

**OPEN SIMPLE PROSTATECTOMY
AND BLOOD TRANSFUSION AT
KENYATTA NATIONAL HOSPITAL,
NAIROBI**

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**A dissertation submitted in part fulfilment of master of medicine
degree in Surgery of the University of Nairobi**

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DEDICATION

To my late father, Jacktone, for showing me clear direction in life

To my son Wesley, and his mum for their support and co-operation

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TABLE OF CONTENTS

Declaration	ii
Dedication	iii
Acknowledgements	iv
Table of contents	v
Operational definitions.....	vi
List of Tables	vii
List of Figures.....	viii
Abstract	ix
Chapter 1 Introduction and Literature review	1
Chapter 2 Problem statement	8
Study justification	8
Study objectives	9
Chapter 3 Methodology	10
Ethical consideration	14
Chapter 4 Results	15
Chapter 5 Discussion	24
Chapter 6 Conclusion	28
Recommendations	28
Study limitation	29
References	30
Appendix I Data collection instrument	33
Appendix II Consent form	34
Appendix III The International Prostate Symptom Score (IPSS)	35
Appendix IV American Society of Anaesthesiologists (ASA) grades of operative risk assessment.....	36
Appendix V Approval letter from Ethical Review committee.....	37

OPERATIONAL DEFINITIONS

1. Peri-operative blood loss – refers to blood loss during and within 72 hours after the surgical operation. This was indicated in the study by the mean decrease in haemoglobin concentration.
2. Significant pre- or post-operative anaemia – haemoglobin concentration of less than 10g/dl.
3. Study outcome – refers to the mean decrease in peri-operative haemoglobin concentration and blood transfusion rate.

LIST OF TABLES

Table 1	Distribution of patients according to American Society of Anaesthesiologists (ASA) grades	17
Table 2	Other pre-operative patient characteristics that determined peri-operative blood loss	20
Table 3	Relationship between some of the intra-operative patient characteristics and the mean decrease in haemoglobin concentration.....	21
Table 4	Relationship between some of the patient factors and peri-operative blood transfusion.....	22
Table 5	Other patient factors that determined peri-operative blood transfusion	23

LIST OF FIGURES

Figure 1	Distribution of patients according to age group	15
Figure 2	Distribution of patients according to the indications of open simple prostatectomy	16
Figure 3	Relationship between the patients' age group and the mean decrease in haemoglobin concentration.....	19

ABSTRACT

Background

Open simple prostatectomy has long been associated with large blood losses; hence allogeneic blood transfusion in this procedure is a standard practice world over. A review of literature suggests significant association between peri-operative blood loss accompanying open simple prostatectomy and certain patient factors^{18,19,20,21,22,23}. While blood transfusion rate in open simple prostatectomy had been widely investigated in other centres^{11,12,17,25}, this seemed not to be the case at Kenyatta National Hospital. The shortage of blood and blood products in our blood transfusion centres as well as the alarming risks of transfusion reactions and disease dissemination demanded a review of these factors with the aim of reducing morbidity associated with peri-operative blood loss and blood transfusion^{28,29,30}.

Objectives

To assess blood loss, determine blood transfusion rate, and define some of the factors associated with peri-operative blood loss and blood transfusion in open simple prostatectomy.

Methodology

A prospective cohort study was conducted in the urology units of Kenyatta National Hospital, Kenya, between June 2004 and May 2005. Ninety-five patients who were admitted with a clinical diagnosis of benign prostatic hyperplasia and underwent open simple prostatectomy were enrolled into the study upon giving a written informed consent. Data on the study variables including the patients' age, pre-operative medication, clinical presentation, pre-operative systolic blood pressure, American Society of Anaesthesiologists (ASA) grade, pre- and post-operative haemoglobin levels, technique of anaesthesia, technique of open simple prostatectomy, weight of resected prostatic tissue, blood loss estimation, units of blood transfused, and the duration of hospital stay was collected and analysed. The peri-operative blood loss was judged from the mean decrease in peri-operative haemoglobin concentration. The mean decrease in haemoglobin was derived from the pre- and post-operative haemoglobin. The post-operative haemoglobin for the patients transfused peri-operatively was

corrected for the transfused volume by subtracting 1g/dl for each transfused unit of blood¹⁴. The main study outcome was defined as the mean decrease in peri-operative haemoglobin and blood transfusion rate.

Results

Ninety-five patients who underwent open simple prostatectomy for benign prostatic hyperplasia were enrolled into the study. Their median age was 70 years (Range 50 to 97). The mean decrease in haemoglobin concentration, which was the main indicator of peri-operative blood loss, was 2.1g/dl (\pm 1.4). The peri-operative blood transfusion rate was 36.8%. Twenty-four (68.6%) of the patients who received either 1 or 2 units of blood had a pre-operative haemoglobin level above 13.5g/dl and a post-operative haemoglobin level above 11.5g/dl, while 11 (31.4%) had severe peri-operative bleeding, that necessitated immediate surgical re-intervention. A total of 68 units of blood was transfused, 42 (61.8%) allogeneic and 26 (38.2%) autologous blood.

The post-operative median hospitalisation time was 8 days (Range 4 to 35). There were 2 (2.1%) post-operative deaths and both patients had intractable intra- and post-operative bleeding, massive blood transfusion and disseminated intravascular coagulopathy.

The factors that were significantly associated with peri-operative blood loss and blood transfusion in open simple prostatectomy were patient's age above 70 years, pre-operative use of acetyl-salicylate or warfarin sodium, pre-operative systolic blood pressure above 140mmHg, general anaesthesia, Freyer's (transvesical) technique and the weight of resected prostatic tissue above 70g.

Conclusion

Open simple prostatectomy performed under spinal anaesthesia using Millin's (retropubic) technique is associated with minimal blood loss. The peri-operative blood transfusion rate was 36.8% and most of the blood transfusion was clinically unjustified. Transfusion of autologous blood in open simple prostatectomy was underutilized at Kenyatta National Hospital.

CHAPTER 1

INTRODUCTION AND LITERATURE REVIEW

1.1 Introduction

The prostate is the largest accessory gland of the male reproductive system, measuring approximately 3 cm long. The normal prostate is firm, walnut-sized and surrounds the prostatic urethra. It has a dense fibrous capsule, which is surrounded by a fibrous prostatic sheath. The sheath is continuous with the Denonvillier's fascia posteriorly and pubo-prostatic ligaments anteriorly. The prostate derives its blood supply from prostatic arteries, which are mainly branches of internal iliac arteries. Its veins join to form the dorsal venous complex around the sides and base of the gland and runs between the fibrous capsule and the prostatic sheath to drain into internal iliac veins¹. The dorsal venous complex is an important source of haemorrhage during prostatectomy.

Benign prostatic hyperplasia (BPH) is one of the most common diseases that affect men beyond middle age. Over 40% of men above the age of 60 years have symptomatic disease. Though its prevalence increases with age, benign prostatic hyperplasia is rarely a life threatening disease but the symptoms of frequency, nocturia and incomplete bladder emptying impact substantially on the patient's quality of life². The treatment options for this disease include watchful waiting, medical and surgical management.

With the emergence of trans-urethral resection of the prostate (TURP) and the development of modern optical instruments, trans-urethral resection of the prostate has replaced open simple prostatectomy as the operation of choice for benign prostatic hyperplasia world over and especially in the developed countries². Nonetheless, open simple prostatectomy, an invasive surgical approach for treatment of medically resistant or advanced lower urinary tract obstruction secondary to benign prostatic hyperplasia, remains the procedure of choice in patients with prostate larger than 75 grams or larger than the surgeon can resect reliably by trans-urethral resection of the prostate in 60 to 90 minutes². In those with concomitant bladder pathology complicating their outlet obstruction

such as a large hard bladder calculus or symptomatic bladder diverticulum, open simple prostatectomy optimizes exposure to both the entire prostate and intravesical bladder. Moreover, patients with musculoskeletal disease precluding proper patient positioning in the dorsal lithotomy position for trans-urethral resection of the prostate may benefit from open simple prostatectomy. Open simple prostatectomy is also indicated in patients with unilateral or bilateral inguinal hernias as these can be repaired preperitoneally at the same time through the same incision³. The three approaches in open simple prostatectomy include retropubic (Millin's), transvesical (Freyer's) and simple perineal.

Retropubic prostatectomy is the enucleation of a hyperplastic prostatic adenoma through a direct incision of the anterior prostatic capsule. The procedure dates to 1945, when Terrence Millin first reported his experience with 20 patients⁴. Transvesical approach is the enucleation of the hyperplastic adenoma through an extraperitoneal incision of the lower anterior bladder wall. Eugene Fuller first performed this procedure in 1894 and by 1912, Peter Freyer, who reported his results with 1000 patients had popularized the procedure⁵. Simple perineal prostatectomy for treatment of lower urinary tract obstruction secondary to benign prostatic hyperplasia illustrates the development in the approach to this common pathology. More than 2000 years ago, surgeons devised and employed a median perineal incision for the removal of bladder calculi and years later it was used for partial removal of the prostate².

The perception nationally is that open simple prostatectomy is associated with large blood losses and allogeneic blood transfusions. Bleeding in open simple prostatectomy, as in other surgical procedures, may be encountered during surgery (primary haemorrhage), within 24- 48 hours after operation (reactionary haemorrhage) or be delayed for several days to weeks (secondary haemorrhage). Excessive haemorrhage during the procedure results in transfusion of allogeneic blood products that may expose the patient to undesirable adverse reactions.

Adverse reactions to transfused blood and blood products occur despite multiple laboratory tests, inspections and checks. Fortunately, the most common reactions are not

life threatening. These reactions may result from immune and non-immune mechanisms. Immune-mediated reactions are often due to preformed donor or recipient antibodies though cellular elements may also be involved. Non-immune causes of reactions are due to the chemical and physical properties of the stored blood components and its additives. Although the incidence of transfusion related infections such as Human immunodeficiency virus (HIV) 1 and 2; Hepatitis B and C virus; Human T-cell leukemia virus (HTLV) 1 and 2; Malaria; Cytomegalovirus (CMV); and Epstein-Barr virus (EBV) has been reduced substantially due to improved donor screening and testing of collected blood, the fear of these complications still remains a primary concern⁷.

Spence, in 1997, noted that the traditional belief of surgeons that allogeneic blood transfusion was an effective and safe therapy with minimal risks had been challenged by a heightened awareness of the problems of transfusion reactions, disease transmission and immunomodulation related to red blood cell transfusion⁸. Subsequently, surgeons have responded to these challenges by reassessing the reasons for transfusions, increasing autologous blood use, modifying surgical techniques to minimize blood loss and employing various drugs to reduce transfusion requirements. Of primary importance is the need for the surgeon to thoughtfully plan allogeneic blood transfusion requirements for each patient. Blood should therefore be transfused only when there is a documented need to increase oxygen delivery in patients who are unable to meet their demands through normal cardio-pulmonary mechanisms. Autologous blood use, an alternative to allogeneic transfusion, is increasingly becoming a standard care for elective orthopaedic procedures and radical prostatectomy. Furthermore, limited supply of blood and blood products demands their rational use. The purpose of this study therefore was to redefine the factors that influence blood transfusion rate associated with open simple prostatectomy with the aim of minimizing unnecessary blood transfusions that pose avoidable risks to these patients.

1.2 Indications of prostatectomy

Before the 1960s, prostatectomy was mainly carried out for urinary retention, recurrent severe urinary tract infection caused by large residual volumes of urine and bladder stone formation⁹. Currently, strong indications for prostatectomy include acute retention, chronic retention with hydronephrosis, large residual volumes of urine with recurrent infection or bladder stone formation. However, because of the increasing safety of prostatectomy and the desire of men to be free from symptoms, the use of prostatectomy, and more so trans-urethral resection of the prostate, was extended to men complaining of a variety of poorly classified symptoms including poor urinary flow, hesitancy, dribbling, incomplete bladder emptying, frequency, urgency and urge incontinence. This symptom complex was described initially as "prostatism" or "symptomatic benign prostatic hyperplasia", and is currently evaluated using the International Prostate Symptom Score (IPSS)¹⁰ (Appendix III).

1.3 Factors associated with peri-operative blood loss and blood transfusion in open prostatectomy

The peri-operative blood loss in open simple prostatectomy has previously been judged from the peri-operative decrease in haemoglobin concentration. Most previous reports estimated the concentration of haemoglobin^{19,22,24,33,34} in effluent irrigation fluid and calculated blood loss from the pre-operative value of the indicator used. These methods measured actual blood loss, albeit with certain limitations³⁵. They had an error margin of 4 - 5%¹⁹ and used extra resources, which limited their use to research. As most of the blood loss usually occurs within 2 days of surgery (time to 50% loss of 16h)²²; the post-operative haemoglobin (at 48 - 72 h) is a practical and useful way of assessing blood loss¹³. The post-operative haemoglobin for the patients transfused peri-operatively was corrected for the transfused volume by subtracting 1g/dl for each transfused unit of blood¹⁴.

The association between open simple prostatectomy and blood transfusion has been reported in many series worldwide. Serretta et al, in 2002, reported a blood transfusion

rate of 8.2% in a contemporary series of open prostatectomy for benign prostatic hyperplasia in southern Europe¹¹ while Luttwak et al reported blood transfusion rate of 57.1% for transvesical prostatectomy in Israel¹². Thurtson et al carried out a study in 1993 to investigate the effect of aspirin (acetyl – salicylate) on post- prostatectomy haemorrhage and noted that 29% of the 136 patients had significant blood loss as judged by the post-operative drop in haemoglobin of more than 2g/dl, or on the basis of receiving more than 2 units of blood though most of his patients had been receiving aspirin (acetyl – salicylate) on a regular basis¹³. Kirolos et al reported transfusion rate of 10.8% in total and 3.6% of more than 2 units¹⁴, while Thorpe et al reported a 2.5% transfusion rate of more than 2 units in trans-urethral resection of the prostate¹⁵.

Excessive haemorrhage during open simple prostatectomy may result in transfusion of allogeneic blood products that may expose the patient to undesirable adverse reactions. Several efforts have therefore been instituted to reduce transfusion rates, including improved surgical techniques, use of erythropoietin, preoperative autologous blood donation and acute normovolaemic haemodilution. Nuttal et al, in 2002, noted that with these measures in place, the mean peri-operative blood loss and need for blood transfusion in patients undergoing open prostatectomy significantly reduced¹⁶. Shaheen et al, in 2004, reported a mean peri-operative decrease in haemoglobin of 2.2g/dl and blood transfusion rate of 16% in 37 consecutive patients who underwent open simple prostatectomy with early vascular control¹⁷.

Hatch noted that general anaesthesia resulted in twice the transfusion rate as regional anaesthesia¹⁸ while Madsen et al showed a statistically significant advantage in blood loss for spinal over general anaesthesia ($P < 0.01$) in a study of 180 patients¹⁹.

Pickard et al, in 1998, noted that patient characteristics associated with the need for blood transfusion were large prostatic glands and age above 70 years²⁰ while Luke et al noted that bleeding remains one of the most important problems associated with open simple prostatectomy. Although haemostasis is usually sufficient during surgery, re-bleeding may continue for several days, requiring blood transfusion and sometimes re-operation²¹. The

risk of post-operative haemorrhage has been related to both the weight of the resected prostatic tissue and aspirin ingestion²².

The technique of open simple prostatectomy also determines the amount of blood loss and subsequent blood transfusion. Ibrahim et al, in 1995, studied the effect of age, type of surgery and co-morbidities on peri-operative complications and mortality of prostatectomy; and reported that open prostatectomy was associated with more haemorrhage, blood transfusion, post-operative pyrexia and a longer bed stay²³. Blood loss and transfusion rate in both the operative and post-operative periods is directly related to the weight of the gland resected, with values of 20 to 37 ml/g of blood loss being reported²⁴. Hill et al in a research done in a rural Kenyan hospital in 2002 reported a mean prostate weight of 70.4 g and a transfusion rate of 4.7% for suprapubic - transvesical prostatectomy ²⁵. Kirolos et al demonstrated a strong correlation between the weight of the resected prostatic tissue and blood loss and noted that it was the most important measurable factor in relation to blood loss ¹⁴.

Other possible variables contributing to blood loss include the age of the patient and the blood pressure, bleeding being more severe in older patients with hypertension²⁶. Of the drugs contributing to haemorrhage after prostatectomy, the most commonly studied is heparin administered subcutaneously as prophylaxis against venous thrombo-embolism. Gavriiliuk, in 1987, reported a high incidence of haemorrhagic complications in patients given aspirin prior to open prostatectomy²⁷.

The need for blood and blood products has continued to exceed the amount available from transfusion services. As a result, there is a shortage of red cells and other blood products. Boral et al attributed this to medical advances that resulted in diseases being treated and lives prolonged by relatively new methods such as chemotherapy and open- heart surgery²⁸. They noted that although this progress had created an increase in demand for blood, the supplies were expanding by only 1% annually, hence predicted significant blood shortages in future. Similar sentiments were echoed by Smallwood in 1983 when he pointed out that a growing demand for blood and its products had exceeded the resources

of his local blood bank thereby disrupting both the planning and the nature of surgical lists at Queen Alexandra Hospital, Portsmouth²⁹. In Kenya, similar trends have been observed by Omar et al at the National Blood Transfusion Centre, Nairobi. While the expected blood collection for the region was 16,000 units in 2003, only 8,000 units of blood had been collected. They also reported infection rates of 6% of all the screened blood in 2003³⁰.

The shortage of blood and blood products coupled with the heightened awareness of transfusion reactions as well as transfusion related infections has prompted surgeons to reassess the reasons for blood transfusion, increase the use of autologous blood and modify surgical techniques to reduce blood loss. Under normal circumstances, loss of blood less than 20% of the total blood volume may be compensated for by infusing intravenous fluids alone, while a loss of less than 10% may not even require such infusion³¹. Mugenya in a study done in 1995 at Kenyatta National Hospital showed that 18% and 78.6% of surgical patients with blood loss less than 500ml, and between 500 - 1000ml respectively, had blood transfusion. While he indicated that blood loss was the major determinant of blood transfusion rate in surgery, other factors need to be incorporated to determine a comprehensive policy that would govern judicious and rational use of blood peri-operatively³². Kirolos et al, in 1997, further concluded that blood transfusion could be markedly reduced and rationalized if all the factors that determine blood loss can be defined¹⁴.

While open simple prostatectomy had long been considered a blood losing surgical operation associated with allogeneic blood transfusion, it was a worthwhile attempt to redefine the factors that influence blood transfusion requirements and the reasons for blood transfusion in this procedure. This would obviously lead to reduction in unnecessary blood transfusion that poses avoidable risks to patients undergoing open simple prostatectomy.

CHAPTER 2

2.1 Problem statement

Benign prostatic hyperplasia (BPH) is one of the most common diseases that affect men beyond middle age. On average, 125 patients with benign prostatic hyperplasia undergo open simple prostatectomy at Kenyatta National Hospital annually. Although open simple prostatectomy has largely been replaced by trans-urethral resection of the prostate (TURP) as the procedure of choice in treatment of benign prostatic hyperplasia, it still has its specific indications in the management of this common problem. While the procedure has been considered a blood losing surgical operation associated with allogeneic blood transfusion, the degree of blood loss, the blood transfusion rate and the factors that determine peri-operative blood loss and blood transfusion associated with open simple prostatectomy remain largely unknown at Kenyatta National Hospital.

2.2 Study justification

Open simple prostatectomy is one of the most common surgical procedures carried out at Kenyatta National Hospital. Though blood transfusion in this procedure is considered a standard practice, the actual degree of blood loss and other determinants of this practice are not documented. The need for this study is further fortified by the shortage of blood and blood products in our blood transfusion centres as well as the obvious risks of transfusion reactions and disease dissemination. This study aimed at redefining the real need for use of blood in prostatic surgery with the hope of making recommendations that if implemented would minimize unnecessary blood transfusion in this kind of surgery.

Study objectives

1. To assess blood loss and determine blood transfusion rate associated with open simple prostatectomy.
2. To determine some of the factors associated with peri-operative blood loss and blood transfusion in open simple prostatectomy.

CHAPTER 3

METHODOLOGY

3.1 Study design

This was a prospective cohort study carried out between June 2004 and May 2005. The study end point was the discharge of the patient from the hospital or death.

3.2 Study area

The study was carried out in the urology units at Kenyatta National Hospital, Nairobi. This is a teaching and referral hospital located in the capital city of Kenya.

3.3 Study population

All patients admitted to the urology units (Wards 5A, 5B and 5D) of Kenyatta National Hospital, with a clinical diagnosis of benign prostatic hyperplasia and underwent open simple prostatectomy by Millin's (retropubic), Freyer's (transvesical) or perineal approach were eligible for the study.

3.3.1 Selection criteria

All the patients admitted to the urology units with benign prostatic hyperplasia and scheduled for open simple prostatectomy were reviewed at admission, and those who gave informed consent were enrolled into the study. Those who declined or were unable to give informed consent were excluded.

3.3.2 Recruitment procedure and sampling method

The investigator visited the urology units every afternoon before an elective urology theatre day. A request was also made to the doctors on duty in those units to inform the investigator whenever a patient with benign prostatic hyperplasia was admitted. Patients who met the selection criteria were informed about the study and an informed consent was obtained. They were enrolled into the study consecutively until the desired sample size was obtained.

3.3.3 Sample size calculation

From a previous study entitled *suprapubic – transvesical prostatectomy in a rural Kenyan hospital*, blood transfusion rate of 4.7% was reported²⁵.

With a 95% confidence interval ± 1 ,

Prevalence (**P**) = 5%

Margin of error (**d**) = 5%

Using the above values, the following formula was used to calculate the minimum sample size.

$$N = \frac{Z^2_{1-\alpha/2} P(1-P)}{d^2}$$

N = 73.

The minimal sample size required was **73**. The level of significance (α) as per the above stated formula was 5%. Thus, with a sample size of 95 patients, the P values of < 0.05 for Chi – square test of independence for categorical variables and odds ratios between 3.3 and 22.2 at 95% confidence interval for linear correlation test for continuous variable were considered statistically significant.

3.4 Clinical procedures

All the patients admitted to the urology units with benign prostatic hyperplasia, scheduled for open simple prostatectomy, were reviewed pre-operatively. The patients' age and presenting symptoms were recorded. Clinical presentation included acute and chronic urinary retention, prostatism that was determined using the International Prostate Symptom Score (IPSS), complications of urinary retention that included hydronephrosis, chronic renal failure, bladder calculus, prostatic bleeding and unilateral / bilateral inguinal hernia. International Prostate Symptom Score has a maximum score of 35 and a score of 20 or more was considered as severe obstructive urinary symptoms (Appendix III).

A history of bleeding disorders and use of drugs such as acetyl-salicylate, heparin sulphate and warfarin sodium was obtained. Cubital venepuncture was done and blood samples collected for haemogram, urea, electrolytes and cross-match. The other pre-operative investigations that were done when indicated included chest x-ray, ECG, trans-rectal ultrasound, abdominal ultrasound and prostatic biopsy. The pre-operative morbid state of the patients was assessed with emphasis laid on the medical conditions that determine peri-operative blood loss such as bleeding disorders and hypertension. The patients were assigned American Society of Anesthesiologists (ASA) grades using the details obtained from the clinical history, physical examination and investigative procedures (Appendix IV).

Intra-operatively, the details of the category of the surgeon performing the operation, the technique of anaesthesia used and the technique of open simple prostatectomy were recorded. The prostatic tissue excised was weighed using a top pan balance before fixation and the weight recorded. The number of units of blood transfused intra- or post-operatively – autologous or allogeneic- was also recorded.

3.5 Patient follow - up

The patients were then reviewed every morning post-operatively until discharge or death. Another blood sample was collected on the third post-operative day to determine the post-

operative haemoglobin concentration. Any excessive haemorrhage that required immediate re-intervention and the duration of post-operative hospital stay were noted.

3.6 Specimen analysis

The blood samples for haemogram were analyzed using the automated electronic counters and the haemoglobin concentration was automatically derived by the machine.

3.7 Data management

All data generated was recorded into a work sheet (Appendix I) and then entered into an IBM personal computer. All the information was stored securely by the investigator with due respect for the patients' confidentiality.

3.7.1 Data analysis

The data was entered into an Epi – info 6 data sheet and exported to the SPSS version 10 statistical software package for analysis. The differences in proportions and means were analysed using Pearson chi – square test of independence and P values < 0.05 were considered as significant. Mann – Whitney U and linear correlation tests were used to analyse continuous variables where appropriate. The data was presented as mean ± standard deviation (SD) for continuous variables and percentages for categorical variables, in frequency tables, bar graphs and pie charts as appropriate.

Peri-operative blood loss was judged by the peri-operative decrease in haemoglobin concentration and hence the main study outcome was defined as the mean peri-operative decrease in haemoglobin concentration and blood transfusion rate. The mean decrease in haemoglobin concentration was derived from the pre- and post-operative haemoglobin concentration of all the enrolled patients. The post-operative haemoglobin for the patients transfused peri-operatively was corrected for the transfused volume by subtracting 1g/dl

for each transfused unit of blood.

3.7.2 Dissemination of results

The results of the study will be distributed to the university library and the Department of Surgery. The results will also be presented in scientific conferences and published in scientific journals where appropriate.

ETHICAL CONSIDERATION

Approval to carry out the study was obtained from Kenyatta National Hospital Ethics Review Committee (Appendix V). The study objectives and clinical procedures were explained to the patients before enrolling them into the study. A written informed consent was obtained (Appendix II). Aseptic technique was used during the venepuncture. The cubital fossa was cleaned thoroughly with methylated spirit or iodine solution before collecting the blood sample using sterile needles and syringes. The used materials especially sharps were disposed safely into designated containers to avoid needle prick injuries.

Recruited patients were identified only using a study number and their in-patient number for confidentiality purposes. The data obtained was stored carefully and regular feedback given to the patients and with their permission, relevant clinical information and laboratory findings were passed on to the caring clinicians to aid in decision making during patient management.

The investigators fully participated in the management of these patients. Emergency care and resuscitation took priority during the study. No major complications solely attributable to the study procedures were recorded during the study period.

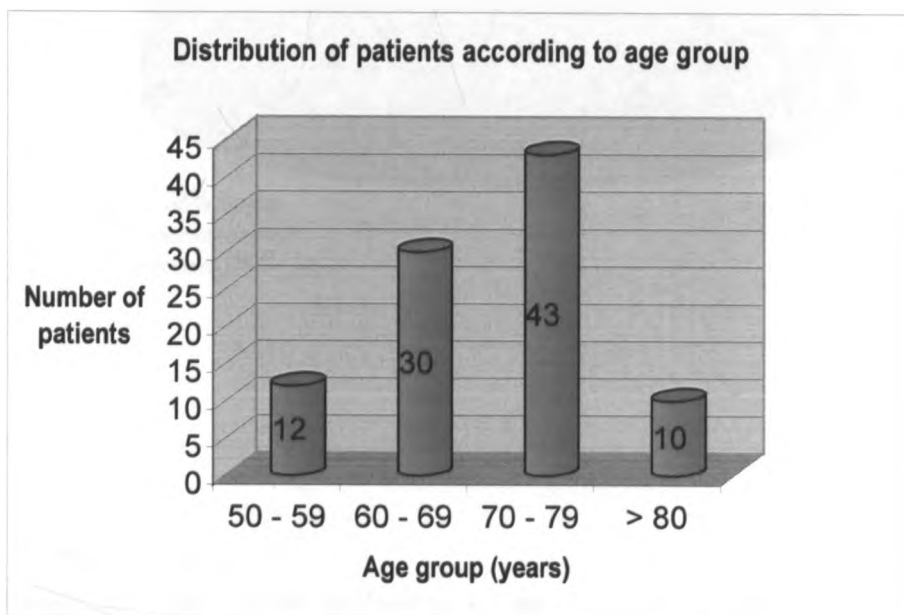
CHAPTER 4

RESULTS

4.1 Study demography

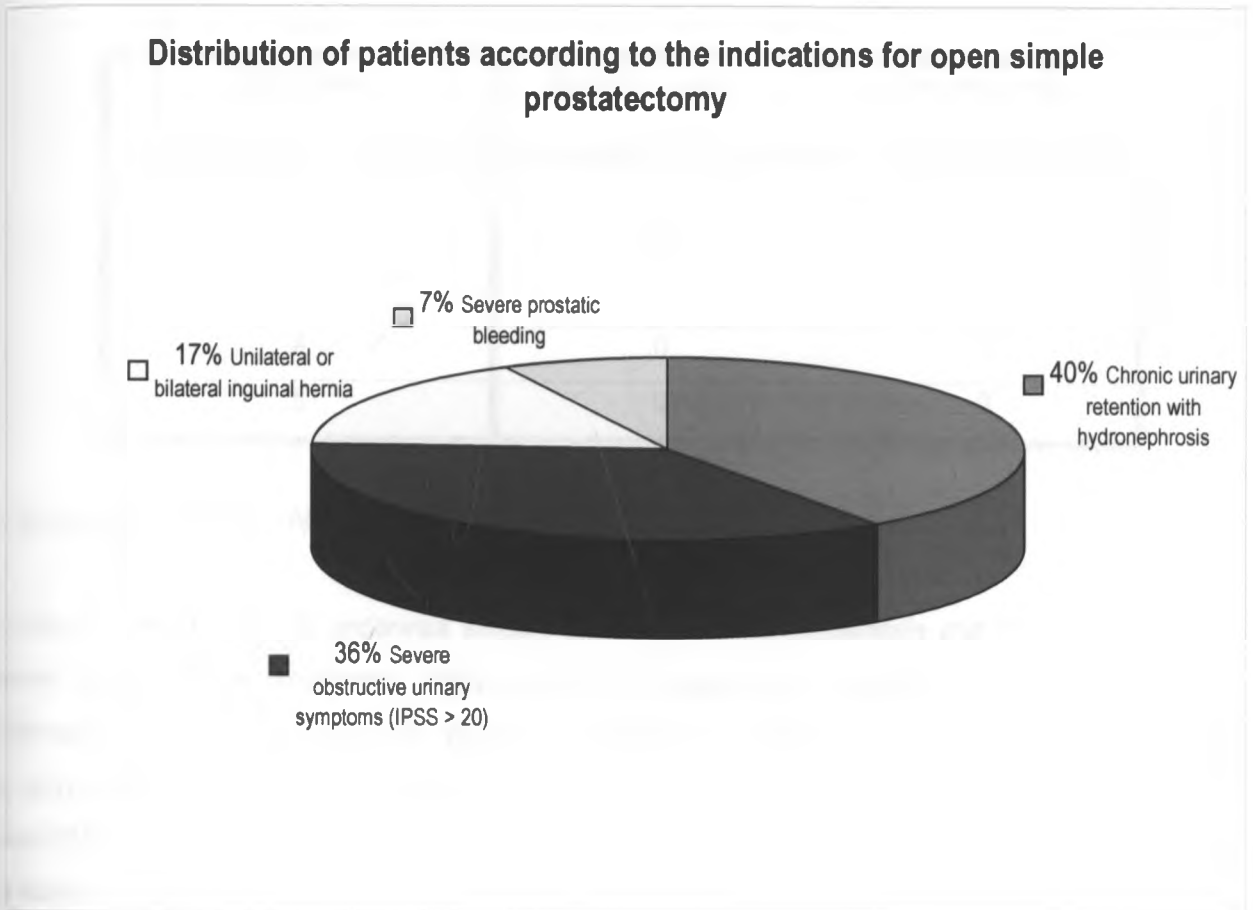
Ninety-five patients who underwent open simple prostatectomy for benign prostatic hyperplasia were enrolled into the study between June 2004 and May 2005. Their median age was 70 years (Range 50 to 97) and 56.8% were above 70 years.

Figure 1.



Majority of the patients were above 70 years.

Figure 2.



The main indications for open simple prostatectomy were chronic urinary retention with hydronephrosis in 38 (40.0%) patients, severe obstructive urinary symptoms (mean International Prostate Symptom Score (IPSS) of 29.4 ± 2.1) in 34 (35.8%) patients, unilateral or bilateral inguinal hernia in 16 (16.8%) patients and severe prostatic bleeding in 7 (7.4%) patients.

The patients' American Society of Anesthesiologists (ASA) grades were as shown in Table 1 (Appendix IV).

Table 1. Distribution of patients according to ASA grades

ASA grade	Number of patients N = 95	Percentage (%)
1	49	51.6
2	40	42.1
3	6	6.3
4	0	0
5	0	0

There were no patients in ASA grades 4 and 5.

Of the patients, 69 (72.6%) underwent surgery while under spinal anaesthesia and 26 (27.4%) while under general anaesthesia. Sixty-one (64.2%) had open prostatectomy via Millin's (retropubic) approach and 34 (35.8%) via Freyer's (transvesical) approach. No patient underwent open prostatectomy via simple perineal approach. The mean weight of the resected prostatic tissue was 66.9g (Range 10 to 250, Median 60). Sixty five point three percent (65.3%) of the resected prostatic tissue weighed less than 75g.

The mean pre-operative haemoglobin level was 13.5g/dl (± 1.8), mean post-operative haemoglobin level was 12.0g/dl (± 1.9) and the mean corrected post-operative haemoglobin level for those who received blood transfusion was 9.9g/dl (± 1.7). The mean decrease in haemoglobin concentration, which was the main indicator of peri-operative blood loss, was 2.1g/dl (± 1.4).

The peri-operative blood transfusion rate was 36.8%. Of the 35 patients who received blood transfusion, 15 (42.9%) received 1 unit, 11 (31.4%) received 2 units, 7 (20%) received 3 units, and 2 (5.7%) received 5 units of blood respectively. Twenty-four (68.6%) of the patients who received either 1 or 2 units of blood had a pre-operative haemoglobin level more than 13.5g/dl and a post-

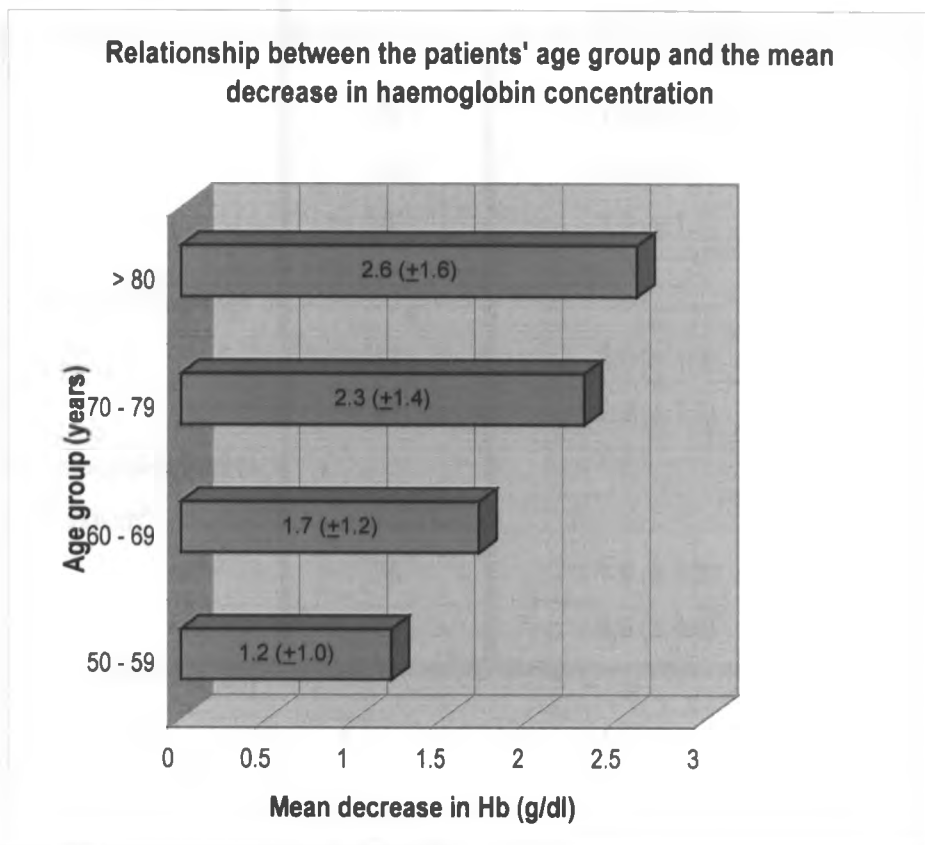
operative haemoglobin level more than 11.5g/dl, while 11 (31.4%) had severe peri-operative bleeding that necessitated immediate surgical re-intervention.

The mean corrected haemoglobin for the patients who received 3 or more units of blood was 9.1g/dl (\pm 1.2). A total of 68 units of blood was transfused, 42 (61.8%) allogeneic and 26 (38.2%) autologous blood.

The post-operative median hospitalization time was 8 days (Range 4 to 35). There were 2 (2.1%) post-operative deaths and both patients had intractable intra- and post-operative bleeding, massive blood transfusion and disseminated intravascular coagulopathy.

4.2 Factors that determined peri-operative blood loss

Figure 3.



Test of significance – Chi – square test

There was a statistically significant association between peri-operative blood loss and patients' age group ($P = 0.024$). Patients in older age groups had more blood loss.

Table 2. Other pre-operative patient characteristics that determined peri-operative blood loss (mean decrease in haemoglobin concentration)

Characteristic	N = 95	Mean decrease in Hb (g/dl) \pm SD	P - value
ASA grade:			
1	49	1.9 (\pm 1.4)	0.140
2	40	2.3 (\pm 1.4)	
3	6	3.0 (\pm 1.7)	
Pre-operative systolic BP (mmHg)			
< 130	53	2.0 (\pm 1.2)	0.982
> 130	42	2.2 (\pm 1.7)	
Pre-operative use of acetyl-salicylate/ warfarin sodium*			
-	75	1.9 (\pm 1.3)	0.008
+	20	2.9 (\pm 1.6)	

Test of significance – Mann – Whitney U

- *
 - Patients who had negative history of drug use
 + Patients who had positive history of drug use

Positive history of pre-operative drug use (acetyl-salicylate / warfarin sodium) showed statistically significant relation to peri-operative blood loss as indicated by the mean decrease in haemoglobin ($P < 0.05$). Though statistically insignificant, comparatively more blood loss was noted in patients in higher American Society of Anesthesiologists (ASA) grades and those who had higher pre-operative systolic blood pressure.

Table 3. Relationship between some of the intra-operative patient characteristics and mean decrease in haemoglobin concentration

Characteristic	N = 95	Mean decrease in Hb (g/dl) ± SD	P - value
Category of surgeon:			
Consultant	65	2.0 (± 1.3)	0.407†
Senior registrar	28	2.4 (± 1.7)	
Registrar	2	1.8 (± 0.8)	
Technique of anaesthesia:			
Spinal	69	1.8 (± 1.1)	0.003†
General	26	3.0 (± 1.8)	
Technique of prostatectomy:			
Millin's (retropubic)	61	1.6 (± 0.9)	< 0.001*
Freyer's (transvesical)	34	3.0 (± 1.8)	
Weight of resected prostatic tissue (g):			
< 30	14	1.3 (± 0.6)	< 0.001‡ (r = 0.41)
30 – 70	46	1.9 (± 1.4)	
> 70	35	2.9 (± 1.4)	

Tests of significance – * - Chi – square test
 † - Mann – Whitney U
 ‡ - Linear correlation co-efficient

The techniques of anaesthesia and open prostatectomy were significantly related to blood loss with more blood loss noted in patients who had Freyer's prostatectomy and those who underwent surgery under general anaesthesia ($P < 0.05$). Moreover, there was significant positive linear correlation between weight of resected prostatic tissue and decrease in haemoglobin ($r = 0.41$; $P < 0.001$), as indicated by the increase in mean haemoglobin decrease with the weight of the resected prostatic tissue.

4.3 Factors that determined peri-operative blood transfusion

Table 4. Relationship between some of the patient factors and peri-operative blood transfusion

Characteristic	Patients transfused N = 35	Patients not transfused N = 60	P - value
Mean age (years)	74.3 ± 8.8	68 ± 9.1	0.003*
Mean pre-operative systolic BP (mmHg)	139.9 ± 16.1	132 ± 12.2	0.021†
Mean decrease in HB (g/dl)	3.3 ± 1.6	1.5 ± 0.8	< 0.001*
Mean weight of resected prostatic tissue (g)	81.8 ± 54.4 Median = 70	54.4 ± 31.1 Median = 50	0.04‡

Tests of significance – * - Chi – square test

† - Mann – Whitney U

‡ - Linear correlation co-efficient

The patients who received blood transfusion had a significantly higher mean age, mean pre-operative systolic blood pressure, mean decrease in peri-operative haemoglobin concentration, and larger resected prostatic tissue compared to those who did not receive blood transfusion ($P < 0.05$).

Table 5. Other patient factors that determined peri-operative blood transfusion

Characteristic	Patients transfused N = 35	Patients not transfused N = 60	Odds ratio	P - value
Pre-operative use of acetyl – salicylate / warfarin sodium: § – +	25 (33.3%) 10 (50%)	50 (66.7%) 10 (50%)	-	0.210†
Technique of anaesthesia: Spinal General	22 (31.9%) 13 (50%)	47 (68.1%) 13 (50%)	-	0.102†
Technique of prostatectomy: Millin's (retropubic) Freyer's (transvesical)	12 (19.7%) 23 (67.6%)	49 (80.3%) 11 (32.4%)	8.5 95% C.I. (3.3 – 22.2)‡	< 0.001*

Tests of significance – * - Chi – square test

† - Mann – Whitney U

‡ - Linear correlation co-efficient

§ – Patients who had negative history of drug use

+ Patients who had positive history of drug use

The technique of prostatectomy was significantly related to the need for blood transfusion with Millin's having an advantage over Freyer's prostatectomy ($P < 0.05$, odds ratio = 8.5).

CHAPTER 5

DISCUSSION

5.1 Principle findings

Although numerous non-operative and minimally invasive techniques are available for treating benign prostatic hyperplasia, trans-urethral resection of the prostate is considered the procedure of choice. However, open simple prostatectomy is still indicated for certain conditions such as large prostate (> 75g), concomitant bladder diverticulum or cystolithiasis, and in patients with unilateral or bilateral inguinal hernia in whom the hernia can be repaired pre-peritoneally through the same incision. It is also indicated in those patients with other medical conditions that prevent proper placement in the dorsal lithotomy position².

This study was designed to assess blood loss accompanying open simple prostatectomy, determine the peri-operative blood transfusion rate and evaluate some of the factors that determine the amount of the peri-operative blood loss and blood transfusion.

Ninety-five patients who underwent open simple prostatectomy for benign prostatic hyperplasia were reviewed during the study period. The median age was 70 years and 56.8% were over 70 years. Majority of the patients underwent open simple prostatectomy due to chronic urinary retention with hydronephrosis (40%), and severe obstructive urinary symptoms (36%). Most of the patients were in American Society of Anaesthesiologists (ASA) grades 1 and 2. The main surgical technique for open simple prostatectomy was Millin's (64.2%) and majority of the patients underwent surgery under spinal anaesthesia (72.6%). The mean weight of resected prostatic tissue was 66.9g.

Most of the peri-operative blood loss usually occurs within 2 days of surgery (time to 50% loss of 16h) hence the post-operative haemoglobin concentration at 48 to 72 hours was the most practical and useful way of assessing peri-operative blood loss¹³. The mean decrease in haemoglobin concentration was 2.1g/dl and the blood transfusion rate was

36.8%. Further analysis of pre- and post-operative haemoglobin concentration confirmed that all blood transfusions of 3 or more units were justified to avoid significant post-operative anaemia (defined as haemoglobin level less than 10g/dl). However, it could be argued that blood transfusion might have been avoided in 24 patients (68.6%) who were transfused either 1 or 2 units, all of whom had a pre-operative haemoglobin level of more than 13.5g/dl and a post-operative haemoglobin level of more than 11.5g/dl. Most of the units of blood transfused were allogeneic, further exposing these patients to the risks of transfusion reactions and disease dissemination. The mortality rate associated with open simple prostatectomy at Kenyatta National Hospital was 2.1%.

5.2 Comparison with other studies

The mean decrease in haemoglobin level, which was the main indicator of peri-operative blood loss, in our study was 2.1g/dl. Shaheen et al, in 2003, reported a mean decrease in haemoglobin level of 2.2g/dl in patients who underwent open simple prostatectomy with early vascular control in Ireland¹⁷, while Kirolos et al reported a decrease in haemoglobin level of 1.5g/dl in patients who underwent trans-urethral resection of the prostate in United Kingdom¹⁴. With the degree of blood loss in open simple prostatectomy that is largely consistent with other series now determined in this study, the common practice of transfusing patients undergoing this procedure at Kenyatta National Hospital seem not to have a clear clinical basis.

The blood transfusion rate associated with open simple prostatectomy in our study was 36.8%. This significantly varied with those reported in other series. Serratta et al, in 2002, reported a blood transfusion rate of 8.2% in Southern Europe¹¹, whereas Shaheen et al reported a blood transfusion rate of 16%¹⁷. Luttwak et al reported a blood transfusion rate of 57.1% for transvesical prostatectomy in Israel¹² while Hill et al reported a blood transfusion rate of 4.7% in a rural Kenyan hospital²⁵. This wide regional variation in blood transfusion rates associated with open simple prostatectomy demonstrates lack of unified approach to this common practice and a multi-centre study could just provide a sound

explanation for this variation.

The study further defined some of the factors that determined peri-operative blood loss. Although the patients' American Society of Anesthesiologists (ASA) grade and pre-operative systolic blood pressure were related to the peri-operative blood loss, only the patients' age and positive history of pre-operative use of acetyl-salicylate or warfarin sodium showed a statistically significant relationship ($P < 0.05$). Gavriluik, in 1987, reported similar results²⁷. It is worth noting that these factors form an important aspect of routine pre-operative evaluation of any surgical patient. The study therefore emphasizes the value of incorporating them in any measures taken to minimize peri-operative blood loss.

The principle intra-operative factors that determined blood loss were the technique of anaesthesia, the technique of open prostatectomy and the weight of resected prostatic tissue. A statistically insignificant relationship between the category of the surgeon doing the procedure and the mean decrease in haemoglobin was demonstrated ($P = 0.407$). The mean decrease in haemoglobin was less for the registrar and the consultant compared to the senior registrar. This could be due to the fact that the registrar operated under the direct supervision of the consultant surgeon. Furthermore, the 65.3% of the patients whose resected prostatic tissue weighed less than 75g had no proper indication for open prostatectomy, hence trans – urethral resection of the prostate as the procedure of choice could have minimized blood loss in these patients.

The study showed a statistically significant advantage in blood loss for spinal (mean decrease in haemoglobin = 1.8g/dl) over general (mean decrease in haemoglobin = 3.3g/dl) anaesthesia ($P < 0.05$). Hatch et al¹⁸ and Madsen et al¹⁹ echoed similar sentiments in their studies. The technique of open simple prostatectomy was significantly related to blood loss with Millin's (retropubic) having an advantage (mean decrease in haemoglobin = 1.6g/dl) over Freyer's (transvesical) (mean decrease in haemoglobin = 3.0g/dl) technique ($P < 0.05$). Like Kirillos et al¹⁴ and Ibrahim et al²³, our study also demonstrated a strong correlation between the weight of resected prostatic tissue and peri-operative blood loss,

and noted that it was the most important measurable factor in relation to blood loss.

Among the factors that were significantly related to the need for blood transfusion were the age of the patient, pre-operative systolic blood pressure, the degree of blood loss and the weight of resected prostatic tissue ($P < 0.05$) (Table 4 & 5). Pickard et al, in 1998, noted a statistically significant relation between the need for blood transfusion, and large prostatic glands and age above 70 years²⁰. Despite the fact that majority (64.2%) of the patients underwent surgery via Millin's (retropubic) technique, only 19.7% received blood transfusion (odds ratio = 8.5). This further fortifies the argument that supports Millin's technique of open simple prostatectomy as the technique of choice if unnecessary blood transfusion was to be avoided in this kind of surgery.

The study further indicated that peri-operative blood transfusion might have been avoided in 68.6% of the patients who received blood transfusion if the principles that govern intravenous fluid replacement therapy were upheld. Mugenya in a study done in 1995 at Kenyatta National Hospital noted that more than 78% of surgical patients with minimal intra-operative blood loss received unnecessary blood transfusion³². This study has further shown that peri-operative autologous blood use is yet to become a standard practice in the urology units of Kenyatta National Hospital, as only 38.2% of the transfused units were autologous despite the mean pre-operative haemoglobin concentration of 13.5g/dl.

The median post-operative hospitalization time of 8 days was comparable to those reported in other series (6²⁵, 7¹¹, 8¹², 11.7¹⁷). The mortality rate of 2.1% associated with open simple prostatectomy in our study was equally comparable to those reported in other studies (0.9%²⁵, 1%¹¹, 3%¹⁷, 3.3%¹²).

CHAPTER 6

6.1 CONCLUSION

1. The mean decrease in haemoglobin level, which was the main indicator of peri-operative blood loss in the study, was 2.1g/dl.
2. The peri-operative blood transfusion rate associated with open simple prostatectomy at Kenyatta National Hospital was 36.8%.
3. The factors that were associated with significant peri-operative blood loss and blood transfusion in open simple prostatectomy were patient's age above 70 years, pre-operative use of acetyl-salicylate or warfarin sodium, systolic blood pressure above 140 mmHg, general anaesthesia, Freyer's (transvesical) technique of open prostatectomy and the weight of resected prostatic tissue more than 70g.
4. Peri-operative blood transfusion was clinically unjustified in 68.6% of the patients transfused.
5. Transfusion of autologous blood in open simple prostatectomy was underutilized at Kenyatta National Hospital.

6.2 RECOMMENDATIONS

1. To minimize blood loss and allogeneic blood transfusion in open simple prostatectomy, we recommend a management protocol that utilizes Millin's technique under spinal anaesthesia for most patients with benign prostatic hyperplasia in whom the prostate weighs more than 75g. Freyer's prostatectomy should be relegated to the books of medical history. The use of autologous blood in open simple prostatectomy should be a standard practice at Kenyatta National Hospital.

2. The defined factors that determine peri-operative blood loss and blood transfusion in open simple prostatectomy should be considered during the peri-operative assessment of these patients. This will enable thoughtful planning of allogeneic and autologous blood transfusion requirements for each patient and minimize unnecessary blood transfusion in open simple prostatectomy.
3. The study has defined blood transfusion rate and peri-operative transfusion practice associated with open simple prostatectomy at Kenyatta National Hospital that should form a basis for further studies that will develop management guidelines for patients with benign prostatic hyperplasia.

6.3 STUDY LIMITATION

The assessment of peri-operative blood loss using the mean decrease in haemoglobin concentration did not accurately measure the actual blood volume lost intra- and post-operatively.

REFERENCES

1. Keith L. Moore, Arthur F. Dalley. *Clinically Oriented Anatomy*. 4th ed. William & Wilkins inc. 369.
2. Walch P.C, Retik A.B, Vaughan E.D, Wein AJ eds, *Campbell's Urology*, Philadelphia: W.B. Saunders Co, 7th ed. 1998: 1529-40, 2327-60.
3. Shlegel P.N, Walsh P.C, The use of the pre-peritoneal approach for the simultaneous repair of inguinal hernia during surgery on the bladder and prostate. *World J. Surg.* 1989; **12**: 555-9.
4. Millin T, Retropubic prostatectomy: New extravesical technique reported on 20 cases. *Lancet*. 1945; **11**: 693.
5. Freyer P, One thousand cases of total enucleation of the prostate for radical care of that organ. *Br. Med. J.* 1912; **2**:868.
6. Ball A.J, Feneley R.C.L, and Abrams P.H. The natural history of untreated "prostatism". *Br J Urol*. 1981; **53**:613-16.
7. Braunwald E., Fauci A. S., Kasper D. L. et-al. *Harrison's Principles of internal Medicine*. 15th ed. McGraw- Hill inc.2001: **vol.1**: 736.
8. Spence R. K, Emerging trends in surgical blood transfusion. *Semin Hematol*.1997 Jul; **34** (3 Suppl 2): 48-53.
9. Thomas-Walker J.W. The Lettsomian lectures on enlarged prostate and prostatectomy. *Trans Med Soc Lond*. 1930; **53**:143- 220.
10. Abrams P. New words for old: lower urinary tract symptoms for "prostatism" (editorial). *Br Med J*. 1994; **308**:929- 30.
11. Serratta V, Morgia G, Fondacaro L et al. Open prostatectomy for benign prostatic enlargement in southern Europe in the late 1990s: a contemporary series of 1800 interventions. *Urology*. 2002 Oct; **60** (4): 623-7.
12. Luttwak Z, Lask D, Abaranel J et al. Transvesical prostatectomy in elderly patients. *J. Urol*. 1997; **157** (6): 2210-1
13. Thurston A.V, Briant S.L. Aspirin and post- prostatectomy haemorrhage. *Br J. Urol*. 1993; **71**:574-6.
14. Kirollos M.M, Campbell N. Factors influencing blood loss in trans-urethral resection of the

- prostate (TURP): auditing TURP. *Br J Urol.* 1997; **80**:111-15.
15. Thorpe AC, Cleary R, Coles J et-al. Deaths and complications following prostatectomy in 1400 men in the Northern Region of England. *Br J Urol.* 1994; **74**: 559-6.
 16. Nuttal G.A, Cragun M.D, Hill D.L et-al. Radical retropubic prostatectomy and blood transfusion. *Mayo Clin Proc.* 2002 Dec; **77** (12): 1301- 5.
 17. Shaheen A, Quinlan D, Feasibility of open prostatectomy with early vascular control. *Br J Urol.* 2004; **93**: 349–352.
 18. Hatch P.D, Surgical and anaesthetic considerations in trans-urethral resection of the prostate. *AIC.* 1987; **15**: 203-211.
 19. Madsen R.E, Madsen P.O. Influence of anaesthesia form on blood loss in trans-urethral prostatectomy. *Anaesthes Analgesia Curr Res.* 1967; **46**: 330-2.
 20. Pickard R, Emberton M, Neal D. E. National Prostatectomy Audit Study Group. The management of men with acute urinary retention. *Br J Urol.* 1998; **81**:712-20.
 21. Luke M, Krist E, Anderson F. et-al. Reduction of post-operative bleeding after trans-urethral resection of the prostate by local instillation of fibrin adhesive (Beriplast). *Br J Urol.* 1986; **58**:672-5.
 22. Lewi HJE, Hales DSM, Mahmoud S et-al. The characteristics of post- trans-urethra resection of prostate blood loss: a preliminary study. *Urol. Res.* 1983; **11**:29- 31.
 23. Ibrahim A.I. A, El-Malik E, Ghali A.M et-al. Effect of age, co-morbidity and type of surgery on peri-operative complications and mortality of prostatectomy. *Br J Urol.* 1995; **76**: 341-45.
 24. Abrams P.H, Shah P.J, Bryning K et-al. Blood loss during trans-urethral resection of the prostate. *Anaesthesia.* 1982; **37**: 71-3.
 25. Hill A.G, Njoroge P, Suprapubic- transvesical Prostatectomy in a Rural Kenyan Hospital. *East Afr. Med. J.* 2002 Feb; **79** (2): 65-67.
 26. Watson CJE, Deane AM, Doyle PT et-al. Identifiable factors in post-prostatectomy haemorrhage: the role of aspirin. *Br J Urol.* 1990; **66**: 85-7.
 27. Gavriiliuk A.I, Fibrinolytic haemorrhages in patients with prostatic adenoma treated with acetyl salicylate in pre-operative period. *Vrach-delo.* 1987; **1**: 96-98.
 28. Boral L.I, Hill S.S, Folland A, The type and antibody screen, Revisited. *Am. J. Clin. Pathol.* 1979; **70**: 578.

29. Smallwood J. A, Use of blood in elective surgery: An area of wasted resources. *Br. Med. J.* 1983; **286**: 868.
30. Omar M, Nyamongo J, Mc William J, *A report on Provision of Safe Blood for Transfusion: The Kenyan effort.* 2002.
31. Greenwalt T.J, Blood banking: *The surgical clinics of North America*, **58**:1095, 1978.
32. Mugenya G.W, Towards establishing a maximum surgical blood ordering schedule (MSBOS) at Kenyatta National Hospital. *Masters of Medicine (Surgery)*, 1995.
33. Niesen KK, Andersen K, Aspjorn J et-al. Blood loss in trans-urethral prostatectomy: epidural versus general anaesthesia. *Int. Urol Nephrol.* 1987; **19**: 287-92.
34. McGowan SW, Smith GFN. Anaesthesia for trans-urethral prostatectomy, a comparison of spinal intradural analgesia with two methods of general anaesthesia. *Anaesthesia* 1980; **35**: 847-53.
35. Freedman M, van der Malen S.W, Makings E. Blood loss measurement during trans-urethral resection of the prostate gland. *Br J Urol.* 1985; **57**: 311- 16.

APPENDIX I

Data collection instrument

(a) Pre- operative data

001. Patient No _____ 002. Age _____ 003. Clinical presentation
(i) Acute urinary retention _____ (ii) Chronic urinary retention _____
(iii) Hydronephrosis/ chronic renal failure _____ (iv) Residual volume of urine _____
(v) Bladder calculus _____ (vi) Prostatism as determined by the IPSS (Appendix III) _____
004. Systolic BP _____ 005. Bleeding disorders as per the medical records _____
006. History of drug use: i) Acetyl- salicylate _____ (ii) Heparin sulphate _____
(iii) Warfarin sodium _____ 007. ASA class _____
008. Pre- operative Hb _____ 009. Units of blood cross-matched
(i) Whole blood _____ (ii) Packed RBCs _____

(b) Intra- operative data

010. Surgeon: (i) Consultant _____ (ii) Senior registrar _____ (iii) Registrar _____
011. Type of anaesthesia: (i) Regional _____ (ii) General _____
012. Surgical approach: (i) Transvesical _____ (ii) Retropubic _____
(iii) Simple perineal _____
013. Weight of prostatic gland excised _____ grams
014. Units of blood transfused: autologous/ allogeneic
(i) Whole blood _____ (ii) Packed RBCs _____

(c) Post- operative data

015. Post- operative Hb (3rd day) _____ 016. Re- operation _____
017. Post- operative Hospital stay _____

APPENDIX II

CONSENT FOR ENROLMENT INTO THE STUDY

My name is Dr. Peter W. Saula. My supervisor and I are carrying out a research on open simple prostatectomy and blood transfusion. This study will enable us to assess blood transfusion requirements in patients undergoing prostatic surgery. Through this study, we will make recommendations that if implemented will minimize blood transfusion rate in this kind of surgery. All the information gathered shall be used solely for the purpose of medical research. You are under **no** obligation to either accept or refuse to be enrolled in this study, and your decision shall in **no** way affect any treatment you may receive in this hospital.

You will be enrolled upon giving consent and allocated a study number. You will undergo a normal history taking, physical examination, and investigations needed. The type of surgery done will also be documented. Thereafter, you will be monitored post-operatively for any complication that may arise till discharge. The blood samples will be collected before and after surgery purely for haemoglobin estimation.

You will only be identified by a study number, which will not even appear in the final report. Apart from the normal risks that any patient undergoing open simple prostatectomy faces, there are no extra risks that you will be exposed to in this study. Please feel free to ask any questions that may arise from the above explanation. Kindly sign below if you agree to enroll in this study.

PATIENT CONSENT FORM

I, _____ of _____ hereby consent to enroll into the study entitled Open Simple Prostatectomy and Blood Transfusion, the nature and effect of which have been explained to me by Dr. / Mr. _____
Date _____ Signed _____

I confirm that I have explained to the patient the nature of this study.

Date _____ Signed _____

APPENDIX III

The International Prostate Symptom Score

	Not at all	Less than 1 time in five	Less than half the time	About half the time	More than half the time	Almost always	Patient score
1 Incomplete emptying Over the past month, how often have you had a sensation of not emptying your bladder completely after you finished urinating?	0	1	2	3	4	5	
2 Frequency Over the past month, how often have you had to urinate again less than 2 hours after you finished urinating?	0	1	2	3	4	5	
3 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	
4 Urgency Over the past month, how often have you found it difficult to postpone urination?	0	1	2	3	4	5	
5 Weak stream Over the past month, how often have you had a weak urinary stream?	0	1	2	3	4	5	
6 Straining Over the past month, how often have you have you had to push or strain to begin urination?	0	1	2	3	4	5	
7 Nocturia Over the past month, how many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?	0	1	2	3	4	5+	
Total IPSS							

APPENDIX IV

American Society of Anaesthesiologists (ASA) grades of operative risk assessment

ASA Grade	Physical status
I	Normal, healthy
II	Mild systemic disease and no functional limitation
III	Moderate- to- severe systemic disease that results in some functional limitation
IV	Severe systemic disease that is functionally incapacitating and a constant threat to life
V	Moribund; no expected to survive 24 hours with or without surgery

APPENDIX V



KENYATTA NATIONAL HOSPITAL

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Date: 17 June 2004

Dr. Peter W Saula
Dept. of Surgery
Faculty of Medicine
University of Nairobi

Dear Dr. Saula

**RESEARCH PROPOSAL "OPEN PROSTATECTOMY AND BLOOD TRANSFUSION AT
KENYATTA NATIONAL HOSPITAL, NAIROBI" (P16/2/2004)**

This is to inform you that the Kenyatta National Hospital Ethics and Research Committee has reviewed and **approved** the revised version of your above cited research proposal for the period 17 June 2004 – 16 June 2005. You will be required to request for a renewal of the approval if you intend to continue with the study beyond the deadline given.

On behalf of the Committee, I wish you fruitful research and look forward to receiving a summary of the research findings upon completion of the study.

This information will form part of database that will be consulted in future when processing related research study so as to minimize chances of study duplication.

Yours sincerely,

**PROF. A N GUANTAI
SECRETARY, KNH-ERC**

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