Evaluating the efficacy of transrectal povidone-iodine application for infection prevention in transrectal ultrasound-guided prostate biopsy: A single-center retrospective study

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ABSTRACT

Introduction: Prostate cancer diagnosis via transrectal ultrasound-guided (TRUS) biopsy carries a significant risk of infectious complications due to potential contamination from the rectal microbiome. This study aimed to evaluate the efficacy of transrectal 10% povidone-iodine application, in combination with antibiotic prophylaxis, in reducing infectious complications following TRUS biopsy.

Materials and Methods: A retrospective analysis was conducted on 643 patients who underwent TRUS biopsy at a single center in a tertiary hospital in Kuala Lumpur between January 2017 and December 2023. Patient records were reviewed for demographic data, biopsy indications, type of antibiotic prophylaxis, and post-biopsy complications. Patients were categorized into two groups: those who received antibiotic prophylaxis alone and those who received both antibiotic prophylaxis and transrectal povidone-iodine. Statistical analyses, including chi-square tests and logistic regression, were performed to compare outcomes and assess the impact of povidone-iodine on infection rates.

Results: Of the 643 patients, 285 received antibiotic prophylaxis combined with transrectal povidone-iodine, was associated with a significantly lower infection rate from 2.23% to 0.7% (P<0.05). There were no significant differences between the povidone-iodine and non–povidone-iodine groups in terms of patient demographics, including age, prostate volume, Prostate Specific Antigen (PSA) levels, and histopathological findings. Logistic regression analysis further confirmed the significant effect of povidone-iodine in reducing post-biopsy infections presenting as fever >37.5 within 30 days after TRUS biopsy.

Conclusion: The results indicate that the use of transrectal 10% povidone-iodine alongside antibiotic prophylaxis is an effective approach for reducing infectious complications following TRUS biopsy.

KEYWORDS:
Prostate biopsy, sepsis, urosepsis, povidone-iodine, prophylactic antibiotic, rectal cleansing

INTRODUCTION

Prostate cancer is the second most prevalent cancer globally, following lung cancer.[1-2] In Malaysia, it ranks as the third most common cancer among men, with incidence rising from 1,186 cases in 2014 to 1,807 cases in 2018, accounting for 8.8% of all cancers in Malaysian men.[3] The increase in case detection is largely due to screening programs that incorporate Prostate Specific Antigen (PSA) continues to be the most crucial and commonly utilized biomarker for prostate cancer.[4] Elevated serum PSA levels, or with abnormal findings from a digital rectal examination (DRE), are primary indicators for performing a prostate biopsy to confirm prostate cancer.

Prostate biopsies can be performed using either the transrectal or transperineal approach. The transperineal method, often supplemented by multiparametric magnetic resonance imaging (mpMRI), has emerged as a viable option for diagnosing prostate cancer in modern clinical practice.[5] This technique minimizes exposure to the rectal microbiome, potentially reducing the risk of infectious complications compared to the transrectal approach. Studies comparing the two methods have shown that the transperineal approach provides diagnostic outcomes comparable to those of TRUS biopsy.[6]

Although transperineal biopsies may offer safety advantages, they present challenges such as the need for general anesthesia, higher costs, longer procedure times, and specialized equipment. As a result, the transrectal ultrasound-guided 12-core systematic biopsy remains the most commonly used method for the initial diagnosis and grading of prostate cancer.[7] However, due to the high density of bacterial flora in the rectum, this approach carries an increased risk of infectious complications, primarily resulting from bacterial contamination during the biopsy procedure.[8]

TRUS biopsy is associated with various complications, with bleeding being the most common. Hematuria and hematospermia occur in approximately 60% of cases, followed by rectal bleeding in 20%.[9] These complications are typically mild and self-limiting. However, infectious complications such as urinary tract infections, epididymitis, orchitis, and prostatitis, pose a more significant risk.

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Although rare, cases of sepsis, septic shock, and even death have been reported, with incidence rates of 5.7%, 0.45%, and 0.2%, respectively.[9]

Various strategies have been implemented to reduce the risk of infectious complications following TRUS biopsy, including the use of oral or intravenous antibiotic prophylaxis. These measures are consistent with the recommendations of the European Association of Urology (EAU) and the American Urological Association (AUA) guidelines.[10] Additionally, transrectal application of povidone-iodine has shown promising results in lowering infection rates. Povidone-iodine, widely recognized for its effectiveness in preventing infections in colorectal surgery and wound care, has also been used alongside prophylactic antibiotics prior to TRUS biopsy to further reduce infection risk.[11] Despite supporting evidence, transrectal povidone-iodine cleansing is not universally adopted in clinical practice due to lack of standardized protocol and logistical barriers to implementation.[12-13] This study aims to provide real-world data on its effectiveness when combined with antibiotic prophylaxis, further supporting its role in infection prevention within a contemporary patient cohort.

Previous research has consistently shown that combining povidone-iodine with antibiotic prophylaxis effectively reduces the risk of infectious complications following TRUS biopsy.[14] Therefore, this study aims to assess whether the application of transrectal 10% povidone-iodine in combination with prophylactic antibiotic prior to the procedure at our center can further decrease the incidence of infectious complications.

MATERIALS AND METHODS

Study Population

A retrospective analysis was conducted on the records of all patients (n = 643) who underwent TRUS biopsy at our center between January 2017 and December 2023. Data collected included patient age, DRE findings, PSA levels, prostate volume, type of antibiotic prophylaxis, histopathological findings, and post biopsy complications. For patients who experienced infectious complications, additional information was collected on comorbidities, culture results, duration of hospitalization, type of antibiotic treatment, and severity of complications.

Study Design

The medical records of 643 patients who underwent TRUS biopsy at a tertiary hospital in Kuala Lumpur between January 2017 and December 2023 were reviewed retrospectively. Indications for biopsy included a PSA level above 4.0 ng/mL and/or suspicious findings on prostate examination. Patients were excluded if they had abnormal coagulation, immunodeficiency (specifically patients undergoing chemotherapy or HIV infection), severe hemorrhoids, indwelling urinary catheters, or known hypersensitivity to povidone-iodine.

All patients received prophylactic antibiotics, either ciprofloxacin (500 mg twice daily) for 5 days starting the day before the procedure, or fosfomycin (3 g once daily) for 2 days starting on the day of the procedure. Additionally, all patients were administered a sodium chloride–glycerine enema (glycerine 25%, sodium chloride 15%) two hours prior to the procedure.

During the procedure, patients were positioned in the left lateral decubitus position with the left knee flexed. The external anal mucosa and surrounding skin were cleansed with 10% povidone-iodine, and sterility was maintained by draping the procedural area. A lubricating gel (Cathejell; 2% lignocaine, 0.05% chlorhexidine) was introduced into the rectum. In addition to external cleansing, 10 mL of 10% povidone-iodine was instilled into the rectum using a 10 mL syringe. Local anesthesia was administered via a periprostatic nerve block. The biopsy procedure commenced after five minutes of povidone-iodine exposure. Transrectal ultrasound was performed to assess the prostate for cystic or suspicious nodular lesions, and prostate volume was recorded. A standard 12-core prostate biopsy was then performed using a 16G biopsy needle with an automatic biopsy gun. Additional cores were taken if suspicious areas were identified during TRUS biopsy. After the procedure, patients were observed in a supine position for approximately 15 minutes and discharged the same day.

Patients were advised to return to the emergency department if they experienced urinary retention, fever, hematuria, dysuria, rectal bleeding, or persistent pain following the procedure. A follow-up appointment at the urology outpatient clinic was scheduled two weeks post-biopsy to review pathology results and assess for infectious or non-infectious complications. Minor complications were defined as self-limiting conditions such as hematuria, rectal bleeding, dysuria, and anal pain. Infectious complications were defined as fever (>37.5°C) occurring within 30 days post-biopsy, accompanied by chills or at least one lower urinary tract symptom (dysuria, urgency, frequency, hematuria, or perineal pain), or a positive urine or blood culture. Sepsis was defined as a systemic infection with hemodynamic instability.

Statistical Analysis

Patient data including age, DRE findings, prostate volume, PSA values, histopathology results, and instances of hospitalization due to post-biopsy fever—were analyzed as basic demographic and clinical information. Categorical variables (e.g., benign vs. suspicious DRE findings and pathology results indicating malignancy) were compared using the Chi-square test, while continuous variables (e.g., age, prostate volume, PSA values) were compared using the t-test. These analyses aimed to assess differences between two groups: one that received antibiotic prophylaxis combined with transrectal povidone-iodine and another that received antibiotic prophylaxis alone.

A multivariate logistic regression analysis was conducted to assess the impact of several factors on the likelihood of developing infectious complications following TRUS biopsy. These factors included the type of prophylaxis (antibiotic prophylaxis with or without transrectal povidone-iodine), patient age, DRE findings, prostate volume, PSA level, and histopathological outcome (malignancy: yes/no). Odds ratios

Table I: Combined statistical results for demographic parameters and infection rates

Variable	Povidone Group (n=285)	Non-Povidone Group (n=358)	Total (n=643)	p-value
Infection Rate	2/285 (0.7%)	8/358 (2.23%)	10/643	0.008
Age (mean ± SD)	70.45 ± 6.21	73.06 ± 6.72	643	0.102
DRE Findings				0.030
- Nodular	105	103	208	
- Smooth, Benign	180	255	435	
Prostate Volume (cc)				0.781
- Mean ± SD	58.41 ± 31.31	55.16 ± 26.43	643	
PSA Level (ng/mL)				0.162
- Mean ± SD	103.19 ± 393.13	115.17 ± 685.51	643	
HPE Results				0.116
- Benign	165	229	394	
- Adenocarcinoma	120	129	249	

Table II: Results of multivariate logistic regression analysis

Variable	Odds Ratio (OR)	95% CI	p-value
Age	1.042	0.944 - 1.152	0.709
DRE	1.314	0.601 - 2.875	0.133
PSA Level	0.999	0.996 - 1.003	0.048
Prostate Volume	0.999	0.976 - 1.023	0.880
HPE	0.911	0.692 - 1.200	0.770
Povidone-Iodine	0.550	0.082 - 3.690	0.149

(ORs) with 95% confidence intervals (CIs) were calculated to determine the strength of these associations. All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS), Version 23.0 (SPSS Inc., Chicago, IL), with a P-value of <0.05 considered statistically significant.

Ethics Approval

This retrospective study was approved by the Research Ethics Committee of the National University of Malaysia (IRB no. JEP-2024-572). In accordance with institutional policy, the requirement for individual written informed consent was waived due to the retrospective nature of the study.

RESULTS

A total of 643 patients underwent TRUS biopsy, with 285 receiving transrectal povidone-iodine in addition to antibiotic prophylaxis, and 358 receiving antibiotic prophylaxis alone. The infection rate was significantly lower in the group that received povidone-iodine, decreasing from 2.23% (8 out of 358 patients) in the non-povidone group to 0.7% (2 out of 285 patients) in the povidone group (P = 0.008) (Table I).

Among the 10 cases of post-TRUS biopsy infection, all complications were mild (Clavien-Dindo Grade II), with no instances requiring ICU admission or intubation. Five of the cases had underlying diabetes mellitus, while the other five had underlying hypertension and dyslipidemia. Most infections responded well to antibiotic treatment, either empirically or based on culture results. Only two cases yielded positive cultures: one blood culture grew Proteus mirabilis, and one urine culture grew Escherichia coli. No patient required hospitalization for more than 10 days.

The combined analysis of demographic and clinical variables, as shown in Table 1, revealed a significant difference between the povidone-iodine and non–povidone-iodine groups only in DRE findings (p=0.030). Other variables, including age (p=0.102), PSA level (p=0.162), prostate volume (p=0.781), and histopathological examination (HPE) results (p=0.116), showed no statistically significant differences between the two groups.

Multivariate logistic regression analysis was performed to evaluate the influence of various factors including the use of povidone-iodine, age, DRE findings, prostate volume, PSA level, and HPE results on the likelihood of developing post-biopsy fever. The analysis identified PSA level as a significant predictor of infection (p=0.048), while other factors, including the use of povidone-iodine, did not reach statistical significance (Table II).

DISCUSSION

Infectious complications following TRUS biopsy have been reported in 0.1% to 7.0% of cases, with sepsis rates ranging from 0.3% to 3.1%.[15] To reduce the risk of post-biopsy infections, various preventive strategies have been implemented, with antimicrobial prophylaxis being one of the most widely supported. Although there is considerable variability in clinical practice regarding the choice and duration of prophylaxis, strong evidence supports the effectiveness of antimicrobial agents in reducing infection risk.[16] A systematic review further confirmed that antimicrobial prophylaxis significantly decreases the incidence of infectious complications, particularly when fluoroquinolones are used.[17]

Fluoroquinolones are preferred for prophylaxis due to their broad-spectrum activity against intestinal flora and their ability to achieve high concentrations in prostatic tissue following oral administration.[18] However, the increasing prevalence of fluoroquinolone resistance has prompted the

exploration of alternative antibiotics, such as fosfomycin, which has shown promising results in patients with fluoroquinolone-resistant infections.[19] Studies have indicated that fosfomycin not only results in fewer septic complications but also has a side effect profile comparable to that of quinolone-based prophylactic regimens for TRUS biopsy.[20] In our study, all patients received either ciprofloxacin (a second-generation fluoroquinolone) or fosfomycin, both of which have demonstrated efficacy in preventing post-biopsy infections.

The role of adjunct measures such as pre-biopsy rectal cleansing enemas in infection prevention remains controversial. Enemas are intended to reduce the rectal microbial load before biopsy, thereby decreasing the number of bacteria introduced during the procedure.[21-23] However, the use of enemas alone has been found to be insufficient in preventing infections following TRUS biopsy.[24] In our study, all patients received an enema the night before the procedure and another two hours prior, which not only helped reduce fecal content but also improved the acoustic window for the biopsy.

Recent guidelines from the EAU recommend the use of rectal povidone-iodine preparation as part of the infection prevention protocol for TRUS biopsy. Our study aimed to evaluate and further support this guideline-recommended practice. While the use of rectal povidone-iodine has been previously reported, this study provides updated real-world data, particularly in the context of rising fluoroquinolone resistance and the increasing use of alternative prophylactic antibiotics.

Comparisons between povidone-iodine and chlorhexidine for rectal mucosal cleansing have also been explored.25 While the effectiveness of povidone-iodine may be reduced in the presence of mucus and feces, which can limit its bioavailability, chlorhexidine in its alcohol-based form may offer better mucosal and skin penetration. However, studies have shown no significant difference between the two agents in preventing infections. Povidone-iodine may be the safer option, as it has been associated with a lower risk of complications such as hematuria, rectal bleeding, and urinary retention.[25]

Substantial evidence supports the transperineal approach for prostate biopsy, as it carries a lower risk of infection.[26] However, recent meta-analyses have shown that infection rates following transperineal and transrectal biopsies are comparable.[27] Widespread adoption of this method particularly in developing or transitioning economies remains challenging. Barriers include the need for general anesthesia (despite the availability of local anesthesia alternatives), limited access to necessary equipment, inadequate reimbursement, and insufficient training during residency. Consequently, efforts to reduce infection risks associated with the transrectal approach remain a priority.

Our study has several limitations. As a retrospective, non-randomized investigation based on consecutive patient data, it is inherently subject to bias. Data were collected through patient questionnaires rather than direct clinical observation, which may have introduced inconsistencies particularly for patients who did not return for follow-up at our institution due to insurance affiliations with other centers. Additionally, evaluations were limited to symptomatic patients, potentially overlooking asymptomatic or mildly symptomatic cases.

While the sample size of 643 patients provides meaningful insight, it may be insufficient to detect very small differences in infection rates. Moreover, the single-center nature of the study limits generalizability, underscoring the need for validation through larger, multi-center prospective randomized trials.

Another limitation is the use of two different antibiotic regimens (ciprofloxacin and fosfomycin) without subgroup analysis. Future prospective studies should stratify outcomes based on antibiotic type to better determine whether variations in infection rates are attributable to the specific regimen used.

CONCLUSION

Our study concludes that rectal cleansing with transrectal 10% povidone-iodine injection, when combined with antibiotic prophylaxis, is an effective, affordable, and easily implementable strategy to reduce infectious complications following TRUS biopsy. This approach aligns with current guidelines and offers a practical solution, particularly in settings where antibiotic resistance is an increasing concern.

CONFLICT OF INTEREST

The authors have no conflicts of interest.

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