

# The Role of Intravesical 1% Povidone-iodine in Reducing Open Prostatectomy Surgical Site Infection

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## ABSTRACT

**Background:** Surgical Site Infections following open prostatectomy are common and can account for as much as 12 - 36% of post-prostatectomy complications. The aim of this study was to determine the role of preoperative bladder irrigation with 1% povidone-iodine in reducing surgical site infection following open transvesical prostatectomy. **Methods:** A prospective randomized study over a period of eighteen months. Sixty patients who met the inclusion criteria were recruited into two groups using a computer-generated random sequence. Study group, A had bladder irrigation with 150mls of 1% povidone-iodine for 10mins before surgery, The Control group B had bladder irrigation for 10mins with 150mls normal saline before surgery. The patients were followed up for 30 days for signs of SSI. **Results:** The incidence of surgical site infections in group A was 6.7% compared to 23.3% in the control group B. There was no statistically significant difference in the surgical site infection rate between the study and control groups. ( $p=0.145$ ). The overall incidence of surgical site infection was 15.0%. *Escherichia coli* was the commonest organism isolated from the culture of infected wounds (34.0%). Surgical site infection was statistically associated with age ( $p=0.044$ ); higher estimated blood loss ( $p=0.032$ ) and duration of hospital stay ( $p<0.001$ ).

**Conclusion:** There was less incidence of surgical site infection in the patients who had pre-operative 1% povidone-iodine bladder irrigation compared to controls, though the magnitude was not statistically significant. The use of 1% Povidone- iodine for pre-operative bladder irrigation in patients undergoing open transvesical prostatectomy may reduce the incidence of postoperative surgical site infection. A larger study is required to confirm the validity.

**Keywords:** Transvesical Prostatectomy, Surgical Site Infections, 1% Povidone Iodine, Pre-operative Bladder Irrigation

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## INTRODUCTION

**B**enign Prostatic Hyperplasia, BPH is an increase in number of the epithelial and stromal cells in the periurethral transition zone of the prostate.<sup>[1-3]</sup> It is a disease of aging males. Beyond the age of 40, the prostate increasingly becomes hyperplastic however, only about 10% of males more than 50 years of age may have symptoms of BPH.<sup>[4]</sup> BPH manifests clinically as lower urinary tract symptoms (LUTS) requiring varied interventions. Lower urinary tract symptoms, LUTS associated with BPH can be bothersome and negatively impact the quality of life of patients and their partners. These symptoms also negatively impact patients' families, health services, and society at large.<sup>[5]</sup>

The prevalence of BPH is about 62% in Ghanaian men, 68.3% in Nigerian men<sup>[1]</sup> but about 36-42% in the United States of America and the United Kingdom.<sup>[2,4,5]</sup> The economic impact of BPH is also alarming, as over 1.1 billion dollars and about 180 million pounds were spent in the United States and the United Kingdom respectively on managing BPH in 2000.<sup>[5]</sup>

Infective complications following open prostatectomy may affect the urinary tract, the surgical wound, or present as epididymorchitis.<sup>[9]</sup> Postoperative surgical site infections, SSI following open prostatectomy are common and can account for as much as 12.1% and 36% of post-prostatectomy complications.<sup>[7, 10, 11]</sup> Surgical site infections can prolong hospital stays, compromise surgical outcomes, and may even require repeat surgery; resulting in an increased financial burden to the patient.<sup>[11,12]</sup>

While surgical site infections may not be eliminated, they could be significantly reduced to low levels to improve patients' quality of life and outcomes. There are certain factors that encourage surgical site infections following prostatectomy. These include infected urine, mainly from prolonged indwelling urethral catheterization which patients often require because of long waiting lists for surgery, lack of finance, and other comorbid conditions. Others are malnutrition,

preoperative infection at the proposed surgical incision site.<sup>[6, 7, 12]</sup> The reduction or elimination of these risk factors can reduce post-prostatectomy SSI. Surgical site infection following open prostatectomy can be life-threatening and increase the overall

hospital stays.<sup>11,13</sup> Various methods have been used as means of prophylaxis to reduce post-prostatectomy SSI. Despite the common availability of prophylactic antibiotics, SSI continues to occur, and this can be devastating for patients. However, irrigating the surgical wound or the bladder with povidone-iodine has proven to be useful in reducing SSI.<sup>[11-13]</sup>

Povidone-iodine is an iodinated polyvinyl polymer that has bactericidal activity against many microorganisms. It has a rapid onset of action, and it has been demonstrated to be safe and effective. Its use as a topical antibacterial agent has been greatly studied. However, literature is sparse on its use as a prophylactic irrigant solution in preventing infection.<sup>[13,14]</sup>

Thus, the aim of this study is to evaluate the role of 1% povidone-iodine as a preoperative bladder irrigant in surgical site infection following open trans vesical prostatectomy.

## Methodology

The study was conducted in the Urology unit of the University of Benin Teaching Hospital, UBTH. This study was a hospital-based, prospective randomized comparative study carried out over a period of 18 months from June 2020 to December 2021. Study participants were drawn from patients attending the urology outpatient clinic of UBTH with a diagnosis of BPH, and who have met the indication for open prostatectomy: consenting adult patients with a diagnosis of BPH associated with recurrent acute urinary retention, obstructive uropathy, recurrent haematuria, severe LUTS, and failed medical therapy. In addition, patients on indwelling urethral catheters with or without evidence of positive urine culture and sensitivity were included. Those with a positive urine culture were given a therapeutic course of antibiotics for

five days based on the culture sensitivity report. A cure of the infection was confirmed with a repeat urine culture before surgery.

The following groups of patients were excluded from the study: patients with uncontrolled diabetes mellitus, immunosuppressed, known sensitivity reaction to povidone iodine, and patients on suprapubic catheter with a skin infection at the proposed incision site.

A sample size formula for comparing two proportions was used. A sample size of 60 was computed and divided into two groups A and B, 30 participants in each group, where the ratio of  $n_1$  to  $n_2$  is 1.

Eligible patients were randomized into the two groups: A (Study arm) and B (Control arm) using a computer-generated table of random numbers.

Patient's socio-demographic data, indication for surgery, duration of indwelling urethral catheter, intravesical instillation of povidone-iodine, or normal saline, the occurrence of surgical site infection, and the type were recorded using a structured proforma. Eligible patients were randomized into two groups: A (Study arm) and B (Control arm). All patients had microscopy cultures and sensitivity of urine specimens done before surgery. They were admitted 48 hours prior to surgery following a full fitness assessment to undergo an open simple prostatectomy. The patient's height and weight were measured to calculate the body mass index BMI.

In study group A, using a Size 18 French urethral catheter, the bladder was completely emptied in the ward. Thereafter, 150mls of 1% povidone-iodine (Manufactured by Jawa International Nigeria Batch no: 2110S. Manufactured July 2020) constituted by diluting 15mls of 10% povidone iodine in 135ml of sterile water solution was instilled into the bladder, an hour before the patient was taken to the theatre. The catheter was spigotted for 10 minutes to ensure that the povidone iodine made adequate contact with the bladder mucosa. Then, the bladder was completely drained of the

povidone iodine before the patient is taken from the ward to the theatre; though the catheter was left within the bladder to be used for bladder distension later in the theatre. The control group (B) had the same procedure but with 150mls of normal saline.

Both groups received intravenous antibiotic prophylaxis, ceftriaxone 1gm at the time of induction of anaesthesia. All patients, (groups A and B) had their bladder distended with 300mls of normal saline. The urethral catheter was then removed. The operative field was prepared consecutively with cetrimide, methylated spirit, and povidone iodine in both groups. All patients had transvesical prostatectomy via a Pfannenstiel incision by a consultant or senior registrar assisted by a consultant.

The wound was cleaned with cetrimide, methylated spirit, and povidone-iodine respectively before applying a sterile gauze dressing. Both groups received post-operative antibiotics (ceftriaxone) 1gm daily for 5 days. Continuous bladder irrigation was discontinued on achievement of clear urine drainage at about 48 – 72 hours postoperatively.

The wounds of the patients were inspected by a designated trained research assistant who was blinded to the patient groups. The wounds were examined on the 3<sup>rd</sup>, 5<sup>th</sup> and 7<sup>th</sup> postoperative days and until when skin sutures and the urethral catheter were removed and the patient was discharged home, if no signs of SSI. The patients were subsequently seen in the clinic for wound examination on the 14<sup>th</sup>, 21<sup>st</sup> and 30<sup>th</sup> postoperative days and whenever SSI was suspected through self-report. Wound swabs for microscopy and culture were obtained from wounds that were determined to be infected to guide antibiotic therapy.

In this study, the primary outcome measure was the occurrence of SSI within 30 days after surgery. Surgical site infection was defined as purulent discharge, with or without laboratory confirmation from the incision site. In addition, at least one of the following signs or symptoms of infection was also identified: localized pain or tenderness, localized

swelling, redness at the incision site.

The secondary outcome measure was the type of SSI determined by the organisms isolated from wound culture or fluid (discharge) culture at the site of the incision.

Data entry and analysis were done using SPSS (Statistical Package for Scientific Solution) version 26. The data obtained were summarized using means and standard deviations for continuous variables and frequencies and proportions for categorical variables. The association between categorical variables was determined using Chi-square test and Fischer's exact test (in cases where more than 20% of the cells had an expected less than 5). Univariate and multivariate logistic regression was used to determine independent predictors of SSI. The level of statistical significance was set at  $p < 0.05$  and 95% confidence interval.

Approval for this study was obtained from the Hospital Ethics and Research Committee (HERC) of the University of Benin Teaching Hospital. Written informed consent was obtained from all participants of the study.

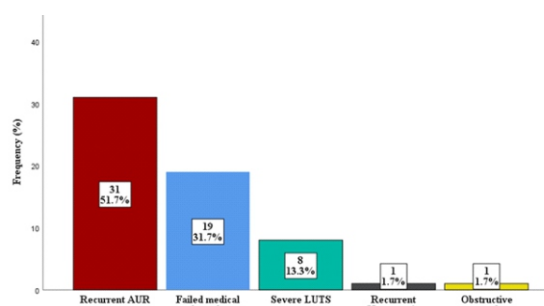
## RESULTS

A total of 60 participants consisting of 30 in both the case and control arms were studied. The main results are displayed in Tables 1 – 4 and Figure 1.

**Table 1: Socio-demographic Characteristics of Patients in both Groups**

	1%Povidone iodine (n=30)	Normal Saline (n=30)	$\chi^2$	p-value
Age (Years) Mean±SD	68.23 ± 6.32	69.10 ± 5.83	0.552*	0.583
BMI (Kg/m) <sup>2</sup>	25.44 ± 3.59	25.31 ± 3.89	0.138*	0.891
Smoking				
Yes	22 (73.3)	26 (86.7)	0.938	0.333
No	8 (26.7)	4 (13.3)		
Alcohol Use				
Yes	18 (60.0)	21 (70.0)	0.659	0.589
No	12 (40.0)	9 (30.0)		
History of Diabetes				
Yes	26 (86.7)	27 (90.0)	0.001	1.000
No	4 (13.3)	3 (10.0)		
Duration of indwelling Urethral catheter (days)Mean±SD	42.90 ± 15.40	50.43 ± 37.68	1.014*	0.317

Independent student t test;  $\chi^2$ = Chi square test



**Figure 1: Indications for surgery**

**Table 2: Surgical Site Infection in Study Participants**

Variable	Freq. (%)		Fisher exact test	p-value
	1%PI Group A (n=30)	Normal Saline Group B (n=30)		
<b>Surgical Site</b>				
Yes	2 (6.7)	7 (23.3)	2.092	0.145
No	28 (93.3)	23 (76.7)		
<b>Type of SSI</b>				
Superficial incisional	2 (100.0)	4 (57.1)	0.080	0.777
Deep incisional	0 (0.0)	3 (42.9)		
<b>Descriptive criteria for SSI</b>				
Localized pain/tenderness/swelling	1 (50.0)	3 (42.9)	0.0001	1.000
Purulent Discharge	1 (50.0)	4 (57.1)		
<b>Wound swab</b>				
MCS	1(50.0)	5(71.4)	0.021	0.891
Yes	1(50.0)	2(28.6)		
No				
<b>Organism culture</b>				
E.coli	1	2	3	
Klebsiella spp.	0	1	1	
Streptococcus spp	0	2	2	

**Table 3: Antibiotics susceptibility among isolates**

	Frequency (n=6)	Percentage
<b>Amikacin</b>	3	50.0
<b>Cefuroxime</b>	4	66.7
<b>Ampicilin</b>	3	50.0
<b>Ciprofloxacin</b>	4	66.7
<b>Nitrofuratoin</b>	1	16.7

**Table 4: Multivariate univariate logistic regression showing independent predictor of surgical site infection**

	Univariate		Multivariate	
	OR (95% CI)	p-value	AOR (95% CI)	p-value
<b>Age</b>	1.903(1.22-2.59)	<b>0.043*</b>	1.235(0.89-2.08)	0.089
<b>BMI</b>	1.382(0.89-1.90)	0.439		
<b>Smoking</b>	6.01(0.33-12.83)	0.228		
<b>Alcohol Use</b>	0.63(0.15-2.63)	0.522		
<b>History of Diabetes</b>	0.180(0.06-2.35)	0.299		
<b>Duration of indwelling catheter Post op (days)</b>	3.023(1.90-7.08)	<b>0.032*</b>	2.835(1.39-6.91)	<b>0.032*</b>
<b>Duration of surgery (mins)</b>	0.982(0.48-2.89)	0.891		
<b>Estimated blood loss (mls)</b>	4.092(2.07-7.87)	<b>0.004*</b>	3.093(1.42-6.38)	<b>0.034*</b>
<b>Duration of hospital stay (Days)</b>	6.011(2.38-12.39)	<b>0.001*</b>	5.926(2.14-10.33)	<b>0.009*</b>
<b>Use of Povidone iodine</b>	0.235(0.04-1.24)	0.090		

OR= Odd ratio, AOR=Adjusted odd ratio, CI=Confidence interval

## DISCUSSION

The study showed lower rates of SSI in participants belonging to the 1% povidone-iodine group compared to participants in the normal saline group. Although prevention of infection following open prostatectomy requires several approaches, evidence from the literature regarding povidone-iodine's antimicrobial efficacy and safety has gained acceptance as a means of mitigating surgical site infection risk.<sup>[11,12,14,16,19,20]</sup> BPH was described as a disease of the aging male,<sup>[4]</sup> so it is not surprising that the mean age of patients involved in this study was more than 65 years. This finding is slightly higher than the mean age of 64 years reported by Richter et al.,<sup>[12]</sup> but is similar to findings from other studies.<sup>[11,21-23]</sup> The commonest indication for open prostatectomy in this study was recurrent acute urinary retention, reported in more than half of the study population. This may be because patients delay acceptance of surgical treatment until when they become dependent on catheter or concerned about imminent dependence on it. This is similar to the finding from a retrospective 10 years review of 247 cases of open prostatectomy in a tertiary health institution in South-western, Nigeria.<sup>[23]</sup> The mean duration of hospital stay of  $9.17 \pm 2.48$  days in the present

study is comparable to the  $9.6 \pm 4.1$  reported by Ofoha et al.<sup>[24]</sup>

Only 9 (15.0%) surgical sites were infected of which two-thirds were superficial incisional while one-third were deep incisional. The overall SSI rate (15.0%) in the present study is comparable to the finding of Emori et al.<sup>[25]</sup> who reported SSI rates of between 14.0% to 16.0%; but the SSI rate in this study is lower compared to that reported by Mukosai et al.<sup>[11]</sup> in Zambia (16.2%), the SSI rate of 26.0% reported by Mawalla et al.,<sup>[26]</sup> and 20.0% reported by Auerbach.<sup>[27]</sup> However, it was higher than rates reported by Amoran et al. in south-western Nigeria,<sup>[28]</sup> who reported an overall SSI rate of 13.0%. These differences in SSI rates may be explained by varying patient factors and the approach to open prostatectomy in the different studies. Olowo-okere et al.<sup>[15]</sup> reported that different types of surgical operations resulted in different surgical wounds and SSI rates. This is because SSI rates are dependent on the type of surgical wound for instance; clean, contaminated, dirty, and trauma-related; as demonstrated by Mawalla et al.,<sup>[26]</sup> Amoran et al.<sup>[28]</sup> and Olowo-okere.<sup>[15]</sup>

The most predominant organism cultured from infected surgical wounds was E. coli. This finding is consistent with the findings of previous

studies.<sup>[3,29-30]</sup> This may be attributed to the nature of host pathogens colonising the lower urinary tract. The isolated organisms were mostly sensitive to Amikacin, Cefuroxime, and Ciprofloxacin while they were mostly resistant to Nitrofurantoin and Genamicin. This finding may have implications for the perioperative choice of antibiotic prophylaxis in open prostatectomy.

The findings of this study indicated that a little above one-fifth of the patients in the control group and less than one-tenth in the study group developed SSI. The SSI rate recorded in the povidone-iodine study group in this study is lower than the 9.2% reported in a study by Mukosai et al.<sup>[11]</sup> and a rate of 8.7% in the study group reported by Richter et al.<sup>[12]</sup> but higher compared to infection rates of 2.9% in the treatment group reported by Sindelar and Mason.<sup>[31]</sup> The difference between the infection rate recorded in this study in the intervention group and that reported from other studies may be due to patients' socio-demographic and clinical variables such as underlying pre-existing morbidity and theatre operating conditions.

However, the difference in SSI rate between the study and control group was not statistically significant. The efficacy of 1% Povidone-iodine against SSI was noted in the intervention group, compared to the control group. This may be due to the bactericidal effects of 1% povidone-iodine in the urine. This may render the urine sterile thus reducing post prostatectomy SSI. Furthermore, though there was no finding of statistical significance, the observation that povidone iodine reduces the risk of SSI is clinically significant.

In this study, age was significantly associated with post-prostatectomy SSI. It was more common in men in the 76 – 81 years age bracket. This finding is in contrast with the findings from other studies.<sup>[23, 32-33]</sup> Age has been a controversial risk factor for SSI. This is because investigators in the past reported contradictory results concerning the relationship between increasing age and risk of SSI.<sup>[34]</sup> Some researchers affirm that increasing age is associated with a greater risk of SSI<sup>[35, 36]</sup> while

others believe factors indirectly related to age such as an increased prevalence of co-morbid conditions, increased severity of acute illness, and decreased host response to bacterial invasion are the real reasons why older patients appear to have an increased risk of SSI.<sup>[37]</sup> A cohort study by Kaye et al,<sup>[34]</sup> involving 144,485 consecutive surgical patients and 72,139 procedures however concluded that increasing age independently predicted an increased risk of SSI only until age 65 years; while after this age, increasing age independently predicted a decreased risk of SSI which is at variance with the present finding. This inconsistency requires more empirical investigation into the relationship between age and risk of SSI.

In this study, there was no statistically significant relationship between SSI and alcohol use although higher level of SSI was recorded among alcohol takers. This is similar to findings from a study conducted by Shabanzadeh and Sørensen,<sup>[39]</sup> who found no significant difference between alcohol users and non-users with respect to SSI.

There was no statistically significant relationship between the duration of surgery and SSI in this study. This finding conflicts with the results of other studies like Mawalla et al.,<sup>[26]</sup> where there was a statistically significant relationship between the duration of operation and SSI. This is because increasing the length of the surgical procedure theoretically increases the susceptibility of the wound to infective agents. The lack of relationship between the duration of surgery and SSI risk in this study may be explained by the meticulousness of the surgeon in making sure that the procedure is completed timeously while adhering to the standard infection control principles.

#### **Limitations of the study**

There was a limitation in the assessment of the wounds for SSI following the discharge of patients from inpatient care. Subsequently, the patients were relied on to visit the hospital for wound examination or to self-report symptoms of SSI.

## CONCLUSION

This study demonstrated that preoperative bladder irrigation with 1% povidone-iodine reduced the incidence of SSI compared to controls. However, the difference was not statistically significant. A larger multicentre study with a larger sample size may be advocated to improve the generalizability of the study findings. Nevertheless, it is a clinically significant finding which carries implications for clinical practice in patients undergoing open prostatectomy.

Furthermore, preoperative bladder irrigation with a 1% povidone-iodine solution significantly reduced the postoperative duration of hospital stays. *Escherichia coli* was the most common causative organism of SSI.

A larger multicentre-based study with a larger sample size may be advocated to improve the generalizability of study findings.

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