EARLY POSTOPERATIVE COMPLICATIONS OF BIPOLAR TRANSURETHRAL RESECTION OF THE PROSTATE AT KENYATTA NATIONAL HOSPITAL

Dissertation submitted in partial fulfillment for the award of the degree of Master of Medicine in Urology, School of Medicine, University of Nairobi

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DECLARATION

I hereby confirm that this dissertation is my original work and has not been presented anywhere for examination or approval

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DEDICATION

To my parents Mr and Mrs El-busaidy and my wife, Yusra, for unwavering support throughout this journey. To my brothers and sisters (Salma, Samya, Swaleh, Aisha and Zubeir) Thank you for your encouragement. May Almighty Allah bless you.

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LIST OF ABREVIATIONS

AUA - American Urological Association

AUR - Acute Urinary Retention

BEP - Bipolar Enucleation of the Prostate

BPH - Benign Prostatic Hyperplasia

B-TURP- Bipolar Transurethral Resection of the Prostate

EAU - European Association of Urology

IPSS - International Prostate Symptom Score

KNH - Kenyatta National Hospital

LUTS - Lower Urinary Tract Symptoms

LVP - Laser Vaporization of the Prostate

PSA - Prostate Specific Antigen

PTMS - Plasmakinetic Tissue Management System

PVR - Post-void residue

TWOC- Trial (of Voiding) WithOut Catheter

UTI - Urinary Tract Infection

OPERATIONAL DEFINITIONS

Terminology	Definition
BPH	Diagnosis of BPH shall be based on history and physical examination (including digital rectal examination) and IPSS score), PSA test and prostate ultrasound.
IPSS score	A screening tool that is used to diagnose and quantify severity of lower urinary tract symptoms due to BPH.
Clot/urine retention	Inability to pass urine due to a bladder/urethral clot that requires either manual clot evacuation or change of urethral catheter.
Persistent hematuria	Persistent bleeding post TURP associated with any of the following: decrease in hemoglobin >2g/dl, need for endoscopic fulguration, blood transfusion or postoperative irrigation >48 hours
Prolonged catheterization	Presence of a urethral catheter for >72 hours after TURP
Urinary tract infection	Urinary tract symptoms (such as dysuria, frequency) associated with a positive urine dipstick or positive urine culture (>10 bacteria/HPF)
Persistent lower urinary tract symptoms (LUTS)	Worsening in the IPSS score or failure of improvement in the IPSS score after surgery
TUR syndrome	Hyponatremia <130mmo/L associated with CVS, CNS or metabolic symptoms (ie hypertension, visual changes, restlessness or confusion)
TWOC (Trial Without Catheter)	Inability to void after urethral catheter removal post TURP
Recurrent hematuria	≥4 episodes of hematuria in one year
Recurrent UTI's	≥3 episodes of symptomatic urinary tract infections in one year
Complications	Shall be defined as any deviation from the normal postoperative course (according to Clavien-Dindo classification).

Early postoperative complications	Shall be defined as those complications occurring within 28 days after surgery
Postvoid residue (PVR)	Amount of urine remaining in the bladder at the end of micturition (High PVR >100mls was taken as bladder outlet obstruction).

ABSTRACT

Background: Bipolar TURP is the gold standard for surgical management of BPH because it uses a physiologic irrigating solution with better hemostasis. Its plasmakinetic tissue management system makes it applicable for small, medium and large-sized prostates. This technique is recently introduced at KNH but data on early postoperative complications is unknown. This information would be useful in the surgical management of patients with BPH.

Study objective: To find out the early postoperative complications of Bipolar TURP at KNH.

Materials and methods: This was a prospective observational study of 72 patients undergoing bipolar TURP at KNH following ethical approval from KNH Ethics and Research Committee. Patients were obtained from general surgery and amenity wards and recruited into the study by consecutive sampling after consent. Patients' data: pre-operative (age, IPSS score, PSA, PVR, indication for surgery, Hb, urinalysis, comorbidities), intra-operative (resection length, weight of prostate resected) and post-operative (duration of irrigation, catheterization & hospitalization, and early postoperative complications) were obtained. Data was analyzed using SPSS version 22. Frequencies, means and standard deviation was obtained for the pre-, intra- & post-operative features. A p value of ≤ 0.05 was considered significant at 95% confidence interval. A comparison of means of pre-op characteristics was done using Independent Student's T-test between the group that developed complications and those who didn't. Chi-square and Fisher's exact test were used to determine factors associated with early postoperative complications for categorical variables such as age, urine infection, comorbidities and indications of surgery.

Results: The mean age of the patients was 70.4 years. The most common indication for TURP was failed medical therapy. Most patients had severe urinary symptoms (mean IPSS score =24), prostate size >75g and an average postvoid residue of >200cc. Over 70% of the patients had one or multiple comorbidities. The overall complication rate was 54.9%, however majority of

the complications were minor (Clavien-Dindo grade I and II). The most common early postoperative complications were failure to void after catheter removal and prolonged hematuria. TURP syndrome occurred in 2 patients. Majority of the patients were catheterized for 2-3 days after surgery. On Chi-square analysis, presence of positive urine culture and age >70 years were significantly associated with early postoperative complications and failure to void after catheter removal (p= 0.002, 95% CI; Fishers exact test).

Conclusion: Bipolar TURP is a relatively safe procedure albeit with minor complications. The most common early postoperative complications were failure to void and prolonged hematuria. Presence of preoperative positive urine culture and age >70 years were significantly associated with early postoperative complications. This category of patients requires due diligence in the immediate postoperative period.

1. INTRODUCTION

Benign prostatic hyperplasia: Incidence, pathophysiology and management

Benign prostatic hyperplasia (BPH) refers to stromal and epithelial proliferation in the transition zone of the prostate. The stromal proliferation has more deleterious effects on urinary function. BPH has an incidence of about 50% in men above the age of 50 years and increases significantly with age to about 75% in the 8th decade (Randal et al, 1931). In addition, the incidence of BPH requiring surgical intervention increases with age to about 10.9 per 1000 men above the age of 80 years (Harbitz et al, 1972).

Lower urinary tract symptoms (LUTS) is a term used to describe voiding and storage symptoms due to BPH. Voiding symptoms include hesitancy, intermittency, urgency, weak stream, terminal dribble and incomplete bladder emptying. Storage symptoms include frequency, urgency, nocturia and urge incontinence. BPH causes LUTS by two mechanisms: direct bladder outlet obstruction (BOO) from the enlarged prostate and increased smooth muscle tone and resistance within the prostate (Berry et al, 1984).

Evaluation of BPH involves detailed history, physical examination and objective assessment of urinary symptoms using validated questionnaires. One of the commonly used tools is the American Urological Association (AUA) International Prostate Symptom Score (IPSS). This scoring system quantifies the severity of urinary symptoms into mild, moderate and severe and has an impact on management. Measurement of serum prostate specific antigen (PSA), prostate size, postvoid residual volume (PVR) and urodynamics are part of standard evaluation for BPH (McVary et al, 2011).

Management of BPH aims to improve lower urinary tract function, prevent development of complications and improve quality of life. Options in the management of BPH include watchful waiting for mild to moderate symptoms and medical or surgical therapy for moderate to severe

symptoms. Indications for surgical therapy include urine retention, gross hematuria, bladder calculi, recurrent urinary tract infections, obstructive uropathy and renal failure (Chia-Chu et al, 2003).

Although medical therapy with 5 alpha reductase inhibitors and alpha blockers is the initial standard management for symptomatic BPH, 20-30% of patients do not respond to this treatment and surgery is often required (McConnell et al, 1998). TURP is the gold standard surgical procedure for the management of LUTS due to BPH.

Transurethral resection of the prostate: Overview, indications and complications

Transurethral resection of the prostate (TURP) is a minimally invasive surgical procedure for lower urinary tract symptoms secondary to BPH. The American Urological Association (AUA) recommends it as the standard procedure for men with BPH who have failed medical therapy (McVary et al, 2011). TURP involves resection of the transitional zone of the prostate by inserting a resectoscope transurethrally. The modern electrosurgical TURP was first described by Stern in 1926 and then modified by McCarty in 1931 (Te et al, 1997). It has been studied extensively and is considered effective in the short term and midterm relief of lower urinary tract symptoms (LUTS) due to benign prostatic enlargement. However, TURP is also associated with significant morbidity.

Indications for TURP

There are several indications for TURP which can be classified as acute, chronic or symptomatic prostatism. Acute indications for TURP include acute urinary retention (AUR) requiring catheterization (urethral or suprapubic). Chronic indications include complications of long-standing urinary obstruction such as hydronephrosis or renal insufficiency, recurrent urinary tract infections (UTI's), bladder stones, high postvoid residue (>100mls) and recurrent hematuria (Chia-Chu et al, 2003). Symptomatic prostatism refers to severe LUTS that require

surgery to restore lower urinary tract function and improve quality of life. It also includes patients who have progressive symptoms despite medical therapy or those who cannot tolerate the side effects of medical therapy (Nickel et al, 2010).

Complications of TURP

The complications of TURP can be classified as early postoperative or late complications. Early postoperative complications include urine (clot) retention, extravasation, bleeding (hematuria), sepsis, incontinence, TUR syndrome and failed trial without catheter (Amr et al, 2009). Late complications include urethral stenosis, stricture and retrograde ejaculation (Mebust et al. 1989).

The problem statement/ research gap

The pattern of postoperative complications of TURP varies in different geographical areas due to different patient demographics. In Moshi (Tanzania) for instance, the major postoperative complication after TURP was bleeding which was associated with a prostate size >40g and low preoperative hemoglobin (Mteta et al, 2012). In Kenya, patients with BPH present with unique characteristics. Majority have prostate size >70g, a history of prolonged urethral or suprapubic catheterization and age above 65 years with comorbidities (Kemei et al, 2014). These factors can influence early postoperative complications after TURP such as bleeding, UTI (urosepsis) and urine retention. Hence the need for the current study in our setup.

2. LITERATURE REVIEW

Evolution and mechanism of action of Bipolar TURP

TURP started with the monopolar system in which electric current runs through the person's body from a positive electrode that is put on the resectoscope, towards the return sheet that is connected to the patient's leg. The problem with this system is that it causes warming of deeper tissues and provocation of nerves and muscles. In addition, a high amount of tissue coagulation remains which is associated with significant irritative voiding symptoms (Reich et al, 2010). Secondly, the monopolar system uses a hypotonic irrigating solution such as purisol, glycine or sorbitol which can cause dilutional hyponatremia and TUR syndrome (Amr et al, 2009). Therefore, the resection time in a conventional monopolar system is traditionally limited to 90 minutes to avert this problem. A review by Onal found a higher incidence of TUR syndrome with resections lasting longer than 60 minutes (Onal et al, 2013).

The Bipolar TURP

The introduction of B-TURP into clinical practice mitigated some of the above problems. In the bipolar system, energy is confined between an active electrode (resection loop) and a passive pole situated on the resectoscope tip (Andrew et al, 2016). Prostatic tissue removal is identical to monopolar system but, bipolar TURP requires less energy/voltage because there is smaller amount of interpolated tissue (Martin et al, 2009). Further, energy from the loop is transmitted to the saline solution, resulting in excitation of sodium ions to form plasma molecules which are easily cleaved under low voltage to enable resection. Secondly, during coagulation heat dissipates within vessel walls, creating a sealing coagulum and collagen shrinkage. This plasmakinetic tissue management system (PTMS) cuts and coagulates simultaneously hence achieving better hemostasis than in monopolar system (Poh et al, 2011).

Advantages of bipolar TURP over other techniques

Bipolar TURP has several advantages over other systems. First, it is not time-limited unlike monopolar systems. Secondly, it uses isotonic irrigating solution which is inexpensive and carries a very low risk of dilutional hyponatremia and TUR syndrome (Martin et al, 2009). Hence with bipolar technique, resection beyond 90 minutes has been employed in tackling large-sized prostates in one sitting (David et al, 2007). Thirdly, the plasmakinetic button cuts and coagulates simultaneously enabling better hemostasis and faster resection. (Emad et al, 2018). Finally, head to head trials have demonstrated a lower duration of irrigation, catheterization and hospitalization in bipolar than monopolar approach (Tolga et al, 2012).

Disadvantages of bipolar TURP

Bipolar TURP can consume significant amount of saline due to the tendency for longer resections. In one study from Irvine, California, a mean of 15L of saline was used per patient (David et al, 2007). Isotonic saline when used in large amounts can cause hyperchloremic acidosis because of its excessive chloride content. Secondly, although it has better hemostatic control, the longer resections can potentiate further bleeding (Olapade et al, 1998). In the above Californian study, the mean drop in serum hemoglobin was >2g/dl. However, comparative studies have not found a significant difference in the transfusion requirements between monopolar and bipolar techniques (Martin et al, 2009). Thirdly, bipolar TURP was shown to have a higher rate of urethral strictures (0-4%) than conventional monopolar system (1.3-1.9%) (Kazumasa et al, 2015).

Early postoperative complications of Bipolar TURP

Postoperative complications of B-TURP can range from mild complications such as transient hematuria to life threatening hemorrhage. They can be classified into early and late complications as shown in the table below (Table 1):

TABLE 1: CLASSIFICATION OF POSTOPERATIVE COMPLICATIONS OF TURP

Early complications (0-28 days)	**Late complications** (>2 months)
Clot/urine retention	Urethral stricture
Extravasation	Bladder neck contracture
Persistent hematuria (bleeding)	Retrograde ejaculation
UTI's/urosepsis	Erectile dysfunction
Failed TWOC (Trial WithOut Catheter)	
Blood transfusion	
Persistent LUTS	
TUR syndrome	
Urinary incontinence	
Cardiovascular events (myocardial infarction, deep venous thrombosis, pulmonary embolism)	

Overview of early post-operative complications of Bipolar TURP

Clot/urine retention is one of the most common complications of TURP. It is a painful condition that requires prompt bladder decompression and clot evacuation to prevent damage to the upper urinary tract (Thomas et al, 2017). Clot retention requiring admission occurs in 2.5–10% of men who have undergone TURP (Mebust et al. 1989) and is usually caused by secondary hemorrhage. It can also be caused by inadequate hemostasis during resection, incomplete resection, obstructing urethral flap, primary detrusor failure or sphincter dyssynergia (Jens et al, 2006). Prospective studies have identified several factors associated

with clot retention after TURP such as the size of the prostate and a previous history of acute urinary retention (Tan et al, 1984).

Intraoperative and early post-operative bleeding requiring blood transfusion is classified as Clavien-Dindo grade II complication (Dindo et al, 2004). This is not uncommon especially when resecting large prostates that are highly vascular. Intraoperative hypertension and coagulopathy are also associated with increased bleeding during TURP (Jens et al, 2006). Preoperative use of 5 alpha reductase inhibitors has been shown to reduce the incidence of bleeding and transfusion in patients undergoing TURP (Aboumarzouk et al, 2013).

Urogenital infections such as UTI and epididimo-orchitis may be related to several factors such as previous history of catheterization or baseline immunosuppression (Salih et al, 2016). Patients with a history of acute urinary retention and frank pyuria are also at risk of developing urogenital infections post TURP. In the study by Tarek et al (2017), postoperative urogenital infections were associated with several factors such as old age, previous history of diabetes, large prostatic size, positive preoperative urine culture, preoperative catheter use, previous urological interventions and longer duration of operation.

Failed TWOC refers to inability to pass urine after removal of urethral catheter post TURP. This can be caused by several factors such as bladder neck contracture or spasms, detrusor-sphincter dyssynergia, obstructing urethral flap or inadequate resection (Reynard et al, 1999). An audit by Ariane et al (2011) found that pre-operative prostate size, clot retention, and history of UTI were significant predictors of post-operative urine retention. In addition, patients who were catheter-dependent before surgery were at risk of urine retention after removal of catheter. Use of alpha blockers prior to catheter removal has been shown to increase the success of TWOC in large prostates with high post void residue (Rohit et al, 2018).

Persistent hematuria post TURP is defined as persistent bleeding that requires either endoscopic fulguration, catheter tamponade, blood transfusion, or irrigation >48 hours (Liam et al, 2011). The study by Olapade et al, (1998) found that hematuria was significantly associated with the weight of prostate resected and duration of operation. Persistent hematuria can also be caused by inadequate hemostasis, underlying urogenital infections or coagulopathy.

Cardiovascular events such as myocardial infarction, have been reported in the early postoperative period following TURP. The etiology of these problems is multifactorial and may be influenced by cardio-metabolic, surgical or age-related factors (Claudio et al, 2013). Patients with baseline cardiovascular abnormality are at risk of developing these complications.

TUR syndrome refers to dilutional hyponatremia (<130mmol/l) that results from using a hypotonic irrigating solution during TURP. It is characterized by cardiovascular, central nervous system and metabolic changes that may range from transient symptoms to life-threatening complications (Amr et al, 2009). It can take hours or days to manifest. Although bipolar TURP rarely leads to TUR syndrome, large volume of fluids during resection can cause vascular overload and pulmonary edema due to absorption by venous channels opened during resection (Hahn et al, 2006). One study documented a reduction in serum sodium up to 4 mmol/l with the bipolar technique (David et al, 2007). In patients with underlying cardiovascular or metabolic problem this reduction may be significant.

The Clavien-Dindo classification of postoperative complications

This is a clinically validated postoperative classification system that has been widely used across multiple specialties including neurosurgery, cardiovascular, thoracic, general and urologic surgery (Dindo et al, 2004). It categorizes postoperative complications into 5 grades

based on severity and need for interventions. It has been shown to positively correlate with the complexity of the surgery and length of hospital stay.

Why the use of Clavien-Dindo classification in the current study

The Clavien-Dindo classification is the most commonly used complication grading system in Urology. It is easy, reliable and correlates with patient morbidity and mortality (Dindo et al, 2004). Secondly, it has been clinically validated and shown to be reproducible in reporting urologic complications (Mathew et al, 2009). The 2014 EAU guidelines recommended it for reporting urological complications (Mitropoulos et al, 2012).

Factors associated with early postoperative complications after Bipolar TURP

Several factors have been associated with development of early postoperative complications after TURP. These are summarized in the table below (**Table 2**).

TABLE 2: FACTORS ASSOCIATED WITH EARLY POSTOPERATIVE COMPLICATIONS OF TURP **(**Albert et al, 2016).

Age of the patient
Size of prostate gland
Resection time
Deranged renal function at baseline
Underlying comorbidities (diabetes, heart disease, hypertension)
Prior history of acute urine retention
Preoperative UTI

Bipolar TURP in Kenya

Bipolar technology for prostate resection is relatively new in Kenya, initially limited to few private institutions. The monopolar system has been in use for close to three decades. With the installation of the new bipolar system in KNH (Olympus PlasmaKinetic^{TM} Bipolar System, Tokyo, Japan- Model: WM-NP2, 2018), data on early postoperative outcomes and complications of this technology is important to plan on surgical management.

Locally, a study by Kiptoon et al (2007) looked at complications of prostatectomy (open and monopolar TURP) at KNH. In this cohort, TURP comprised 19% of patients. Complications that were common to both open prostatectomy and TURP included urinary tract infection (15%), clot retention (10%), pyrexia (10%) and pneumonia (8.2%). From these results it is difficult to draw definitive conclusions on the complication profile of TURP as the discrepancy in the sample size between the TURP and open prostatectomy group was significant (16 patients vs 69 patients respectively). However, the duration of postoperative catheterization and hospital stay were significantly lower in the TURP group. The postoperative complications that were analyzed in this study included those that occurred within 72 hours after surgery.

Another study by Koech et al (2001), looked at uroflowmetry outcomes in patients who had undergone monopolar TURP and open prostatectomy at KNH. TURP arm comprised 39% of the patients. In this study the maximal urine flow rate improved in the 1st month after TURP then progressively declined in the 3rd and 6th month. For the open prostatectomy group the flow rate progressively increased with time. However, the authors acknowledged that there were significant variations in the uroflowmetry parameters that would limit their clinical utility in the follow-up period.

3. STUDY JUSTIFICATION

Bipolar TURP is recently introduced in KNH with 3 to 4 cases performed per week. Regional and international data on its surgical safety and efficiency in relieving LUTS due to BPH are promising. However local data on early postoperative outcomes and complications are unknown. This information would be useful in the surgical management of BPH in our setup.

4.STUDY QUESTION

What are the early postoperative complications of patients undergoing Bipolar TURP at KNH?

5.STUDY OBJECTIVES

5.1 BROAD OBJECTIVE

To find out the early postoperative complications of Bipolar TURP at KNH

5.2 SPECIFIC OBJECTIVES:

1. To determine the pattern of early postoperative complications of B-TURP
2. To determine factors associated with early postoperative complications of B-TURP

6. METHODOLOGY

6.1 Study Design

Prospective observational study.

6.2 Study Site:

This study was conducted on patients undergoing Bipolar transurethral resection of the prostate (TURP) at the Kenyatta National Hospital. Patients were obtained from general surgical and amenity wards.

6.3 Source of data

Patients undergoing Bipolar TURP at Kenyatta National hospital.

6.4 Inclusion criteria:

- Patients scheduled for Bipolar TURP at Kenyatta National Hospital
- Adults above 18 years (usually most of the patients are above 50 years)
- Voluntary verbal and written informed consent

6.5 Exclusion criteria:

- Previous surgery to the prostate
- Urethral stricture disease
- Concurrent bladder carcinoma
- Known bleeding disorder

6.6 Sample size estimation

The following formula for calculating sample size in longitudinal studies was used:

$$n = \frac{Z^2 x\ P(1-P)}{d^2}$$

Where,

n = Desired sample size

Z = value from standard normal distribution corresponding to desired confidence level (Z=1.96 for 95% CI)

P = estimated proportion of an attribute present in the population (5% was the incidence of clot retention after TURP from a local study (Kiptoon et al, 2007).

d = desired precision (0.05)

$$n_0 = \frac{1.96^2 x\ 0.05(1-0.05)}{0.05^2} = 72$$

Therefore, a sample size of **72** patients was used in the present study.

6.7 Hypothesis

Null hypothesis: The is NO association between pre-operative patient characteristics and development of early post-operative complications after TURP

Alternative hypothesis: There is an association between pre-operative patient characteristics and development of early post-operative complications

6.8 Sampling method

This study used consecutive sampling method and patients fulfilling the inclusion criteria were recruited into the study.

6.9 Screening and recruitment

Patients scheduled for TURP were screened by trained assistants for eligibility. Those who met the inclusion criteria were selected. Patients were given all the relevant information about the study and those who gave written informed consent (Appendix I & II) were recruited into the study.

6.10 Study variables

The variables evaluated in the current study included age, comorbidities, specific indication for TURP, PSA levels, IPSS score, prostate size, postvoid residual volume, urine culture, baseline

serum creatinine and urea, full blood count, length of resection (mins), weight of prostate tissue resected (g), duration of postoperative irrigation, catheterization and hospitalization, and early postoperative complications

6.11 Study Equipment

The equipment used in the current study was an Olympus PlasmaKinetic^{TM} Bipolar generator, Tokyo, Japan- Model: WM-NP2, 2018) at the settings of 120W coagulation and 200W cutting. The irrigating solution was 0.9% isotonic saline.

6.12 Procedures (Methods)

Demographic data was obtained through interviewer-administered questionnaires and included age, residence, occupation, history of hypertension, diabetes, prior urethral catheterization and IPSS score. The IPSS score was calculated using the IPSS symptom score sheet. The indication(s) for TURP, PSA levels, prostate size, post-void residual volume, dipstick urinalysis, baseline serum creatinine, urea and full blood count were obtained from patient's admission notes. Prostate volume (mls) was estimated from the pelvic ultrasound by using the ellipse formula: prostate volume = height x width x length x 0.52 (Nikolaos et al, 2015). Patients with indwelling catheters and positive urine culture were treated with culture-specific antibiotics for at least 5 days before undergoing surgery. Intraoperatively, the length of resection, weight of prostate tissue resected (g), duration of postoperative irrigation and catheterization was recorded. The weight of prostate chips resected was measured using a digital weighing scale (FX-2000i digital gram scale, Japan) accurate to 0.01g (**Figure 1**).

After surgery patients were reviewed 12 hourly and as necessary until discharge. During these reviews the duration of postop irrigation, catheterization and any postoperative complications were recorded. Complications were divided into three groups: intraoperative, immediate postoperative (0-48 hours) and delayed post-operative (up to 28 days). They were graded into

minor or major complications according to Clavien-Dindo classification. Urethral catheters were generally removed when the urine was clear.

FIGURE 1: FX-2000I DIGITAL GRAM SCALE, MITUTOYO, JAPAN (SHOWING RESECTED PROSTATE)

6.13 Ethical considerations

Ethical approval was obtained from the Kenyatta National Hospital Ethics and Research Committee before the commencement of the study. Patients were recruited into the study after obtaining voluntary verbal and written informed consent. The benefits of participating in the study were explained to the patients and the decision to do so was solely theirs. The raw data (without patient names for confidentiality) is stored in the department of surgery for future referencing. There is no conflict of interest for the patient, investigators or the institution. Patients had a right to withdraw from the study at any stage.

6.12 Data analysis and presentation

Data was analyzed using SPSS version 22.0 (Chicago, Illinois, USA). General descriptive statistics were applied to derive the frequencies of the Pre-operative features (Age, indication for surgery, ejection fraction, PSA, IPSS score, Postvoid residue, prostate size, hemoglobin), intra-operative features (duration of resection (min), weight of resected prostate) and Post-operative features (duration of post-op irrigation, urethral catheterization and length of hospital admission). Preoperative continuous variables such as the mean age, PSA, prostate size, IPSS score were compared in those who developed complications against those who did not develop complications. Differences in means between these two groups was measured using the independent Student's t-test to determine statistical significance. A p-value of ≤ 0.05 was considered significant at a confidence interval of 95%. Chi-square test and Fisher's Exact test were used to measure association of categorical variables such as comorbidities, pre-op urine culture and indications for surgery with development of early postoperative complications. Data was then presented in form of tables, graphs and pie charts.

7. RESULTS

A total of 72 patients met the inclusion criteria and were analyzed in the present study.

7.1 Baseline pre-operative parameters for the patients

Their baseline clinical parameters are shown in the table below (Table 3).

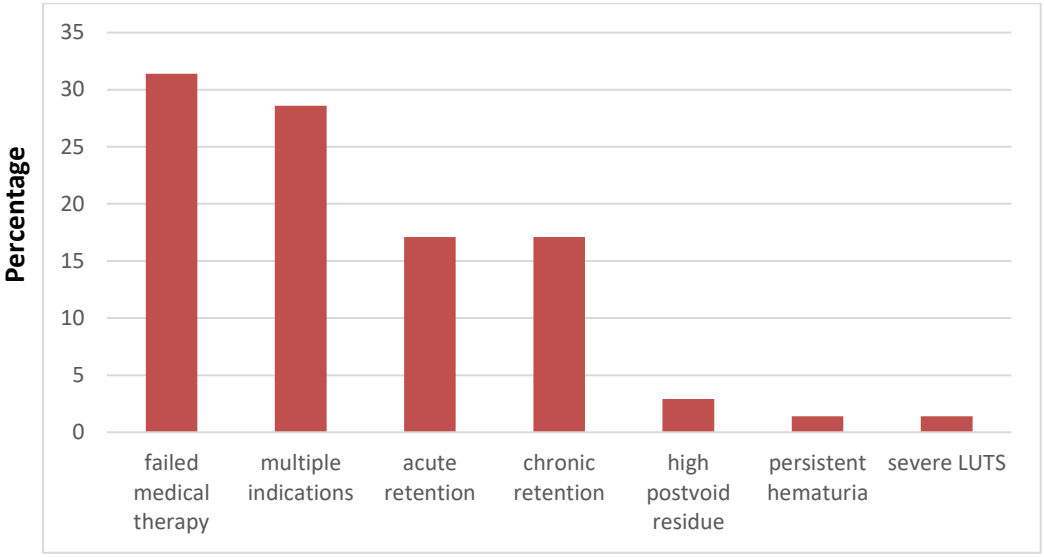
TABLE 3: BASELINE PREOPERATIVE PARAMETERS FOR PATIENTS UNDERGOING TURP IN THE STUDY

Parameters	Mean	Range	Std. Deviation
Age (years)	70.4	51-92	9.44
Ejection fraction (%)	63.4	39-75	7.91
PSA (ng/ml)	10.3	0.4-13	2.04
IPSS score	24.1	11-34	5.10
Postvoid urine residue (mls)	211.2	19-900	179.77
Prostate size (mls)	76.3	30-253	40.75
Hemoglobin (g/dl)	15.2	8.2-16.7	4.61
Length of resection (min)	94.9	30-165	28.31
Weight of resected prostate (g)	10.0	5-30	7.40
Duration of post-op irrigation (hrs)	40.1	3-96	21.19
Duration of catheterization (days)	3	1-24	3.33
Length of Hospital admission (days)	3.5	2-10	1.92

7.2 Indications for TURP

There were various indications for TURP in the current study as shown in the bar graph below (**Figure 2)**. The most common indication was failed medical therapy (31.4%) followed by acute and chronic urine retention (17%).

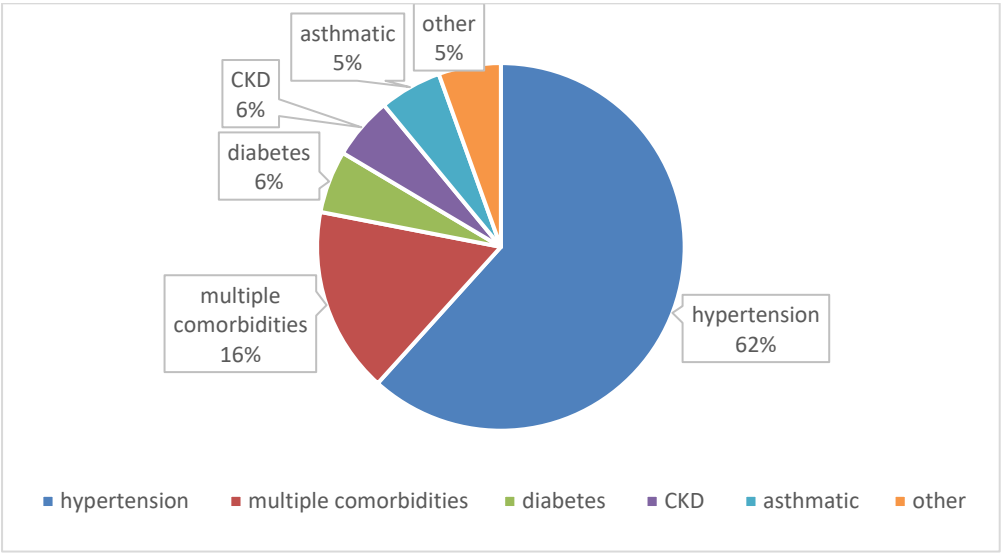
FIGURE 2: FIGURE SHOWING INDICATIONS FOR TURP IN THE CURRENT STUDY



7.3 Patient comorbidities

The most common comorbidity in the current study was hypertension (60.7%). 17% of the patients had multiple comorbidities, as shown in the pie chart below (**Figure 3**).

FIGURE 3:FIGURE SHOWING PATIENT COMORBIDITIES



7.4 Duration of urethral catheterization after TURP.

The general trend in the duration of urethral catheterization after TURP is shown in Table 4. Majority of patients (>80%) were catheterized for 2-3 days postop, however some had prolonged catheterization beyond one week because of persistent hematuria. The mean duration of catherization in the study was 3 days.

TABLE 4: DURATION OF URETHRAL CATHETERIZATION AFTER TURP

Duration of catheterization	**Number of patients**	**Percentage**
1 day	8	11.3
2 days	42	58.3
3 days	10	14.1
4 days	**2**	2.8
5 days	**4**	5.6
6 days	**3**	4.2
10 days	**2**	2.8
24 days	**1**	1.4

7.5 Pattern of postoperative complications

There were 2 intraoperative complications. One patient developed TURP syndrome with delirium and bradycardia and the other patient sustained capsular perforation of the prostate. Both were managed conservatively and resolved.

Immediate postoperative complications (0-72 hrs) occurred in 26 patients while delayed postoperative complications (up to 28 days) occurred in 24 patients. The Overall complications rate was 54.9% (39/71 patients). However, majority of the complication were minor (Clavien-Dindo grade I and II)- **Table 5**.

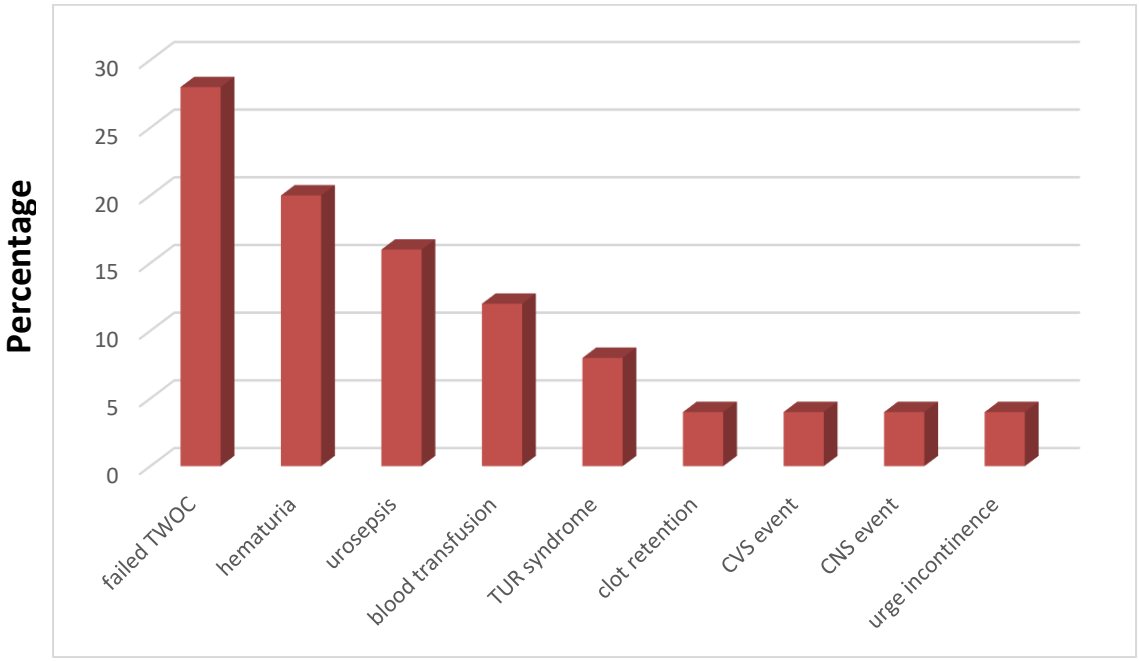
TABLE 5: CLASSIFICATION OF OVERALL COMPLICATIONS ACCORDING TO CLAVIEN-DINDO SYSTEM.

Postoperative complication	Percentage (%)	Clavien-Dindo grade
Failed TWOC	28	III
Hematuria	20	I
Urosepsis	16	II
Lower urinary tract symptoms	54	I
Recurrent UTI	12.5	II
Blood transfusion	12	II
CNS/CVS events	1	IV

7.6 Immediate postoperative complications (0-72 hours)

Complications arising in the immediate postoperative period are shown in the bar graph below (**Figure 4**). The most common complication was failed trial without catheter (28%) followed by persistent hematuria.

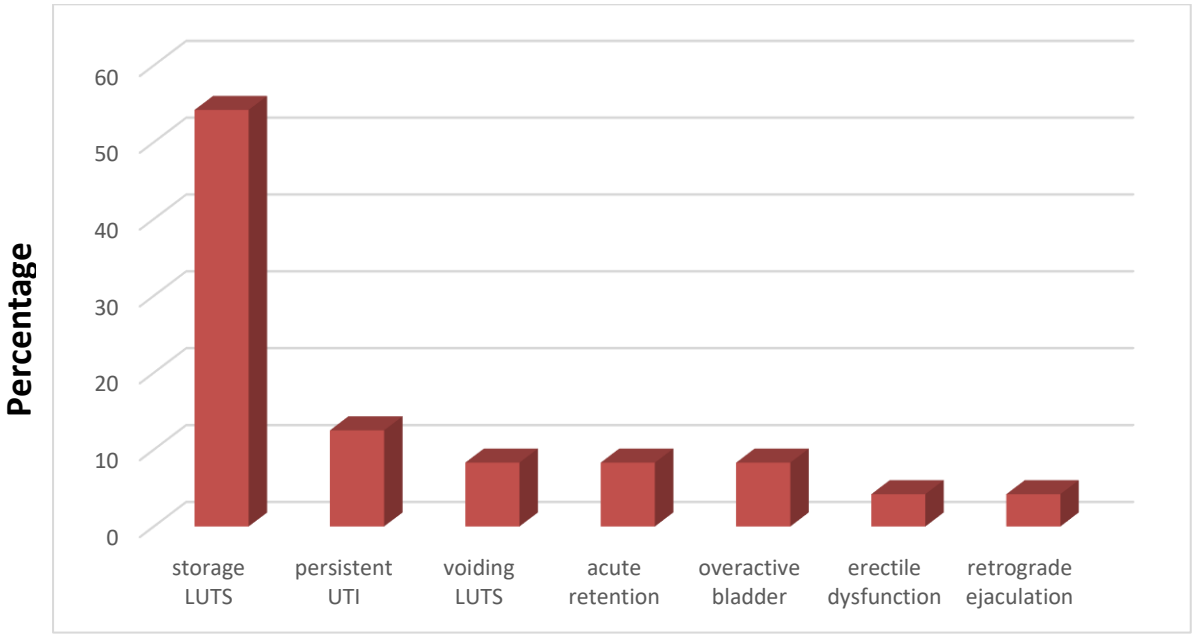
FIGURE 4: FIGURE SHOWING PATTERN OF IMMEDIATE POSTOPERATIVE COMPLICATIONS AFTER TURP



7.7 Delayed postoperative complications (up to 28 days)

The most common delayed postoperative complication after TURP was storage LUTS such as urgency, frequency and nocturia. This occurred in 54% of patients. The pattern of delayed postoperative complications is shown in the bar graph below (**Figure 5**).

FIGURE 5: FIGURE SHOWING PATTERN OF DELAYED POSTOPERATIVE COMPLICATIONS AFTER TURP



7.8 Factors associated with early postoperative complications

7.8.1 Effect of positive urine culture on surgical outcome

In the current study 15 patients (20.8%) had positive preoperative urine culture. Majority (>90%) were above 70 years with an indwelling urethral catheter and multiple comorbidities. These patients received at least 5 days of culture-directed antibiotics before undergoing surgery. However, the surgical outcome was poor in these patients. On Chi square analysis, those patients with positive urine culture had positive association with development of higher complication rates compared to those with a negative culture (**p=0.006**; Fishers' Exact test) (Table 6). Further analysis revealed that these complications were more likely to occur within

the first 5 days after surgery. The early complications included prolonged hematuria, clot retention and failure to void- **Table 6**.

TABLE 6: EFFECT OF POSITIVE URINE CULTURE ON SURGICAL OUTCOME

Positive urine culture vs early postoperative complications Cross tabs

		Early complications		
		None	Yes	Total
Urine culture	Positive	25.0%	75.0%	100.0%
	Negative	71.2%	28.8%	100.0%
Total		63.4%	36.6%	100.0%

Contingency table

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	9.165[a]	1	0.002		
Continuity Correction[b]	7.283	1	.007		
Likelihood Ratio	8.928	1	.003		
Fisher's Exact Test				.006	.004
Linear-by-Linear Association	9.036	1	.003		
N of Valid Cases	71				

7.8.2 Influence of age on surgical outcome

In the current study, age >70 years was significantly associated with failed TWOC, regardless of the duration of catheterization (**p =0.032**; Pearson Chi-Square) (**Table 7).** These patients required immediate reinsertion of urethral catheter due to urine retention. In addition, 60% of those above 70 years developed ≥1 complication in the postoperative period and they were more likely to have persistent storage (irritative) symptoms after TURP.

TABLE 7: INFLUENCE OF AGE ON UNSUCCESSFUL TWOC

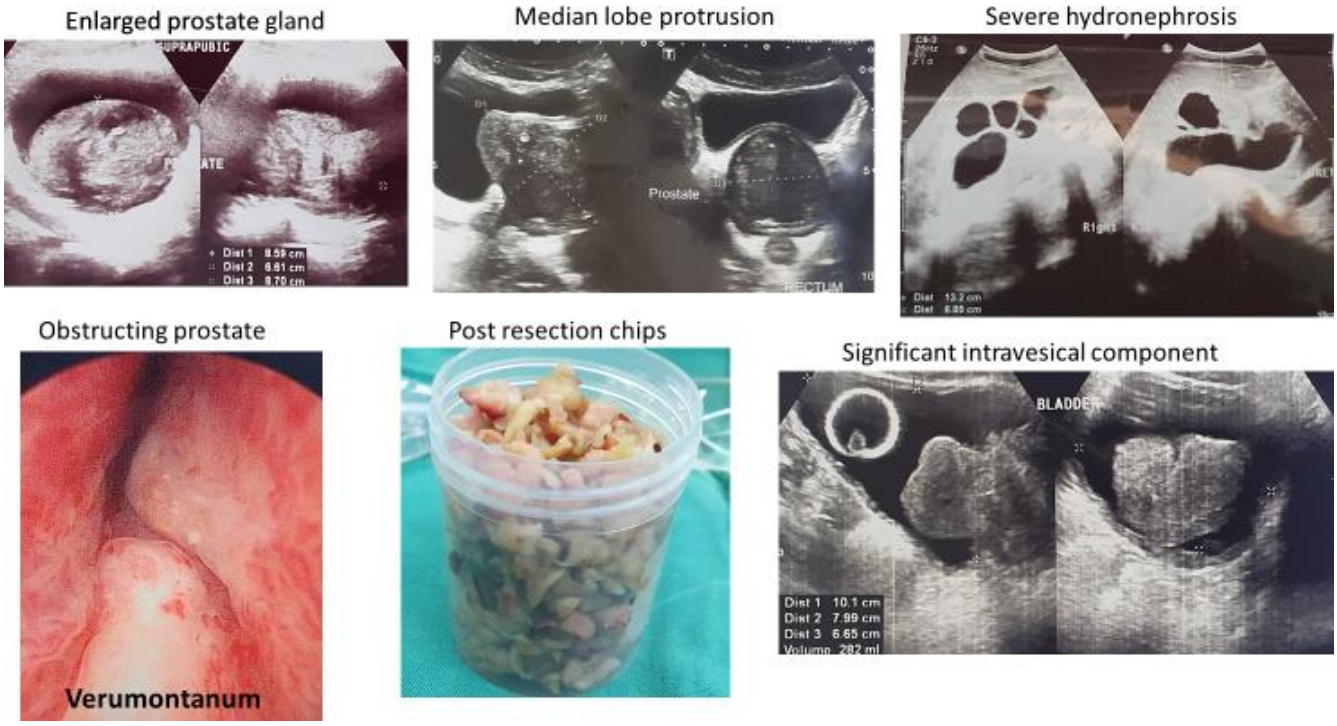
Influence of age on unsuccessful TWOC Crosstabs

			TWOC		
			Successful	Unsuccessful	Total
Age group	<70yrs	Count	8	0	8
		% within age group	100.0%	0.0%	100.0%
	>70yrs	Count	10	7	17
		% within age group	58.8%	41.2%	100.0%

Contingency table

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	4.575[a]	1	**0.032**		
Continuity Correction[b]	2.761	1	.097		
Likelihood Ratio	6.613	1	.010		
Fisher's Exact Test				.057	.040
Linear-by-Linear Association	4.392	1	.036		
N of Valid Cases	25				

FIGURE 6: FIGURE SHOWING PREOPERATIVE AND INTRAOPERATIVE IMAGES OF THE PATIENTS STUDIED



8. DISCUSSION

In the current study the most common indication for TURP was failed medical therapy (31.4%). This was similar to the study by Chia-Chu et al (1993) who found an incidence of 42%. Our figure is relatively smaller because some of our patients with failed medical therapy also had other indications for surgery and were therefore categorized under "multiple indications". Failed medical therapy is one of the most common indications for TURP because majority of patients visiting urology clinic with symptomatic prostatism are started on medical therapy and previous reports have shown up to 20-25% of these patients end up with surgical intervention (McConnell et al, 1998).

Majority of patients in our study were catheterized for 2-3 days after surgery (83.1%). This is similar to the findings by Mebust et al (1989), who recorded a 3-day catheterization time in 82% of his cohort. However, other studies have reported a 1 or 2-day catheterization period but in highly selected patients (Tatsuo et al, 2006). This variable is dependent on several factors such as patient clinical status, degree of ongoing hematuria and patient comorbidities. In our study patients who had indwelling catheter for >5 days had persistent hematuria, capsular perforation or severe comorbidities.

In the current study, the most common early postoperative complication after TURP was failed trial without catheter (TWOC), 28%, followed by hematuria (bleeding) at 20%. This is similar to the findings by Mebust et al (1989) who found that the most common complications after TURP in an analysis of 3885 patients were failure to void, persistent hematuria and clot retention. In a local study by Kiptoon et al (2007), the most common complications after prostatectomy were urinary tract infections (15%), clot retention (10%) and pyrexia (10%). Similarly, 12% of patients in the current study had persisted UTI in the postoperative period. An interesting finding in the current study is that, 54% of patients complained of storage LUTS after surgery (frequency, urgency, nocturia), necessitating treatment with antimuscarinics or

alpha blockers. This has quality of life and financial implications as their symptoms were not fully relieved by surgery. This finding has also been reported by Liang et al (2019), who found that 46.8% of his patients still took medication for BPH for over a month after the surgeries. Hence further studies are required to evaluate the long-term outcome of these patients.

The overall post-operative complication rate in the current study was 54.9% however, majority of the complications (75%) were minor (Clavien-Dindo grade I or II). This is not at great variance with world literature as meta-analysis by the BPH guideline panel showed that the morbidity rate associated with TURP ranges from 7% to 43% (Fung et al, 2005). A study by Chia et al (2003) from China found an overall complication rate of 36% while another study by Mebust et al (1989) from USA found a morbidity rate of 18%. Bipolar resection is a relatively new technology in KNH and like any other new technology it is associated with a learning curve. This and the delayed presentation for most of our patients could explain the slightly higher complication rate observed in the present study.

An important finding in the current study is that presence of preoperative positive urine culture was significantly associated with worse outcomes after surgery. Several authors have reported this finding (Ariane et al 2011; Salih et al, 2016; Tarek et al, 2017). Suhani et al (2013) found that patients with positive urine culture had higher complications after TURP despite 1-week of prior treatment with antibiotics. He noted that these patients had higher incidence of failure to void, acute urine retention and mild improvement in their urodynamic parameters. A long-lasting impact that a UTI can have on the urinary system was described by Benjamin et al (1996). He stated that the urological variables reflecting recurrent UTI and markers of obstructive uropathy (such as calculi and bladder diverticuli) may be associated with worse outcomes following prostatectomy due to non-reversible changes in the detrusor in these patients. This may explain why our patients with prior UTI still had poor outcomes despite prior treatment with antibiotics. Further, we noted that patients with preoperative UTI were

more likely to have an indwelling bladder catheter, age >70 years and admitted as an emergency with acute urinary retention. These patients therefore require due diligence in their preoperative management as they are at high risk of postoperative complications.

Another important finding in the current study was that age >70 years was significantly associated with failure to void after surgery and >1 postoperative complication. This finding was reported by Liang et al (2019) who found that age <70 yrs was associated with higher success rate of TWOC. Another study by Ankur et al (2017) showed that age older than 65 years and a high IPSS score were associated with a lower success rate of TWOC after an episode of AUR. Another study by Li et al (2017) found that the occurrence of UTI in patients undergoing TURP was closely associated with patient's age > 65 years, history of diabetes and prior urinary catheterization.

The influence of age on the urinary system as far as infections are concerned was explained by Li et al (2017). He stated that UTI is mainly caused by the interaction of urinary tract pathogens, bacterial virulence, and imperfect host defense mechanisms. In elderly patients the body resistance to pathogens is obviously reduced and susceptibility to infections is increased. Further, degenerative changes of prostate can decrease the function of the urinary tract and defense mechanisms of the urethral mucosa creating a neurogenic-like bladder thus impairing micturition reflex. This can increase the residual urine volume and increase the incidence of urine retention, which will facilitate the invasion and reproduction of bacteria. Secondly, TURP is an invasive procedure to the urethral mucosa which can easily be damaged by instrumentation and perioperative catheter intubation, creating a more convenient environment for bacterial invasion. In another study by Tarek et al, there was a significant relationship between persistent post-TURP bacteriuria to the patient's age, positive preoperative urine culture, preoperative catheterization, and history of diabetes (Tarek et al, 2017).

9. CONCLUSION

Bipolar TURP is a relatively safe procedure albeit with minor complications. The most common early postoperative complications were failure to void and prolonged hematuria. Presence of preoperative positive urine culture and age >70 years were significantly associated with early postoperative complications. This category of patients requires due diligence in the immediate postoperative period.

10. STUDY LIMITATIONS

- ✓ Some patients were lost to follow-up which led to incomplete data collection
- ✓ In some instances, it was not possible to quantify the amount of saline used for irrigation in the post-operative period as this was not consistently documented in the patients' records.

11. STUDY RECOMMENDATIONS

1. A study with a bigger sample size would be able to derive the specific factors predicting early post-operative complications through multiple logistics analysis.
2. Studying the long-term outcomes after TURP (beyond 28 days) would be important in our setup as they remain unknown.
3. Patients admitted as an emergency with urine retention and positive urine culture should in addition to 1 week of culture-directed antibiotics, be screened and managed for other comorbidities before undergoing any invasive surgery.

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13. APPENDIX

13.1 Appendix 1: PARTICIPANT INFORMATION AND CONSENT FORM

TITLE OF STUDY: Early postoperative complications of bipolar transurethral resection of the prostate at KNH.

*Principal investigator and institution affiliation**: Dr Hemed El-busaidy- University of Nairobi***

*Co-investigators and institution affiliation**: Dr Francis Owillah (University of Nairobi) and Dr James Ikol (KNH)***

Introduction

I would like to inform you about this study being conducted by the above listed researchers. The purpose of this consent form is to give you the information you will need to help you decide if you will be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form.

Aim of the study (what is this study about?)

This study is about Bipolar TURP (bTURP) which is the current gold standard procedure for surgical management of symptomatic BPH. It is applicable for small, medium and large-sized prostates. Although this procedure is frequently done in our setup, data on early postoperative complications is unknown. This information would be useful in the surgical management of BPH.

This study has been authorized by the KNH/UoN Ethics and Research Committee for the period extending from ___**August 2019**_____ to ___**August 2020**_____

Objectives of the study

To find out early postoperative complications of Bipolar TURP at Kenyatta National Hospital

Benefits of the study

Bipolar TURP is being done frequently at KNH (about 5 to 6 procedures per week). Regional and international data on its safety and efficiency in relieving symptoms of BPH are promising. However local data on early postoperative complications is unclear. This study will inform on these complications and help reduce their incidence in future.

What will happen if you decide to be in this research study?

If you agree to participate in this study, the following things will happen: You will be interviewed by a trained interviewer in a private area where you feel comfortable answering questions. The interview will last approximately 15 minutes. The interview will cover topics related to your urinary symptoms and habits. After the interview we will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reasons why we may need to contact you is to follow up on the outcome of your surgery.

Are there any risks, harms or discomfort associated with this study?

Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort will always be put in place to minimize these risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a code number to identify you in a password-protected computer database and will keep all our paper records in a locked file cabinet. However, no system of protecting your confidentiality can be absolutely secure, so it is still possible that someone could find out you were in this study and could find out information about you. Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview. In case of an injury, illness or complications related to this study, contact the study staff right away at the number provided at the end of this document. The study staff will treat you for minor conditions or refer you when necessary

Will being in this study cost you anything?

Absolutely NO. All tests/procedures in this study are part of the standard evaluation and management of the condition being treated. There are no extra or hidden costs.

Reimbursement to participants

During the follow up period, patients will be seen on their normal clinic days. However, in the event that a patient needs to appear earlier than their scheduled appointment, a sum of ksh 200 per patient will be given to cater for transport. There will be no direct benefits for the patient or her next of kin. No harm is expected to be encountered in the course of the study, either to the researcher or to the patient.

Humble request

In order to carry out this study, we will need your participation during regular clinic visits at the surgical (urology) outpatient clinic. In these visits you will be asked questions regarding your urinary symptoms in relation to your disease. The follow up visits for this study shall be done up to 4 weeks. Thereafter you shall continue with your regular clinic visits as determined by your doctor in the clinic. Participation will be entirely on a voluntary basis and there will be no financial remuneration. The lead researcher will explain this research to you.

The lead researcher (Dr Hemed) can be reached on telephone number **0729 666 777.** Besides, if you have any complaints pertaining this study, the chairperson of the KNH-UoN Ethics and Research Committee that authorizes this study can be reached on the number 020-2726300 ext. 44102.

Denial of consent will be duly respected and will not in any way affect your treatment at KNH.

Confidentiality

Your identity will be confidential and no information will appear on either the data sheets or the final report.

CONSENT FORM (Participant's statement)

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that

my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study. I understand that all efforts will be made to keep information regarding my personal identity confidential. By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: Yes No

I agree to provide contact information for follow-up: Yes No

Signature/thumbprint…….. Date……..

I, the principal investigator, having explained in detail the purpose of this study, hereby submit that, confidentiality of the data collected will be maintained and only details relevant to the study will be revealed.

Signature_____ Date _____

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13.2 APPENDIX II: CHETI CHA RIDHAA

KICHWA: <u>MATOKEO YA OPARESHENI YA KIMA (ISIYO SARATANI) KATIKA HOSPITALI KUU YA KENYATTA</u>

*Mtafiti Mkuu**: Dr Hemed El-busaidy- University of Nairobi***

*Wasaidizi**: Dr Francis Owillah (University of Nairobi) and Dr James Ikol (KNH)***

Kianzilishi

Ningependa kukujulisha kuhusu huu utafiti unaofanywa na watafiti walioandikwa hapo juu. Kiini cha barua hii ni kukupatia taarifa ambayo itakuwezesha uweze kufanya uamuzi wa kujiunga na huu utafiti au la. Kuwa huru kuuliza swali lolote kuhusu utafiti huu, nini litakalofanyika pindi unapoamua kujiunga na utafiti huu, madhara au maafa yatakayotokea, haki zako kama mhudhuriaji au jambo lengine lolote. Pindi tumeyajibu maswali yako yote na umeridhika, uamuzi wa kujiunga na utafiti huu ni wako. Pindi umefahamu na kuridhia kujiunga na utafiti huu nitakuomba usahihishe jina lako katika barua hii.

Lengo kuu la uchunguzi

Ugonjwa wa kima (sio saratani) ni moja katika magonjwa yanayowakumba wakenya wengi. Baadhi ya wanaougua ugonjwa huu wanahitaji oparesheni. Ni muhimu kujua matokeo ya oparesheni kwa wale wanaoathirika ugonjwa huu kwa sababu baadhi yao wana majukumu muhimu sana katika familia zao. Kwa hivyo elimu ya matokeo ya oparesheni katika kikundi hiki kitasaidia kutoa mwanga juu ya ugonjwa huu. Elimu hii pia itatusaidia kutambua namna ya kuwatibu wagonjwa wengine katika siku zijazo.
Uchunguzi huu umeruhusiwa na tume yamaadili inayoidhinisha utafiti (KNH-UoN Ethics and Research Committee) kuanzia tarehe __ **August 2019**____ hadi tarehe ___ **August 2020**___

Malengo hususan

Katika uchunguzi huu, mtafiti mkuu ataweza kumuuliza maswali kadhaa mgonjwa kuhusu njia yake ya mkojo na namna inavyomuathiri maisha yake.

Manufaa

Elimu ya matokeo ya oparesheni ya wanaougua ugonjwa wa kima (sio saratani) kitasaidia kutoa mwanga juu ya ugonjwa huu. Elimu hii pia itatusaidia kutambua namna ya kuwatibu wagonjwa wengine katika siku zijazo.

Uchunguzi huu utafaidi maelezo kuhusu ugonjwa wa kima (sio saratani) na hivyo kuchangia katika kutengeza matibabu yenye manufaa kwa wanaougua ugonjwa huu.

Hakuna manufaa ya papo hapo kwa mgonjwa au jamaa zake.

Kuna madhara yoyote kwa kujiunga na utafiti huu?

Utafiti wa mambo ya afya yaweza kuyafichua mambo ya ndani ya siri za mgonjwa. Jambo hili laweza kuathiri siri na uhuru wa mgonjwa. Lakini bidii itafanywa kupunguza mambo haya. Tutahifadhi kila unachotuambia kwa vile tutakavyoweza. Tutatumia nambari maalum katika makaratasi na tarakilishi ili usiweze kujulikana kwa urahisi. Makaratasi haya yatahifadhiwa katika vyombo maalum. Hii haimaanishi kuwa hakuna mtu yoyote ataweza jujua habari zako kabisa bali kuna uwezekano wa kuweza jutambulika baadaye. Kama kuna maswali ambayo huku radhi kuyajibu tutaelewa na hutalazimishwa kuyajibu. Una uhuru wa kukubali au kukataa swali lolote utakaloulizwa.

Kujiunga na utafiti huu utakugharimu nini?

Hakuna gharama yoyote atakayoipata mgonjwa katika utafiti huu ispokuwa zile gharama za kawaida za uchunguzi na matibabu yanayohusikana na ugonjwa huu. Hakuna gharama zilizojificha au gharama zengine zozote.

Kulipwa kwa wagonjwa wanaojiunga na utafiti huu

Baada ya oparesheni, wagonjwa wataonekana katika kliniki katika siku zao walizopangiwa. Kukitokea dharura ambayo mgonjwa atahitajika hospitalini kabla ya siku zake za kawaida, shilingi mia mbili taslimu atapewa mgonjwa ili aweza kusafiri na kupata chakula cha siku ile. Hakuna marupurupu yoyote atakayopata mgonjwa kando na haya.

Ombi

Ili kutekeleza uchunguzi huu, tutahitaji ruhusa yako ya kuweza kujiunga na utafiti huu. Iwapo haujaelewa maagizo haya unahiari ya kumuuliza mtafiti maswali yoyote kuhusu matumizi hayo.

Nambari ya simu ya mtafiti huyu ni **0729 666 777**.

Pia, iwapo una malalamishi yoyote kuhusu utafiti huu, mwenyekiti watume yamaadili inayoidhinisha utafiti huu (KNH-UoN Ethics and Research Committee), anaweza kupatikana kupitia nambari **020 7263009**.

Kukubali kujiunga katika uchunguzi huu silazima na hauna gharama yoyote.

Usiri

Hatutafichua wala kuchapisha mambo yoyote kukuhusu ila yale tu yanayohusiana na uchunguzi huu.

Uamuzi wa mgonjwa

Nimesoma na kuyaelewa yaliyomo katika barua hii. Nimepata fursa ya kujadiliana yaliyomo katika barua hii na mtafiti mkuu. Maswali yangu yamejibiwa kwa lugha ninayoifahamu. Naelewa kuwa kujiunga kwangu na utafiti huu ni kwa hiari yangu na naweza kujiondoa katika utafiti huu wakati wowote. Kwa hivyo nimeridhia kujiunga na utafiti huu kwa hiari yangu. Ningependa mambo yangu yawekwe siri katika utafiti huu.

Nimekubali kujiunga na utafiti huu: Yes No

Nimekunali kutoa nambari yangu ya rununu : Yes No

Sahihi…….. Tarehe……..

Nathibitisha nimeyafahamu aliyonieleza mtafiti na nimekubali kwa hiari yangu mwenyewe kushiriki katika uchunguzi huu.

Sahihi/kidole cha gumba…… Tarehe _____

Mimi, mtafiti nimemweleza mgonjwa kuhusu uchunguzi huu ipasavyo.

Sahihi ya mtafiti _____ Tarehe _____

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13.3: DATA COLLECTION SHEETS

1. BIODATA

IP No (serial number)	
Age (years)	
Residence	
Occupation	

2 INDICATION(S) FOR TURP- Tick the appropriate:

Acute urine retention	
Hydronephrosis/renal insufficiency (chronic retention)	
Recurrent hematuria	
Recurrent UTI's	
High postvoid residue (>100mls)	
Severe LUTS (persistent IPSS score>20)	
Failed (refractory) medical therapy (>6/12)	
Others (specify)	

3 COMORBIDITIES- Tick where appropriate:

Diabetes	
Hypertension	
Heart disease (specify)	
Others (specify)	

4 PREOPERATIVE LABORATORY AND RADIOLOGICAL DATA:

PARAMETER	RESULT
PSA (ng/ml)	
IPSS score	
Prostate size (mls)	
Postvoid residue (mls)	
Hemoglobin (g/dl)	
Urea, electrolytes	
Urinalysis & culture	

5 INTRAOPERATIVE AND POSTOPERATIVE VARIABLES

VARIABLE	RESULT
Length of resection (min)	
Weight of prostate tissue resected (g)	
Amount of irrigating saline used (L)	
Duration of postoperative irrigation	
Duration of urethral catheterization	
Length of hospital stay	

6 <u>POSTOPERATIVE COMPLICATIONS</u>

COMPLICATION	TICK WHERE APPROPRIATE
Clot/urine retention	
Persistent hematuria	
UTI/urosepsis	
Failed TWOC (Trial Without Catheter)	
Blood transfusion	
Cardiovascular events: M.I, CVA, DVT	
Persistent LUTS	
TURP syndrome	
Urinary incontinence	
Others (specify)	

American Urological Association BPH Symptom Score Index Questionnaire

Having to urinate more frequently, as well as more urgently, can definitely interrupt the flow of your day. You should know that frequent urination is often a symptom of benign prostatic hyperplasia (BPH), a noncancerous enlargement of the prostate gland. BPH is a common condition among men over the age of 50. Waking up several times a night to urinate and having a weaker, slower, or delayed urine stream are other common symptoms.

Patient Name **Date**

Circle the number that best applies to you.

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

Add the score for each number above, and write the total in the space to the right **TOTAL_____**

SYMPTOM SCORE: **1-7 = MILD** **8-19 = MODERATE** **20-35 = SEVERE**

13.4 THE CLAVIEN-DINDO GRADING OF POSTOPERATIVE COMPLICATIONS

GRADE	Definitions
I	Any deviation from the normal postoperative course without the need for pharmacological treatment other than the "**allowed therapeutic regimens**", or surgical, endoscopic and radiological interventions
II	Requiring **pharmacological** treatment with drugs beyond those allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.
III	Requiring **surgical, endoscopic or radiological intervention.**
IV	**Life-threatening complication** requiring critical care management; CNS complications including brain haemorrhage and ischemic stroke (excluding TIA), sub-arrachnoidal bleeding.
V	**Death** of a patient