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ROLE OF POVIDONE-IODINE-SOAKED GAUZE IN PREVENTING INFECTIOUS COMPLICATIONS FOLLOWING TRANS RECTAL DIGITAL GUIDED PROSTATE BIOPSY

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ABSTRACT

Objective: To identify the role of povidone iodine-soaked gauze following transrectal digital guided prostate biopsy in the prevention of infectious complications.

Methodology: This prospective comparative study was conducted in the urology department of Lady Reading Hospital including 201 patients. Patients who had indications for prostate biopsy, including an elevated prostate-specific antigen (PSA) or abnormal prostatic nodule on digital rectal findings were included. Patients were distributed into two groups by the closed envelop method. Group, I (n=101) received a povidone-iodine-soaked gauze intrarectally along with xylocaine lubricant for 5 minutes just before biopsy, while group 2 (n=100) did not receive povidone-soaked gauze. The transrectal digital guided prostate biopsy guided method was used in this study. The rectal swab was taken before using povidone-soaked gauze and after doing biopsy in both groups. The bacterial colonies were counted in swabs before using povidone-soaked gauze and after biopsy using biopsy Mueller-Hinton agar medium.

Results: The mean age of group 1 was 64 years (range, 39–80) and group 2 was 61.7 years (range, 35–82). The average PSA values were 7.3 ng/ml and 8.34 ng/ml in groups 1 and 2, respectively. The rate of infectious complications in group 1 was 0.9% (n=1) whereas in group 2 was 10% (n=10). A single-use of povidone-soaked rectal gauze significantly lowered the risk of infectious complications $P < 0.05$. There was a 99.9% decrease in the mean number of colony-forming units after rectal preparation.

Conclusion: Findings concluded that using povidone iodine-soaked gauze before doing digital guided prostate biopsy is a significant method to minimize complications.

Key Words: Transrectal ultrasonography; Prostate biopsy; Povidone-iodine; Sepsis

INTRODUCTION

Prostate biopsy is a gold standard test for the detection of prostate cancer.¹ It is reported that prostate cancer is the second most prevalent malignancy after lung cancer in 2018, accounting for more than 1276100 new cases and 358900 deaths (3.8% of all cancer deaths) globally.^{2,3} The rate of prostatic biopsy techniques has dramatically increased after the introduction of prostate-specific antigen (PSA). PSA is a vital parameter in the diagnosis of prostate carcinoma.¹ Nowadays Transrectal ultrasound (TRUS) guided biopsy is the standard protocol for the precise mapping of the suspicious hypoechoic lesions in the prostate. Previously six-core biopsy was in fashion but to increase the sensitivity of TRUS guided biopsy twelve core biopsy is recommended now a days⁴. A previous study reported that rectal cleansing with povidone-iodine before the transrectal ultrasound-guided prostate biopsy was

safe⁵. Due to economic constraints, our institute is not having the facility of TRUS, that's why Digital guided prostate biopsy is still in practice in our setup. Digital guided prostate biopsy is a safe procedure not requiring specific and complicated preoperative preparations but still one can come across minor as well as major complications like urosepsis⁶. One of the disastrous complications encountered after trans rectal prostate biopsy are the pathologies having infectious etiology prostatitis, epididymitis, prostatic abscess, sepsis eventually leading to death⁷.

The most common practice by urologists in most of the Khyber Pakhtunkhwa institutions is to administer antibiotics prophylactically to minimize the infection chances after biopsy, but despite these protocols still, the chances of infection persist. That's why to reduce infectious complications a bowel preparatory technique in the form of rectal scrubbing has been in use. How-

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ever, the effects of rectal scrubbing are not established as per recent guidelines up till yet. Literature about povidone-iodine-soaked gauze in preventing infectious complications after a Transrectal digital guided prostate biopsy is lacking in Pakistan. This study is the first in our setting to the best of our knowledge. Therefore, this study was conducted to determine the role of povidone iodine-soaked gauze following transrectal digital guided prostate biopsy in the prevention of infectious complications.

METHODOLOGY

This prospective comparative study was conducted in the Urology department of Lady Reading Hospital Pakistan from January 2014 to January 2018 including 201 patients. The study was approved by the ethical review board of the selected hospital vide notification number [(10-1/LRH/ MTI)]. Patients of any gender with indications for prostate biopsy, abnormal prostatic nodule on digital rectal findings, and an elevated PSA were enrolled in this study.

A single dose of 1gm intravenous 3rd generation cephalosporin (Ceftriaxone) was administered to all the patients just before biopsy in combination with oral ciprofloxacin (500mg BD) on the morning of the procedure, then followed by 5 days post-procedure in both groups. All (n=201) patients were distributed into two groups by the closed envelop method. Group, 1 received a povidone-iodine-soaked gauze intrarectally along with xylocaine lubricant for 5 minutes just before biopsy, while group 2 did not receive povidone-soaked gauze. All patients were informed a consent form shall be signed by all of them prior to the procedure for biopsy. Transrectal digital guided Trucut prostate biopsies were performed after applying 2.5% topical lidocaine gel using a 16-gauge Trucut spring-loaded needle in an operation theatre by an experienced urologist. From both, groups 4 core prostatic bi-

opsy was obtained. At one-week follow-up, Patients were assessed for post-biopsy complications which were recorded on computerized proforma. Due to the non-availability of Transrectal ultrasonography (TRUS) in our region, we used TRUS digital guided method in this study.

The classification of infectious complications was sepsis-free fever and sepsis. Sepsis was characterized as two or more of the following infection-related conditions: body temperature < 36 or > 38 , heart rate more than 100 beats/minute, breathing rate equal to or more than 20 breaths/minute, and WBC counts $>10\ 000$ cells or < 4000 cells⁷. A body temperature of more than $38\ ^\circ\text{C}$ was considered as fever. Other complications like haematospermia, hematuria, and perineal discomfort/pain were also evaluated.

For the determination of the bactericidal properties of povidone-iodine gauze, bacterial colonies were counted in the rectum which was obtained by the insertion of the gauze before the rectal swab and after biopsy. Colonies were counted by dilution of agar. Rectal swabs were diluted and immersed in sterile saline before being put to the Mueller-Hinton agar medium in sections. The bacterial colonies counts were determined after the entire night of incubation. The final data was analyzed using Statistical Package for Social Sciences (SPSS) software, version 22 (IBM Corp. USA). To determine the significance t-test was applied.

RESULTS

The mean age of group 1 was 64 ± 5 years (range, 39–80), while group 2 was 61.7 ± 8 years (range, 35–82). The average PSA level in groups 1 and 2 was 7.3 ± 1.5 ng/mL and 8.34 ± 1 ng/mL respectively. Demographic and complications data of the enrolled subjects are presented in table 1. There was no substantial difference between Groups 1 and 2 in terms of statistical demographic results.

In the no rectal preparation group (group 2) 10 cases (10%) developed infectious complications and whereas only 1 patient (0.9%) in group 1 got infected. Out of 10 infectious complications in the no rectal preparation group (group 2), 8 subjects had fever without any septic element and two patients got septic. One patient from group 1 complained of feverish sensation, which resolved with a stat dose of two tablets of Panadol orally. Hematuria developed in 15 (14.8%) patients in group 1 and 10 (10%) in group 2. In group 1 9.9% of cases presented with rectal bleeding whereas 8% in group 2. No transfusion or intervention is required to manage these noninfectious complications as shown in table 1.

A single-use of povidone-soaked rectal gauze significantly lowered the risk of infectious complications $P < 0.05$.

This study revealed that the bacterial colony count before the rectal preparation was in the range of 2.19×10^5 to 7.5×10^5 but decreased to less than 3×10^1 after biopsy. After rectal scrub by povidone, a significantly decreased by 99.9% in the mean number of colony-forming units was observed. The data show that the bacterial count decreases when the povidone gauze is inserted. The use of povidone statistically lowered the colony count as shown in table 2.

DISCUSSION

In this study, a single use of povidone-soaked rectal gauze significantly lowered the risk of infectious complications. After the rectal preparation, there was a 99.9% decrease in the mean number of colony-forming units. hematuria and rectal bleeding complications were also observed. According to the previous studies, one of the most common complications was perineal pain which was noticed in more than 65% of patients and the frequency is still on the increasing side due to an increase in the

Table 1: Patients demographic details (n=201)

Variables	Group 1	Group 2	T-Test
Patients number	101	100	
Mean age (years)	64±5	61.7±8	
Average PSA (ng/mL)	7.35±1.5	8.24±1	P=0.231
Prostate cancer diagnosis	42 (40.6%)	16 (16%)	
Infective complications			
Sepsis	0	2 (2%)	
Sepsis-free fever	1 (0.9%)	8 (8%)	P=0.02
Other complications			
Hematuria	15 (14.8%)	10 (10%)	P=0.289
Rectal bleeding	10 (9.9%)	8 (8%)	P=0.25

Table 2: Colony counts before insertion of povidone-iodine-soaked gauze and after biopsy

	Colony counts before povidone-iodine soaked gauze	Colony counts after povidone-iodine soaked gauze
1	2.19×10 ⁵	5×10 ²
2	1.93×10 ⁴	≤3×10 ¹
3	1.09×10 ⁴	≤3×10 ¹
4	7×10 ³	≤3.6×10 ¹
5	7.2×10 ⁵	≤3×10 ¹
6	7.5×10 ⁵	≤3×10 ¹

number of biopsy chunks^{8,9}. Furthermore, hematuria, local pain, haemospermia, dysuria, and rectal bleeding complications were also reported in previously published literature. Hematuria after a biopsy has been reported in up to 60% of cases whereas the frequency of haemospermia is also more or less equal to hematuria about 64%¹⁰. Rectal bleeding is also one of the common complications reported in 75% of patients and very rarely 1% of patients suffer from massive rectal bleeding requiring blood transfusions up to 5 pints¹¹. Rectal bleeding heals by itself in the majority of patients and is not bothersome. Unlike rectal bleeding and hematuria, haemospermia has a transient harmful effect on sexual activity. A short-term worsening of symptoms of the lower urinary tract has been described in 6 to 25% of patients with a reported incidence of 0.4% urinary retention cases¹²⁻¹⁵. A small number of patients also complain of the transient erectile dysfunction which reverses by itself after 1-3 months without any medication¹⁶.

Infection is one of the adverse complications represented by prostatitis, epididymitis, Prostatic abscess, and sepsis. Antibiotic prophylaxis is defined as the administration of antibiotics before contamination by surgical incision has occurred and is given to prevent infection. The usage of prophylactic antibiotics is a standard of care to minimize infectious complications¹⁷⁻²⁰. Ciprofloxacin is the drug of choice for the long long-term because of its broad-spectrum activity and high concentration in prostatic tissue. The Resistance to ciprofloxacin is on rising because of excessive prescriptions which ca urinary tract infections, which is a quite alarming situation for healthcare professionals, to tackle this intervention it is recommended to use multidrug prophylaxis.²¹ The fever is associated with lower urinary tract and septicemia were reported 3-10% and 5% respectively in patients after prostatic biopsy. Despite consensus on prophylactic administration of antibiotics, regimen duration, timings, and administration route are still debatable. Ciprofloxacin at a dosage of 100 mg BID for

3 days was the minimum effective dose for the treatment of uncomplicated urinary tract infection.

Although the incidence is low but still the possibility of infectious complications is there despite prophylactic antibiotic administration. For this reason, some urologists use a rectal cleansing enema to reduce the chances of infection. Anastasiadis et al. reported that chances of bacterial infection can be lessened by a pre-biopsy administration of an enema. They highlighted that about 4% of patients presented with bacteremia had an enema before biopsy as compared to 28% of patients who didn't have a pre-biopsy enema. This study provides a solid base for use of rectal enema scrub before the prostatic biopsy. While searching international literature it is evident that a minority of patients for example 1.1-1.4% require hospitalization secondary to sepsis whereas in our study 2% required hospitalization in the non-rectal prepared group and none of the patients developed sepsis in the rectal prepared group²².

Even with the use of prophylactic antibiotics, there is the possibility of getting infection chances are there-which can be reduced by using a povidone-iodine rectal swab preoperatively. When Povidone-iodine rectal prophylaxis was combined along with the use of antibiotics as compared to the only use of antibiotics significant difference was there with combination therapy.²³ Povidone-iodine is commonly used in surgical and allied fields due to its broad-spectrum antimicrobial activity and anti-inflammatory activity. Povidone-iodine is used in different concentrations as an antiseptic solution. Jordan et al. reported a 97% decrease in the colonies after using the povidone-iodine rectal swab whereas in our study the result was even more significant with a 99% decrease in colonies²⁴. Borghesi et al. determined that parenteral use of piperacillin with a povidone-iodine enema which is a method of de-

livery of liquids through rectum significantly decreases the complication caused by bacterial infections.²⁵ A meta-analysis of eight studies reported by Walker et al. showed a significant drop in the incidence of bacteriuria and sepsis after prostatic biopsy²³.

Microbial growth of bacteria in colonies was counted in the rectum collected from rectal swabs before and after povidone-iodine injection and biopsy to investigate the antibacterial effects of povidone-iodine. Bacterial colony counts were reported to be significantly lower following the prostate assay when compared to counts before rectal preparation. These local antiseptic treatments appear to be one of the least expensive ways to reduce the occurrence of infection problems. Our study also indicated that using a povidone-iodine rectal swab to prevent infective consequences is a dependable, cost-effective, and trusted strategy.

An ultrasound-guided prostate biopsy is a gold standard, well-tolerated and one of the most common procedures used as a diagnostic tool for prostate cancer, but due to scarce financial resources, trust digital guided prostate biopsy is utilized as a diagnostic tool in all tertiary care hospitals of Khyber Pakhtunkhwa. Although we do not come across complications most of the time yet it's not a harmless procedure. Secondly, the strength of our study is that comparison has been done between two groups and large sample size, but on the other hand weakness is that randomization was lacking in our study.

■ LIMITATION

Firstly, an ultrasound-guided prostate biopsy is a gold standard, well-tolerated, and one of the most common procedures used as a diagnostic tool for prostate cancer, but due to scarce financial resources, Trust digital guided prostate biopsy is utilized as a diagnostic tool in all tertiary care hospitals of Khyber Pakhtunkhwa. Although we do not

come across complications most of the time yet it's not a harmless procedure. Secondly, the strength of our study is that comparison has been done between two groups and large sample size, but on the other hand weakness is that randomization was lacking in our study.

■ CONCLUSION

The current study concluded that rectal preparation using a povidone-iodine soaked rectal gauze for 5 minutes is an effective and cheap method in controlling and minimizing the complications of the infection significantly. Thus, due to its effectiveness in managing rectal bacterial colony-forming units, we suggest povidone-iodine rectal swab preparation before prostate biopsy. Further multi-institutional and longitudinal studies are needed to explore and validate the role of povidone iodine-soaked gauze in various health care settings and special populations.

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Author's Contribution

KF and MA conceived the idea, designed the study and wrote initial manuscript. KF, MA and NM reviewed the draft critically, carried out corrections and supervised the whole study. Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflict of Interest

Authors declared no conflict of interest

Grant Support and Financial Disclosure

None

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.