

**THE SHORT TERM SUCCESS OF DIRECT VISION
INTERNAL URETHROTOMY (DVIU) IN THE
MANAGEMENT OF ANTERIOR MALE URETHRAL
STRICTURES**

**A dissertation submitted in part fulfilment of the requirements of the University of
Nairobi for the degree of Master of Medicine (M.MED) in GENERAL
SURGERY.**

By

DR. JAMES OMBOGA OSORO MBChB (MOI UNIVERSITY)

©2014

DECLARATION

Student's declaration

I hereby declare that this study is my original work and has not been presented for dissertation at any other university.

Dr. James Omboga Osoro, MBChB.

H58/70985/2009

Sign_____ Date_____

Supervisor's declaration

I hereby declare that this study is being submitted to the University of Nairobi for examination with my approval as the university supervisor.

Dr. Francis Owillah, MBChB (Nrb), M.MED (surg), cert. Urology.

Consultant urologist and lecturer,

Department of Surgery, University of Nairobi.

Sign_____ Date_____

Supervisor's declaration

I hereby declare that this study is being submitted to the University of Nairobi for examination with my approval as the university supervisor.

Prof. Peter Mungai Ngugi, MBChB (Nrb), M.MED (surg), cert. Urology

Department of Surgery, University of Nairobi.

Sign_____ Date_____

DEDICATION

I devote this dissertation to my parents Soteri Nyambane and Selefinah Kerubo whose persuasion, encouragement, and prayers greatly contributed towards the completion of this dissertation.

ACKNOWLEDGEMENT

I wish to convey my sincere gratitude to my supervisors Dr Owillah and Prof Mungai Ngugi for their guidance during the entire period of the study and writing of this dissertation.

I express my sincere appreciation to Prof Ndaguatha for his words of encouragement and guidance during this dissertation writing.

I wish to express my deep admiration to my family especially my dear wife Josphine Manyeki and daughters Joan, Nelly and Valerie. I acknowledge their patience and understanding during the entire study period.

TABLE OF CONTENTS

DECLARATION	ii
DEDICATION	iii
ACKNOWLEDGEMENT	iv
TABLE OF CONTENTS.....	v
LIST OF ABBREVIATIONS	vii
DEFINITION OF OPERATIONAL TERMS.....	viii
LIST OF TABLES	ix
LIST OF FIGURES.....	x
ABSTRACT.....	xi
INTRODUCTION.....	1
LITERATURE REVIEW	3
STUDY JUSTIFICATION	8
STUDY QUESTION.....	8
NULL HYPOTHESIS	8
STUDY OBJECTIVES.....	9
PATIENTS AND METHODS	10
STUDY LOCATION.....	10
STUDY DESIGN	10
STUDY POPULATION	10
INCLUSION CRITERIA.....	10
EXCLUSION CRITERIA.....	10
STUDY DURATION	11
STUDY END POINTS.....	11
SAMPLE SIZE ESTIMATION	12
SAMPLING METHOD.....	13
ETHICAL CONSIDERATIONS	14
DATA COLLECTION AND ANALYSIS	15
RESULTS	18
Characteristics of urethral strictures	19
Anterior male urethral stricture length.....	20
The causes of anterior male urethral strictures.....	22
The uroflowmetry measurements in male anterior urethral stricture disease.....	22

The average flow rates	25
Changes seen in the Voiding curve patterns	25
The re-operation rate for male anterior urethral strictures managed using DVIU procedure	27
DISCUSSION	28
CONCLUSIONS	31
RECOMMENDATIONS.....	31
REFERENCES.....	32
Appendices:	36
Appendix 1	36
Appendix 2.....	39
Fomu ya idhini	39
Appendix 3.....	42
Study data collection form	42
LETTER OF APPROVAL FROM KNH/ERC	44
APPENDIX 5.....	46
STUDY TIME FRAME.....	46
Declaration Form for Students	47
Declaration Form for Staff.....	48

LIST OF ABBREVIATIONS

DVIU- Direct vision internal urethrotomy

KNH- Kenyatta National Hospital

Q max- maximum flow rate

RUG- retrograde urethrography

MCU- micturating cystourethrogram

TURP- Transurethral resection of prostate

POS- passage of sounds

ANOVA- analysis of Variance

Fr- French gauge

mm- millimetres

cm- centimetres

ml/s -millilitres per second

ml- millilitres

DEFINITION OF OPERATIONAL TERMS

- Pre operative period- one day before the DVIU procedure.
- Immediate post operative period- 24 hours after the DVIU procedure.
- Twelve weeks post operative period- a period of twelve weeks starting from the first day after the DVIU procedure.
- DVIU procedure- a single incision with a cold knife at 12 o'clock position in the male urethra in lithotomy position with a subsequent insertion of a silicon coated size 20Fr Foleys urethral catheter for a duration of 24 hours after the DVIU procedure.

LIST OF TABLES

Page

Table 1: Location of anterior urethral strictures according to the patients' age group.....20

Table 2: Stricture length and its association with bulbar or penile location.....21

Table 3: Aetiology of urethral strictures in patients undergoing DVIU at KNH.....22

Table 4: Shows the uroflowmetry measurements done during the study.....24

Table 5: Repeat surgical procedures conducted following DVIU.....27

LIST OF FIGURES

	Page
Figure 1: Percentage age distribution of male patients with urethral strictures at KNH.....	18
Figure 2: Location of urethral strictures among male patients undergoing DVIU at KNH...19	19
Figure 3: Linear regression analysis of the patient's age and the stricture length.....	21
Figure 4: Changes in voiding curve patterns seen before and after DVIU procedure.....	25
Figure 5: showing the trends in the patients' voiding curve patterns.....	26

ABSTRACT

Background: The male urethral stricture disease is a common urethral tract disease that occurs in all age groups. Direct vision internal urethrotomy (DVIU) is a common intervention procedure for anterior male urethral strictures less than two centimetres in length. The outcome studies on DVIU procedure have shown a wide range of success rates. The purpose of this study was to evaluate the short term success of DVIU in treating male anterior urethral strictures in patients presenting to Kenyatta National Hospital (KNH).

Objective: To determine the short term uroflowmetry outcomes after the DVIU procedure in male anterior urethral strictures treatment at KNH using uroflowmetry measurements.

Study design: This was a prospective descriptive study.

Study Setting: The general surgical wards, the minor theatre in clinic 24 and the urology outpatient clinic in Kenyatta National Hospital, in Nairobi, Kenya.

Patients and methods: Sixty six consenting male patients above the age of eighteen years old presenting to KNH with anterior urethral strictures less than two centimetres in length as per their RUG/MCU films were studied. The following data was obtained: maximum flow rate (Q max), average flow rate per second, voided volume and a voiding curve from a urodyne100 uroflowmetry machine stationed at the minor theatre in clinic 24. These uroflowmetry results were obtained in the pre operative period, the immediate post operative period and at twelve weeks post operation during the follow up of the patients.

Results: A total of 66 male patients with anterior urethral strictures were included in the study. The mean preoperative maximum flow rate was 7.2 ± 5.2 .

The Q max rate increased significantly by an average of 6.1 mls/sec (95% CI 3.9-8.2) in the immediate post intervention period ($p < 0.001$) and by 3.1mls (95% CI 2.3-3.8) at 12 weeks

follow up post operation ($p < 0.001$). In the pre operative period 63 patients (95.4%) had flat voiding curves. The percentage of patients with flat voiding curves reduced to 57.6% in the immediate post operation period. At twelve weeks post intervention 63.4% of patients had flat voiding curves. A total of five patients had a re-operation during the study period. The reoperation rate for the urethral strictures was 7.6%.

Conclusion: The maximum flow rates achieved during DVIU procedure has a significant decline by twelve weeks post operation .The DVIU procedure may be used as a palliative procedure while awaiting a definitive procedure for male anterior urethral strictures less than two centimetres in length.

INTRODUCTION

Urethral stricture disease is a common global disease that affects all age groups ^{1, 7, 16, 37}. Urethral strictures continue to be a great burden on the patients' health and their quality of life ^{2, 7, 13}. The morbidity of urethral stricture disease and the costs of treating it are also quite significant ^{3, 4}.

Urethral strictures treatment dates back to the sixth (6) century and since then several treatment procedures have been utilised for urethral stricture disease treatment ^{7, 16}. The commonest and widely utilised initial techniques in male urethral stricture disease treatment are still DVIU and bouginage despite their varied success rates ^{8, 10, 16, 21, 22}.

The classical DVIU procedure done today is the one initially popularised by Hans Sachse in 1971 ¹⁰. It is a minimally invasive transurethral endoscopic procedure done under general anaesthesia, spinal anaesthesia or local anaesthesia. Cystoscopy is done at the outset to visualize the urethral stricture and then a guide wire is passed through the urethral stricture. The standard technique involves making an incision at 12 o'clock position in lithotomy position using a cold knife ^{2, 10, 23}. The incision at 12 o'clock results in a full thickness division of the urethral stricture and widening of the urethral lumen at the stricture site. A urethral catheter is usually inserted after the DVIU procedure and removed after a variable period of time ranging from one day to six weeks ^{2, 10}. The other modifications for the DVIU procedure includes making radial incisions at 10, 2, 6 o'clock positions but have not yielded a better outcome than the classical DVIU procedure ¹⁰.

The main application for direct vision internal urethrotomy is in the treatment of strictures in the male anterior urethra ⁹. Outcome studies on DVIU have shown a wide range of success rates ^{10, 31}. Earlier reports had shown high success rates associated with DVIU in treating urethral strictures ²⁰.

Studies done Later have shown that the success rate for DVIU is far less than earlier reported^{10, 31}. Consequently the place of DVIU in male anterior urethral strictures management has been questioned.

This study intended to assess the short term success of DVIU in the treatment of male anterior urethral strictures at KNH, a tertiary care hospital in Kenya. This will help to determine whether the common utilization of DVIU is justified by its success rate in this set up.

LITERATURE REVIEW

The actual incidence of urethral strictures is not known but is estimated to be 0.6% in the vulnerable population. The incidence rises with age^{3, 27}. In Kenya, urethral strictures have a peak between the ages of twenty to fifty years¹³ unlike in the USA where the elderly population is the most affected²⁷.

The trends in urethral strictures causation in Kenya are similar to those reported in the developed countries^{8, 29}. Urethral strictures due to trauma are now more than those from inflammatory conditions^{2, 29}. Adwok had found in 1985 that post infective strictures were the commonest cause of urethral strictures at KNH¹⁹. A study done later at KNH found that the commonest cause of urethral strictures was now trauma¹³. However, the commonest cause of urethral strictures reported in Senegal was still gonococcal urethritis⁵.

The site and length of a urethral stricture are some of the factors that determine the treatment option to be adopted in treating urethral strictures^{6, 7, 10, 16, 19}. Strictures in the anterior male urethra accounted for 61.4% of all the strictures while those in the posterior urethra accounted for 38.6%. 62.1% of the patients studied had urethral stricture lengths of less than two (2) centimetres⁶. These findings were similar to those found in Senegal whereby the anterior urethra's bulbar region was the commonest site for strictures accounting for 72.7% and 59.6% of all the urethral strictures were less than one centimetre in length⁵.

Direct vision internal urethrotomy has been in common use from the early 1970s^{4, 30, 31}. It is still among the commonest interventions used in treating urethral strictures^{9, 10, 13, 22, 32, 37}. It is simple to use, has a shorter learning curve than urethroplasty and has a short convalescence period¹⁰. DVIU was being used by 97% of the urologist in Netherlands for urethral stricture disease³² and by 86% of the urologists in the USA in treating urethral stricture disease²².

Direct vision internal urethrotomy was the second most utilised technique after Passage of sounds (POS) in the treatment of male urethral strictures at KNH ¹³.

The outcome studies on DVIU have had a wide range of results and the reported success rates for DVIU varies from 20% to 60% ^{10, 31}. Pansadoro et al had found that the recurrence rate after one urethrotomy was 68% overall but bulbar urethra strictures had a lower recurrence rate of 58% after one DVIU as compared to strictures in the penile urethra which had a recurrence rate of 84% ²⁰. The length of the urethral stricture determined the treatment outcome. The success rate for bulbar urethral strictures less than 10mm in length was 71% and 18% for strictures longer than 10mm in length. Multiple urethral strictures had a poor outcome after a DVIU procedure ¹⁸.

A study done in Tanzania on urethral strictures found the success rates for DVIU to be 88.4% and 35.5% at three months and twenty six months post operation respectively. The failure rate of strictures in the posterior urethra was three times higher than those found in the anterior urethral. The outcome measure used in the study was the occurrence of complications during the follow up period ⁶.

Richard had reported a success rate of 8% for the initial urethrotomy at one month follow up and they had projected that the success rate for DVIU was likely to be zero with longer follow up ³¹. They noted that the previous studies had overestimated the successes of DVIU and concluded that DVIU should only be used as a provisional measure while awaiting definitive surgery for urethral strictures ³¹.

A study done at KNH on outcomes of urethral strictures treatment found the success rate for DVIU to be 42.3 % ¹³. Direct vision internal urethrotomy had the best immediate results at 94% as compared to other modalities of treatment. Recurrence of symptoms after DVIU was 53.2% during the study period.

The criteria used to determine the success rate of the procedures done was based on the patient's subjective assessment of the quality of the urinary stream after treatment ¹³. The lack of consensus on the criteria of determining success rates after DVIU procedures is partly a reason for a wide range of success rates reported by urologists after DVIU procedure ¹⁰.

There are factors which determine the outcome of urethral strictures treatment .They include the site of the urethral stricture, the aetiology of the stricture and the length of urethral stricture. Urethral strictures more than two centimetres in length had more recurrences than those less than two centimetres in length. Bulbar strictures had less recurrence rates than penile urethral strictures. Strictures due to TURP had poor outcomes after DVIU in this study ¹¹. Poor success rates were associated with increasing percentage of urethral luminal narrowing ²⁵.

The place and role of DVIU in urethral stricture management ladder has been questioned. Conflicting views have been put forward regarding when DVIU procedure should be used in urethral stricture treatment ^{4, 10, 12, 37}. A study done in Italy found that DVIU was still the commonest utilised technique for urethral stricture treatment despite the high failure rates and frequent need for repeat surgery ⁹. Bullock and Brandes concluded that the high utilisation of DVIU they found in USA was improper. Its' choice was not based on literature findings and was mainly due to lack of being conversant with urethroplasty techniques. The overuse of DVIU was not consequently beneficial to the patients in the long run ^{22,37}.

Direct vision internal urethrotomy just like urethral dilatation in the treatment of urethral strictures is not curative. These two procedures are more likely to subject patients to many repeat surgeries. Direct vision internal urethrotomy thus ought to be utilised as a palliative procedure in urethral stricture disease treatment^{18, 23}. Urethroplasty should thus be used as an initial treatment option in anterior urethral strictures ³⁷.

Some urologists still recommend DVIU to be utilised in the treatment of anterior urethral strictures less than two centimetres in length ¹⁷.

Urethroplasty was found to be less costly than direct vision internal urethrotomy in the treatment of short bulbar urethral strictures ⁴. Urethroplasty was thus recommended over DVIU as the initial procedure in short bulbar urethral strictures in regard to the cost of the procedure⁴. This was contrary to the findings of Wright et al who however favoured the continued utility of DVIU as an initial procedure for short bulbar urethral strictures. They had found that it was more cost effective to the patient in doing DVIU as an initial procedure and then do urethroplasty only for those strictures that recurred ¹².

Uroflowmetry is a common procedure in urology. It provides an objective and quantitative information on the voiding patterns of a patient. Uroflowmetry is the commonest primary tool utilised in screening for recurrences of urethral strictures after interventions. The voided flow rate was the commonest parameter used to assess urethral stricture recurrence ^{14, 15}. It is also used to assess the efficacy of a procedure in urethral strictures ¹⁴.

Mundy in a treatise of urethral strictures noted that urethral strictures produced distinctive features in uroflowmetry. He documented that normal voiding during uroflowmetry will produce a curve that is bell shaped with an even outline. An abnormal voiding produces a voiding curve that is normally flat in shape. He further reported that a normal flow rate in both young and middle aged men is likely to be above 15ml/sec but the peak flow rate in a patient with urethral stricture is likely to be low. The peak flow rates less than 5ml/s will most often suggest that there is a urethral obstruction and these patients have a high risk of acute urine retention. ¹. A minimum voided volume of 125-150mls is required to be able to predict an abnormality from a uroflowmetry reading ¹⁵. The pattern of voiding curves is used to screen for voiding abnormalities ²⁸.

The comparison of pre-operative and post-operative maximum flow rate values and voiding curves will reliably show the success or failure of a procedure in relieving urinary obstructive symptoms. A successful procedure will have significant changes in peak flow rate and the pattern of the voiding curve as compared to pre operative values. The mean change in Q max for successful procedures was 19.2 ml per second and for unsuccessful procedures it was 0.2 ml per second. The number of voiding curves with a flat pattern reduced from 92.5% to 29.7% for successful operations ¹⁴.

Uroflowmetry was used to assess the efficacy of clean intermittent self catheterization as compared to urethral dilatation. The mean flow rates for the two procedures were compared at baseline, three months and at six months to assess the efficacy of each method. Clean intermittent self catheterization had a better rise in urine flow rates during follow up of patients as compared to repeat urethral dilatation with sounds ³².

STUDY JUSTIFICATION

The current role and place of DVIU as an intervention in the male anterior urethral strictures treatment has been questioned ^{4, 10, 25, 37}. The outcome studies done in other regions have reported a wide range of success rates, varying from 20% to 60%, for DVIU in male urethral strictures treatment ^{10, 31}. Conflicting views have been put forward regarding when DVIU procedure should be used in urethral stricture treatment ^{4, 10, 12, 37}. Some authors recommend that the use of DVIU is not beneficial to patients in the long run ^{4, 22, 27, 31} while others still advocate for its use as an initial procedure in urethral stricture treatment¹².

A study done previously at KNH on the outcome of interventions in urethral strictures treatment was a retrospective study. It was recommended in that study that a further prospective study be done possibly using uroflowmetry as one of the outcome measures to assess success rates in urethral stricture treatment. A prospective study was thus needed to assess the success rate of DVIU procedure in male anterior urethral strictures treatment at KNH and determine whether its continued use is justified by outcome studies.

STUDY QUESTION

What is the short term success of DVIU in the treatment of male anterior urethral strictures at KNH?

NULL HYPOTHESIS

There is no difference between the pre operation uroflowmetry measurements and the post operation uroflowmetry measurements at twelve weeks follow up period after DVIU procedure in anterior male urethral strictures treatment.

STUDY OBJECTIVES

A) Main objective

To determine the short term uroflowmetry outcomes after the DVIU procedure in male anterior urethral strictures treatment at KNH using uroflowmetry measurements.

B) Specific objectives

- i. To compare the maximum flow rates and the average flow rates obtained in the pre operative period with those corresponding maximum flow rates and the average flow rates obtained in the immediate post operative period and at twelve weeks post operation period.
- ii. To compare the pattern of the voiding curves obtained in the pre operative period, the immediate post operative period and at twelve weeks post operation period.
- iii. To determine the reoperation rate of male urethral strictures after DVIU procedure at three months post operation.

PATIENTS AND METHODS

STUDY LOCATION

The study was conducted at KNH general surgical wards, the minor theatre in clinic 24 and the urology outpatient clinics. Kenyatta National Hospital receives referrals from all over Kenya and from some parts of East Africa.

STUDY DESIGN

This study was a prospective descriptive study.

STUDY POPULATION

The study involved adult male patients with anterior urethral strictures scheduled for DVIU procedure at KNH during the study period.

INCLUSION CRITERIA

The patients selected for the study included all consenting male patients above 18 years old with anterior urethral strictures less than two centimetres in length who had been scheduled for DVIU procedure at KNH. Recruitment for the study was done by the principal investigator and the attending urologist in the KNH urology clinic. The recruiting clinicians provided informed consent to the patients.

EXCLUSION CRITERIA

- i. Patients with multiple urethral strictures
- ii. Patients with complete urethral obstruction on MCU/ RUG
- iii. Patients who had undergone previous DVIU intervention
- iv. Patients with a confirmed neuropathic bladder
- v. Patients who refused to sign informed consent
- vi. Patients whose age is below 18 years

STUDY DURATION

The study was conducted between the month of July 2012 and June 2013.

STUDY END POINTS

The last data was collected from the individual patients twelve weeks after the first DVIU procedure during the study duration.

SAMPLE SIZE ESTIMATION

The sample size was calculated using the formulae for estimating sample size for continuous outcomes in paired comparisons proposed by Guenther:

$$n = \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2}{d^2} + \frac{Z_{1-\alpha/2}^2}{2}$$

Here, d (standardised difference) = $\frac{\delta}{\sigma_d}$ is set at 0.4, where δ is the effect size to be detected (in this study a change of maximum flow rate from 11.8 ml per second reported by Bradley to at least 15 ml per second i.e. 5 ml per second)¹⁴ and σ_d is taken as the standard deviation of the difference between maximum flow rate (Q max at baseline – Q max at follow up)

$Z_{1-\frac{\alpha}{2}} = 1.96$ indicating significance at 0.05 level.

$Z_{1-\beta} = 1.28$ giving 90% power to detect a difference of 5 ml per second

$$n = \frac{(1.96+1.28)^2}{0.4^2} + \frac{1.96^2}{2}$$

To detect an average difference of 5 ml per second in maximum flow rate with a two-sided α of 0.05 and a power of 0.90, at least 68 patients were needed.

SAMPLING METHOD

Consecutive sampling was carried out to select patients for the study. The patients for the study were selected from the urology surgical outpatient clinics by the principal investigator and the urologists running the urology clinic.

The patients with anterior urethral strictures were identified from those patients attending the urology outpatient clinic. The length of the urethral strictures on the RUG/MCU films was measured by the principal investigator. The RUG/MCU films are usually taken with a radiographic ruler to aid in the measurement of length in order to avoid exaggeration of the length of the urethra due to magnification error in the process of taking the film. A half open vernier calliper was used to estimate the length of the anterior urethral stricture on the RUG/MCU film. This estimated length using the vernier calliper of the urethral stricture was then measured on the radiographic ruler on the same RUG/MCU film to give the actual length of the anterior urethral stricture.

Those adult male patients with anterior urethral strictures less than two centimetres and who met the study inclusion criteria were selected. Informed consent was given to these patients and those patients who signed the study consent form or consent form signed on their behalf by a guardian were selected for the study.

The patients selected for the study were subjected to the routine booking for surgery and admitted one day before surgery to one of the general surgical wards.

ETHICAL CONSIDERATIONS

Approval to conduct the study was sought from the UON department of surgery and KNH/UON Ethics and Research Committee. The collection of data for the study began once the request to conduct the study was granted.

All the patients selected for the study were requested to sign an informed consent or the consent was signed on their behalf by their guardian before data was collected from them. The informed consent was administered by the principal researcher or attending urologist in the KNH urology clinic. The selected patients were informed that participating in the study was voluntary and that withdrawing from the study at any time was not to interfere with their right to receive treatment at the hospital. Patient's confidentiality was assured by not disclosing the patient's name in the data collection form.

DATA COLLECTION AND ANALYSIS

The patients selected for the study underwent the routine history taking and physical examination by the principal investigator or the urologist in the urology clinic. The following data about the patient was entered in the standard data collection form: the IP number, the mobile phone number, the study number, the recruitment date, the age in years, the cause of the anterior urethral stricture if known and the length of the urethral stricture by the principal investigator.

The procedure for uroflowmetry measurements was explained to the patients by a trained nurse stationed in minor theatre in clinic 24 and she took the uroflowmetry measurements. The uroflowmetry measurements were done in the minor theatre in clinic 24 from the Urodyne 100 machine stationed in the minor theatre. Each patient was requested to come for uroflowmetry measurements when his bladder was full. The patient was asked to void into a funnel connected to the Urodyne 100 uroflowmetry machine located in a privately secured room in minor theatre in clinic 24. The patient was requested to repeat voiding after some time when his bladder was full again if the voided volume was less than 125mls.

Pre operative Q max, average flow rate per second, voided volume and the pattern of the voiding curve from the uroflowmetry readings were recorded in the respective patient's data collection form by the principal investigator. The voiding curve was automatically generated by the Urodyne 100 uroflowmetry machine together with the Q max, voided volume and the average flow rate per second as uroflowmetry results. The pattern of the voiding curve generated by the uroflowmetry machine was interpreted and recorded in the data collection form as either being bell shaped (normal curve) or flat shaped (abnormal curve) by the principal investigator in minor theatre. The data entered in the data collection form was only for those patients with voided volumes above 125mls.

The immediate post operative uroflowmetry readings were obtained upon the removal of the silicon coated size 20Fr. Foleys urinary catheter 24hours to seven days after the DVIU procedure. These patients were taken to the minor theatre in clinic 24 for uroflowmetry readings by the principal investigator when their bladder was full. The same procedure for uroflowmetry as was done during the pre operative period was repeated. The obtained Q max, average flow rate per second, voided volume and the pattern of voiding curve was entered in the respective patient's standard data collection form.

A third uroflowmetry reading was done at twelve weeks post operation. This was done when the patient come for routine review post operation in the urology clinic. The patients were sent to the minor theatre for uroflowmetry measurements after he had been examined by the attending urologist or principal investigator. The same procedure for uroflowmetry as was done during the pre operative period was repeated. The obtained Q max, average flow rate per second, voided volume and the pattern of voiding curve were entered in the respective patient's standard data collection form.

The number of any repeat surgery done due to recurrence of lower urinary tract symptoms after DVIU procedure during the twelve weeks post operation period was recorded in the respective patient's standard data collection form by the principal investigator. This information was obtained from the operation notes in the patient's file.

To ensure consistency and reproducibility of all uroflowmetry results the following were done and repeated for all the clients. The recruitment of the patients for the study was done by the principal investigator and attending urologists who had read the research proposal. The principal researcher was tasked with the responsibility of explaining the procedure of uroflowmetry to the patients and take uroflowmetry measurements.

The same urodyne 100 uroflowmetry machine was used to obtain uroflowmetry results for all the recruited patients during the study period.

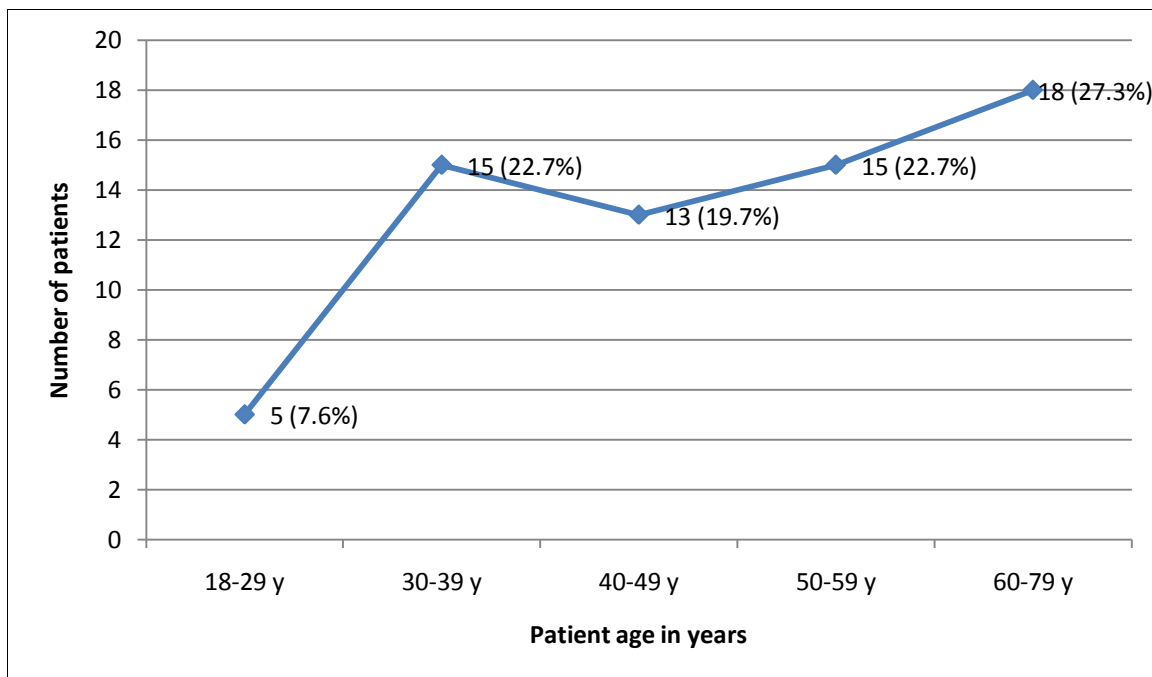
The obtained uroflowmetry results were entered in the data collection form by the principal investigator. The entire automatically generated voiding curves from the urodyne 100 uroflowmetry machine were interpreted by the principal investigator. All the data obtained in the pre-operative period, the immediate postoperative period and at twelve weeks postoperative period was entered in the standard data collection form by the principal investigator.

RESULTS

Sixty-eight (n = 68) male patients fitted the inclusion criteria and were recruited in the study. A total of two (2) patients were excluded from the study due to inadequate uroflowmetry studies and loss to follow up and were not included in the analysis. All the patients in the study were black African males.

The average age of the participants was 49.6 years (SD 15.3) and the age range was 18-79 years (Figure 1). Approximately 8% of patients with anterior urethral strictures were below 30 years of age. Those patients with anterior urethral strictures in the age group of 60-70years accounted for approximately 27% of all the patients in the study (Figure 1).

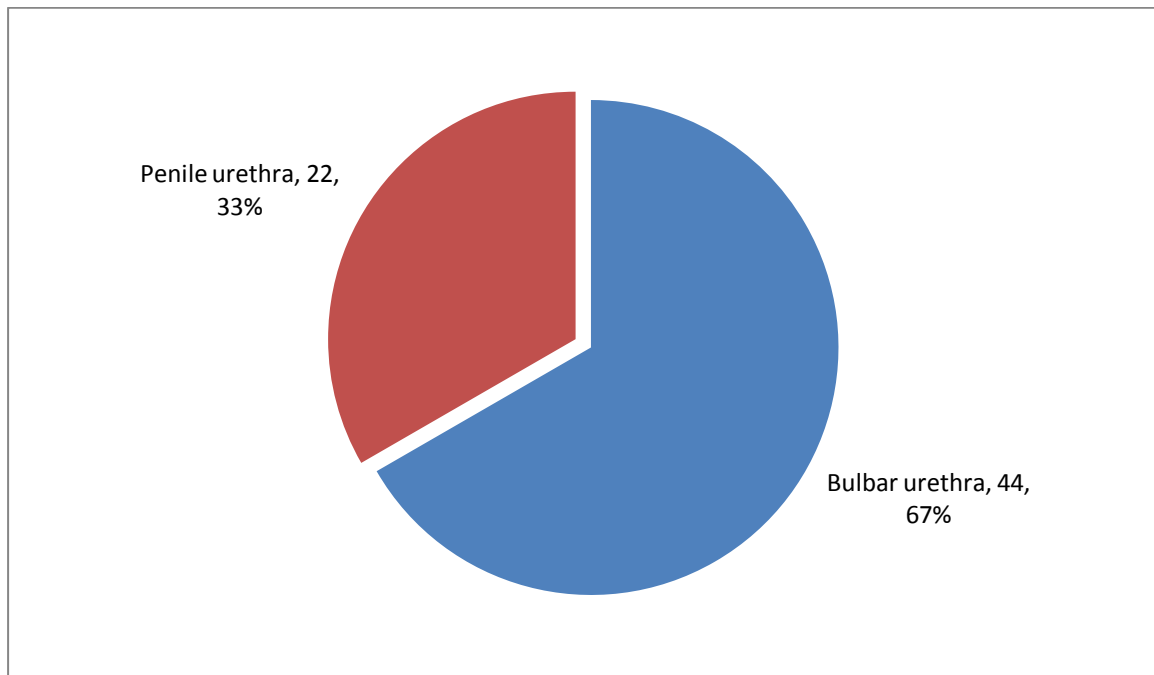
Figure 4: Percentage age distribution of male patients with urethral strictures at KNH



Characteristics of urethral strictures

The location of anterior urethral strictures among the patients in the study is presented in Figure 2. Forty-four (67%) patients had urethral strictures in the bulbar urethra. Twenty two (33%) of the patients in the study had urethral strictures in the penile urethra.

Figure 5: Location of urethral stricture among male patients undergoing DVIU at KNH



All the patients presenting with anterior urethral strictures before 30 years of age had urethral strictures located in the bulbar urethra (Table 1). Most penile urethral strictures occurred in the age groups 30-39 years (7 out of 22) or 50-59 years (6 out of 22). There was, however, no statistically significant association between the anterior urethral stricture location and the age of the patients ($p = 0.40$).

Table 1: Location of anterior urethral strictures according to the patients' age group

				P value
	Bulbar	Penile	Total	
Patient age in years				
18-29 y	5	0	5	0.40
30-39 y	8	7	15	
40-49 y	9	4	13	
50-59 y	9	6	15	
60-79 y	13	5	18	
Total	44	22	66	

Anterior male urethral stricture length

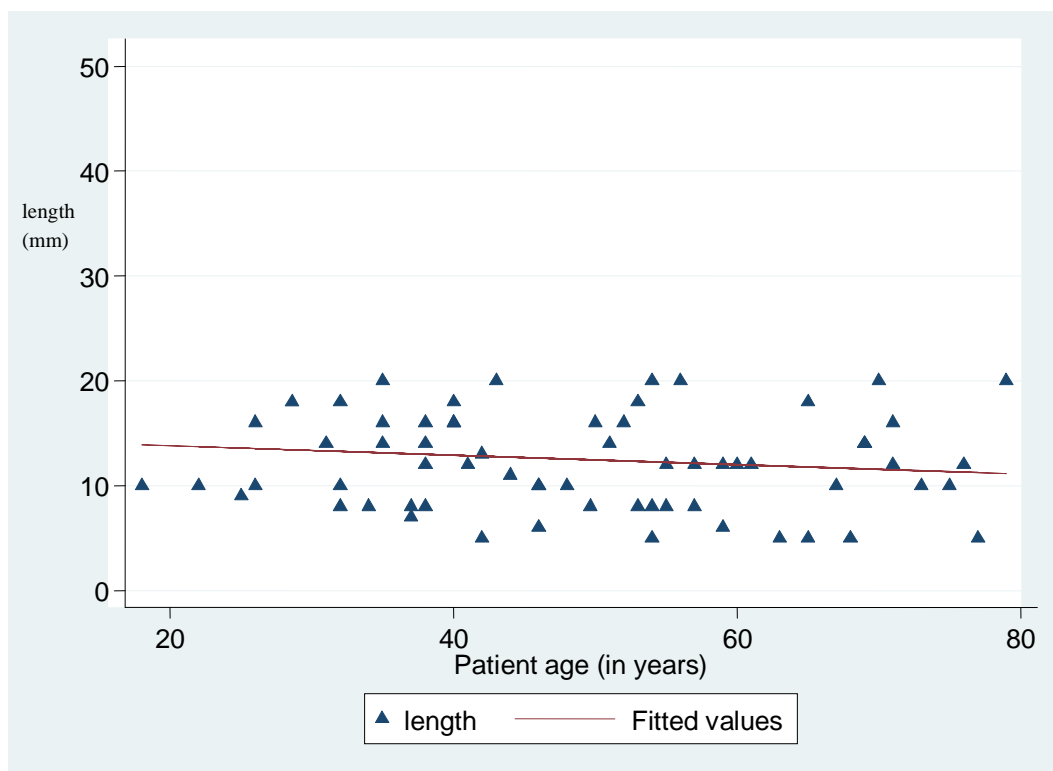
The stricture lengths studied were those anterior urethral strictures less than twenty (20mm) millimetres. The mean length of anterior male urethral strictures was 12.5 mm (SD 6.6), range (5 to 20 mm). On average, penile urethral strictures were longer than bulbar urethral strictures (difference 2.4 mm, 95% CI -0.97 to 5.8 mm) but the difference in the length of the anterior urethral strictures was not significant ($p = 0.16$) as shown in Table 2.

Table 2: Stricture length and its association with bulbar or penile location

	Mean length (SD)	Range(mm)	P value
Stricture location			
Bulbar	11.7 (1.1)	5 - 20	0.16
Penile	14.1 (0.9)	7 - 20	
Difference (95% CI)	2.4 mm (-0.97 to 5.5)		

Figure 3 shows the findings of a linear regression analysis of anterior male urethral stricture length and the patients' age. The male urethral stricture length reduced by 0.04 mm (95% CI - 0.2 to 0.06) for each additional year in age but this reduction was not statistically significant ($p = 0.41$).

Figure 6: Linear regression analysis of relationship between patient age and the urethral stricture length



The causes of anterior male urethral strictures

The main cause of male anterior urethral strictures was trauma accounting for 34 (51.2%) of the patients studied as shown in Table 3.

Inflammation of the anterior male urethra was the second commonest known cause of male anterior urethral stricture (19.7%) while the remaining male urethral strictures were idiopathic.

Table 3: Aetiology of urethral strictures in patients undergoing DVIU at KNH

	Number	Percent (%)
Aetiology		
Trauma	34	51.5
Inflammatory	13	19.7
Idiopathic	19	28.8
Total	66	100

The uroflowmetry measurements in male anterior urethral stricture disease

Table 4 shows the uroflowmetry measurements done during the study including maximum flow rates, average flow rates and the voiding curve patterns.

a) Maximum flow rate

As shown in table 4 the maximum flow rate increased significantly in the post intervention period compared to the pre intervention period. Before DVIU, the mean maximum flow rate was 7.2 ± 5.2 . This rate increased significantly by an average of 6.1 mls/sec (95% CI 3.9-8.2) in the immediate post intervention period ($p < 0.001$).

The maximum flow rate had increased by 3.1mls (95% CI 2.3-3.8) at 12 weeks follow up post operation ($p < 0.001$) as compared to the pre operative period.

This shows a decline of an average of 3mls/sec from the immediate postoperative period up to twelve weeks post operation period.

b) Voiding volume

As shown in table 4, the average voiding volume increased significantly after DVIU procedure from 141.8 ± 22.4 to 160.6 ± 36.4 post intervention ($p = 0.0003$) and 159.4 ± 41.5 at 12 weeks ($p = 0.0004$).

Table 4 shows the uroflowmetry measurements done during the study.

	Pre intervention (mean ± SD)	Post intervention (mean ± SD)	12 weeks post intervention (mean ± SD)
Maximum flow rate	7.2 ± 5.2	13.3 ± 10.9	10.3 ± 6.3
-	-	-	-
Difference post vs. Pre intervention	-	6.1 (95% CI 3.9-8.2)	3.1 (95% CI 2.3-3.8)
P Value	-	< 0.001	< 0.001
Average flow rate	4.4 ± 2.1	6.3 ± 4.3	5.2 ± 3.3
-	-	-	-
Difference post vs. Pre intervention	-	1.9 (95% CI 1.0-2.8)	0.8 (95% CI 0.3-1.3)
P Value	-	0.0001	0.003
Voiding volume	141.8 ± 22.4	160.6 ± 36.4	159.4 ± 41.5
-	-	-	-
Difference post vs. Pre intervention	-	18.9 (95% CI 9.0-28.5)	17.6 (95% CI 8.1-27.1)
P Value	-	0.0003	0.0004

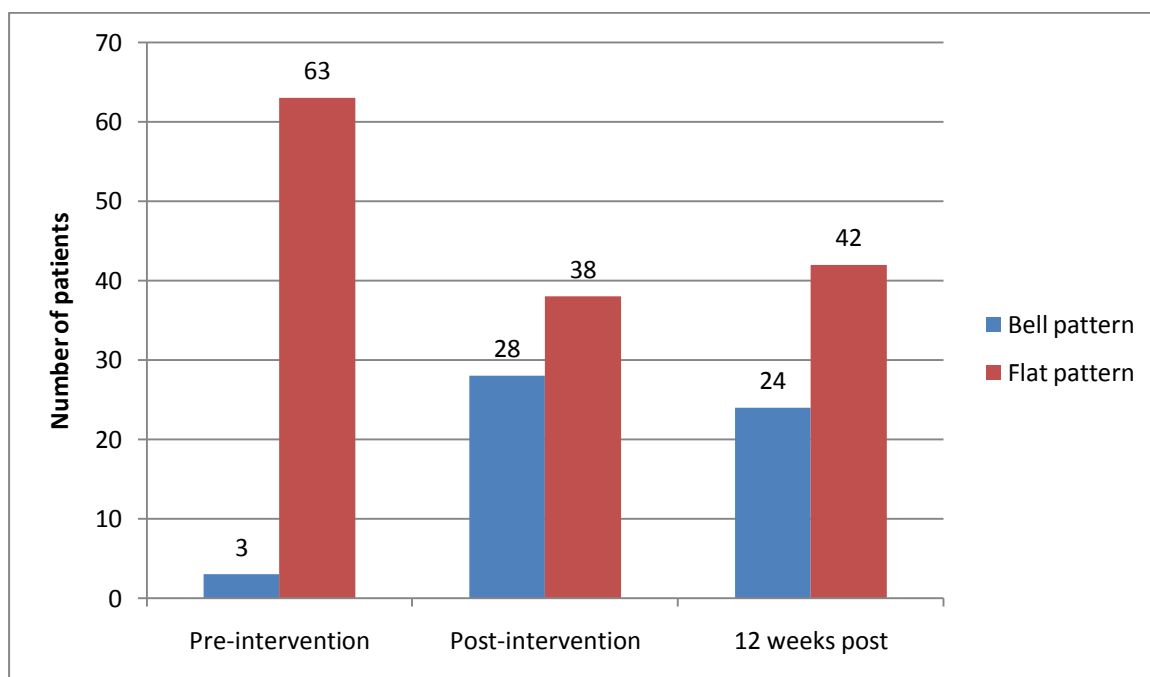
The average flow rates

The average flow rate increased in the immediate postoperative period by an average of 1.9mls/second. At twelve weeks post intervention the average flow rate had increased by an average of 0.8mls/sec as shown in Table 4 above.

Changes seen in the Voiding curve patterns

Figure 4 below shows the changes obtained in the patients' voiding curve patterns from the uroflowmetry measurements in the pre operative period, in the immediate post operative period and at twelve months follow up during the study.

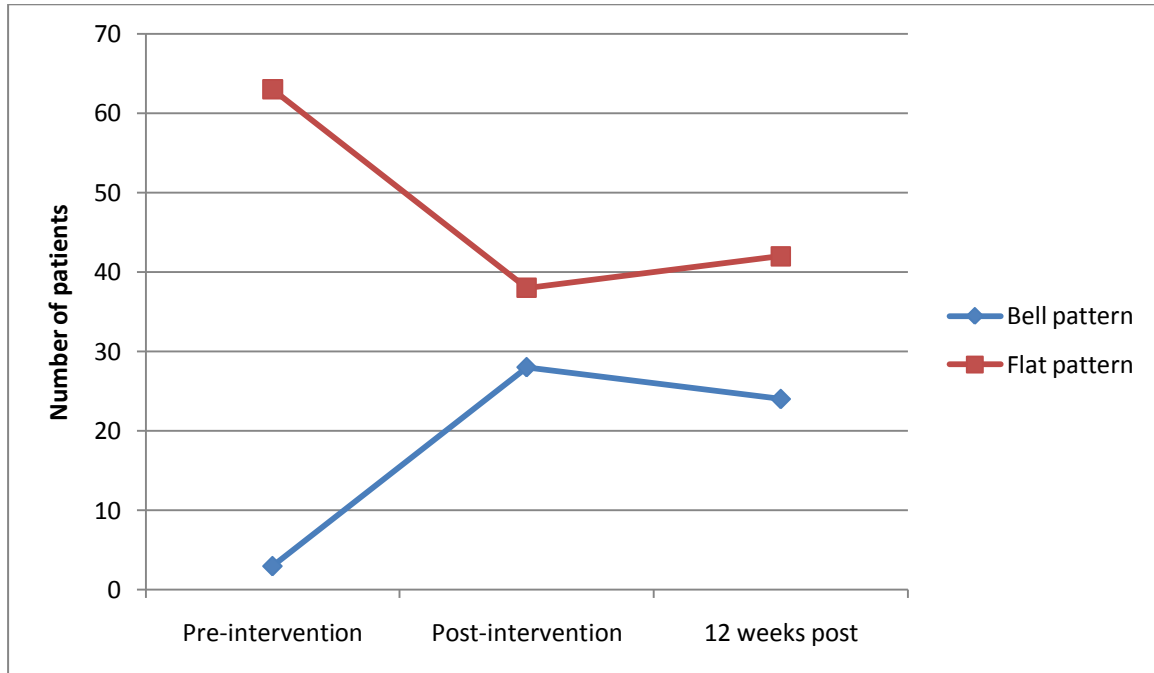
Figure 4: Changes in voiding curve patterns of urethral strictures before and after DVIU procedure



In the preoperative period 63 patients (95.4%) had flat voiding curves while three (3) patients had bell shaped voiding curve patterns. The number of patients with flat voiding curve patterns reduced from 63 (95.4%) in the pre-intervention period to 38(57.6%) after the DVIU procedure. The percentage reduction in the number of patients with flat voiding curves was 37.8% after the DVIU procedure in the immediate post operative period.

At twelve weeks post intervention 42 patients (63.4%) had flat voiding curves while only 24 patients (36.6%) had bell shaped voiding curve patterns.

Figure 5 showing the trends in the patients' voiding curve patterns



The number of flat shaped voiding curves showed a significant decline in the immediate postoperative period. There was however a gradual increase in the number of patients with flat voiding curves at twelve weeks post operation.

The number of patients with bell shaped voiding curves showed a significant increase in the immediate post operation from the pre intervention period. There was however a gradual decrease in the number of patients with bell shaped curves at twelve weeks.

The re-operation rate for male anterior urethral strictures managed using DVIU procedure

A total of five patients (7.6%) out of the sixty six (66) patients with anterior urethral strictures underwent repeat surgery following the performance of the initial DVIU procedure. These repeat surgical procedures done for the anterior urethral strictures were all urethroplasty (Table 5).

Three urethroplasty procedures were conducted in patients with bulbar urethral strictures and the remaining two in those patients with penile urethral strictures. Three of the urethroplasty procedures were done in patients with anterior urethral strictures of unknown aetiology. A single repeat procedure was conducted for those patients with traumatic and inflammatory urethral strictures.

Table 5: Repeat surgical procedures conducted following DVIU

	Repeat surgery	
	Yes	No
Stricture aetiology		
Trauma	1	33
Inflammatory	1	12
Idiopathic	3	16
Stricture location		
Bulbar urethra	3	41
Penile urethra	2	20
Total	10	122

DISCUSSION

Anterior urethral stricture disease is common and mainly affects men^{6,37}. The age distribution in men with anterior urethral stricture disease in this study was 18 to 76 years (Figure 1). This age range was similar to that reported in other studies.^{25,34} The average age for male patients with anterior urethral strictures was 49.9 years. The mean age for male patients with anterior urethral strictures reported in other studies included 49.4 years and 48 years which were similar to our study.^{6,11}

The bulbar urethra is the commonest site involved in male anterior urethral strictures¹¹. This was a similar finding in this study in which the commonest site for male anterior urethral strictures was the bulbar urethra followed by the penile urethra (Table 1).

The main cause of anterior urethral strictures in males in this study was trauma accounting for 51.5% of the anterior urethral strictures as shown in Table 3. Similar findings were reported by Musau who had found that trauma accounted for 50% of all the male urethral strictures⁶.

The pre operative mean peak flow was 7.2mls in this study. This is similar to the findings by Pansandro who had reported a mean peak flow rate of 6.8mls pre operatively before DVIU procedure²⁰. There was a significant improvement in Q max, on average 6.1mls/sec, in the immediate post operation period from the pre operative period (Table 4). This significant improvement in urine flow was also reported in the initial period after DVIU procedure in other studies^{20,13}.

The Q max at twelve weeks follow up showed a significant decline from the level achieved in the immediate post operation period. There was an average of 50.8% decline in Q max at twelve weeks follow up post DVIU procedure when compared to the Q max immediately after the DVIU procedure. The success rate of DVIU is reported to be short lived and limited.

The success rate of DVIU tends to decline with time which was the case in our study too during the follow up period^{6, 20}. The male urethral strictures can recur as early as twelve weeks after the DVIU procedure and this can be depicted as a decline in peak urine flow during uroflowmetry measurements¹⁰. Treatment of anterior male urethral strictures had failed in 53% of patients within a median interval of eleven months after DVIU procedure¹⁷.

The average flow rate increased in the immediate post operative period from the values in the pre operative period by a mean of 1.9 mls per second. However there was a gradual decline in the average flow rates seen at twelve weeks as compared to those obtained in the immediate post operative period on average by a mean of 0.8mls per second. This was a similar trend to the maximum flow rate which could suggest a recurrence of the voiding symptoms in these patients.

The percentage of patients with obstructive pattern of voiding curves declined in the immediate post operative period from 95.4% to 57.6% coinciding with improvements noted in the Q max and the average urine flow rates. However, the number of patients with an obstructive voiding curve patterns increased to 63.4% at twelve weeks follows up. This was also reflected in the decline in the Q max and the average flow rates during the same follow up period of twelve weeks which suggested a decline in the success of DVIU procedure.

The reoperation rate in this study after the initial DVIU procedure was 7.6%. These included patients who needed a second operation after the first DVIU procedure within three months of the initial operation. These patients had a significant decline in maximum flow rates and had lower urinary tract symptoms. Ishogooka had reported a recurrence rate for short urethral strictures after a single DVIU to be 4.4 % while other studies had reported recurrence rates of 40% depending on the choice of tool used to assess recurrence rates^{36, 10, 35}. The changes in Q max were used to assess the recurrence of urethral strictures in our study.

The reoperation rate after recurrence of anterior urethral strictures in this study was thus similar to the other studies. The tool used to assess success rate and recurrence rates of urethral strictures varies from urologist to urologist ¹⁰. The recurrence of urethral strictures can be seen as early as three to four months after the DVIU procedure which was similar to this study findings^{10, 33}.

The reoperation rate for the urethral strictures increases with longer follow up of the patients treated with DVIU procedure. Pansandro had found that the recurrence rate after one DVIU procedure was approximately 68% with longer follow up of the patients²⁰.

There is lack of a standard follow up time for urethral stricture recurrence and a clear definition of recurrence of urethral strictures ¹⁰. This makes comparison of studies after a single DVIU treated for urethral stricture recurrence and success rates difficult ³⁵.

CONCLUSIONS

The DVIU procedure produced marked improvements in maximum flow rate in the immediate period after DVIU procedure for short anterior urethral strictures less than two centimetres in length. The maximum flow rate showed a significant decline after three months of the DVIU procedure. Direct vision internal urethrotomy thus may be used to provide symptomatic relief to lower urinary tract symptoms due to short anterior urethral strictures before a definitive procedure is done.

RECOMMENDATIONS

Future studies assessing the success of DVIU in anterior urethral strictures to include patient symptomatology with assessment of post void urine using ultrasound and uroflowmetry. This will give a complete assessment of the patients' urinary symptoms.

REFERENCES

1. Mundy, A.R. Management of urethral strictures. *Postgraduate med J.* 2006; **82**:489-493.
2. Mundy, A.R. and Daniela, E.A. Urethral Strictures. *BJU International.* 2011; **107**:6-26.
3. Jennifer, T.A. Richard, S. Anna, L.S. Christopher, S.S. The morbidity of urethral stricture disease among male Medicare beneficiaries. *BMC urol.* 2010; **10**:3.
4. Keith, F.R. and Gerald, H.J. Primary urethral reconstruction: the cost minimized approach to the bulbous urethral stricture. *J urol.* 2005; **173**:1206-1210.
5. Fall, B. Sow, Y. Mansouri, I. Sarr, A. et al. Etiology and current clinical characteristics of male urethral stricture disease: Experience from a public teaching hospital in Senegal. *International urology and Nephrology.* 2011; **43**(4):969-74.
6. Musau, P. and Mteta, A.K. Urethral Strictures in a tertiary care Hospital in Tanzania. *EAMJ.* 2009; **86**(1):3-6.
7. Hameed, A. Mohammed, A. Nasir, S. Plamer, M. Management of bulbar urethral strictures: Review of current practice. *Can J Urol.* 2011; **18**(3):5676-82.
8. Guido, B. and Massimo, L. urethral Reconstruction. *Curr opin Urol.* 2006; **16**:391-395.
9. Guido, B. and Massimo, L. Surgical treatment of anterior urethral stricture disease: Brief overview. *International Braz J Urol.* 2007; **33**(4):461-469.
10. Andre', M. Naude, M. and Chris, F. H. What is the place of internal urethrotomy in the treatment of urethral stricture disease? *Nature Clinical Practice Urology.* 2005; **2**(11):538-545.

11. Zehri, A.A. Ather, M.H. Afshan, Q. Predictors of recurrence of urethral stricture disease following optical urethrotomy. *International journal of surgery*.2009; **7**:361-64.
12. Jonathan,L. Wright. Hunter,W. Avery, B. et al. What is the most cost-effective treatment for 1- 2 cm bulbar urethral stricture: Societal approach using decision analysis? *Urology*.2006; **67**:889-893.
13. Kamande L.Njanga. A review on the management procedures for urethral stricture disease at Kenyatta National Hospital. M.MED Dissertation University of Nairobi.2003.
14. Bradley, A.E. Benjamin, N.B. and Jack, W.M. Changes in uroflowmetry maximum flow rates after urethral reconstructive surgery as a means to predict for stricture recurrence. *J Urol* .2011; **186**:1934-1937.
15. Meeks, J.J. Bradley, A.E. Granieri, M.A. and Gonzalez, M.C. Stricture recurrence after urethroplasty: A systematic review. *J Urol*.2009; **182**:1266-1270.
16. Peterson, A.C. Webster, G.D. Management of urethral stricture disease: Developing options for surgical intervention. *BJU Int* .2004; **94**: 971–976.
17. Steenkamp, J.W. Heyns, C.F. De cock, M.C. Internal urethrotomy verses Dilatation as treatment for male urethral strictures: Prospective randomised comparison. *J urol*.1997; **137**:98-101.
18. Andrich, D.E. Mundy, A.R. Urethral strictures and their surgical treatment. *BJU International*. 2000; **86(5)**:571-80.
19. Adwok, J.A. Urethral strictures at Kenyatta National Hospital. *E.Afri.Med.J*.1986; **63**:175-81.

20. Pansadoro, V. and Emilliozzi, P. Internal urethrotomy in the management of anterior urethral stricture: long term follow up .*J Urol*.1996; **156**:73.
21. van Leeuwen, M.A. Brandenburg, J.J. Kok, E.T. Vijverberg, P.L. Bosch, J.L. Management of adult anterior urethral stricture disease: nationwide survey among urologists in the Netherlands. *Eur Urol*. 2011; **60**(1):159-66.
22. Bullock, T.L. and Brandes, S.B. Adult anterior urethral strictures: a national practice patterns survey of board certified urologists in the United States. *J Urol*. 2007; **177**(2):685-690.
23. Tonkin, J.B. and Jordan, G.H. Management of distal anterior urethral strictures. *Nat Rev Urol*. 2009; **6**(10):533-8.
24. Schouten, H.J. Sample size formula with a continuous outcome for unequal group sizes and unequal variances. *Stat med*.1999; **18**:87-91.
25. Mandhani, A. Chaudhury, H. Kapoor, R. Srivastava, A. Dubey, D. Kumar, A. Can outcome of internal urethrotomy for short segment bulbar urethral stricture be predicted? *J Urol*.2005; **173**(5):1595-7.
26. Sanya V. Okumu. Epidemiological and Clinical Aspects of Posterior Urethral strictures as seen at Kenyatta National Hospital 1985-1995. M.MED Dissertation University Of Nairobi.1998.
27. Richard, A.S. Geoffrey, F.J. and Mathew, W. Male urethral stricture disease. *J Urol*.2007; **177**: 1667-1674.

28. Bradley, A. Erickson. Benjamin, N. Breyer and Jack, W.M. The use of uroflowmetry to diagnose recurrent strictures after urethral reconstruction. *J Urol*.2010; **184**:1386-1390.
29. Nicolaas, L. Piet, H. Pieter, W. Bart, D.T. et al. Etiology of urethral stricture disease in the 21st century. *J Urol*. 2009; **182**(3):983-987.
30. Dubey, D. Management of urethral strictures. *Indian J Urol*. 2011; **27**:363.
31. Richard, S. and Lauren, E. Urethrotomy has a much lower success rate than previously reported. *J Uro*.2010; **183**:1859-1862.
32. Ngugi, P.M. and Kassim, A. Clean intermittent catheterization in the management of urethral strictures. *EAMJ*.2007; **84**(11):522-525.
33. Bodker, A. Ostri, P. Rye-Andersen, J. et al. Treatment of recurrent urethral stricture by internal urethrotomy and intermittent self catheterization:a controlled study of a new therapy. *J. Urol*. 1992; 148-308.
34. Greenwell. T. J, Castle, C. Andrich, D. E. et al. Repeat urethrotomy and dilation for the treatment of urethral stricture are neither clinically effective nor cost-effective. *J Uro*. 2004; **175**: 275-277.
35. Pitkamaki, K.K, Teuvo L.J. and Matti J.K. Recurrence of urethral strictures and late results after optical urethrotomy: comparison of strictures caused by toxic latex catheters and other causes. *Scand J Urol Nephrol*.1992. **26**:327-331.
36. Ishigooka M, Tomaru M, Hashimoto T, et al. Recurrence of urethral stricture after single internal urethrotomy. *Int Urol Nephrol*. 1995; **27**(1):101-6.
37. Stein, M.J, Desouza, R.A. Anterior urethral stricture review. *Transitional Andrology and Urology*. 2013; **2**(1):32-38.

Appendices:

Appendix 1 Study Consent form

Title of study: The short term success of DVIU in the management of male anterior urethral strictures

IP number..... Study number.....

Introduction

You are being invited to participate in a study being conducted by **Dr James Omboga Osoro**, currently undertaking a master of medicine degree in General Surgery at the University of Nairobi as part of his course work. The purpose of this study is to determine the short term success of the procedure that you will undergo known as DVIU in the management of anterior male urethral strictures at KNH. As you read through the consent form/being read to you, you are free to stop and seek explanation/clarification on a word/procedure as necessary.

Procedures

The procedures that you will undergo during the study are the same standard procedures that patients with a similar condition as yours not participating in the study will normally undergo at KNH in the course of their DVIU treatment.

During the study uroflowmetry measurements will be taken to assess your voiding patterns at three different intervals. This will be done a day before surgery, one day after surgery and at twelve weeks after surgery as you come for your routine follow up at the urology clinic.

During surgery you will undergo DVIU procedure which is a standard procedure even for those patients with urethral strictures who are not participating in the study. For this

procedure you will be given either general anaesthesia or spinal anaesthesia depending on what you agree with the anaesthetists, which will ensure you don't feel pain during the procedure. A special knife will be used to make a single incision/cut at the site of the urethral scar to widen your urethral lumen. A urethral catheter will be inserted immediately after the incision and be removed after 24 hours. After the procedure you're expected to recover from general anaesthesia/ spinal anaesthesia without difficulties.

Risk and benefits

You will be undergoing a standard procedure that has been done at KNH for a long time. In rare occasions the DVIU procedure may result in bleeding after the cut/incision, and extravasations of irrigation fluid. These rare untoward outcomes when they occur require the assessment by the ward senior house officer and/or the urologist who will assess you and institute appropriate treatment to you. This can occur whether you are participating in the study or not. Therefore participating in this study does not confer an extra harm or risk to you. No additional tests outside the usual ones for managing male anterior urethral strictures will be done during the study.

Voluntary participation

Participation in this study is out of your own free will. You will not be denied medical care in case you refuse to participate in this study. You may stop participating in this study at any time with no consequences whatsoever regarding your right to receive treatment.

Confidentiality

All information will be treated with confidentiality. Your identity will not be exposed to the public.

I,, have been explained to/ have been explained to on behalf of my, understood the above information, and voluntarily accept/allow my..... to participate in this study.

Signature/Thumb print of (Patient/guardian)..... Telephone
.....

I confirm that I have fully read to and explained to the patient/the guardian the contents of the study consent form.

Signature of researcher..... Date.....

Enquiries

For any enquiries or further clarification, please contact the following people:

1. DR OSORO JAMES – PRINCIPAL RESEARCHER Tel. **0721 291 442**
2. THE CHAIRMAN, KNH/UON ERC Tel. **020-2726300** Extension **44355**

Appendix 2

Fomu ya idhini

Cheo cha utafiti: Kiwango cha mafanikio kwa muda mfupi ya Upasuaji wa aina ya

DVIU katika tiba ya kovu ya njia ya mfereji wa mkojo wa wanaume.

Nambari ya utafiti

Nambari ya hospitali

.....

Utangulizi

Unaalikwa kushiriki katika utafiti huu unaofanywa na daktari **James Omboga Osoro** ambaye ni mwanafunzi wa shahada ya mwalimu wa tiba katika chuo kikuu cha Nairobi. Lengo la utafiti huu ni kuchunguza kiwango cha ufanisi unaotokana na upasuaji ambao wewe utafanyiwa wa aina ya DVIU kwa muda mfupi katika kutibu kovu ya mfereji wa mkojo wa wanaume katika hospitali kuu ya Kenyatta.

Utaratibu

Utaratibu utakaopewa kwa kushiriki katika utafiti huu ni kama ule ambao wagonjwa wengine walio na kovu ya mfereji wa mkojo ambao hawatashiriki katika utafiti huu watapewa.

Kwenye utafiti huu, muundo wa mkojo wako utapimwa mara tatu. Mkojo utapimwa siku moja kabla ya upasuaji, siku moja baada ya upasuaji na wiki kumi na mbili baada ya upasuaji ili kuonyesha kiwango cha matokeo uliyoyapata kutokana na upasuaji.

Utaratibu wa DVIU katika utafiti huu ni ule ambao umekuwa ukitumiwa kwa miaka mingi. Kwanza, kovu itatibitishwa kwa kuangaliwa na kifaa maalum kinachoitwa cystoscope. Kisha waya mwongozo itapitishwa kwenye kovu. Kisu maalum kitatumika kukata mara moja kovu kwenye sehemu moja ya kovu. Mpira wa kutoa mkojo kwenye kibofu cha mkojo itawekwa baada ya DVIU na itatolewa baada ya masaa ishirini na nne.

Hatari na Faida

Utaratibu utakaopewa katika DVIU ni ule ambao umekuwa ukitumika kwa muda mrefu. Ni nadra kupata matatizo kwenye utaratibu huu. Tatizo linaloweza kutokea ni kuvuja kwa damu. Hii hutokea baada ya upasuaji na daktari aliyekufanya upasuaji au daktari wa kata atakuhudumia. Kwa hivyo kwa kushiriki katika utafiti huu hakutakuwa na hatari au madhara kwako zaidi ya wale wagonjwa ambao watapelewa matibabu ya DVIU na kutoshiriki kwenye utafiti huu. Hakuna uchunguzi wa ziada utakaohitajika kufanya bali ni ule tu wa kawaida ambao wagonjwa kama wewe hufanyiwa kabla na baada ya matibabu.

Ushiriki wa hiari

Kushiriki kwako katika utafiti huu ni kwa hiari yako. Utapata huduma kama kawaida hata kama utakataa kushiriki katika utafiti huu na hakuna dhuluma yoyote utakaopewa kutokana na uamuzi wako. Unaweza kuondoa ushiriki wako wakati wowote na hakuna dhuluma yoyote utakayopewa.

Usiri

Habari zozote zitakazopatikana kutokana na kushiriki katika utafiti huu zitahifadhiwa kwa siri na jina lako litabanwa kutoka kwa umma.

Mimi,,nimeelezewa, nimeelewa, na kwa hiari yangu/ kwa niaba ya..... ninakubali kushiriki/ashiriki katika utafiti huu.

Sahihi/Alama ya kidole gumba. (Mjonjwa/mlinzi) nambari ya simu.....

Nadhibitisha kuwa nimemsomea na kumweleza mshiriki/mlinzi yote yaliyomo katika fomu ya idhini ya utafiti huu.

Sahihi ya mtafiti tarehe.....

Maelezo ya ziada

Kwa maelezo ya ziada au ufafanuzi zaidi, tafadhali wasiliana na:

1. DR JAMES OSORO – MTAFITI MKUU, NAMBARI YA SIMU: **0721291442**.
2. MWENYEKITI, KAMATI YA MAADILI NA UTAFITI KATIKA HOSPITALI YA KITAIFA YA KENYATTA, NAMBARI YA SIMU: **020-2726300** Extension **44355**

Appendix 3

Study data collection form

Study. No. ----- Date ---/---/20...

The short term success of DVIU in the management of male anterior urethral strictures

IP number

Mobile phone number

Age (years)

Marital status (tick as appropriate)

Married separated

Single widowed

Patient's tribe.....

Race.....

Occupation of the patient

Patient's associated morbidity.....

Signed informed consent.... yes No

Site of the urethral stricture

Length of the urethral stricture in mm

Cause of the urethral stricture

Any repeat surgery for the urethral stricture after DVIU?

YES: NO:

If yes, type of surgery done.....

Results of Uroflowmetry:

Type of reading	Pre operative Period	Immediate operation Period	Post 12 weeks post operation Period
Maximum flow rate (ml/s)			
Average flow rate (ml/s)			
Voided volume (mls)			
The Pattern of the voiding curve			

APPENDIX 4

LETTER OF APPROVAL FROM KNH/ERC



UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 01002
Telegrams: varsity
(254-020) 2726440 Kxt 44355
Ref: KNH-ERC/A/200

KNH/UoN-ERC
Email: knh_erc@uonbi.ac.ke
Website: www.uonbi.ac.ke
Link: www.uonbi.ac.ke/activities/KNHUoN

KENYATTA NATIONAL HOSPITAL
P O BOX 29723 Code 00202
Tel: 726300-9
Fax: 726272
Telegrams: MEDSUP, Nairobi
11th July 2012

Dr. James Ombaga Osoni
Dept. of Surgery
School of Medicine
University of Nairobi

Dear Dr. Ombaga

Research proposal: "Short-term success of direct vision internal Urethrotomy(DVIU) in the management of Anterior Male Urethral strictures"
(P242/04/2012)

This is to inform you that the KNH/UoN Ethics & Research Committee (ERC) has reviewed and **approved** your above revised research proposal. The approval periods are 11th July 2012 to 10th July 2013.

This approval is subject to compliance with the following requirements:

- a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
- c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
- d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
- e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
- f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
- g) Submission of an executive summary report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website www.uonbi.ac.ke/activities/KNHUoN

Yours sincerely



PROF. A.N. GUANTAI
SECRETARY, KNH/UN-ERG

c.c.

The Deputy Director CS, KNH
The Principal, College of Health Sciences, UoN
The Dean, School of Medicine, UoN
The Chairman, Dept. of Surgery, UoN
The HOD, Records, KNH
Supervisors: Dr. Francis Owillah, Dept. of Surgery, UoN
Prof Peter Mungai Ngugi, Dept. of Surgery, UoN

APPENDIX 5

STUDY TIME FRAME

Activity	Jan 2012 -April 2012	May 2012- july 2012	July 2012- july2013	Aug 2013 -Oct 2013	Nov 2013- April 2014
Proposal writing/ presentation to UON Surgery Department					
Proposal presentation to UON/KNH Ethics & Research Committee					
Data collection					
Data analysis and discussion					
Presentation of findings to UON Department of Surgery					

Declaration Form for Students

UNIVERSITY OF NAIROBI

Declaration of Originality Form

This form must be completed and signed for all works submitted to the University for Examination.

Name of Student _____ *Dr james omboga osoro* _____

Registration Number _____ *H58/70985/2009* _____

College _____ *of Health sciences* _____

Faculty/School/Institute _____ *of Medicine* _____

Department _____ *of Surgery* _____

Course Name _____ *General surgery* _____

Title of the work: *The short term success of DVIU in the management of male anterior urethral strictures.*

DECLARATION

1. I understand what Plagiarism is and I am aware of the University's policy in this regard
2. I declare that this _____ (Thesis, project, essay, assignment, paper, report, etc) is my original work and has not been submitted elsewhere for examination, award of a degree or publication. Where other people's work, or my own work has been used, this has properly been acknowledged and referenced in accordance with the University of Nairobi's requirements.
3. I have not sought or used the services of any professional agencies to produce this work
4. I have not allowed, and shall not allow anyone to copy my work with the intention of passing it off as his/her own work
5. I understand that any false claim in respect of this work shall result in disciplinary action, in accordance with University Plagiarism Policy.

Signature _____

Date _____

Declaration Form for Staff

UNIVERSITY OF NAIROBI

Declaration of Originality Form

This form must be completed and signed for all scholarly works produced.

Name of Staff _____

Payroll Number _____

College _____

Faculty/School/Institute _____

Department _____

Title and bibliographic details of the work

DECLARATION

1. I understand what plagiarism is and I am aware of the University's policy in this regard.
2. I declare that this _____ scholarly work (Paper, book chapter, monograph, review, etc) is my original work. Where other people's work, or my own work has been used, this has properly been acknowledged and referenced in accordance with the University of Nairobi's requirements.
3. I have not allowed, and shall not allow anyone to copy my work with the intention of passing it off as his/her own work.
4. I understand that any false claim in respect of this work shall result in disciplinary action, in accordance with University Plagiarism Policy.

Signature _____

Date _____