

ORIGINAL RESEARCH

Analysis of risk factors for infection after transrectal ultrasound-guided prostate biopsy and analysis of the value of preoperative prophylactic antimicrobial use

Jing Li^{1,*}, Linjie Wang²

¹Hospital infection management office, the First Affiliated Hospital of Shihezi University, 832008 Shihezi, Xinjiang Uygur Autonomous Region, China

²First Clinical College, Changsha Medical University, 410219 Changsha, Hunan, China

***Correspondence**

lj6526@163.com

(Jing Li)

Abstract

This study aimed to identify risk factors associated with infections after Transrectal ultrasound-guided prostate biopsy (TRUSPB) and to analyze the efficacy of preoperative prophylactic antimicrobial administration. A retrospective analysis was conducted on 766 patients who underwent TRUSPB at our hospital from January 2020 to January 2023. Among them, 450 patients were given a three-day prophylactic course of antimicrobial fluoroquinolones before TRUSPB (Group A), while the remaining 316 patients were administered a single dose of 750 mg oral ciprofloxacin 1 h before TRUSPB (Group B). We calculated the incidence of post-TRUSPB infections in both groups and employed a binary logistic regression model to analyze factors influencing post-TRUSPB infections and evaluate the effectiveness of prophylactic antimicrobial use. Among the 766 patients who underwent prostate biopsy, 62 cases (8.1%) developed post-TRUSPB infections, and there was no statistically significant difference in the rate of post-TRUSPB infections and types of infections between Group A and Group B. Blood and urine cultures from all the 62 infected patients were positive, with *Escherichia coli* being the most commonly detected pathogen, demonstrating a positive detection rate of 100.0% and accounting for 76% of all infections. Logistic regression analysis identified age (Odds ratio (OR) = 1.15, 95% Confidence Interval (CI) 1.05–1.25), a history of diabetes mellitus (OR = 1.31, 95% CI 1.12–1.52), and history of indwelling urinary catheter within 7 days before biopsy (OR = 1.43, 95% CI 1.15–1.77) as risk factors for post-TRUSPB infections. In summary, a single application of ciprofloxacin demonstrated similar efficacy in reducing the risk of post-TRUSPB infection compared to a three-day course of oral fluoroquinolones before biopsy while also reducing the risk of quinolone resistance. Conversely, advanced age, comorbid diabetes mellitus, and a 7-day history of indwelling urinary catheter before TRUSPB increased the risk of post-TRUSPB infection.

Keywords

Antibiotic prophylaxis; Paracentesis; Wound infection

1. Introduction

Transrectal ultrasound-guided prostate biopsy (TRUSPB) is an important method for prostate cancer screening and early diagnosis [1–3]. However, complications following TRUSPB have raised significant concerns, with infection being one of the most perilous sequelae post-TRUSPB, and can jeopardize patients' lives if not managed effectively [4, 5]. In 2011, the Cochrane system published guidelines regarding antibiotic prophylaxis for TRUSPB, highlighting the advantages of prophylactic antibiotics for TRUSPB, with a notable emphasis on fluoroquinolones. However, the recommendations were based on prolonged antibiotic use, which increases the risk of resistance and adverse drug reactions [6]. Consequently, major hospitals worldwide are gradually using single-application antibiotic prophylaxis protocols before TRUSPB, but their

efficacy remains an area of ongoing research [7].

Given this, we designed this present study to understand the current status of infections after TRUSPB, the efficacy of fluoroquinolone before biopsy, and single-application antibiotic regimens for TRUSPB in clinical settings.

2. Material and methods

2.1 Study population

In this retrospective study, we assessed the data of 766 patients who underwent prostate aspiration biopsy between January 2020 and January 2023 at the First Affiliated Hospital of Shihezi University and the First Clinical College of Changsha Medical University.

2.1.1 Inclusion criteria

All patients with suspected prostate cancer on initial screening and met the indications for undergoing TRUSPB [8]: (1) the presence of a palpable prostate lesion detected through rectal examination irrespective of the Prostate-specific antigen (PSA) value; (2) abnormal findings on ultrasound, Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) irrespective of the PSA value; (3) PSA >10 ng/mL, regardless of free-to-total (f/t) PSA and Prostate-specific antigen density (PSAD) values; and (4) PSA ranging from 4 to 10 ng/mL, in conjunction with abnormal f/t PSA or abnormal PSAD values.

Note: Abnormal manifestations on ultrasound, CT or MRI including ultrasound revealing multiple hypoechoic nodules in the prostate; CT indicating tumor invasion of adjacent prostate tissues or organs, as well as the presence of enlarged pelvic lymph nodes, *etc.*; Magnetic Resonance Imaging-T2weighted Imaging (MRI-T2WI) scans displaying the absence of distinct high and low signals in the peripheral zones, unclear boundaries between the peripheral bands and the central sulcus, and reduced diffusion of water molecules in Magnetic Resonance Imaging-Diffusion Weighted Imaging (MRI-DWI) scans; and Magnetic Resonance Spectroscopy (MRS) examination indicating abnormal Pop line in prostate tissue; PSAD value represents the ratio of the total serum PSA value to prostate volume. Under normal circumstances, a PSAD value is <0.15, while a PSAD value >0.15 is considered abnormal. fPSA refers to free PSA, and tPSA denotes total serum PSA. Under normal circumstances, a f/tPSA value >0.16 is expected, and f/tPSA ≤0.16 is considered abnormal.

2.1.2 Exclusion criteria

Those who have received invasive surgery or other treatments within one month before surgery; those who are in the stage of acute and chronic infections; those who have urine leukocytes higher than normal; those who have combined severe cardiopulmonary insufficiency; those have poor glycemic control of diabetes mellitus; those who have combined severe internal and external hemorrhoids or rectal pathology; those are unable to cooperate with bowel preparation; those who have combined coagulation disorders; those who are not able to tolerate the puncture.

2.2 Methods

2.2.1 Biopsy of the prostate gland

(1) Instruments and equipment: Siemens Acuson Aspen color Doppler (Siemens Acuson Aspen, Siemens, Berlin, Germany) ultrasound diagnostic instrument, end-scan intracavitary probe, frequency 5.0–9.0 MHz, with a special biopsy frame, and Bard disposable automatic biopsy snatch (MG1522, Bard Medical Technologies Inc., NJ, USA).

(2) Preparation before biopsy: Patients were instructed to discontinue the use of anticoagulant drugs (*i.e.*, warfarin, aspirin/nonsteroidal anti-inflammatory drugs, clopidogrel, *etc.*) 1 week before the biopsy. Among the 766 patients, 450 (group A) patients were given norfloxacin 400 mg orally twice daily starting 3 days before the biopsy procedure. The remaining 316 patients (group B) were given ciprofloxacin 750 mg orally in a single dose for 1 hour before the biopsy. All patients

underwent a comprehensive pre-biopsy evaluation, which included urine microscopy, urine bacterial culture, and drug sensitivity testing, all of which yielded normal results. Additionally, assessments of blood and urine profiles, coagulation function and blood glucose levels were conducted, as well as prostate ultrasound and other relevant imaging examinations. To facilitate complete bowel defecation, patients were given 180 g of compound polyethylene glycol electrolyte powder the night before the biopsy. On the day of the biopsy, the food was changed to a slag-free diet, and 250 mL of diluted iodine povidone-iodine enema was administered for 1 hour before the biopsy.

(3) TRUSPB: The patient was placed in the left lateral position, with knees and hips flexed within 90°, ensuring that the back remained parallel to the examination table. Pillows were placed between the two knees to maintain this posture throughout the procedure. Local infiltration anesthesia was administered using 1% lidocaine. Subsequently, 0.5% povidone-iodine enema was retained for 5 min and then guided by the ultrasound diagnostic instrument. A 12-point perforation biopsy was performed with the MaxCore Disposable Fully-Automatic Biopsy Penetration Gun System, and if abnormal echoes were detected on the transrectal ultrasound, it could be followed by another biopsy with the MaxCore disposable fully-automatic biopsy gun system. If abnormal echoes are found on the transrectal ultrasound, another 1–3 needle was added to the abnormal area. Following the biopsy, the tissue specimens were promptly fixed with 10% formaldehyde solution and immediately sent for examination. The procedure was ended by intrarectal acupressure on the biopsy site for 5 min.

2.2.2 Diagnostic criteria for post-TRUSPB infection [9]

Patients with clinical core temperature >38 °C, accompanied by urinary tract irritation symptoms, positive urine culture (colony count >100,000/mL), and notable deviations (*i.e.*, significantly elevated or lowered) in white blood cell count or the total number of central granulocytes in laboratory tests, necessitated the administration of antibiotics or intensified antibiotic treatment. These conditions included febrile urinary tract infection, simple fevers, epididymitis, prostatitis, sepsis, and other ailments requiring further anti-infective treatment.

2.3 Research methods

(1) We conducted an assessment of infection after TRUSPB in both study groups and analyzed the outcomes of blood/urine bacterial culture and drug sensitivity tests.

(2) Relevant clinical data, including patient's age, PSA level, prostate volume, history of underlying diseases, whether the urinary catheter was left in place before the procedure, the number of biopsy needles, biopsy results, history of hospitalization within the last month, history of leaving the urinary catheter in place within the last week, and whether antibacterial agents were applied prophylactically, were collected. Whether the patients developed an infection after TRUSPB was considered as the dependent variable and the above indicators were considered as the independent variables. A binary logistic regression analysis was then performed to identify significant

factors associated with infection after TRUSPB.

2.4 Statistical methods

Data analysis was performed using the statistical SPSS 19.0 software (BMI Corporation, Chicago, IL, USA). Count data were expressed as percentages and analyzed using the chi-squared (χ^2) test. Measurement data as mean (\pm standard deviation) and was analyzed using the *t*-test. Variables that were statistically significant in the univariate analysis were subjected to multivariate logistic regression analysis, with variable selection screened using the *post hoc* method. Statistical significance was set at $p < 0.05$.

3. Results

3.1 Infection after TRUSPB in two groups of patients

Among the 766 cases of TRUSPB patients, a total of 62 cases of infection occurred after TRUSPB, indicating an infection rate of 8.1%. Further analysis showed no statistically significant difference in infection rate and the type of infection after TRUSPB between Group A and Group B ($p > 0.05$) as shown in Table 1.

3.2 Blood/urine bacterial culture results and drug resistance analysis of infected patients

Blood and urine cultures were positive in 62 infected patients, demonstrating a positive detection rate of 100%. Few patients were positive for *Klebsiella*, *Staphylococcus epidermidis* or *Enterococcus faecalis* in blood/urine specimens, and we observed no statistically significant difference in the blood/urine bacterial culture results between Group A and Group B patients ($p > 0.05$). In group A, there were 40 cases of quinolone resistance and 14 cases of quinolone resistance in group B. Most patients were resistant to cephalosporin antibiotics, with group A patients demonstrating a greater risk of quinolone resistance compared to group B ($p < 0.05$) as shown in Table 2.

3.3 Significant factors affecting infection after TRUSPB

Univariate analysis suggested that age, BMI (Body Mass Index), a history of diabetes mellitus and a history of indwelling urinary catheter 7 days before biopsy were significantly associated with infection after TRUSPB ($p < 0.05$), as shown in Table 3.

3.4 Independent factors affecting infection after prostate aspiration biopsy (TRUSPB)

Indicators that were statistically significant in the univariate analysis were included in the multivariate regression analysis model, and the results showed that age, a history of diabetes, and an indwelling catheter 7 days before the procedure were the independent risk factors affecting infection after prostate biopsy TRUSPB (Table 4).

4. Discussion

Prostate cancer is a prevalent malignancy of the genitalia that accounts for 11% of all cancers in men. In the context of China's aging population, there has been a noticeable increase in both the detection rate and incidence of prostate cancer in recent years [10, 11]. TRUSPB has emerged as a valuable tool for prostate cancer diagnosis due to its straightforward maneuverability and clinically significant and beneficial outcomes [12–14]. Nevertheless, the widespread adoption of TRUSPB in clinical practice has drawn attention to its associated complications. After TRUSPB, patients commonly experience bleeding, discomfort, dysuria and urine retention, with infection being the most concerning and severe among these complications [15–17].

TRUSPB may result in infections due to the necessity of penetrating the urethral or rectal mucosa, which can facilitate the entry of bacteria from the rectum to the bloodstream or urine, resulting in infection. Some studies have indicated that the incidence of bacteremia after TRUSPB ranges from 16% to 73%, while the incidence of bacteriuria ranges from 20% to 53% [18, 19]. Although the need for prophylactic antibiotics before TRUSPB is controversial, most scholars still believe that the application of prophylactic antibiotics before biopsy can reduce infection risks, and the choice of prophylactic antibiotics remains a hot topic in current research. Fluoroquinolones have been the recommended antibiotics by the American Urological Association (AUA) since 2008; however, this recommendation has been based on the prolonged duration of antibiotic use, which may increase concerns regarding adverse pharmacologic reactions and drug resistance. Furthermore, due to the numerous complications associated with fluoroquinolones, their usage in prostate biopsy procedures has been prohibited in Europe [20]. In response to this issue, single-antibiotic prophylaxis programs are gradually being used in clinical practice [21, 22].

In this present study, 62 of the 766 patients with TRUSPB had concomitant infections, demonstrating an infection rate of

TABLE 1. Patients' post-TRUSPB infections and statistics of blood culture results and drug sensitivity tests (n (%)).

Cases of infection	Number of cases (cases)	Group A (n = 450)	Group B (n = 316)	χ^2	<i>p</i>
Febrile urinary tract infection	35 (4.57)	19 (4.22)	16 (5.06)	0.30	0.58
Simple fever	5 (0.65)	3 (0.67)	2 (0.63)	0.00	0.95
Epididymitis	9 (1.17)	5 (1.11)	4 (1.27)	0.04	0.84
Prostatitis	8 (1.04)	6 (1.33)	2 (0.63)	0.88	0.34
Sepsis	5 (0.65)	3 (0.67)	2 (0.63)	0.00	0.95
Total	62 (8.09)	36 (8.00)	26 (8.23)	0.01	0.91

TABLE 2. Blood/urine bacterial culture results of the infected patients.

Pathogenic species	Number of cases	Group A (n = 450)	Group B (n = 316)
Escherichia coli	58 (7.57)	36 (8.00)	22 (6.96)
Klebsiella	5 (0.65)	3 (0.67)	2 (0.63)
Staphylococcus epidermidis	3 (0.39)	1 (0.22)	2 (0.63)
Enterococcus faecalis	3 (0.39)	2 (0.44)	1 (0.32)

TABLE 3. Univariate analysis of factors affecting infection after TRUSPB.

Factors	Grouping	n	Infected group (n = 62)	Non-infected group (n = 704)	χ^2/t	<i>p</i>
Age						
	<60 age	243	12	231		
	60–70 age	411	35	376	7.58	0.02
	>70 age	112	15	97		
BMI (kg/m ²)						
	<20	110	3	107		
	20–25	489	39	450	7.65	0.02
	>25	167	20	147		
PSA level (ng/mL)			18.12 ± 2.58	18.43 ± 2.79	0.84	0.40
Prostate volume (mL)						
	<30	160	15	145		
	30–60	321	22	299	1.19	0.55
	>60	285	25	260		
History of diabetes						
	yes	221	28	193		
	no	545	34	511	8.74	<0.001
History of hypertension						
	yes	263	24	239		
	no	503	38	465	0.57	0.45
Chronic bronchitis						
	yes	113	12	101		
	no	653	50	603	1.14	0.27
Cerebrovascular disease						
	yes	96	10	86		
	no	670	52	618	0.80	0.37
Number of biopsies needles						
	2–5	36	3	33		
	6–9	50	6	44	1.11	0.57
	10–16	680	53	627		
Biopsy results						
	Benign	535	46	489		
	Malignant	231	16	215	0.61	0.44
The urinary catheter was left in place 7 days before the biopsy						
	yes	20	6	14		
	no	746	56	690	13.25	<0.001
History of hospitalization within 1 month before biopsy						
	yes	302	25	277		
	no	464	37	427	0.02	0.88
Whether prophylactic antimicrobials were applied						
	yes	450	36	414		
	no	316	26	290	0.01	0.91

BMI: Body Mass Index; PSA: Prostate-specific antigen.

TABLE 4. Multivariate regression analysis affecting infection after prostate aspiration biopsy (TRUSPB).

Factors	β	Wald χ^2 value	OR	<i>p</i>	95% CI
Age	0.14	10.00	1.15	<0.001	1.05–1.25
BMI	0.14	3.27	1.15	0.07	0.99–1.34
History of diabetes	0.27	11.63	1.31	<0.001	1.12–1.52
The urinary catheter was left in place 7 days before the biopsy	0.36	10.42	1.43	0.001	1.15–1.77

Note: BMI = weight (kg)/height (m)². BMI: Body Mass Index; OR: Odds ratio; CI: Confidence Interval.

8.09%, with *Escherichia coli* being the most frequently detected bacterium, emphasizing its continued role as the primary causative agent of infections after TRUSPB. The detection rate of post-TRUSPB infection and the type of pathogenic bacteria identified in Group A, where patients received fluoroquinolone antibiotics three days before biopsy, were similar to those in Group B, where antibiotics were administered as a single dose before biopsy. This suggests that single antibiotic prophylaxis regimens before biopsy may also have good efficacy in preventing post-TRUSPB infections. However, it is essential to acknowledge that our study had limitations, such as its retrospective nature, a relatively small sample size, and being conducted at a single center. Consequently, the conclusions drawn from our reported results may carry a degree of bias. To enhance the reliability of our findings, future research studies could consider expanding the sample size and conducting prospective studies.

Analyzing the relevant factors related to post-TRUSPB infection is important in developing targeted measures to reduce the rate of post-TRUSPB infection and improve the safety of TRUSPB procedures. In this study, age, history of diabetes mellitus, and indwelling urinary catheter 7 days before biopsy were identified as risk factors affecting infection after TRUSPB.

Older patients typically have more comorbid underlying conditions, longer disease durations, poorer overall body function, and impaired immunological function, which increases their risk of developing infections following biopsy [23, 24].

In addition, combined diabetes mellitus is a high-risk factor for causing infection after TRUSPB in several studies. People with combined diabetes have poor body resistance, and some studies have shown that diabetes can promote the growth of *Escherichia coli* and induce pyelonephritis [25]. Moreover, diabetic patients often develop insulin resistance, which may also promote the release of various inflammatory factors, resulting in hypoxia, fibrosis, centrocyte infiltration, and other changes in the prostate tissue, and with the prolongation of diabetes, the body's immune-regulatory function may decrease even under glycemic control, which may increase the chance of infection after TRUSPB [26].

In this present study, we found that patients who had indwelling urinary catheters for 7 days before undergoing TRUSPB had a greater risk of infection after TRUSPB. This could be because indwelling catheters provide a pathway for germs to enter the urinary system, raising the risk of infections acquired while receiving medical care as well as bacterial reproduction and growth [27, 28]. In addition, patients with indwelling catheters are more often associated with urinary tract pathology, which also increases the risk of infection after

TRUSPB [29].

Based on the above findings, it is recommended that clinics prioritize thorough bowel preparation before biopsy and institute vigilant post-TRUSPB infection monitoring and prevention strategies, particularly for elderly TRUSPB patients, to effectively reduce the risk of post-TRUSPB infections. Additionally, meticulous blood glucose management should be implemented for diabetic patients to minimize the impact of diabetes on post-TRUSPB infection risks. Furthermore, for individuals with indwelling urinary catheters before the procedure, close pre-TRUSPB monitoring and timely administration based on appropriate broad-spectrum antibiotics are advised as precautionary measures. These comprehensive measures aim to enhance patient safety and mitigate the incidence of infections after TRUSPB.

5. Conclusions

In conclusion, the efficacy of a single preoperative administration of ciprofloxacin in reducing the risk of infection after TRUSPB was similar to that of those who received oral fluoroquinolones three days before biopsy. Conversely, advanced age, concomitant diabetes mellitus, and the presence of an indwelling urinary catheter 7 days before TRUSPB increased the risk of post-TRUSPB infection. Hence, it is advised that clinical focus be directed towards meticulous pre- and post-biopsy preparations, particularly in the monitoring of patients with these aforementioned characteristics.

AVAILABILITY OF DATA AND MATERIALS

The authors declare that all data supporting the findings of this study are available within the paper and any raw data can be obtained from the corresponding author upon request.

AUTHOR CONTRIBUTIONS

JL, LJW—designed the study and carried it out—supervised the data collection, analyzed the data, interpreted the data, prepared the manuscript for publication, and reviewed the draft of the manuscript. All authors have read and approved the manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Ethical approval was obtained from the Ethics Committee of the First Affiliated Hospital of Shihezi University (Approval no. 2019-030). Written informed consent was obtained from

a legally authorized representative for anonymized patient information to be published in this article.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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