chronic prostatitis, DM, and type of disinfection | 0.91 |

Estimates represent the log odds of "Infections=0" versus "Infections=1." $SE_M$=Standard error of estimate, which measures the accuracy of predictions, a smaller $SE_M$ means more accurate predictions, AUC=Area under the curve derived from respective receiver operating curves, DM=Diabetes mellitus, BMI=Body mass index, OR=Odds ratio, CI=Confidence interval

## *Poststudy analysis*

No infections were resistant to piperacillin plus tazobactam. None of our patients developed ascending upper tract infections and there were no mortalities. Complete resolution of infection occurred in all patients as confirmed by subsequent negative urine cultures. Both patients with discordant cultures had chronic prostatitis on biopsy histopathology.

## DISCUSSION

The goal of this study was to compare the efficacy of two common methods of disinfection during TRUSPB in preventing postbiopsy infectious complications. We believe that this is the first prospective randomized trial comparing them directly. Our study suggests that povidone-iodine disinfection of the rectum 10 min before TRUSPB is a superior adjunct to antibiotic prophylaxis than formalin needle sterilization after each core for infection prevention.

A Cochrane systematic review established the benefits of prophylactic antibiotics for TRUSPB.[7] However, fluoroquinolone resistance was not considered at the time of review. More contemporary literature suggests that >50% of infections post-TRUSPB are due to fluoroquinolone-resistant *E. coli,* and consequently cefuroxime was given in this study for prophylaxis.[21] Infections typically happen within 3-day postbiopsy; hence, our patients were followed up daily for a week after procedure looking for evidence of infections.[22] Nitrofurantoin was the empiric drug of choice for suspected infection because it causes negligible collateral damage, due to its minimal effects on gut flora, and local antibiogram showing high susceptibility to it. Although known risk factors for TRUSPB urosepsis include recent catheterization, hospitalization, and antibiotic use, none of these factors were found to be significantly predicting infections in our study.[23,24]

Most of the reported literature used a quinolone for antibiotic prophylaxis; hence, our results may not be directly comparable to them. Whereas Abughosh *et al.* demonstrated insignificant infection reduction with povidone-iodine, Park *et al.* and Ryu *et al.* with a similar protocol of parenteral cephalosporin for prophylaxis had no infections with povidone-iodine rectal suppository.[25-27] In contrast, our study protocol showed a 2.3% infection rate in Group P. Our study corroborates literature justifying the use of intrarectal povidone-iodine over formalin disinfection of needles for TRUSPB.[14] Rate of hospitalization in the current study ($n$ = 8, 1.3%) was comparable with another reported series, which had 1.9% admission rates and like our study, reported no mortality.[28] This study concurs with other reported series regarding elevated BMI being significantly and independently associated with an increased likelihood of postbiopsy infections.[29] Our BMI cut-off value of 28.95 kg/m$^2$ for predicting infections was very close to the value (28.19 kg/m$^2$) cited by Wu *et al.* for predicting infections.[30] Despite many reports associating an elevated BMI with increased incidence of surgical infections, the exact mechanism of increased infectious complications after prostate biopsy remains to be elucidated.[31,32] Our study was consistent with multiple studies confirming that the presence of diabetes increased the risk of infection after biopsy.[24,33] That being said, high BMI often coexists with DM and could serve as confounders. Future studies eliminating this effect are needed to determine the exact causal relationship between these factors and subsequent postbiopsy infections.

Bacterial virulence is dictated by bacterial density, which also determines the amount of disinfectant needed to inhibit its growth.[22] We assume that since formalin did not reduce the bacterial density enough, bacterial virulence easily established a clinical infection, eliciting a systemic symptomatic response. On the other hand, povidone-iodine reduced bacterial density enough to prevent a systemic symptomatic response and instead caused only localized infection leading to asymptomatic bacteriuria. Extrapolating, this explains the finding of a solitary admission in Group P and seven in Group F. Intravascular seeding of resistant bacteria during biopsy could be the reason for this discordance.

In contrast to existing literature, our study showed no association between antecedent antibiotic usage, hospitalization, or prior infections.[34] This study concurs with other reports that prior biopsy does not predispose to infections after repeat biopsies.[35] Although reported in the literature, none of our patients had any significant distant sites of infection (for example meningitis or osteomyelitis).

A perfect ROC model has a curve with an AUC of 1.0, while a model with no predictive worth has a value of 0.5. Our results indicate that it is valid to predict likelihood of postbiopsy infections using BMI, chronic prostatitis, DMs, and type of disinfection used (AUC 0.91).

### *Limitations*

Being an interventional trial, it was difficult to blind both subjects and provider to the method of disinfection used, although initial randomization was blinded. This potentially led to alteration of symptoms by the patients when quizzed by an independent observer. Patients could have assumed that by virtue of their group allotment, they could have been provided better care. In addition, patients with a higher tolerance to localized and systemic symptoms may have under-evaluated their symptoms considering them to be a natural consequence of TRUSPB. On the other hand, some patients with a more sensitive health constitution may have overestimated their symptoms, suggesting infections when none was present. Hence, reporting bias may not have been eliminated completely. Although this bias was likely overcome by daily temperature reporting and by mandatory urinalysis after a week of biopsy. Number of cores taken during biopsy could be another confounding factor which was not considered as a parameter for analysis in this study.

## CONCLUSIONS

Intrarectal povidone-iodine 10 min before TRUSPB is a useful adjunct to oral cephalosporin antibiotic prophylaxis

in preventing post-TRUSPB infectious complications. It is superior to formalin needle disinfection. The ROC curve of BMI, chronic prostatitis, DMs, and type of disinfection used together had an AUC of 0.91, suggesting that these parameters collectively are an excellent predictor of infection.

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