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Transrectal povidone-iodine efficiency in reducing infections occurring after transrectal ultrasound guided biopsy of the prostate

Ender Siyez, MD*

Abstract

The present study aimed to compare infectious complications in men undergoing transrectal ultrasound-guided prostate biopsy (TRUS-Bx) with and without povidone-iodine transrectal injection using a gavage syringe.

The records of 112 patients, who underwent TRUS-Bx between January 2016 and December 2019, were retrospectively reviewed. The biopsy indication was considered high prostate-specific antigen (PSA) level and/or suspicious digital rectal prostate examination findings. Patients' ages, underlying diseases, PSA levels, prostate volumes, pathologic results, and infectious complications after the biopsy were investigated. All the patients received 1500 mg of ciprofloxacin (750 mg twice a day) for 5 days, starting from the day before the procedure. Forty-seven (41.96%) patients received ciprofloxacin prophylaxis with povidone-iodine transrectal injection, while 65 (58.03%) only received ciprofloxacin prophylaxis. All the patients, who were readmitted to the hospital after the procedure, especially with a temperature of higher than 37.8°C, were detected. For the purposes of the study, the priority was placed on the emergence of the rate of febrile infectious complications. Differences in febrile infectious complications in patients, who received ciprofloxacin prophylaxis with transrectal povidone-iodine, and those, who received ciprofloxacin prophylaxis alone before TRUS-Bx, were studied.

Febrile infectious complications developed in 10 cases (15.38%) in patients, who received ciprofloxacin antibiotics prophylaxis alone. In the povidone-iodine rectal disinfection group, there was only 1 case of febrile infectious complication (2%). There was no significant difference by clinicopathologic features, age, PSA level, and cancer detection rate between both groups ($P > .05$). Multivariate logistic regression analysis did not identify any patient subgroups at a significantly higher risk of infection after prostate biopsy. There was no significant side effect associated with povidone iodine.

In addition to the use of prophylactic antibiotics, transrectal povidone-iodine was useful in reducing the febrile infection complications following TRUS-Bx.

Abbreviations: PCa = prostate cancer, PSA = prostate-specific antigen, RCTs = randomized-controlled trials, sd = standard deviation, TRUS-Bx = transrectal ultrasound-guided prostate biopsy.

Keywords: antibiotic prophylaxis, povidone-iodine, prostate, transrectal ultrasound-guided prostate biopsy

1. Introduction

Prostate cancer (PCa) is the second most prevalent cancer (lung cancer 14.3%, PCa 14.1%) in men and the fifth leading cause of death (lung 21.5%, liver 10.5%, colorectal 9.3%, stomach 9.1%, and prostate 6.8%) worldwide.[1] Upon the landmark publication by Stamey et al,[2] the prostate-specific antigen (PSA) emerged as the most important and most widely used biomarker for PCa. PCa diagnoses increased with the introduction of PSA. Prevalence of PCa and associated mortality rates vary between the different countries around the world. The transrectal ultrasound-guided prostate biopsy (TRUS-Bx) is the gold standard and frequent outpatient procedure in patients with suspected PCa. Each year, approximately 400,000 new cases are diagnosed with PCa throughout Europe.[3] At least twice as many TRUS-Bx biopsies are performed, taking into account the negative biopsies. This multiple-core biopsy procedure involves in rectum, where there are rich blood vessels and the bacterial flora is very dense. The main source of urological infections following the biopsy is contamination and inoculation from rectal flora. Although the procedure is generally recognized as safe and well-tolerated, it may cause adverse effects such as hematuria, rectal bleeding, hematospermia, urinary retention, pain, as well as impairment in sexual functions due to

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The present study protocol was reviewed and approved by the institutional review board of Buca Seyfi Demirsoy Trainin and Research Hospital (Reg. No. 2021/1-2). Informed consent was submitted by all subjects when they were enrolled.

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The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Department of Urology, Izmir Demokrasi University Buca Seyfi Demirsoy Training and Research Hospital, Buca Izmir, Turkey.

** Correspondence: Ender Siyez, Department of Urology, Izmir Demokrasi University Buca Seyfi Demirsoy Training and Research Hospital, Buca İzmir 9035150, Turkey (e-mail: edsiyez@yahoo.com).*

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psychological tension after prostate biopsy. Infectious complications such as acute urinary tract infection, epididymitis, prostatitis, rarely urosepsis, and fatal consequences may also develop.[4,5] The most common complications following TRUS-Bx are hematuria and hematospermia with a rate of 60%, followed by rectal bleeding with a rate of 20%. The incidence of dysuria is 14% and that of urinary tract infection is 10%; where sepsis, septic shock, and even death were reported at rates of 5.7%, 0.45%, and 0.2%, respectively.[5]

Both the European Association of Urology Guidelines and the American Urological Association Guidelines recommend oral or intravenous administration of fluoroquinolones prophylaxis to prevent infectious complications before TRUS-Bx.[6–8] However, there is still no consensus as regards to the antibiotic of choice and the duration of antibiotic prophylaxis. Among the fluoroquinolones, ciprofloxacin is often preferred for TRUS-Bx due to its ability to diffuse well into the prostate parenchyma and its high activity on intestinal flora and coliform bacteria.[9,10] While at least 50% to 70% of ciprofloxacin is not metabolized in the urine, this rate is almost twice as much than the rate of norfloxacin.[11] Hospitalization rates following prostate biopsy started to increase in the recent years.[5,12] Relevant studies suggested that quinolone resistance accounted for up to 50% increase.[13–15]

Until now, many different materials and techniques have been introduced to reduce infectious complications after TRUS-Bx: pre-operative anal swab culture, targeted antibiotic prophylaxis, cleansing of the biopsy needle tip with formalin between each biopsy, and the transperineal approach instead of the transrectal biopsy.

Targeted prophylaxis based on rectal swab culture has been extensively studied, yet ambiguity remains regarding the utility of routinely performed targeted prophylaxis in patients undergoing TRUS-Bx. However, more recent studies were not able to suggest a decrease in severe infectious complications with targeted prophylaxis. Studies on comparative effectiveness of targeted versus empirical antibiotic prophylaxis with an aim to prevent sepsis due to transrectal prostate biopsy found no difference in sepsis rates between patients receiving targeted prophylaxis versus empiric prophylaxis in a large series.[16] The failure of targeted prophylaxis to reduce severe infectious complications in large-scale studies were questioned; whether it was appropriate for routine clinical practice, given the cost of additional labor, multiple clinic visits by the patients, lack of adoption by microbiology laboratories, and requirements for special culture media. Overall, the utility of targeted prophylaxis appears to be limited.

It was stated that cleaning the needle tip using 10% formalin after each biopsy was effective in reducing the infectious complications after TRUS-Bx.[17] Although the use of formalin failed to suggest statistical significance in the clinical sample, the authors performed ex vivo experiments that offered strong empiric support for the ability of formalin to completely inhibit the growth of fluoroquinolones-resistant bacteria. However, no prospective studies or randomized-controlled trials (RCTs) explored the efficacy of disinfection of the biopsy needle tip with formalin. Well-powered RCTs are required in order for formalin disinfection to be recommended for widespread clinical use.

Several studies comparing transperineal and transrectal prostate biopsy suggested that transperineal biopsy was equivalent to TRUS-Bx in the diagnosis of PCA.[18] The transperineal route, which represents an alternative pathway for prostate biopsy to avoid direct contact with the rectal microbiome, showed a significantly lower incidence of infectious complications compared to the transrectal route. Despite its greater safety profile, there are several disadvantages associated with transperineal biopsies, such as the requirement for general anesthesia, higher costs, longer labor time, and the necessity for special equipment.[19] Nonetheless, the lower rate of severe complications underscores transperineal biopsy a promising alternative to TRUS-Bx.

Povidone-iodine, which was previously shown to be effective in reducing infection rates in colorectal surgery and treatment of wound infections, was also used in combination with prophylactic antibiotics prior to TRUS-Bx, with an aim to reduce the infection rates.[20] Combined use of povidone-iodine and prophylactic antibiotics was suggested to be more effective.[21–25] The study aimed to investigate, whether infectious complications following TRUS-Bx decreased by transrectal 10% povidone-iodine injection using a gavage syringe 10 minutes before TRUS-Bx.

2. Material and methods

2.1. Study design

The records of 112 patients, who underwent TRUS-Bx between January 2016 and December 2019 in our hospital (secondary hospital, located in Izmir), were retrospectively investigated. Biopsy indications were set as high PSA level above 4.0 ng/mL and/or suspicious prostate examination findings. Urine cultures were collected and microscopic analysis of the urine was performed for all the patients prior to the biopsy. Patients with abnormal state of coagulation, immune deficiency, severe hemorrhoids, indwelling urinary catheters, hypersensitivity to povidone-iodine, thyroid dysfunction, and radioiodine treatment were excluded from the study. Ethical approval was obtained from Ethical Research Committee of Izmir Demokrasi University Buca Seyfi Demirsoy Training and Research Hospital (Committee Board Approval No.: 2021/1-2). Informed consent, including a description of the procedure and potential hazards, was obtained from all patients before the procedure.

All the patients received prophylactic ciprofloxacin (750 mg twice a day) for 5 days beginning from the day before the procedure. Out of a total of 112 men that underwent TRUS-Bx, 47 (41.96%) received ciprofloxacin prophylaxis with transrectal povidone-iodine, while 65 (58.03%) received ciprofloxacin prophylaxis without transrectal povidone-iodine. All the patients received sodium phosphate enemas (19 g monobasic sodium phosphate and 7 g dibasic sodium phosphate Libalaks) 2 hours before the procedure. The patients were placed in the left lateral decubitus position with their left knee bent, and then the patients were draped. The anus mucosas of the patients were wiped 10 minutes before the biopsies, first with 10% povidone-iodine, and then a mixture of 20 cc 10% povidone-iodine (20 cc povidone-iodine costs 0.1 euro) and 2% xylocaine jelly (AstraZeneca Global) was injected into the rectum by a 50 mL gavage syringe. Subsequently, the biopsy procedure was introduced in the usual way in the outpatient department biopsy room by the same urologist.

All biopsy procedures were introduced using General Electric Logiq 500 Pro Series Ultrasound device (General Electric). During the procedure, the biopsy needle was inserted via a

steering device attached to the 5.0 to 7.5 MHz transducer to visualize the needle path parallel to the electronic guideline provided by the ultrasound images. Using the same protocol and under local anesthesia, 12 core biopsy and an 18 G biopsy needle with an automatic biopsy gun (Geotek Medical, Turkey) were used. One or 2 additional biopsies were performed, when a suspicious focus was noticed during TRUS-Bx. After the TRUS-Bx, patients were placed on their back for approximately 15 minutes. The patients were discharged on the same day after the procedure.

Subsequently, all patients were asked to return to our emergency department should they experience any problems such as urine retention, fever, shivering, or rectal bleeding after the procedure. All the patients returned to the urology outpatient clinic 10 days after the biopsy to receive their pathology reports, and thus, we could ascertain, whether any infectious or non-infectious complications had occurred. Self-resolving complications after TRUS-Bx such as hematuria, rectal bleeding, dysuria, and anal pain were grouped as "minor complications". Infectious complications were defined as body temperatures exceeding 37.8°C with accompanied urinary tract infection symptoms such as chillness, frequency, urgency, and dysuria. Sepsis was defined as the presence of infection together with systemic manifestations of infection. Only the patients, who had temperatures reaching to 37.8°C and above were hospitalized. Urinalysis and urine and blood culture were taken from all the hospitalized patients having these complaints.

2.2. Statistical analysis

Patients' ages, prostate volumes, PSA values, pathology results of biopsies, presence of underlying diseases such as diabetes mellitus, hospitalizations due to fever after biopsy were analyzed as basic demographic information. Chi-square test and *t* test were used for categorical variables (i.e., prostate volume, diabetes mellitus, and being positive for malignancy) and continuous variables (i.e., age, PSA values), respectively, in order to compare the 2 groups (those received ciprofloxacin prophylaxis with transrectal povidone-iodine and those received ciprofloxacin prophylaxis alone). Later on, multivariate logistic regression analysis was performed to assess the effects of the 2 groups' (those received ciprofloxacin prophylaxis with transrectal povidone-iodine rectal cleansing and those received ciprofloxacin prophylaxis alone), ages, prostate volumes, PSA values, diabetes mellitus (Yes/No), pathologic results cancer (Yes/No) on the occurrence of fever reaching 37.8°C and above due to infection. All statistical analyses were performed by using the Statistical Package for the Social Sciences Version 24.0 (SPSS Inc, Chicago, IL). A *P* value of less than .05 was considered statistically significant.

3. Results

The electronic medical records (including demographic data, prostate volume, PSA level, presence of infectious complications, and underlying diabetes mellitus) were analyzed by the urologist. Temperatures above 37.8°C were seen in 10 patients (15%) in non-povidone-iodine group, while there was only 1 patient (2%) with high fever in the transrectal povidone-iodine group. The infection rate dropped from 15% (10/65 patients) to 2% (1/47 patients), which was statistically significant ($P < .05$). Epididymitis and orchitis were not present. Blood and urine culture data were obtained for all infection-related hospitalizations. The most commonly isolated microorganisms were *Escherichia coli* (80%), *Klebsiella pneumonia* (10%), and *Staphylococcus* spp. (10%), respectively, in urine and blood cultures. Medical treatment was successfully administered based on blood and urine culture results and all the patients were discharged with full recovery after a mean hospitalization duration of 5 days (2–13 days). There were no local irritation or any complications due to povidone-iodine.

Table 1

Characteristics of the study population (n = 112).

Variables	Transrectal povidone-iodine injection (n = 47)	Non-rectal batticon (n = 65)	*P* value
Mean age (sd)	66.55 yrs (6.99)	64.95 yrs (7.38)	.25
Mean PSA level (sd)	11.05 ng/mL (14.31)	14.59 ng/mL (20.13)	.31
Prostate volume (sd)	64.89 cc (33.22)	56.06 cc (35.68)	.25
Diabetes mellitus (%)	21.7%	25.0%	.72
Positive for malignancy	12.5%	14.3%	.54

PSA = prostate-specific antigen, sd = standard deviation.

The ages of the patients varied between 50 and 90 years (M = 65.63 years, standard deviation [sd] = 7.23). Prostate volume ranged from 16 to 185 cc (M = 59.89 cc, sd = 34.71). PSA level ranged from 4.03 to 125.7 ng/mL (M = 13.11, sd = 17.94). Biopsies were performed in 6 patients twice, in 3 patients thrice, and in other patients (103) once. As a result of the biopsy procedures, the final diagnoses were PCa (n = 30, 26.8%), benign prostate hyperplasia (n = 15, 13.5%), atypical small acinar proliferation (n = 23, 20.5%), and prostatitis (n = 44 39.2).

No statistically significant difference was found between the povidone-iodine and non- povidone-iodine groups for mean age 62.26 years versus 52.34 years (U = 1257.0, W = 3402, $P > .05$), mean prostate volume 47.33 cc versus 37.91 cc (U = 654, W = 1782, $P > .05$), mean PSA level 51.65 ng/mL versus 60.01 ng/mL (U = 1299.50, W = 2427.50, $P > .05$), incidence of PCa 29.8% versus 24.6% ($X^2 = 0.37$, $P > .05$), number of previous biopsy (first biopsy: 91.5% vs 92.3%; second biopsy: 6.4% vs 4.6%; more than 2 biopsies: 2.1% vs 3.1%; all $P > .05$ vs 2.0%; all $P = .99$). Temperature of 38°C and higher was reported from 2% of the patients in povidone-iodine group versus 15.4% of the patients in non-povidone-iodine group ($X^2 = 7.94$, $P < .05$) (Table 1).

Multivariate logistic regression analysis was conducted to assess the effects of 2 groups' (transrectal povidone-iodine group vs non-transrectal povidone-iodine group), age, prostate volume, PSA level, diabetes mellitus (Yes/No), pathologic diagnosis of cancer (Yes/No) on the occurrence of temperatures above 37.8°C. Results showed that only 1 patient, who received the transrectal povidone-iodine before TRUS-Bx, predicted the model odds ratio = 0.14, 95% confidence interval = 0.01 to 1.20, $P < 0.05$ (Table 2).

4. Discussion

TRUS-Bx is the gold standard for the diagnosis of PCa. The method may lead to a considerable cost and morbidity in case of possible complications. Patients are at risk of serious sepsis and hospitalization due to infection, one of the most important complications, and even death. The quest for new strategies has started due to the resistance that emerged in the last 10 years against the quinolones, the previously preferred treatment. Those

Table 2

Results of multivariate logistic regression analysis.

Variables	OR (95% CI)	*P* value
Age	1.01 (0.93–1.03)	>.05
PSA level	1.02 (0.99–1.04)	>.05
USG	0.98 (0.95–1.01)	>.05
Diabetes mellitus	2.07 (0.59–7.27)	>.05
Cancer diagnosis	1.02 (0.25–4.16)	>.05
Povidone-iodine	0.14 (0.01–1.20)	<.05

CI = confidence interval, OR = odds ratio, PSA = prostate-specific antigen, USG = ultrasonography.

introduced as an alternative include alteration of prophylactic antibiotic regimens, pre-operative anal swab culture and targeted antibiotic prophylaxis, cleansing of the biopsy needle tip with formalin between each biopsy, and the transperineal approach instead of the transrectal biopsy and mucosal antisepsis with povidone-iodine or chlorhexidine solution.

Enema alone was insufficient to prevent infections following TRUS-Bx.[26] Due to the first rectal preparation with enema 2 hours before the procedure, large amount of feces in the rectum was reduced and a superior acoustic window was obtained. Doctors used to administer ciprofloxacin for prophylaxis before TRUS-Bx for many years, but as seen in the study, postprocedural infectious complications may reach to 15%. In the present study, a mixture of 20 cc 10% povidone-iodine and lidocaine gel was applied to the patient 10 minutes before the process. It was observed that the infection rate decreased from 15% to 2% with transrectal povidone-iodine application before TRUS-Bx. There were no local irritation or any complications due to povidone-iodine. Transrectal povidone-iodine is considered as an easy-to-apply, simple and inexpensive method; it reduces the infection rates by diminishing the bacterial load in the rectum. Antibiotic administration is still the most preferred method in prophylaxis to prevent infections that develop after TRUS-Bx. It was found that the decrease in infection rates after transrectal povidone-iodine administration was statistically significant. ($P < .05$)

In the present study, it was observed that age, prostate volume, number of biopsies performed, and underlying diabetes mellitus did not play a role in the development of infectious complications. We asked for urine analysis and urine cultures from all the patients 1 week before the procedure. Additional examinations were performed on those, who were hospitalized due to fever after the procedure.

Different pre-procedural rectal preparation with povidone-iodine methods were used thus far. Ghafoori et al[23] demonstrated that the injection of the povidone-iodine solution into the rectum significantly decreased the rate of postprocedural infectious complications. A study by Park et al[27] claimed that soaking the rectum with a povidone-iodine suppository was more effective than a povidone-iodine enema. Another study reported that this direct cleansing of the rectal vault and perianal area by povidone-iodine reduced the rate of postbiopsy infectious complications by decreasing rectal microbial colonization.[28] Chen et al[29] adopted a direct method of cleansing the rectal mucosa by overlaying the prostate gland using povidone-iodine gauze that showed a 9.6% decrease in the incidence of postprocedural infectious complications. In contrast, studies specifically evaluating povidone-iodine rectal cleansing strongly support the use of pre-biopsy bowel preparation (with topical enema, or suppository) to reduce post-TRUS-Bx infections. In a meta-analysis of RCTs povidone-iodine disinfection plus antibiotics significantly reduced the rate of overall infectious complications.[30] Additionally, Hwang et al[31] reported povidone-iodine enemas significantly reduced the incidence of bacteremia and sepsis in a retrospective analysis at a Korean hospital. These studies reported decreases in infection rates.[14,20–22,28,29] Ryu et al[32] did not achieve a decrease in infection rates after TRUS-Bx with povidone-iodine suppositories. However, they used 2 g of ceftriaxone instead of quinolones as a prophylactic antibiotic. Considering that the reason for the increase in infection rates is quinolone resistance, it is understood that it cannot be attributed to the ineffectiveness of povidone-iodine.

As regards to the limitations of our study, it is a retrospectively non-randomized study design based on data derived from the medical records of the enrolled patients and the procedure notes of TRUS-Bx. Although urinalysis was performed in all patients, additional evaluation including urine culture, blood culture, or other laboratory studies were performed only for the patients, who were hospitalized after TRUS-Bx due to fever. Thus, outpatients, who were asymptomatic or had mild symptoms and did not undergo these additional investigations, were not included in the study. Finally, it can be said that the number of patients in the study group is limited and the study is single-hospital-centered. Further large prospective a randomized clinical trial is required to confirm the outcomes of the present study.

5. Conclusions

According to our results transrectal 10% povidone-iodine injection with gavage syringe added to antibiotic prophylaxis before TRUS-bx is an effective, cheap, and easy-to-apply method in reducing infectious complications.

Author contributions

Conceptualization: Ender Siyez.
Data curation: Ender Siyez.
Formal analysis: Ender Siyez.
Funding acquisition: Ender Siyez.
Investigation: Ender Siyez.
Methodology: Ender Siyez.
Project administration: Ender Siyez.
Resources: Ender Siyez.
Software: Ender Siyez.
Supervision: Ender Siyez.
Validation: Ender Siyez.
Visualization: Ender Siyez.
Writing – original draft: Ender Siyez.
Writing – review & editing: Ender Siyez.

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