Effect of rectal mucosa cleansing on acute prostatitis during prostate biopsy: A randomized prospective study

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ABSTRACT

Objective: Infectious complications after transrectal ultrasound-guided prostate biopsy (TRUS-PB) can range from asymptomatic bacteriuria and febrile or non-febrile urinary tract infection (UTI) to sepsis. Cleaning of rectal mucosa with topical antiseptics such as povidone iodine or chlorhexidine before the procedure are alternative prophylaxis methods. We aimed to investigate the effects of these two different topical antiseptic agents on infectious complications and their superiority to each other.

Material and methods: The study was conducted with 200 patients. Rectal mucosa cleansings were performed in 50 patients with povidone iodine and 49 patients with chlorhexidine. The remaining 101 patients did not receive any antiseptic treatment. The results were examined according to the hospital admissions or hospitalization for the first 30 days after the procedure due to UTI, body temperature >38.5°C, sepsis, hematuria, rectal bleeding, and urinary retention.

Results: The mean age of study population was 63.3±7.26 years, and the mean prostate specific antigen value was 13.96±29.5 ng/mL. Acute prostatitis occurred in 14 patients (7%), 9 of whom were hospitalized due to sepsis after TRUS-PB. Statistically significant less acute prostatitis was observed in those patients who were treated with topical rectal antisepsis (topical rectal antisepsis 2% vs. no rectal antisepsis 12.1%, p=0.01). Chlorhexidine and povidone iodine were not superior to each other in terms of inhibiting the development of acute prostatitis (chlorhexidine 2% vs. povidone iodine 2%, p=1.00).

Conclusion: Rectal mucosal cleansing with chlorhexidine or povidone iodine before TRUS-PB prevented the development of sepsis due to acute prostatitis. We recommend that this effective method, which is easy to apply, cheap, reliable, easily tolerated should be used in all prostate biopsy practice.

Keywords: Acute prostatitis; chlorhexidine; povidone iodine; prostate biopsy; rectal mucosa cleansing.

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Introduction

Prostate cancer is the most common non-skin cancer in men and is the second most common cause of cancer-related death.[1] A histological diagnosis of prostate cancer is made by transrectal ultrasound-guided prostate biopsy (TRUS-PB) in the presence of abnormal appearance in prostate imaging, abnormal findings in digital rectal examination (DRE), and elevated prostate specific antigen (PSA) levels. Since PSA has been used as a marker in the diagnosis of prostate cancer, there has been an increase in the number of TRUS-PB.[2]

With the help of TRUS-PB performed under local anesthesia, systematic sampling is performed from the prostate to evaluate prostate cancer. Each biopsy core is taken in such a way that the same needle pierces the rectal mucosa and creates a passage each time. The bacteria present in the rectal mucosa colonized by the host bacterial flora may inoculate into tissue layers, the urinary tract, or the bloodstream by the needle, leading to severe infection, from prostatitis to sepsis, requiring hospitalization or intensive care. Meanwhile, bacteria found in the rectal mucosa colonized with the host's bacterial flora are inoculated with the needle and by entering the tissue layers of the prostate, into the urinary system or bloodstream, it

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can cause a serious infection from prostatitis to sepsis requiring hospitalization or intensive care. With two different strategies, it is possible to reduce this risk. The first strategy is to apply antibiotic prophylaxis. The second is to apply technical modifications, such as the cleaning of the rectal mucosa with antiseptic solutions, the use of clean needles in each sampling and small-diameter needles, the preference of the transperineal approach instead of the transrectal route and the use of enema for rectal cleansing.[3,4]

Infectious complications after TRUS-PB are observed in a wide range, from asymptomatic bacteriuria, febrile or non-febrile urinary tract infection (UTI), to approximately 3% life-threatening sepsis.[5] In the Surveillance, Epidemiology, and End Results Program study conducted between 1991–2007, the hospitalization rate was 1.1% due to sepsis after prostate biopsy.[3] The main reason for this increase over time is quinolone and multiple drug resistance.[6]

Alternative prophylaxis methods have been developed to reduce the increased infectious complications after TRUS-PB. One of them is cleaning of rectal mucosa with topical antiseptics such as povidone iodine or chlorhexidine before the procedure. The aim is to reduce the bacterial load of the microbial flora in the rectal mucosa and thereby theoretically reduce the potential risk of infection. This has been demonstrated in some bacteriological studies with a low rate of bacteriuria and bacteremia in TRUS-PBs after decreasing bacterial load in the rectal mucosa.[7]

Main Points:

- There is a risk of acute prostatitis after TRUS-PB. Some different strategies, it is possible to reduce this risk. A strategy is that cleaning of the rectal mucosa with antiseptic solutions such our study.
- A total of 200 patients 99 of these patients were treated with topical rectal antisepsis, and 101 of them did not undergo any rectal antisepsis procedure. Rectal mucosa cleansing was performed in 50 patients with 10% povidone and 49 patients with 4% chlorhexidine.
- Acute prostatitis occurred in 14 patients; in 2 patients (2%) with topical rectal antisepsis group; in the group without rectal preparation in 12 patients (12%). According to this result which was statistically significant (p=0.01).
- In the subgroup analysis, no significant difference was found between the group treated with chlorhexidine and povidone iodine in terms of infective complications. Chlorhexidine and povidone iodine were not superior to each other in terms of inhibiting the development of acute prostatitis (1 vs. 1, p=1.00).
- We recommend that this effective method before all TRUS-PB procedure; which is easy to apply, cheap, reliable, and easily tolerated.

In the light of this information, povidone iodine and chlorhexidine are seen as two different topical antiseptic agents in rectal mucosa cleansing, which can be used easily, inexpensively, and reproducibly, and can be applied without requiring any preparation prior to TRUS-PB. In this study, we aimed to investigate the effects of these two different topical antiseptic agents on infective complications and their superiority to each other.

Material and methods

This study was performed prospectively after obtaining the approval of the ethics committee of our hospital in March 2019 with the 2019/4-23 approval number. Inclusion criteria of the patients in this study with abnormal findings on a digital rectal examination, abnormal appearance in prostate imaging (multiparametric magnetic resonance imaging) or PSA elevation who underwent TRUS-PB in our hospital. All patients underwent oral fluoroquinolone (ciprofloxacin) 500 mg bid and intramuscular aminoglycoside (amikacin 1 g) prophylaxis for 3 days starting on the TRUS-PB day. Patients who could not be given ciprofloxacin and/or amikacin prophylaxis for any reason, had been hospitalized, and had a history of urethral catheterization and urological intervention in the past month, received antibiotherapy for different reasons, and immunosuppressive patients were excluded from the study.

A total of 200 patients who met inclusion criteria were included in the study (Figure 1). Informed consent was given to all pa-

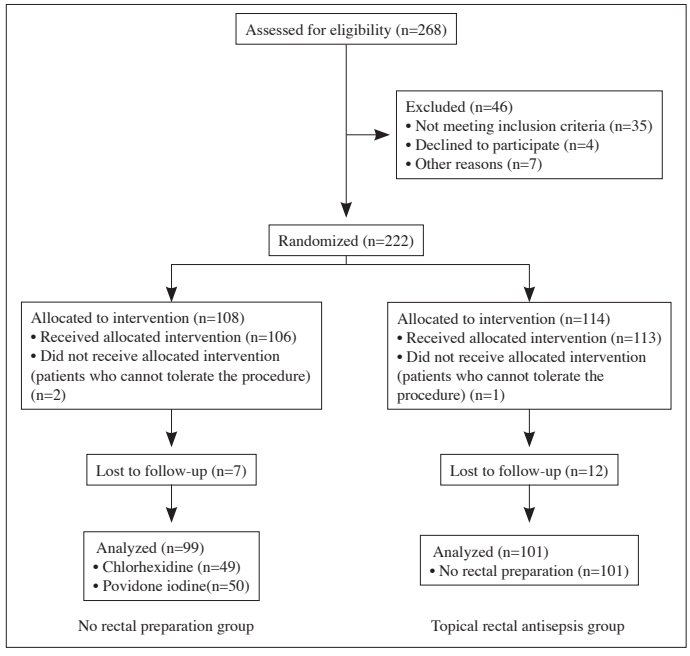

Figure 1. Flowchart of patients included in the study

tients before the procedure. Ninety-nine of these patients were treated with topical rectal antisepsis, and 101 of them did not undergo any rectal antisepsis procedure. Rectal mucosa cleansing was performed in 50 patients with 10% povidone and 49 patients with 4% chlorhexidine, which does not contain alcohol to prevent local irritation in the rectal mucosa. Randomization of all patients was performed by the nurse assisting the TRUS-PB procedure by the dice method. The study was conducted confidentially in accordance with ethical rules under the supervision of the nurse assisting the TRUS-PB procedure, and all patients, the outcome assessor, and physicians performing the procedure were blind. No patient underwent bowel preparation with enema.

10% povidone iodine and 4% chlorhexidine, not containing alcohol used for rectal mucosa cleansing, were mixed separately with 2% lidocaine gel. With the mixture to be applied, the perianal region was first stained with a sterile sponge to prevent the bacteria from moving into the rectal mucosa. Then, the rectal mucosa was purged with this mixture for 2 minutes by the nurse assisting the TRUS-PB procedure and allowed to dry for 2 minutes to produce a bactericidal effect.[8] Then, the physicians started performing the procedure.

Ultrasound-guided transrectal prostate biopsy's were performed to patients in the left decubitis position using the SSI-2000 BW system (SonoScape, Co. Ltd, China) ultrasound machine and a biplanar transrectal probe. After 2% lidocaine gel was instilled into the rectum and was allowed to dwell for at least 5 minutes, the transrectal probe was introduced to rectum. A 22-gage needle was introduced through the probe, and 10 mL of 2% lidocaine was injected into the junction between the prostate and seminal vesicle. After achieving sufficient analgesia, a standard 12-core or 24-core saturation biopsy was taken from each patient with a 18 gage 20 cm biopsy needle attached to an automated biopsy gun. All biopsies were performed by two urologists.

Basic demographic data included age, diabetes, PSA, history of previous TRUS-PB; variables such as the number of cores taken at the last biopsy and its pathology result, development of UTI or acute prostatitis, antibiotherapy given after acute prostatitis, history of hospitalization, and intensive care follow-up, and development of complications were examined.

The results were examined according to the hospital admissions or hospitalization for the first 30 days after the procedure due to UTI without fever and UTI with fever (body temperature higher than 38.5°C), so this state was defined acute prostatitis, sepsis, hematuria, rectal bleeding, and urinary retention. Hospitalization indications were acute prostatitis and sepsis. All hospitalized patients were septic. These data were collected from the patient on their first polyclinic visit. These results were recorded using our hospital's database. In addition, the patients were not admitted to our hospital in the first month after the procedure were questioned about TRUS-PB-related complications.

Statistical analysis

First, descriptive statistics (arithmetic mean, standard deviation, minimum, maximum) were calculated from the data obtained from the study. Shapiro–Wilk test was used for the detection of normal distribution of the data, and it was determined that it did not comply with normal distribution ($p<0.05$). The independent two group comparisons were evaluated using the Mann–Whitney U test, and the categorical data were evaluated using the Chi-squared test. A p-value <0.05 was considered statistically significant. The Statistical Package for the Social Sciences 25.0 (IBM SPSS Corp.; Armonk, NY, USA) package program was used for statistical data analysis. Power analysis was done using the Minitab 19.

Results

Out of a total of 200 patients, 101 did not undergo any rectal antisepsis procedure. Rectal mucosa cleansing was performed in 50 patients with povidone iodine and in 49 patients with chlorhexidine. The mean age of the entire population in the study was 63.3±7.26 years, and the mean PSA value was 13.96±29.5 ng/mL, 15% was diabetic and 24% had a history of TRUS-PB up to four times. Acute prostatitis history was found in 3% of the group who did not undergo any rectal antisepsis before TRUS-PB. The mean number of cores was 14 (6–25), and prostate cancer was detected in 34% of the patients. Table 1 shows the basic demographic data and TRUS-PB characteristics among the groups. No difference was found between the groups that were treated with topical rectal antisepsis and the group without rectal preparation ($p>0.05$). Only the patients in the group who received rectal mucosal antisepsis with chlorhexidine were significantly younger than the group treated with povidone iodine (61.22±5.9 vs. 64.5±8.45 years, $p=0.038$).

Table 2 shows the infection and complication rates among the groups. Thus, 8 patients (4%) had UTI after TRUS-PB. A total of 9 patients (4.5%) were hospitalized due to sepsis, but no patients were hospitalized in the intensive care unit. There was no statistically significant difference between the groups. Acute prostatitis occurred in 14 patients (7%), 9 of whom were hospitalized due to sepsis after TRUS-PB. In 2 patients (2%) with topical rectal antisepsis group; in the group without rectal preparation acute prostatitis developed in 12 patients (12%). According to the resulting 10% difference less, acute prostatitis was observed in those patients who were treated with topical rectal antisepsis which was statistically significant (2% vs. 12.1%, $p=0.01$; RR 0.16, 95% CI 0.03–0.72; NNT 9.9, 95% CI 5.84–32.25). In the subgroup analysis, no significant difference

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Table 1. Comparison of basic demographic data between groups

	Topical rectal antiseptic (n=99)	No rectal preparation (n=101)	p	Chlorhexidine (n=49)	Povidone iodine (n=50)	p
Age, avg. (min–max) years	62.88 (42–92)	63.87 (45–84)	0.265	61.22 (49–72)	64.5 (42–92)	0.038
PSA, avg. (min–max) ng/mL	13.62 (2.2–356)	14.29 (2.42–149.4)	0.102	16,12 (2.2–356)	11.11(3.2–95.97)	0.40
DM (n, %)	17 (17.2)	13 (12.9)	0.394	5 (10.2)	12 (24.0)	0.069
Number previous TRUS-PB (n, %)	19 (19.2)	29 (28.7)	0.115	7 (14.3)	12 (24)	0.22
Acute prostatitis history (n, %)	0	3 (3)	0.246	0	0	
Number of cores (min–max)	14 (6–25)	14 (6–24)	0.439	14 (12–25)	14 (6–24)	0.358
Positive biopsy (n, %)	31 (31.3)	37 (36.6)	0.427	15 (30)	16 (32.7)	0.776

PSA: prostate specific antigen; DM: diabetes mellitus; TRUS-PB: ultrasound-guided transrectal prostate biopsy

Table 2. Comparison of infection-complication rates between groups

	Topical rectal antiseptic (n=99)	No rectal preparation (n=101)	p	Chlorhexidine (n=49)	Povidone iodine (n=50)	p
Post-TRUS-PB UTI (n, %)	3 (3)	5 (5.1)	0.721	1 (2)	2 (4)	1.00
Post-TRUS-PB acute prostatitis (n, %)	2 (2)	12 (12.1)	0.01	1(2)	1 (2)	1.00
Post-TRUS-PB hospitalization (n, %)	1 (1)	8 (7)	1.00	0(0)	1 (2)	1.00
Post-TRUS-PB intensive care unit (n, %)	0	0	-	0	0	-
Post-TRUS-PB complication (n, %)	8 (8.1)	15 (14.9)	0.133	2 (4.1)	6 (12)	0.269

TRUS-PB: ultrasound-guided transrectal prostate biopsy; UTI: urinary tract infection

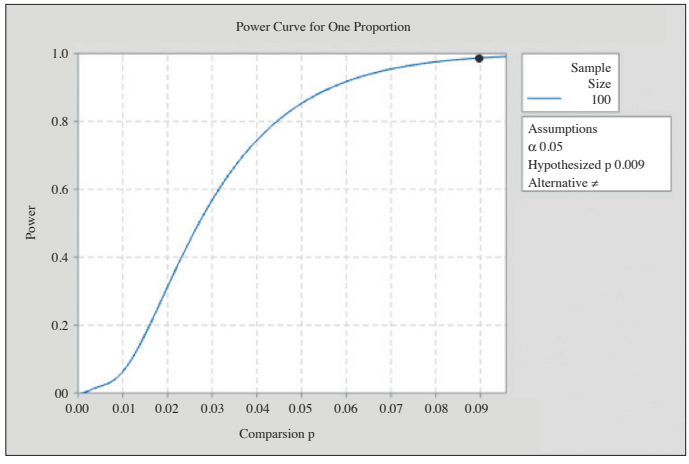

Figure 2. Power analysis of this study

was found between the group treated with chlorhexidine and povidone iodine in terms of infective complications (p>0.05) Chlorhexidine and povidone iodine were not superior to each other in terms of inhibiting the development of acute prostatitis (2% vs. 2%, p=1.00).

In this study, it was concluded that rectal mucosal antisepsis reduced bacteremia rates by 0.9% compared to patients who did not undergo any rectal antisepsis, but this difference was not statistically significant (p=0.119) (15). In our study, it was concluded that rectal mucosal antisepsis reduced bacteremia rates by 9%, and this rate was statistically significant (p=0.01) (power, 0.985757) (Figure 2).

Five of the 14 patients who had acute prostatitis after TRUS-PB and were treated as outpatients were prescribed second-generation cephalosporin with antianaerobic activity. Seventeen of the 22 patients treated with UTI and acute prostatitis had *Escherichia coli in* urine cultures; The *Enterecoccus faecium* growth was observed in the other 5 patients. Seven of the patients who received inpatient treatment for sepsis had *Escherichia coli* in urine cultures, and the *Enterecoccus faecium* growth was observed in the other 2 patients. All hospitalized patients were treated with Ertapenem intravenously for 10–14 days.

When the complication rates of TRUS-PB were evaluated, a total of 23 patients (11.5%) had complications (Table 2). Several complications were observed in some patients. According to the order of frequency, acute prostatitis, body temperature >38.5°C, sepsis, UTI, dysuria, hematuria, stranguria, acute urinary retention, orchitis, erectile dysfunction, syncope, and hematospermia were observed. It was concluded that rectal mucosal clearance did not affect the complication rates after TRUS-PB (8.1% vs. 14.9%; p=0.133) In addition, no local or systemic complications

such as dermatitis or hypersensitivity were observed in any patient who underwent topical rectal mucosal antisepsis.

Discussion

Ultrasound-guided transrectal prostate biopsy is the gold standard for the diagnosis of prostate cancer. In fact, many men are exposed to this not-so-harmless procedure, although they are healthy. The method has a considerable cost and morbidity in case of possible complications.[9] Patient are at risk of serious sepsis and hospitalization due to infection, one of the most important morbidities.[5] Several strategies have been developed in reducing this risk. First, prophylactic oral or parenteral antibiotic regimens were administered to the patients. Fluoroquinolones which are used until now, have high oral bioavailability, affect rectal flora, and penetrate the prostate tissue are the main ones. However, increasing infective complications after TRUS-PB have led to the development of different strategies due to increased fluoroquinolone resistance in the last 10 years.[10]

Reduce for infective complications after TRUS-PB, approaches, such as the alteration of prophylactic antibiotic regimens or targeted prophylaxis according to the rectal flora culture, transperineal surgical approach instead of the transrectal path, sterilization of the needles or changing the size of the needles used during surgery, reducing the bacterial load in the rectal flora by enema, changing the number of cores taken, using local anesthesia before the procedure, and using povidone iodine for rectal antisepsis have been attempted.[11-13] In our study, we concluded that the application of topical mucosal antisepsis with chlorhexidine or povidone iodine prior to TRUS-PB reduces infectious complications.

In the literature, there are a limited number of studies evaluating the effect of rectal mucosal antisepsis on infective complications after TRUS-PB. In these studies, povidone iodine was used as an antiseptic agent. Kanjanawongdeengam et al.[14] reported that the rate of patients with sepsis decreased from 18% to 4% (p=0.025). In the study from Iran with similar results, 19.3% of patients with infectious complications were in the povidone iodine group; and 36.4% were in the control group (p=0.001).[15] There is only one study using povidone iodine and chlorhexidine seperately. In this study, it was concluded that the application of rectal mucosal antisepsis decreased the bacteremia rate by 0.9%, but this difference was not statistically significant (p=0.119).[8] In our study, it was concluded that the use of rectal mucosal antisepsis decreased the bacteremia rates by 10%, and this rate was statistically significant (p=0.01). Different studies have shown that the administration of topical mucosal antisepsis with various agents reduces the bacterial load in the host flora. In 2017, in a study performed by Tsai et al.[16], hand scrubbing using 10% povidone iodine, 4% alcohol-free chlorhexidine, and anhydrous 61% ethyl alcohol was evaluated in surgical hand washing. As a result, in hand rubbing with the chlorhexidine and ethyl alcohol group, a statistically significantly lower bacterial load was detected than in the povidone iodine group. According to their results, hand scrubbing with chlorhexidine and anhydrous ethyl alcohol are more effective in bacterial inhibition than povidone iodine. The topical antiseptic applied to the rectal mucosa is no different from this result. According to a study performed by Park et al.[8], in the rectal mucosal antisepsis procedure applied before TRUS-PB, bacterial load amount decreased 97.5% in the povidone iodine group, and 99.3% in the chlorhexidine group (p=0.03). However, bacteremia rates of both groups are not different from each other (1 vs. 0 patient, p=0.5). In our study, although the rectal bacterial colony count was not performed, a higher occurence of sepsis due to acute prostatitis in the group without mucosal antisepsis (12 vs. 2 patients, p=0.01) supports these results. In our study, like in the aforementioned study, chlorhexidine and povidone iodine had no superiority in preventing the development of sepsis due to acute prostatitis (1 vs. 1 patient, p=1.00).

According to our results, povidone iodine and chlorhexidine are reliable agents in preventing infective complications due to TRUS-PB. Other antiinfective enemas are uncomfortable and expensive for patients.[17] The cost of chlorhexidine and povidone iodine in this application is about 0.5 Euro.[18] The application has been shown to be an effective method because it is cheap, easy, fast, comfortable, tolerable, and simple for the patient, and it is a successful method in preventing infective complications. The limitations of our study are the fact that bacterial load in rectal flora decreased with topical mucosal antisepsis was not demonstrated by swab culture; some patients were admitted to a different hospital in the first month for first polyclinic visit after the procedure and the data were obtained from the patients only by questioning and not by observing infective outcomes in order to eliminate subclinical complications, and there was the lack of full standardization because the procedure was not performed by a single urologist in all patients.

As a result, rectal mucosal cleansing with chlorhexidine or povidone iodine before TRUS-PB prevented the development of sepsis due to acute prostatitis in our patients. Thus, we recommend that this effective method, which is easy to apply, cheap, reliable, and easily tolerated, be used in the current prostate biopsy practice.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Health Science University İzmir Tepecik Training and Research Hospital (13.03.2019./Approval No: 2019/4-23).

Informed Consent: Verbal and written informed consent was obtained from all patients before to the procedure.

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