1. INTRODUCTION

Benign prostatic hyperplasia (BPH) is histologically defined as proliferation of smooth muscle cells and epithelial cells arising in the region of the transition zone (Marwan et al., 2003). It is one of the most common disease processes affecting the ageing male. The aetiology of BPH is multifactorial (Marwan et al.,2003). Clinical manifestation of BPH include symptoms, signs and sequelae of bladder outlet obstruction (BOO) caused by abnormal growth and age induced detrusor dysfunction (Marwan et al.,2003). Different treatment modalities worldwide exist for BPH which include; watchful waiting, medical therapy, minimally invasive surgery, open and endoscopic prostatectomy (Roger, 1999).

Open prostatectomy is the enucleation of the hyperplastic adenomous growth of the prostate gland. There are two main approaches to prostate surgery i.e. open and closed prostatectomy. Open prostatectomy can either be transvesical, retropubic or perineal prostatectomy. While closed prostatectomy is done endoscopically. For the purpose of this study transvesical prostatectomy was used since this is the most commonly used surgical method for benign prostatic enlargement at the University Teaching Hospital due to limited facilities.

Open transvesical prostatectomy is considered when the prostate gland is larger than 50-70g or larger than the surgeon can resects reliably with transurethral resection of the prostate gland (TURP) (James and Thomas, 2004).

1.1 Indications for Open Prostatectomy

The following are indications for open prostatectomy (Roger, 1999);

- Persistent or recurrent urinary tract infections in BPH
- Acute urinary retention
- Significant haemorrhage or recurrent haematuria
- Bladder calculi secondary to bladder outlet obstructions
- Significant symptoms from bladder outlet obstructions not responsive to medical therapy
- Renal insufficiency secondary to chronic bladder outlet obstruction
- Documented significant residue urine after voiding with or without overflow incontinence.
- International prostate symptom score (IPSS) – severely symptomatic[appendix B]

1.2 Contraindication to Open Prostatectomy

- a small fibrous gland
- Carcinoma of the prostate
- Prior prostatectomy in which most of the prostate has been resected or removed and the planes are obliterated (James and Thomas, 2004).

1.3 Advantages for Transvesical Prostatectomy

- Allows visualisation of the bladder neck and ureteral orifices
- Makes it easier to remove an enlarged protuberant median prostatic lobe
- Easier to operate patient with concomitant symptomatic bladder diverticulum and large bladder calculi (James and Thomas, 2004).

1.4 STATEMENT OF THE PROBLEM

Benign prostatic hypertrophy (BPH) accounted for over 42% of the total urological diseases attended to at UTH during the period 2006 to 2012 (UTH medical records). Majority of these patients present with acute or chronic urinary retention. Due to the long waiting list for surgical operative procedures these patients are usually on long term catheterization. Over 80% of these patients come from rural area and cannot afford medical therapy (UTH medical records). Long term urethral catheterisation is a risk factor for urinary tract infection (Stamm and Countino1999). Urinary tract infection is a risk factor for subsequent development of prostatectomy surgical site infection (Richter et al., 1991). Various methods have been investigated to reduce post-operative surgical site infections (Richter et al., 1991). In this study we investigate the efficacy of using povidone iodine pre-operative bladder irrigation in reducing open prostatectomy surgical site infections (SSIs).

1.5 STUDY JUSTIFICATION

Povidone iodine (Betadine) is a simple and inexpensive antiseptic solution consisting of polyvinylpyrrolidone with water, iodide and 1% available iodine; it has bactericidal ability against a large array of pathogens (Jayaraja et al., 2009). Statistical data on the rate of prostatectomy SSI in Africa and SADC inclusive is scanty. Though in general rates of SSI have been reported following different surgical operations (Shrimpaka, 2007; Mawalla et al., 2011; Rogers et al., 2006). The incidence of SSI reported in some surgical audits (Audit 2010) at UTH has been done retrospectively with the potential to either under report or overestimate the incidence. Moreover, no similar study has been done in Zambia in particular to look at the efficacy of using povidone-iodine in pre-operative urinary bladder irrigation to reduce open prostatectomy SSI. Therefore this study was carried out for the above purpose.

1.6 HYPOTHESIS

The hypothesis of this study was that the use of 1% povidone-iodine pre-operative bladder irrigation can reduce the incidence of post-operative surgical site infections. The null hypothesis was that irrigating the bladder with 1% povidone-iodine has the same effect on the incidence of post prostatectomy surgical site infections with no using 1% povidone.

1.7 **GENERAL OBJECTIVE**

Aim: To determine the efficacy of using povidone iodine 1% bladder irrigation in reducing open prostatectomy surgical site infections.

1.8 SPECIFIC OBJECTIVES

i) To determine the prevalence of open prostatectomy surgical site infection at UTH,
ii) To identify the aetiology of bacteria causing surgical site infection in open prostatectomy,
iii) To assess the effectiveness of preoperative bladder irrigation with 1% povidone iodine in reducing the risk of SSI in open prostatectomy patients.

2. LITERATURE REVIEW

2.1 Background to Surgical Site Infections

Until the middle of the 19th century, when Ignaz Semmelweis and Joseph Lister became the pioneers of infection control by introducing antiseptic surgery, most wounds became infected. In cases of deep or extensive infection this resulted in a mortality rate of 70-80% (Bowter et al., 2009). Since then a number of significant developments, particularly in the field of microbiology, have made surgery safer. However, the overall incidence of healthcare associated infections (HAIs) remains high and represents a substantial burden of disease.

In the USA alone 27 million surgical procedures are performed each year. The CDC's National Nosocomial Infection Surveillance (NNIS) report in 1993 found SSI to be the third most frequently reported nosocomial infections accounting for 14 to 16 % of all nosocomial infections among hospitalised patients Alicia et al., 1999)].

Approximately 500,000 episodes of SSI occur in the United States every year, accounting for an average of 7.3 excess hospital days and more than 1.6 billion dollars of extra hospital charges (Haley, 1998).

In 1992, the US Centres for Disease Control (CDC) revised its definition of 'wound infection', creating the definition 'surgical site infection' (SSI) (Wong, 1999) to prevent confusion between the infection of a surgical incision and the infection of a traumatic wound. Most SSIs are superficial, but even so they contribute greatly to the morbidity and mortality associated with surgery (Eli et al., 2003). Estimating the cost of SSIs has proved to be difficult but many studies agree that additional bed occupancy is the most significant factor. A review of the incidence and economic burden of SSIs in Europe estimated that the mean length of extended stay attributable to SSIs was 9.8 days, at an average cost per day of £325 (Dipro et al., 1998).

Surgical site infection is an infrequent but serious complication of surgery (Delissovy et al., 2009). Postoperative infections often require repeat surgery and prolonged hospitalisation, and may compromise ultimate surgical outcome (Hedrick et al., 2013). Moreover the cost of care of such patients with such complications in terms of human resource, medication, food and bed space tends to go

up (Hedrick et al., 2013). Though infections can't be eliminated completely, it can however be reduced significantly to such lower levels so as to improve patient quality of life and outcome. This in turn will reduce cost of care for the patients on the part of the health institution providing the service (Hedrick et al., 2013). The control of wound infection is one of the surgeons most sought after aspiration (Hedrick et al., 2013).

In developing countries the risk of developing surgical site infection might even be more due to malnutrition, high HIV prevalence and low social economic status (Amoran et al., 2013).

At the University Teaching Hospital patients undergoing open prostatectomy are commonly on long term intermittent catheterisation due to severe lower urinary tract symptoms (LUTS), complications of bladder out flow obstruction due to BPH or failed medical therapy and some are unable to afford medical treatment for BPH. Studies have shown that long term catheterisation increases the risk of urinary tract infection (Stamm and Countino, 1999). Moreover studies have also shown that infected urine is a risk factor for surgical site infection following open prostatectomy (Hamasuna, 2004).

A number of studies have been done on the use of diluted povidone-iodine irrigation to reduce the incidence of surgical site infections (Miimoz, 2007; Chundamala and Wright; Martin, 2001). At the University Teaching Hospital, however, the practice is the use of pre-operative and post-operative antibiotic prophylaxis in most patients undergoing open prostatectomy. No study has ever been done in Zambia to assess or determine the efficacy of using diluted povidone iodine in reducing the incidence of surgical site infections.

Despite widespread use of prophylactic antibiotics, however, surgical site infection continues to occur and is devastating for the patients (Klevens et al., 2002). Wound irrigation with povidone-iodine may be useful for reducing surgical site infection (Crusedy and Foord, 1980).

SSI is associated with morbidity in open transvesical prostatectomies. It leads to prolonged hospital stay, greater use of antibiotics and increased in hospital costs (Salim et al., 2004).

2.2 Studies on the Use of Povidone Iodine

Richter and colleagues, 1991a conducted a prospective comparative study on infected urine as a risk factor for open prostatectomy surgical site infection. Their objective was to determine the relation between preoperative infected urine and subsequent occurrence of post prostatectomy wound infections in patients with and without indwelling catheters. In this study, patients undergoing prostatectomy were evaluated for the presence of infected urine prior to prostatectomy and postoperative wound infections. The results showed wound infections in 19 out of 81 i.e. 23.5% and 6 out of 69 (8.7%) patients with infected and sterile urine respectively at (p=0.028). No risks were found. The study further showed that organisms obtained from infected urine were identical to those obtained from culture of the infected surgical wound in 84% of cases. These results were obtained despite antibiotic prophylaxis.

In another study Richter and colleague (Richter et al., 1991b) carried out a prospective comparative cohort Study, looked at the effectiveness of preoperative bladder washing with povidone-iodine to prevent post prostatectomy wound infection. A total of 156 patients with an indwelling catheter and scheduled for prostatectomy were recruited. 76 patients had their catheter removed without irrigation while 80 patients had their bladder irrigated with non diluted povidone iodine 50 to 60ml for 10 to 13 minutes prior to surgery. Results: wound infection appeared in 17 of 76 (22.4%) control group and 4 of 80 (5%) Study group at p=0.001. Incidence of bacteriuria remained unchanged in control group 100% but was reduced to 22.5% in the treated group (p=0.001). No risks were identified.

Vande broek and colleagues, 1985 carried out a prospective case control study to determine the efficacy of bladder wash out with povidone iodine in the prevention of urinary tract infection after a single or intermittent catheterisation. In the control group (36 patients) the catheter was removed after urethral catheterisation and emptying of the bladder and in the trial group (42 patients) 50 ml povidone-iodine 2% was instilled and allowed to drain immediately before removal of the catheter. The incidence of bacteraemia was 28% in the control group and 4% in the povidone-iodine group. After the introduction of bladder irrigation with povidone-iodine in the Orthopaedic Department of Leiden University Hospital the incidence of hospital-acquired bacteriuria decreased from 6.9% to 3.7%.

Rogers and colleagues, 2006 undertook an RCT of 187 patients (mean age 60.2 years) undergoing general surgery at Nashville Veterans Administration Hospital during a 6-month period from July 1, 1979, to December 31, 1979. Patients were categorized as clean, clean-contaminated, or dirty. Antibiotics were used in the latter 2 group's perioperatively. The treatment group (n = 86) received 1-minute irrigation of the subcutaneous tissue with saline followed by the instillation of about 60 mL of 10% povidone-iodine (1% available iodine). The control group (n = 101) received 1 minute irrigation of the subcutaneous tissue with normal saline alone. Infection was defined as pus from the wound up to 1 month after surgery. The wound infection rate was 4.6% (4/86) in the treatment group and 10.9% (11/101) in the control group (p = 0.117). No risks were identified.

In a prospective comparative study, Singh and colleagues, 1997 examined 90 patients undergoing clean-contaminated operations who were divided into 3 equal groups. Group A patients received irrigation of the operative wound with 5% povidone-iodine. Group B patients received irrigation with 5% povidone-iodine and 5 mg/mL of metronidazole. Group C patients received irrigation with sterile normal saline. The infection rate was 30% in Group C and 10% in Group A and Group B (p = 0.056). Participants' age and adverse effects were not identified.

Two other studies investigated the use of povidone-iodine irrigation in multiple types of surgery. Sindelar and Mason 1996 conducted an RCT at the University of Maryland Hospital where patients ranged in age from 9 to 80 years and had surgery that included general (abdominal and gastrointestinal) and urologic (genitourinary) procedures. Of the 500 patients enrolled, 242 were randomly allocated to 10% povidone-iodine (1% available iodine) irrigation of the subcutaneous tissue for 60 seconds at operation, and 258 were randomly allocated to an equivalent amount of saline irrigation. Patients were classified as clean, potentially contaminated, contaminated or dirty. Patients in the latter 3 groups received combined clindamycin and gentamicin as antibiotics preoperatively to 48 hours postoperatively. When possible renal impairment or allergy was present, doxycycline was used instead. Infection was defined as pus from the incision site within 12 weeks after surgery along with bacteria recovered from a wound culture. The infection rate was 2.9% in

the treatment group and 15.1% in the control group ($p < 0.001$). The treatment group did not experience any interference with wound healing or adverse reactions.

2.3 EPIDEMIOLOGY OF SURGICAL SITE INFECTION

In a survey conducted by the by CDC's NNIS in the USA, during the year 1986 and 1996, they reported 15,523 SSI following 593,344 operations, of these 38% represented SSI (Alicia 1999).

In another survey sponsored by WHO in the USA, the prevalence of nosocomial infections varied from 3 to 21 percent, with surgical site infection accounting for 5 to 34% of the total. Up to two percent of people undergoing clean abdominal surgical will develop SSI and about 30 percent undergoing clean contaminated surgical operation will develop SSI (CDC, 1999). Mawalla et al., 2011 in Tanzania reported SSI rate of 26% among patients undergoing major surgery at Bugando Medical Centre. While Amoran et al., 2013 in Nigeria reported SSI rate of 13%. Freedom and colleague, 2009 in India reported SSI rate of 12%. In Zambia,
Martin and colleague, 2007 reported SSI rate of 23% at Livingstone General Hospital. In 2007 Shrimpaka reported SSI rate of 8.7% among patients undergoing elective abdominal surgery at UTH.

2.4 Surgical Site Infections

2.4.1 Definition

Is a type of soft tissue infection following surgical operation occurring within 30 days of operation. It is characterized by induration, seropurulent pus discharge wound dehiscence, and a positive bacteriological pus swab result.

2.4.2 Classification of Surgical Site Infections

Clean - Elective, not emergency, non-traumatic, primarily closed; no acute inflammation; no break in technique; respiratory, gastrointestinal, biliary and genitourinary tracts not entered.

Clean-contaminated

Urgent or emergency case that is otherwise clean; elective opening of respiratory, gastrointestinal, biliary or genitourinary tract with minimal spillage (e.g. appendectomy) not encountering infected urine or bile; minor technique break.

Contaminated - non-purulent inflammation; gross spillage from gastrointestinal tract; entry into biliary or genitourinary tract in the presence of infected bile or urine; major break in technique; penetrating trauma <4 hours old; chronic open wounds to be grafted or covered.

Dirty -Purulent inflammation (e.g. abscess); preoperative perforation of respiratory, gastrointestinal, biliary or genitourinary tract; penetrating trauma >4 hours old.

(Adapted from Berard F, Gandon J, Annals of Surgery 1964)

2.5 Classification of SSI Risk

Risks for SSI are classified according to patient and operative factors

2.5.1 Patient Factors

- Co-morbidity
- Poor nutritional status

- Uncontrolled diabetes
- Co-existing infection at a remote site
- Colonisation with micro-organism
- Length of pre-operative stay
- Smoking (Mangram et al., 1999)

2.5.2 Operation Factors

These include factors such as:

Pre-operative shaving- has been found to increase SSI

- Preoperative skin preparation
- Duration of operation; its estimated that infections rate nearly doubles with each hour of surgery
- Antimicrobial prophylaxis
- Operation room ventilation; positive pressure, air changes and air filtration are ideal but expensive to install and maintain
- Instrument processing
- Presence of foreign material at the surgical site
- Surgical drains –use of closed drain is advised
- Surgical technique- specifically it is important to handle soft tissue gently to avoid crushing tissue that can result in tissue death necrosis

- Absorbable sutures whenever possible because permanent sutures, especially silk sutures increases the likelihood of SSI
- Use of suction drains that exit through a separate stab wound to prevent accumulation of tissue fluid in the wound (Mangram et al., 1999).

2.5.3 Postoperative Prevention of SSI

Dressing should be ideally changed within 24 to 48hrs for clean wound, and the patient should be discharged promptly (Mangram et al., 1999).

2.5.4 Superficial Incision Surgical Site Infection

Infection involves only skin or subcutaneous tissue of the incision, and least one of the following;

1. Purulent drainage, with or without laboratory confirmation, from the superficial incision
2. Organisms isolated form an aseptically obtained culture of fluid or tissue from the superficial incision.
3. At least one of the following signs or symptoms of infection: pain or tenderness, localised swelling, redness, or heat and superficial incision are deliberately opened by surgeon, unless incision is culture-negative.
4. Diagnosis of superficial incision SSI by the surgeon or attending physician (Mangram et al., 1999).

Do not report the following condition as SSI:

1. Stitch abscess (minimal inflammation and discharge confined to the points of suture penetration).
2. Infection of an episiotomy or newborn or newborn circumcision site.
3. Infected burn wounds.
4. Incision SSI that extends into the fascia and muscle layers (see deep incisional SSI) (Mangram et al., 1999).

2.5.5 Deep Incision Surgical Site Infection

Infection involves deep soft tissues (e.g. fascia and muscle layers) of the incision
And at least one of the following:

1. Purulent drainage from the deep incision but not from the organ/space component of the surgical site.
2. A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever (>38 ˚C), localised pain, or tenderness, unless site is culture-negative.

3. An abscess or other evidence of infection involving the deep incision is found on direct examination, during re-operation, or by histopathology or radiological examination.
4. Diagnosis of a deep incision SSI by surgeon or attending physician (Mangram et al., 1999).

2.5.6 Organ/Space Surgical Site Infection

Infection involves any part of the anatomy (e.g. organ or spaces), other than the incision, which was opened or manipulated during an operation, and at least one of the following:

1. Purulent drainage from a drain that is placed through a stab wound into the organ/space.
2. Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space
3. An abscess or other evidence of infection involving the organ/space is found on direct examination, during re-operation, or by histopathology or radiological examination (Mangram et al., 1999).

2.5.7 Enhancement of Host Defences

This is achieved through:

- Increased oxygen delivery –evidence have shown that increased oxygen delivery helps in reducing SSI.
- Optimising core body temperature- control of intra-operative and postoperative temperature may reduce the risk of SSI
- Blood glucose control- good blood sugar control appears to have a value in reducing SSI. Hyperglycaemia may have an effect in increasing SSI (Grief et al., 2000).

2.5.8 Economic Impact of Surgical Site Infection

Surgical site infections causes significant morbidity and mortality, prolongs hospital stay and adds between 10 to 20% to hospital costs (Poulsen et al., 1994). Although total elimination of infection is not possible, a reduction in infection rates to a

minimal level could have significant benefit in terms of both patient comfort and medical resources used (Poulsen et al., 1994).

Although no study has been conducted in Zambia and particularly at UTH, to ascertain or estimate cost of post-operative wound infection, it is without doubt, that surgical site infection increases patient's morbidity and mortality, prolongs hospital stay and significantly contributes to overall hospital health costs (Fry, 2002).

2.6 Povidone Iodine

2.6.1 History

Elemental iodine was discovered in 1811 by Benard Courtois, a French chemist. The name iodine derives is from the greek word ioedides meaning violet due to the intense violet colour of its vapours. Iodine has been used as a wound antiseptic for over 150 years (Fleischer and Reimer 1997). Tissue friendly preparation comes in the name of iodophores such as povidone-iodine which emerged towards the end of 1960's (Fleischer and Reimer 1997).

2.6.2 Chemical nature

Povidone iodine is an iodophore. The iodine is linked to povidone (polyvinypyrrolidone), a dextran like molecule, via hydrogen bonds. An equilibrium reaction occurs in aqueous environment where approximately 10% of the bond iodine is released as free iodine to exert an antiseptic effect. This equilibrium reaction allows further free iodine to dissociate from the povidone-iodine molecule as it is used up, which helps to maintain the anti-microbial effect of povidone-iodine ((Fleischer and Reimer 1997).

2.6.3 Action

Free iodine has a strong oxidative effect. The povidone molecule by virtue of its affinity for cell membrane, delivers diatomic free iodine directly to the bacterial cell surface (Piyush and David, 2008). It's thought to exert its effect on amino acids and unsaturated fatty acids, which results in the destruction of cell membranes and enzymes (Garner et al., 1996). Povidone iodine appears to be active against all micro-organisms including Gram-positive and Gram-negative bacteria, spores, cysts, mycobacteria, fungi, viruses and protozoa (Leveen et al., 1997).

2.6.4 Antimicrobial effects.

Dilution of 10% povidone-iodine solution of up to 1:100 has demonstrated more rapid killing of *Staphylococcus aureus* and *Mycobacteria chelonei* than the undiluted solution (Selvaggi et al., 2003). The mechanism for this effect of increased antibacterial activity at lower concentration is thought to be due to weakening of the bonds between the povidone molecule and the iodine, leading to a higher level of free iodine(Ferguson et al., 2003).

3. RESEARCH METHODOLOGY

3.1.0 Study site and duration

The study was conducted in the department of surgery, Urology Section at the University Teaching hospital for a period of 18 months from June 2011 to December 2012.

3.1.1 Study Design:

This was a prospective randomized cohort study with blinding of patients and outcome adjudicator regarding group assignments.

3.1.2 Ethical approval

The study protocol was approved by the Biomedical Research Ethics Committee of the University of Zambia and all patients provided written informed consent.

3.1.3 Inclusion criteria

The patients were obtained from the waiting list of Urology Section in the department of surgery of the University Teaching Hospital. The waiting list consisted of patients who had been assessed for treatment and placed on a waiting list. The International Prostate Symptom Score (IPSS) see appendix B, was used to access patients that met surgical operative criteria:

- Patients of age group between 50 and 80 years undergoing elective open prostatectomy were considered in the study.
- All patients of bladder outflow obstruction due to BPH with IPSS > 20-35
- Patients of BPH with complications of vesical calculi and diverticula
- Patients with acute urinary retention, persistent or recurrent UTI, Haematuria and renal insufficiency secondary to BPH.
- Patients of BPH with co-existing inguinal hernia

3.1.4 Exclusion criteria

Patients were excluded from involvement in the study if they had the following:

- Patients with small fibrotic prostate gland
- Suspected case of cancer of the prostate
- Patients not willing for open prostatectomy
- Those not fit for open surgery

- And those with an active tissue infection.
- Patient with diabetes were excluded from the study

3.1.5 Sample Size:

The sample size was estimated with the use of Open Epi version 2.3 software, the calculation was based on the estimation for reducing incidence of SSI in clean contaminated wounds i.e. open prostatectomy, from 30 to 10% (Cruse, 1992) with prophylactic povidone iodine bladder irrigation. The level of power of the study was set at 80 percent and that for statistical significant at 5 percent (p value =0.05).

Sample Size for Cross-Sectional, Cohort, & Randomized Clinical Trial Studies[40]			
Two-sided significance level(1-alpha):			95
Power(1-beta, % chance of detecting):			80
Ratio of sample size, Unexposed/Exposed:			1
Percent of Unexposed with Outcome:			10
Percent of Exposed with Outcome:			30
Odds Ratio:			3.9
Risk/Prevalence Ratio:			3
Risk/Prevalence difference:			20
	Kelsey	**Fleiss**	**Fleiss with CC**
Sample Size – Exposed	63	62	72
Sample Size-Non exposed	63	62	72
Total sample size:	126	124	144

Sample size of 124 with an additional 10% lost to follow up patients once they have been enrolled in the study. A final sample size of 130 was calculated.

Ratio of sample size of Exposed/ Unexposed is 1, which gives 65 cases and 65 controls.

3.1.6 Sampling Technique:

The non-probability convenience sampling technique was used. Any consenting patient who presented to the Department of Surgery for open prostatectomy and fulfils the inclusion criteria was selected.

3.1.7 Randomisation:

Patients were divided into two groups i.e. control and study. Cards with numbers up to 130 sample size were placed in a box and patients were asked to pick a card to avoid bias. Patients who picked an **odd** number were placed in the control and those with **even** numbers were automatically included in the study group.

3.1.8 Experimental and Control groups:

All patients who presented to the Department of Surgery scheduled for open transvesical prostatectomy for BPH were approached for inclusion in the study. After informed written consent for the study all patients who met inclusion criteria were consecutively enrolled into the study. HIV test was done in all the patients as per Ministry of Health HIV testing guideline(Ministry of Health HIV testing guideline, 2010). Patients were assessed fully for fitness to undergo open prostatectomy. They were admitted 48hours prior to surgery. Pre-operative, intraoperative and post-operative data were collected on a standardised data collection forms.

The study group had their bladder preoperatively irrigated with diluted povidone iodine 1% 50cc and drained upon opening the bladder. In the control group transvesical prostatectomy was performed without prior bladder irrigation. Both groups received pre-operative antibiotic prophylaxis.

The patients were operated on by the consultant surgeon and or Registrar/ Post-graduate student (under supervision) through an open suprapubic or transvesical approach.
Post operatively both the study and the control groups received post-operative antibiotic prophylaxis e.g. Ciprofloxacin, Ceftriaxone, Cefotaxime, respectively for 5 days as is routinely done at UTH.

Wounds were exposed on day 2 and cleaning was done with methylated spirit twice per day. Post-operative bladder Irrigation with normal saline was done in all patients for 12 to 24 hours to clear the blood clots. Fr 24 or 22 3way Foley's catheter was used for irrigation and removed after 9 to 12 days in our Urology outpatient clinic.

Each patient was followed up in clinic7 after discharge on day 12, 19 and day 30. After which they were declared either free or having acquired SSI using the CDC guidelines. Pus swab were obtained from surgical incision and transported to laboratory within an hour of collection.

3.2.1 Diagnosis of SSI

3.2.2Clinical Criteria CDC (Garner et al., 1996)

- A purulent exudate draining from the surgical site
- A positive fluid culture obtained from a surgical site that was closed primarily
- The surgeon's diagnosis of infection
- A surgical site that requires reopening

3.2.3 Laboratory Criteria

- Pus swabs were collected for microscopy, culture and sensitivity
- A bacterial count higher than 10,000 organisms per gram of tissue was considered as positive fluid culture.

3.3 Statistics:

The patient data was summarised using means and standard deviations for continuous variables and percentages for each categorical variables. Chi-square to compare binary variables, and student T test to compare mean values of continuous variables. The computer software used to create a spread sheet for data entry and for statistical analysis of results was SPSS version 16. Power of $P<0.05$, and Confidence interval of 95% was considered statistically significant throughout. The primary outcome variable was presence or absence of SSI.

4. RESULTS

4.1 Comparison of study groups

The study population consisted of 130 patients 65 from each of the study and control group.

4.2 Age

The study population consisted of 130 patients with BPH who were evaluated for open prostatectomy, 65 in each of the study group and control group. The mean age of the patients in the control group was 71.1 (S.D.± 6.633) and 71.4 years (S.D. ± 6.039) in the study group. The difference between the mean ages of the two groups was not statistically significant (t=0.318, p=0.75, d f= 126.89, independent t-test). See table 1 and 2. The range was 54 to 80 years. The majority of the patients (36) were in the age range of between 65 to 69 years (27.7%) as shown in Figure1 below.

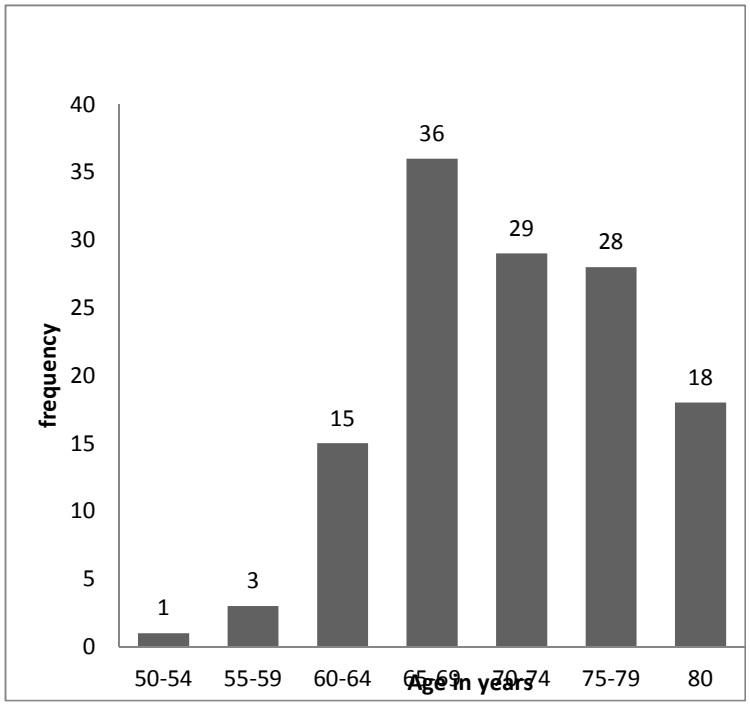

Figure 1. Age of patients in years

	Group after Randomization	N	Mean	Std. Deviation	Std. Error Mean
Age	Group I	65	71.09	6.633	.823
	Group II	65	71.45	6.039	.749

Age Summary statistics and significance Independent t-test

	Levene's Test for Equality of Variances		t-test for Equality of Means						
	F	Sig.	T	Df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
								Lower	Upper
Equal variances assumed	.681	.411	-.318	128	.751	-.354	1.113	-2.555	1.848
Equal variances not assumed			-.318	126.891	.751	-.354	1.113	-2.555	1.848

Out of the total number of patients recruited for the study, one hundred and twenty nine (99.2%) were married.

Majority of the patients Hundred and seventeen (82.3%) came from the rural area. Eighty (61.5%) had a primary form of education.

4.3 Factors predisposing to Infection

4.3.1 Patient factors

All the 130 patients tested negative for HIV and none was diabetic. Five of them had history of smoking but didn't develop surgical site infection (SSI). One hundred twenty four (95.4%) had shaved within six hours before the operation. No gross contamination was observed during operation.

The preoperative admission days ranged from 1 to 15 days. The mean preoperative admission days were 2.6 for the study group and 3.1 days for the control group. None of the patients had coexisting infections at a remote site.

4.3.2 Operative Factors

One hundred and twenty eight patients (98.5%) had a shower night before operation. And all of them had similar antiseptic skin preparation using chlorhexidine, iodine and methylated spirit solution. The majority of the patients, hundred twenty four (95.4%) had shaved within 6 hours of the operating time. The mean operating time was 50.2 minutes in the control group and 48.6 minutes in the study group. The difference in mean operating time between the two groups was not statistically significant (t=1.076; df=116.078; p>0.5).

Independent Samples Test									
	Levene's Test for Equality of Variances		t-test for Equality of Means						
	F	Sig.	t	Df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
								Lower	Upper
Equal variances assumed	4.531	.035	1.076	128	.284	1.60000	1.48632	-1.34093	4.54093
Equal variances not assumed			1.076	116.078	.284	1.60000	1.48632	-1.34381	4.54381

4.3.3 Outcome

4.3.4 Surgical site infections: Out of 130 patients, 21 developed surgical site infections representing 16.2%. Six (9.2%) patients developed SSI in the study group and fifteen (23.1%) developed SSI in the control group. Table 1. Shows SSI rate and compares for control and study group. (χ^2=4.60; df=1; p<0.05). The difference in the rate of SSI between the study group and control was statistically significant.

Table 1: Surgical Site Infections

	No. of Operations	**No. of SSI**	**SSI Rate**
Control Group	65	15	23.1
Study Group	65	6	9.2
Total	130	21	16.2

Chi-Square Tests						
	Value	Df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)	Point Probability
Pearson Chi-Square	4.600[a]	1	.032	.055	.027	
Continuity Correction[b]	3.635	1	.057			
Likelihood Ratio	4.729	1	.030	.055	.027	
mFisher's Exact Test				.055	.027	
Linear-by-Linear Association	4.565[c]	1	.033	.055	.027	.020
N of Valid Cases	130					

1. 0 cells (.0%) have expected count less than 5. The minimum expected count is 10.50.

4.3.5 Bacterial isolates recovered: The pathogens isolated were *Escherichia coli* (13 isolates, 35.1%) as the most common infecting organism cultured from infected wounds. *Streptococcus sp* was isolated in 7 patients (18.9%) The rest of the organisms isolated are as shown in table 2 below.

Table 2: Organisms Cultured from Surgical Wounds

Pathogens isolated	Frequency	Percent
Escherichia coli	13	35.1
Streptococcus sp	7	18.9
Citrobacter koseri	5	13.5
Klebsiella sp	4	10.8
Pantoea agglomerans	2	5.4
Staphylococcus Coagulase negative	2	5.4
Enterobacter cloacae	1	2.7
Pseudomonas sp	1	2.7
Serratia Marcescens	1	2.7
Staphylococcus aureus	1	2.7
Total	**37**	**100.0**

4.3.6 Bacterial Sensitivity Pattern: *Escherichia coli, Streptococcus sp*, and *Citrobacter kosseri* were sensitive to ciprofloxacin and were the most common isolated organisms. *Pantoea agglomerans* was sensitive to ceftazidime, *staphylococcus coagulase* was sensitive to imipenem, *Pseudomonas sp* was sensitive to piperacillin and *Tazobactam, Staphylococcus aureus* was sensitive to chloramphenicol. *Enterobacter cloacae* was sensitive to none of the antibiotics.

4.3.7 Post-Operative Hospital Stay: The study group had a cumulative post-operative hospital stay of 354 days and a mean of 5.4 days, while in the control group; the cumulative post-operative hospital stay was 451days with a mean of 6.9 days. Table 3 shows the duration of post-operative hospital stay in both control and study group. The difference in the mean post operative hospital stay between the control and study group was statistically significant ($t=4.105$; $df=91.134$; $p<0.05$).

Table 3: Post-Operative Hospital Stay

	Cumulative Post-Operative Hospital stay in Days	**Post-Operative Hospital Mean stay in Days**
Control Group	451	6.9
Study Group	354	5.4

Post operative stay (including operation day) (days)

Independent Samples Test									
	Levene's Test for Equality of Variances		t-test for Equality of Means						
	F	Sig.	T	Df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
								Lower	Upper
Equal variances assumed	62.295	.000	4.105	128	.000	1.492	.364	.773	2.212
Equal variances not assumed			4.105	91.134	.000	1.492	.364	.770	2.214

4.3.8 Follow up:

Complete follow up was achieved in 126 patients representing 96.9%.

5. DISCUSSION

The aims of study were to investigate the effects of povidone-iodine pre-operative bladder irrigation on the incidence of transvesical prostatectomy surgical site infections; to determine the magnitude of transvesical prostatectomy SSI; to identify the nature and susceptibility of bacteria causing prostatectomy SSI. The povidone-iodine solution used in this study (betadine) was supplied as 10% w/v povidone-iodine which then diluted 1:9 in normal saline. The final dilution of povidone-iodine was 1% w/v.

Benign prostatic hyperplasia (BPH) is a common urological problem with an average age at presentation of 60 to 70 years (Abdus, 1993). In this study the mean age is 71.2 and the median is 72 years with the range of 54 to 80 years. This is comparable to other reported studies [Thomas et al., 2009; Amos et al.2009).

In this study the rate of SSI is 16.2% which is lower than that reported by Mawalla et al. 2011 who reported overall SSI rate of 26%. Amoran et al. reported overall SSI rate of 13%. Emori et al.1993 reported SSI rate of between 14 to 16%. And Auerbach reported SSI rate of up to 20%. A study by Shirimpaka, 2007 reported rate of SSI of 8.7% which is much lower than what we have found. This may be attributed to small sample size and the nature of the operations. In this study 15 out 65 (23.1%) patients in the control group and 6 out of 65(9.2%) patients in the study group respectively developed SSI. This compares favourably with the study reported by Richter et al. 1991 with SSI rate of 23.5% in the control and 8.7% in the study group (Richter et al., 1991a). This is due the effects of povidone-iodine in making the urine sterile and hence reducing post prostatectomy SSI. In another study by Sindelar and Mason 1996 reported infection rate as 15.1% in the control group and 2.9% in the treatment group. Their findings of magnitude of infection rate is much lower than what has been reported in this study. This may be attributed to multiple different surgical operations on which their study was based.

Furthermore in this study the most common organism cultured from infected surgical wounds following prostatectomy was *Escherichia coli* 35% followed by *Streptococcus sp* accounting for 18.9%.These results compares favourably with results from a study done by Salim et al., 2002 on surgical treatment of BPH, were *Escherichia coli* was found to be the most commonly recovered species accounting for 37.14%, followed by *Proteus* 18.57%. In our study, however, the second most common species of bacterial cultured was *Streptococcus*. Shirimpaka, 2008(Unpublished) reported *Escherichia coli* as the most common causative

organism in his study on the effectiveness of single antibiotic prophylaxis in abdominal operations.

All the three common causative organisms that is Escherichia coli, Streptococcus sp and Citrobacter *koseri* were sensitive to ciprofloxacin. *Pantoea agglomerans* was sensitive to ceftazidine. *Staphylococcus aureus* was sensitive chloramphenicol. *Enterobacter cloace* was resistant to all the available antibiotics used to test for sensitivity pattern. This particular patient was treated by daily wound cleaning with hydrogen Peroxide.

The post operative hospital stay ranged from 4 to 13 days with an average of 6.2 days. In the control group the mean post-operative hospital stay was 6.9 days and 5.4 days in the study group. This means that patients stay much longer on the wards post-operatively once they develop SSI there by increasing hospital costs. The results are fairly comparable with that reported by Salim et al. 2004, on surgical treatment of BPH were the post-operative hospital stay ranged from 6 to 21 days with an average of 7.2 days (Salim et al., 2004).

6. CONCLUSION

The research has shown that pre-operative bladder irrigation with 1% povidone-iodine was effective in reducing the incidence of post open prostatectomy surgical site infection by approximately 55.6%. Furthermore pre-operative bladder irrigation with povidone-iodine significantly reduced the bed occupancy post-operatively. *Escherichia coli* is the most common causative organism in prostatectomy SSI. The three most common isolated organisms were sensitive to ciprofloxacin.

7. RECOMMENDATIONS

On the basis of the results, it is therefore recommended that the department of surgery adopt use of povidone-iodine pre-operatively for bladder irrigation in patients undergoing open transvesical prostatectomy to reduce the rate of surgical site infections.

A longitudinal study could be carried out in future to have a much bigger sample size and longer duration of patient follow up.

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APPENDIX A
CONSENT FORM

TITLE: PRE-OPERATIVE BLADDER IRRIGATION WITH 1% POVIDONE IODINE IN REDUCING OPEN PROSTATECTOMY SURGICAL SITE INFECTION AT UTH, LUSAKA.

STUDY SITE : UNIVERSITY TEACHING HOSPITAL

RESEARCHER : DR MUKOSAI .S

PURPOSE OF THE STUDY:

The goal of this research is look at the effectiveness of preoperative povidone iodine bladder irrigation in reducing post prostatectomy surgical site infections at UTH.

You are invited to participate in this study on a voluntary basis. You will be required to attend at least two reviews after discharge from the hospital.

The research project is anticipated to continue for a period of 26 weeks. You will be screened and necessary investigations that include taking blood from you in order to prepare you for the operation. You will be admitted two days prior to operation.

The operation will be performed on the lower anterior abdominal wall by the Surgeon in the presence of the consultant. After the operation you may feel pain on the operation site.

Confidentiality (No one will know that you are taking part in the study)

The researcher shall keep a record of all your personal data in a secure database. The data will be coded and will have no identifiers will be used.

Benefits and Risk

You may benefit from the study by having reduced risk of post operation surgical site infection as well as length of hospital stay. You will make a major contribution to the information known about reduction in surgical site infection using povidone iodine. In future other patients may benefit from this study as well. Possible side effects of povidone

iodine include hypersensitivity and may interfere with thyroid function test. Other risks from operation are; pain, bleeding, incontinence of urine, stricture formation and retrograde ejaculation. Care will be taken to minimize these risks.

Compensation (Travel Reimbursements)

The study will refund any costs that you will have due to coming back to the hospital for reviews. You will get K30, 000, for travel during the three days for each review appointment.

Voluntariness (you are free to withdraw from the study)

Your participation in the study is entirely voluntary and you have the right to refuse or withdraw without penalty. If you feel that you have been injured as a direct result of participating in the study, please contact: Dr Mukosai S. at 0977848960.

Signature of participant/Thumb Print Witness Date

(a) Contact People are:

i. Dr. S. Mukosai, Department of Surgery, UTH
Tel. 0977848960

ii. Dr Nenad Spasojevic, Department of Surgery, UTH
Tel.

iii. Prof Kasonde Bowa, Dean School of Medicine, Copperbelt University
Tel.

iv. Dr James Munthali
University of Zambia-School of Medicine
Department of Surgery
P.O. Box 50110, UTH
LUSAKA
Tel. 0966765422

Appendix B

International Prostate Symptom Score (IPPS)

Name: Date:

	Not at all	Less than 1 time in 5	Less than half the time	About half the time	More than half the time	Almost always	**Your Score**
Incomplete emptying Over the past month, how often have you had a sensation of not emptying your bladder completely after you finish urinating?	0	1	2	3	4	5	
Frequency Over the past month, how often have you had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5	
Intermittency Over the past month, how often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5	
Urgency Over the last month, how difficult have you found it to postpone urination?	0	1	2	3	4	5	
Weak stream Over the past month, how often have you had a weak urinary stream?	0	1	2	3	4	5	
Straining Over the past month, how often have you had to push or strain to begin urination?	0	1	2	3	4	5	

	None	1 time	2 times	3 times	4 times	5 times or more	**Your score**
Nocturia Over the past month, many times did you most typically get up to urinate from the time you went to bed until the time you got up in the morning?	0	1	2	3	4	5	

Total IPSS score	

Total score: 0-7 mildly symptomatic; 8-19 moderately symptomatic; 20-35 severely symptomatic.

Appendix C

Study Schema and Protocol

Study Activity	Day 0	Day 2	Day 5	Day 12	Day 24	Day 30
Informed Consent Process	√					
Assign Participant No.	√					
Medical History and Physical Examination,	√					
Investigations performed: Urea and electrolytes , Full blood count, Random blood sugar, HIV test, Urinalysis	√					
Transvesical Prostatectomy Procedure Performed		√				
Patient Discharged			√			
Catheter Removed				√		
Follow up of wound Healing Visits				√	√	√
Assessment for SSI Clinical			√	√	√	√
Assessment for SSI lab (Pus swab , White blood cell count)			√	√	√	√

Appendix D

Data Capture Sheet

I. DEMOGRAPHIC DATA

1. Study number..... .....
2. Group after Randomization (Group I or II):
3. Age.....
4. **Marital Status :** Married =1 ☐
   Divorced =2 ☐
   Single = 3 ☐
   Widower =4 ☐
5. **Residence:** Town =1 ☐ Rural =2 ☐
6. **Education:** University:
   Collage = 1 ☐ Secondary = 2 ☐ Primary =3 ☐ None = 4 ☐
7. **Occupation:** Formal employment = 1 ☐ Informal Employment = 2 ☐
   Self Employed = 3 ☐ Non Employed = 4 ☐

II. PAST MEDICAL AND SURGICAL HISTORY

8. Any Previous Surgical Operation?
   ……..
9. If yes to number 8, when was it done?
   Within the last one month = ☐ within the last three months = ☐
   More than three months = ☐

10. Any Current Surgical Infection? Yes ☐ No ☐

If Yes to number 10 Specify.....

11. If the answer to number 10 is yes, Estimate in centimetres the distance between the infection focus and the expected operation incision line .....cm.

12. Current medical condition: (specify).....

13. HIV test……...

13. b. Type of test …….

14. CD4 count…… date……

III. SOCIAL HISTORY

15. Do you smoke cigarettes? Yes = ☐ No = ☐

IV. PRE-OPERATIVE PREPARATIONS

16. Number of days in admission before operation.....

17. Did the patient have any general bath using antibacterial soap the evening before operation day? Yes = ☐ No = ☐

18. If the patient required shaving, was it done :

a). In theatre = ☐ b). Within 6 hours of the operation = ☐

c). More than 6 hours of operation = ☐ d). Before the operation = ☐

e). Not applicable = ☐

19. Pre- operative bladder wash out with povidone iodine?

a). Yes = ☐ b). No = ☐

20. a). Skin preparation with: Savlon + Iodine + Methylated Spirit = ☐

b). Savlon + Iodine = ☐ c). Savlon + Spirit = ☐

c).Iodine + Methylated Spirit = ☐ d). Just one solution = ☐

V. INTRA-OPERATIVE EVENTS

21. Estimation of blood loss: .....ml

22. Any gross contamination during surgery? a). Yes = ☐ b). No= ☐

23. Was the glove drain used on surgical wound together with suction drain?

a). Yes = ☐ b). No = ☐

24. Only suction drain was used?

a). Yes = ☐ b). No = ☐

25. Total duration of operation: min……

VI. POST-OPERATIVELY

26. Interval between wound closure and the first wound exposure? .....hours

27. Was wound cleaning adequate? Yes = ☐ No= ☐

28. Administered dose of ciprofloxacin.....mg/kg

29. Did the patient have any fever? a). Yes = ☐ b). No = ☐

30. If yes how long after surgery? .....days

31. Post operative hospital stay including (operation day):.....days

VII. FOLLOW UP

32. Did the patient develop surgical site infection at any time in the post-operative period (refer to Surgical Site Infection diagnosis)?

a). Yes = ☐ b). No = ☐

33. If yes specify at least 2 symptoms / signs of infections observed in the patient.....

34. How long after the operation did the symptoms/signs begin? .....days

35. In case of wound infection, what was (were) the organism(s) isolated on culture?

……

36. Which drug(s) was (were) the organism sensitive to?

……

37. Which drug(s) was (were) the organism(s) resistant to?

……

38. How many follow up visit did the patient have?

…….

Appendix E

Patient Information Sheet

You are schedule to be admitted to University Teaching Hospital for an open suprapubic prostatectomy. It's anticipated that you will be ready for discharge approximately 5 to 6 days after your surgery although this may vary depending on individual needs. The health care team will help will you with any concerns you may have about your discharge. If you have questions please speak with your doctor or nurse.

Before Surgery

You will be admitted two days before surgery. On the day of admission you will:

- Be assessed by the resident doctor from the surgical team
- Meet an anesthesiologist who will explain the type of anaesthesia you will have.
- Have blood tests for; full blood count, Urea, electrolytes & creatinine, X-Match and urine test.
- Discuss with your doctor what your options are for blood replacement

Do not eat or drink anything after midnight before surgery. Take your medications as directed with sip of water.

Day of Surgery

Immediately before you go to the Operating Room you will need to change into a hospital gown and remove all jewellery, including wedding ring, dentures, etc. You may be given a sedative to help you relax. The surgery will generally take 1 to 2 hours (preparation and actual surgery*)* you will then spend an additional 1 hour in the Recovery Room before transfer to the main ward. . Visitors are not allowed in the Recovery Room but your family members or friends will be able to visit you as soon after you are transferred to the main surgical ward GO1.

Post-Operatively on the Ward

Initially after surgery, your blood pressure, pulse and temperature will be taken frequently. Your nurse will check the incision site and help you change position to help make you comfortable. In addition, your nurse will monitor your urine output, drainage, and Intravenous lines. You will receive pain medication when needed and your pain relief will be assessed. You will have an abdominal incision with a drainage tube (the suprapubic tube), a

surgical drain in the lower abdomen, and a urinary catheter in place. The surgical drain will be removed in a day or two.

Diet

Immediately after surgery you will not be allowed to eat, or drink anything by mouth. Once you can eat you will start on a clear liquid diet and advance to your usual diet as tolerated.

Activity

You will generally need to stay in bed until the morning after your surgery. You will be encouraged to get out of bed as much as possible and increase your activity level as tolerated.

Medication

You will have an intravenous line and will receive some medications, such as antibiotics, intravenously. Antibiotics may be given by mouth the next day. Of course, you will receive your routine medications as well. Notify your nurse if medications are not given. The nurse will obtain a medication order from the doctor. ***DO NOT TAKE YOUR OWN MEDICATIONS, PLEASE GIVE TO THE NURSE AND TO BE ORDERED BY THE DOCTOR.***

Pain Management

Your nurse will give you pain medication which the surgeon has ordered. Right after your surgery you will receive injections for pain relief. These injections can be either into a muscle, into a vein. Your surgeon will determine the most appropriate method for your specific needs. As your level of discomfort decreases and you are able to tolerate liquids and food, you will receive pills for pain management. In addition, since it is important that you do the coughing and deep breathing exercises and increase your activity, it may be helpful to take pain medications prior to these activities.

Surgical Drains and Foley's Catheter

You will have a surgical drain in place in the lower abdomen. The drain removes fluid that collects in the surgical area. The doctor will remove it when the amount of drainage decreases, on the 1st, 2nd or 3rd day after surgery. A Foley Catheter (Urethral tube) will be inserted during surgery to drain urine from the bladder. The Foley Catheter remains for 9 to 12 days.

Bowel Function

You may experience some constipation after surgery. This can be minimized by increasing fluids and fibre in your diet.

Follow-Up Reviews

You will be expected to come for reviews 7 days after discharge then at 2 weeks and 4 weeks after surgery respectively.