THE ROLE OF UROFLOWMETRY

IN

BENIGN PROSTATIC HYPERPLASIA

THE ROLE OF UROFLOWMETRY

IN THE

OUTCOME OF SURGICAL THERAPY

OF PATIENTS WITH

BENIGN PROSTATIC HYPERPLASIA

A SIX-MONTH PROSPECTIVE SERIES STUDY MARCH—OCTOBER 2001

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nFCLARATION

This thesis is my original work and has not been presented for any award of a degree in any other university.

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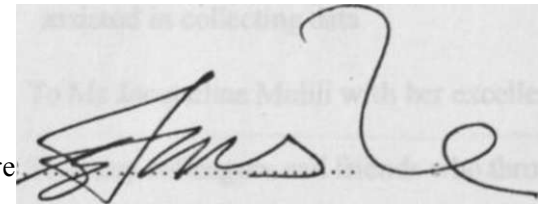
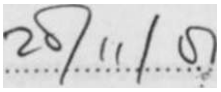
This thesis has been submitted for examination with my approval as a university Supervisor

Signature  Date 

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DEDICATION

This Work is dedicated to my father Mr. Reuben Mugun for teaching me the value of discipline and reward of hard honest work. To my dear mother, Priscilla, a loving and prayerful lady who is always positive thinker full of encouragement To my brother Dr Eric Koech who impressed upon me, ever since childhood, the old adage "constant pressure cracks even the hardest of all diamonds".

To my other brother, Peter for taking care of my concerns while away in training Finally to all who made it possible for me to train in this difficult period; their efforts cannot be forgotten.

SUMMARY

This is a consecutive senes of 74 patients who presented with lower urinary track symptoms (LUTS suggestive of bladder outlet obstruction (BOO), between March to October 2001. The study was ca out at Kenyatta National Hospital.

The mean age of the patients was 68 years. 22.5% of them were aged below 59 years 25% were a between 60-69 years while 52.5% were over 70 years of age. 39% (29) of them underwent transun resection of prostate (TURP) while 36% (27) underwent millin's retro pubic prostatectomy.

Transvesical (Freyers') prostatectomy was performed in the remaining 25% both Millin's and Frey procedures were termed open prostatectomy in this study Patients who underwent TURP had a sh period of symptoms before surgery (mean of 7.62 months as compared to open method group with mean 8.66 months.

The length of stay in hospital and length of catheterization after surgery was also remarkably short TURP group (3.17 and 2.17 days respectively) compared to open method group (6.22 and 3.89 daj respectively).

The mean International Prostate symptom score (I-PSS) was better for TURP group (25.97) than \ open method (29.27) before surgical intervention. This improved after surgery in similar proporli 7.62,6.25 for TURP group and 10.66, 8.31 for open group in the first and third months At the si: month, TURP continued to improve to 5.54 while open method deteriorated to 9.19.

The change in the Quality of Life (QOL) indices score was similar for both groups.

The Uroflowmetric maximum velocity (Qmax) variable was notably higher for TURP group (7.8 compared to open method (6.16) before surgery.

This improved remarkably to 32.29 (TURP) and 18.58 (Open) in the first month after surgery However, this dropped to 27.74 and 18 46 in the 3"[1],6th month follow-up in the TURP group On th other hand there was improvement on the open method group to 21.73,23.85 in the 3"[i] and 6* moth There were great Intra individual variations in the post void residual volume, voiding time and void volume to be of any useful parameters in the follow-up of the patients after prostatectomy

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INTRODUCTION

More than half of men over the age of fifty years develop voiding dysfunction during their life- time **(1,27).**

The syndrome of symptoms is complex and often collectively termed as lower urinary tract sympton (LUTS). The etiology of this is most frequently by an enlarged prostate, but can also be caused by disorders of the bladder, bladder neck or sphincter

In 1882 Mosso and Pellacani used a smoked drum with a catheter in the urinary bladder to show cha in bladder volumes at a constant bladder pressures (2,3).

After the 1960's accurate transducers attached to machines with photographic paper recordings wer developed.

Today there are computerized urodynamic machines with video screens making urodynamic investigations easier to perform and giving more accurate interpretations (4)

Urodynamic tests have become a basic investigative procedure for the urinary tract dysfunctions in developed countries. This has provided an essential complement to the modem practice of urology

Symptoms of the urinary tract dysfunction have a subjective bias and often present an overlap betv symptom complexes making their clinical evaluation even more difficult. As a result for many yea bladder has been reported as an "unreliable witness". (2,5)

Urodynamics have made it possible to objectively evaluate these symptoms and provide reproduci clinical data hence enabling a more rational approach to the management of urinary tract dysfuncl

LITERATURE REVIEW

ANATOMY

Prostate

The prostate is an accessory gland of the male reproductive system.

It resembles a compressed inverted cone approximately 3cm from apex to base and 3.5cm across the base. It is firm in consistency due to the presence of dense fibro muscular stroma in which the glandi elements are embedded. It weighs only a few grams at birth; at puberty it undergoes androgen-medica growth and reaches the adult size of about 20 grams by age of 20 years. It remains stable in size for about 25 years, and during the fifth decade a second growth spurt commence in the majority of men.

The prostate surrounds the urethra, and any enlargement is a potential of urinary tract obstruction Indeed in overall about 10% of men at some time require prostatic surgery to relieve urinary tract obstructions.

McNeal has described prostate anatomy, dividing it into five zones; the peripheral, transitional, centre Periurethral, and anterior fibro muscular stroma. (6)

80% of prostate cancer develops in the peripheral zone while benign prostatic enlargement occurs as i result of hyperplasia of periurethral glands in the transitional zone of the prostate

Histologically the prostate show two well defined concentric zones separated by an ill-defined irregul capsule. The outer larger zone is composed of large branched glands, the ducts of which curve backwards and open mainly into the prostatic sinuses. The inner smaller zone is composed of sub-mucosal glands and a group of short simple mucosal glands surrounding the upper part of the urethra

BLADDER

Urinary bladder is a muscular reservoir of urine, which vanes in size, shape, and position according t< the amount of urine it contains and the person It is tetrahedral in shape with an apex, base and neck ***a*** three surfaces and four borders

The bladder capacity is, in an adult male, 450 to 500 mis and females 400 to 450 mis Filling beyond 500mls in males causes a desire to micturate and the bladder is usually emptied when filled to about 1 to 600 mis.

Its muscular layer is thick and consists of bundles of smooth muscle running in many directions Towards the neck they come together to form a ring, which surrounds the uppermost part of the ureth forming the involuntary sphincter of the bladder Other muscle fibres run radially into this region and tend to open the urethral orifice when they contract on mircturition. (8)

PATHOPHYSIOLOGY

Bladder and urethral function are concerned with the storage and the voiding of urine.

The detrusor muscle and urethral sphincters function as a coordinated unit and dependent on both anatomical and neurological integrity for optimum function.

Anatomical abnormalities such as prostatic enlargement, fistula or sphincter injury are expected to ca symptoms while disruption of the nerve pathways to or from the bladder such as occurs in spinal injui multiple sclerosis, or pelvic plexus injury following pelvic surgery may equally lead to development c symptoms.

Benign prostatic enlargement (BPE) describes a proliferating process of both the stromal and epithelii

elements of the prostate gland It arises in the peri-urethra] and transition zones of the prostate (6,8)

Histological BPH represents an inescapable phenomenon for the ageing male population approximate 90 % of men will develop histological evidence of BPH by 80 years of age and as many as 50% of mt by age of 60 yrs (7,31)

Although nearly all men develop histological BPH, the degree of prostatic enlargement resulbng froft hyperplasia is highly variable. The volume of prostate is most accurately determined using imaging studies such as ultrasound, CT scan, or MRI

Oesterling et al recently measured prostate volumes of 464 men aged 40-80 years selected at random There was statistically significant correlation between age and prostate volume with $p<0.001$ $r2 = 0.1085$ (9)

CLINICAL PRESENTATION

The symptomatology of BPH often varies, and significant intra-and intenndividual variation in symptoms exist Nocturia, urinary urgency and frequency and pain or burning on urination are typical irritative symptoms, while obstructive symptoms manifest with urinary hesitancy, straining or dribblir during micturition, and a weak or interrupted stream of urine. Initially, the bladder can expel urine paJ the prostatic blockade. Eventually the bladder is no longer able to compensate, which results in incomplete emptying and stasis of urine within the bladder. Patients may present with severe symptort that are hallmark of advanced disease, such as urinary retention, urinary tract infections, nephrolithias Hydronephrosis, gross hematuria and compromised renal function. (46)

TABLE 1

Urinary symptoms of BPH	
Irritative symptoms	**Obstructive**
Dysuria	Hesitancy
Nocturia	Straining
Urgency	Dribbling
Frequency	Weak stream
Burning	Incomplete emptying

EVALUATION

The severity of lower urinary tract symptoms (LUTS) is best qualified using qualitative symptom indices like international prostate symptom score (I-PSS)(10)

TABLE II

INTERNATIONAL PROSTATE SYMPTOM SCORE (I-PSS)

	Never	About 1 time in 5	About 1 Time in 3	About Time in 2	About 2 Times in 3	Almost always
Incomplete emptying: Over the past month, how often have you had a sensation of not emptying your bladder completely after you have finished urinating?	0	1	2	3	4	5
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

Intermittency: Over the past month, how often have you found you stopped and started again several times when you urinated	0	1	2	3	4	5
Urgency: Over the past month, how often have you found it difficult to postpone unnation?	0	1	2	3	4	5
Weak stream: Over the past month, how often have you noticed a reduction in the force of your urinary stream	0	1	2	3	4	5
Straining: Over the past month, how often have you had to push or strain to begin urination	0	1	2	3	4	5
Nocturia: Over the past month, how many times did you most typically get up to urinate from the time you went to bed until the time you got up in the morning	**None**	**1 time**	2 **times**	**3 times**	4 **times**	**5 or more times**
TOTAL IPSS SCORE OUT OF A TOTAL OF 35						

	Delighted	Pleased	Mostly satisfied	Mixed	Mostly dissatisfied	Unhappy/terrible
Quality of life due to urinary symptoms: If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about it	**0**	**I**	2	3	**4**	**5**

The development of LUTS is also associated with advancing age and often attnbuted to BPH. (II) Indeed, until recently the constellation of obstructive and irritative symptoms observed «n aging mer was termed prostatism'. The differential diagnosis of LUTS in ageing men includes both urologic non-urologic conditions;

Neurological conditions such as Parkinsonism

Cerebrovascular accidents

Diabetes mellitus

Congestive cardiac failure

Bladder carcinoma J ^ ^ ^ T * * 0 0 1

UTI 1*TVB*SVTV °

Urethral stricture

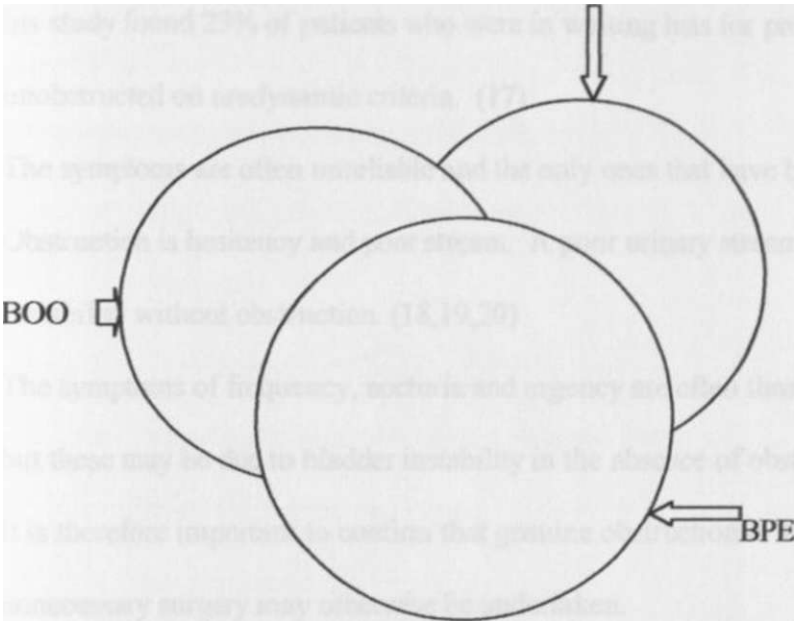
Bladder neck hypertrophy

Nevertheless LUTS in the presence of some degree of prostate enlargement often establishes the diagnosis of BPH. It has often been assumed that the patho-phys.ology of LUTS in men is the resu the bladder outlet obstruction (BOO) associated with the prostatic enlargement (12)

The observarions that the development of prostatic enlargement, BOO, and LUTS are age depend* was interpreted to include a casual relationship. Three overlapping c.rcles have represented the relationship among these three factors. (13,14,29)

FIGURE I

LUTS



This schematic diagram suggest that a significant subset of men with enlarged prostate causes BOC LUTS.

The patho-physiology of BOO in men with BPH has been attributed to both static and dynamic fact **(15)**

Static obstruction arises from the bulk enlargement of the prostate encroaching upon the prostatic Urethra and bladder outlet whereas dynamic obstruction is related to the tension of the prostatic sir muscles. The medical therapies widely used today for the treatment of BPH are targeted at reducir prostatic volume and relaxing prostate smooth muscle tension. (16)

The clinical data showed the effectiveness of androgen suppression and alpha-blockage for the

treatment of BPH has validated the hypothesis that the pathophysiology of BPH is causcd by BOO

The lack of appropriate equipment means that many surgeons and even urologists must select paticn With BOO for prostatectomy based on symptoms and clinical examination alone In fact Mcloughli his study found 23% of patients who were in waiting lists for prostatectomy were found to be unobstructed on urodynamic criteria (17)

The symptoms are often unreliable and the only ones that have been reliably associated with outflov Obstruction is hesitancy and poor stream. A poor urinary stream, however may result from bladder instability without obstruction. (18,19,20)

The symptoms of frequency, nocturia and urgency are often those that the patients find most distres but these may be due to bladder instability in the absence of obstruction (21)

It is therefore important to confirm that genuine obstruction is the cause of patient's symptoms sine unnecessary surgery may otherwise be undertaken

However, clinical experience suggests that the degree of obstruction is not always related to the vol of prostate. Small prostates in younger men can cause severe obstruction and voiding disorders, but large adenomas can present without causing obstruction (22)

In the treatment of patients with LUTS and BPE, the success of surgical treatment seems to be clos* related to the presence of BOO (23,24)

Therefore, if patients with LUTS and BPE are to be treated appropriately, information about the grc obstructions should be obtained

Urodynamic investigation with pressure/flow analysis is considered to be the gold standard' to determine BOO (25)

However rather than performing this invasive investigation uroflowmetry is used most often to document voiding disorders because it is simple, readily available and easy to use. (26)

UROFLOWMETRY

This is the simplest urodynamic investigation, which can be performed in all patients with bladder dysfunction but commonly on male patients with prostatic enlargement and bladder outlet obstructiv symptoms.

It consists of a simple recording of the following;

- Voiding time T100 in seconds
- Flow time TQ
- Time to maximum flow TQ max
- Maximum (peak) flow rate in mis/sec Qmax
- Total voided volume in mis
- Daily time in sees

The test is reliable and reproducible when the voided volume is greater than 200 mis and peak flow i values less than 15 mis per second wound indicate a degree of bladder outlet obstruction.

In many appropriate instances it may be appropriate to record post-mircturition residual urine volum either by ultrasound or catheterization as an additional investigation in patients following uroflowm< particularly in proved or suspected neurogenic cases.

Uroflowmetry is now considered an essential pre-operative investigation in all male patients with be prostatic hypertrophy in developed centers.

The urodynamic unit at Kenyatta National Hospital is at the minor Theatre of the surgical outpatienl Clinic number 24.

The theatre is mostly utilized by other specialists of the hospital for minor operations and procedure usually under local anesthesia.

In the minor theatre room where the equipment is installed there is a small operation table as well as screen, which serve to shield the patients from the equipment during the test.

The installed equipment is ***Dantec urodyrt" 1000*** composing the following:

- Monometer Stand
- Micturition Row meter with a commode
- Monometer lines
- 2-membrane pressure Transducers

Other necessary items are:

- Sterilized gloves
- Disposable catheters
- Infusion saline
- 0.02% chlorhexidine solution
- Sterile cotton wool
- Sterile urine collecting device

The ***daniec urodyrf I(XX)*** is a fully automatic uroflowmeter. As soon as the urodyn 1000 is switch© it is ready for recording. The start of the flow and end of micturition is detected automatically. The attendant recording is automatically printed out during micturition.

The unit is operated via three buttons controlling the manual start/stop function defining uroflow interpretation and male/female. The ***urodyn I(XX)*** prints out a strip chart with the flow rate curve, it of uroflowmetry and I.D frame.

PROCEDURE

The procedure was explained fully to the patients. A full bladder was necessary Oral fluids were gi if the bladder was not full. The patient was then taken to the uroflowmetry room adjacent to the mm theatre. He was then requested to void while standing to micturition flow meter diaphragm

After voiding a catheter is passed and the post-void residual volume was recorded.

STUDY JUSTIFICATION

Researcher's personal observation of patients attending the KNH surgical outpatient clinics (SOPCs with LUTS prompted this study

In almost all cases, only symptoms and basic clinical examination were tools of assessing prostate enlargement with subsequent scheduling the patient for prostate surgery. The pre-operative investigations do not include any urodynamic parameters.

The uroflowmeter is comfortably stored next door in the minor theatre un-utilized. The urologists ii units seldom utilize the facility in spite of the know-how.

Other surgeons apart from the urologists invariably handle the bulk of patients with BOO

It should be stressed to any surgeon, therefore, the value of uroflowmetric pre-operative evaluation < patients with suspected BOO After all, the equipment is already installed hence little extra cost to I patient.

Uroflowmetry provides a quantitative estimate of a patient's ability to empty his bladder Pre-opera

Uroflowmetric assessments together with international prostate symptom score should form the guidelines in management in patients LUTS. (See flow chart.)

OBJECTIVES

OVERALL OBJECTIVE

In general, this study seeked to evaluate the utility of flow rates and 1-PPS in patients with LUTS arv monitoring outcomes of surgical therapy for BPH.

Fundamental questions remained unanswered about the value of uroflowmetry on the assessment of Presenting the LUTS thought to be due to BOO. (34)

SPECIFIC OBJECTIVES

- To compare period of symptoms between TURP and open prostatectomy groups
- To compare the length of stay in hospital, and length of catheterization of the two groups
- To compare uroflowmetric variables in the TURP and open prostatectomy groups,
- To compare IPSS in TURP and open prostatectomy groups.
- To compare QOL in the two groups.
- To establish guidelines for evaluation of patients with LUTS, and make recommendations o ideal surgical treatment for BPH patients at KNH
- To compare my data with reports in the literature.

PATIENTS AND METHOD

From March 2001,64 consecutive men presenting at the surgical outpatient clinics of Kenyatta National hospital with BOO caused by BPH were recruited into the study Another 16 patients were admitted by their respective consultant urologists at the amenity ward. In total 80 patients were recn into the study

The investigator undertook a thorough history and physical examination including DRE.

Informed consent was sought in all the patients.

Voiding symptoms and quality of life were graded according to the International prostate symptom s (I-PSS) and its quality of life assessment index (QOL) (36).

The minimum criteria for entry were:

- I-PSS not less than 13
- QOL index not less than 3
- Maximum urinary flow rate (Qmax) of < 15 ml/s with or without a significant post void resit volume (PVR)
- Age of more than 45 years

Patients with a known neurogenic bladder, known or suspected cancer of the prostate, previous pro; Surgery, urethral stricture, bladder stones and patients on anticoagulant therapy or diabetes mellitus were excluded.

The study protocol was approved by the Kenyatta National Hospital ethical and research com mi net KNH- ERC/10/1015)

The diagnostic evaluation included:

- History
- Physical examination including DRE
- Laboratory evaluation—urine analysis, serum electrolytes and renal function, haemogram, an PSA measurement (not all)
- Uroflowmetry using ***Daniec urcxlyn*** ***R*** ***1000*** uroflow equipment
- Measurement of PVR
- Prostatic biopsies were performed in patients with suspected prostatic malignancy on DRF. ai /or a high PSA level and were thus excluded from the study.

The patients were scheduled for operation depending on surgeon's preference to a surgical procedur

Patients were assessed at the baseline, and at one, three and six months after surgery.

The variables evaluated included.

- International prostate symptom score (I-PSS)
- Quality of life index score (QOL)
- Maximum flow rate velocity (Q max) ^j^plCA^- ^^^fclvJit
- Voiding time ^ i l V B ^ °J
- Voided volume
- Post-void residual volume (PVR)

KNH is a public tertiary care teaching hospital that also houses the Nairobi University Medical Scho< This 2000 bed hospital also serves as a general Hospital for an estimated 2 Million people residing in and around the Metropolis.

It is also a referral hospital receiving approximately a third of its patients from provincial, district ar* mission hospitals in Kenya. Male patients with urinary obstruction therefore may come directly to Kenyatta National Hospital or referred from the hospitals alluded above.

SURGICAL TECHNIQUE

(1) RETROPUBIC PROSTATECTOMY *(Millin* 1945)

Using a low, curved transverse suprapubic pfannenstiel incision, which includes the rectus sheatl the recti are split in the midline and retracted to expose the bladder with its typical appearance o pale brown muscle bundles with a loose covering of fatty tissue and veins.

With the patient in trendelenberg position, the surgeon separates the bladder and the prostate fr the posterior aspect of the pubis

In the space thus obtained the anterior capsule of the prostate is incised with diathermy below th bladder neck, care being taken to obtain complete control of bleeding from divided prostatic veil suture ligation. The prostatic adenoma is enucleated with a finger.

A wedge is taken out of the posterior lip of the bladder neck to prevent stricture of this region 1 exposure of the inside of the prostatic cavity is good and control of hemorrhage is achieved with diathermy and suture ligation of the bleeding points before closure of the capsule over a Foley catheter (inserted per urethra) draining the bladder.

(2) TRANSVESICAL PROSTATECTOMY *(Freyer* s 1901)

The bladder is opened, and the prostate is enucleated by putting a finger into the urethra pushu forwards towards the pubis to separate the lateral lobes and working the finger between the aden and the false capsule. In the Freyer's operation **(1901)** the bladder was left open widely and dran by a suprapubic tube with a 16 mm lumen in order to allow free drainage of blood and urine.

Harris **(1934)** advocated control of the prostatic arteries by lateral stitches; the bladder wall was closed and the wound drained.

(3)* TRANSURETHRAL RESECTTION OF THE PROSTATE *(TURP)

This has been described as the "gold standard " treatment of BPH.

In developed countries TURP has largely replaced the other methods.

The earlier instruments developed by McCarthy have been replaced by single -hand- operated instruments often being used under video control. Perhaps the greatest advance in the history of TURP was marked by the development of the rigid lens system by Professor Harold Hopkins. H lenses illuminated by a fibre optic light source permit un-paralleled visualization of the workinj field.

Strips of tissue are cut from the bladder neck down to the level of the verumontanum. Cutting i: performed by a high frequency diathermy current, which is applied down a loop mounted on th hand held trigger of the resectoscope. Coagulation of bleeding points can be accurately achieve damage to the external sphincter is avoided provided one uses the verumontanum as a guide to most distal point of the resection.

The "chips" of the prostate are then removed from the bladder using an Ellik evacuator.

Hyponatremia is avoided by using 1.5% isotonic glycine for irrigation and thee recent introductu of continuous flow resectoscope makes the procedure swift and safe in experienced hands At the end of the procedure, careful haemostasis is performed and a three way catheter irrigated with isotonic saline is introduced into the bladder to prevent ant further bleeding forming clots. Irrigati is continued until the outflow is pale pink and the catheter usually removed on the second or thir Postoperative day.

SAMPLE SIZE AND SAMPLING PROCEDURES

Sample size estimation was derived from the formula:

$$N = \frac{Za \times Za f(p(p-1)1}{D \times D}$$

Where:

Za = Standard deviation of the 95th percentile (1.96)

D = Width of the confidence interval (0.05)

P = Expected proportion amongst surgical admission (5% as at February 2001)

N = Sample size.

$$N = \frac{1\ 96 \times 1.96\ [0.05\ (0.05 - 1)1}{(0.05)^2}$$

$$= 73$$

DATA ANALYSIS

Data obtained was carefully studied and entered into an IBM - compatible computer Analysis was carried out in a statistical analysis software (SAS) programme to derive descriptive statistics and flow rate distributions

STUDY LIMITATIONS

Although uroflowmetry can provide useful information suggesting whether a patient has BOO, and possible underlying pathology, the interpretation of results may sometimes be difficult and misleading I

The following problems were encountered during the period of the study

- *42%(3*1) of the patients presented with complete urinary obstruction and hence the baseline fl< rates were not possible
- In this study single flow rates were done. Blaivas et al in their conclusion suggested multiple flow rates to improve on the accuracy (20)
- Turp was performed by three consultant urologists The technique may vary depending on the learning curve and hence the outcome of surgery Due to small numbers it was not possible to pool to one particular surgeon. On the other hand all cadres of surgeons from consultant Urologists, newly qualified consultants to registrars performed open prostatectomies.
- Within the three surgical firms of KNH, there was no protocol as to the management of a patic presenting with BOO. Patients are booked for surgery depending on the desire of the surgeon do a particular type of procedure.
- Some of the PSA levels and histology done were not recovered and hence the slim possibility I have included patients with prostatic carcinoma in the study.
- 10% (8) of the patients were lost to follow up during the course of the study.

For the appropriate use of the results of Uroflowmetry, certain aspects should be considered i.e.

1. Reproducibility
2. Artefacts
3. Orcadian changes
4. Variation within and between observers
5. Association with volume and outlet obstruction
6. Reference values
7. Clinical relevance to BPH

DANTEC URODVN R 1000 EQUIPMENT

IJROFLOWMETRIC CHARTS

RESULTS

Between March and October 2001,80 consecutive patients with moderate to severe BOO caused by I Were recruited and underwent TURP and open prostatectomy by either Freyer's or Millings method patients defaulted from the early follow-up, leaving 74 patients who completed 3 months follow-up. Six months 2 patients were lost to follow-up leaving 72 patients. Most were admitted from the waiti lists of the three surgical firms while some were admitted by their urologist to the amenity ward Mc those admitted in the amenity ward underwent TURP.

The DRE showed a benign -feeling prostate in all patients.

The PSA levels were available in 11 patients and all were less than 5 ng/ml.

45 patients underwent open prostatectomy with a mean age of 68.4 years while TURP was perforn in 29 patients with a mean age of 67.6 years.

TURP was performed by three consultant urologists in the 29 patients.

27 patients underwent millin's prostatectomy of which 68%(18) were performed by consultants anc 32% by registrars.

Freyer's prostatectomy was performed by registrars' in 10 patients (56%) and consultants in 8 patier (44%)

AGE DISTRIBUTION

74 Patients were entered into the study, all males, and age ranging from 49 to 100 years with a mean **68**

years.

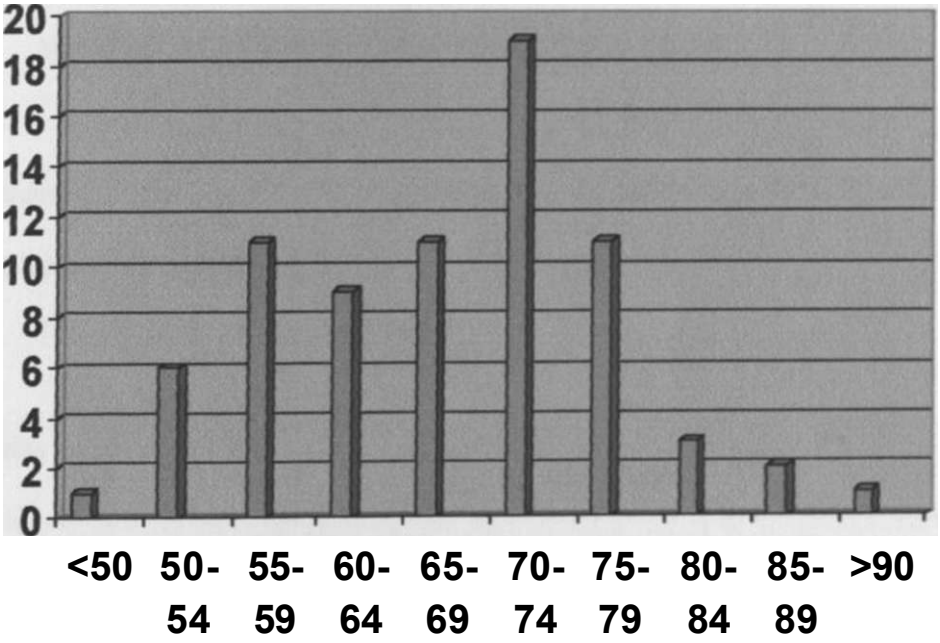


Figure H AGE DISTRIBUTION OF ALL PATIENTS RECRUITED (YEARS)

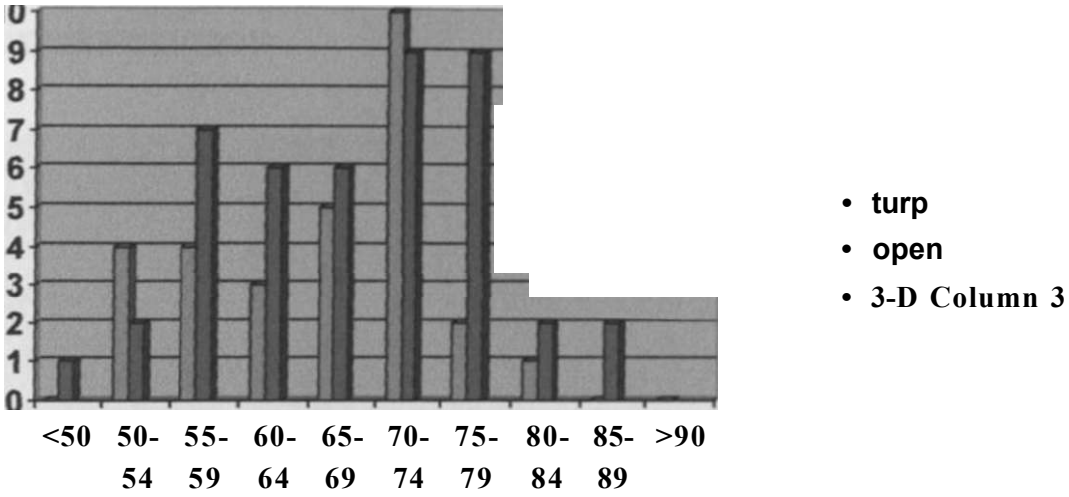


Figure 111 AGE STRARA ACCORDING TO SURGERY DONE (YEARS)

Table 1 summarizes the pen-operative data; the histology was available in 46%(34) of the patients i all confirmed benign hyperplasia.

TABLE 111

MEAN (sd)|N)	TIIRP	OPEN PROSTATECTOMY	p*
AGE (YEARS)	67.6 **(10 8)[29]**	68.44 **(9 3)[45]**	0.0571
Period of symptoms (Months)	7.62 **(4.26)[29]**	8.66 **(4.41)[44]**	0.0001
Length of stay in hospital (Days)	**3.17(1 03 H29]**	6.22 (1 **66)[451**	<0.0001
Length of catheterization (Days)	2.17 **(0.60)[29]**	3.89 (1 **40)[45]**	0.0001

MEAN AGE DISTRIBUTION

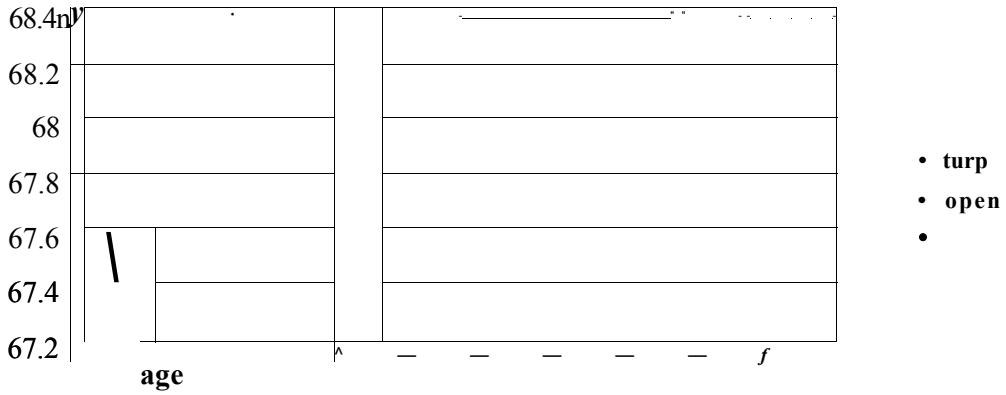
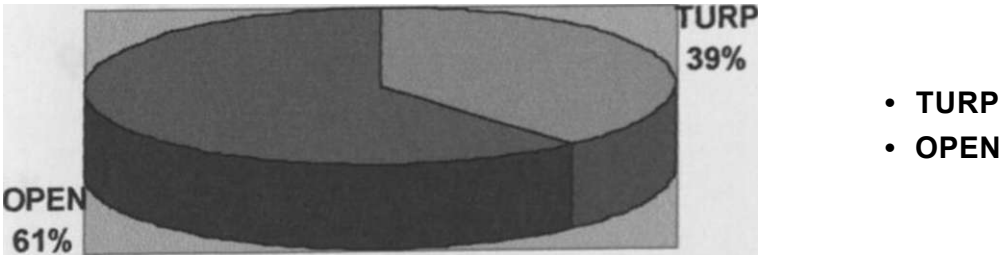


Figure IV Mean age distribution

PIE CHART

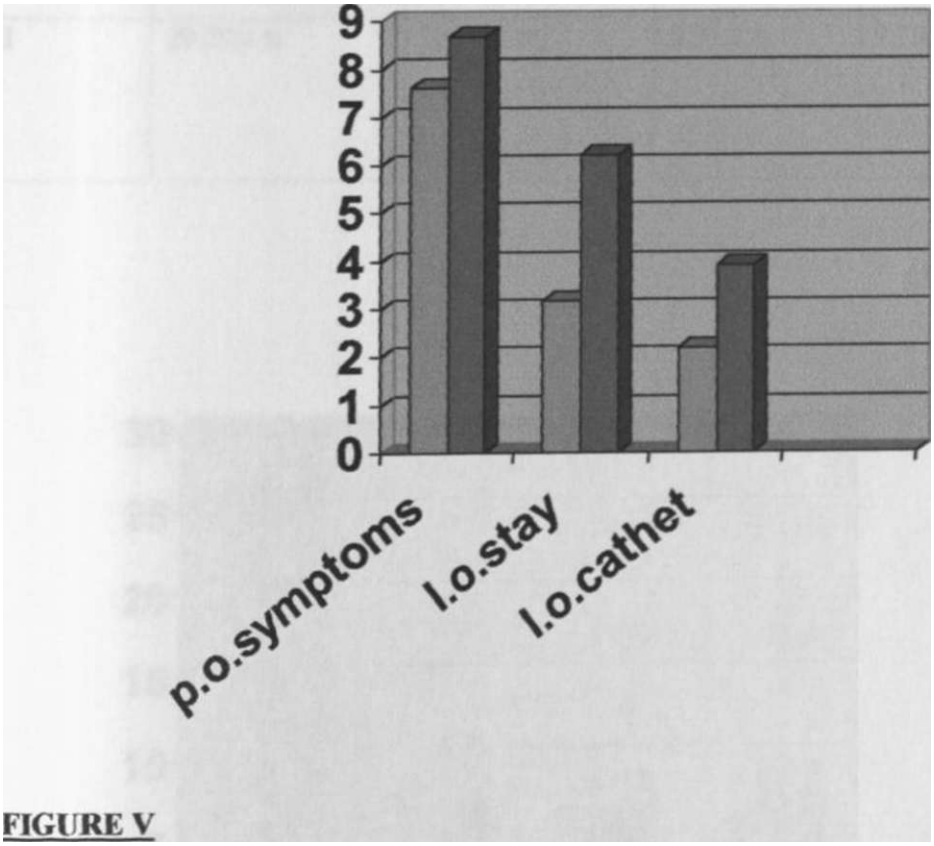
PROPORTION OF PATIENTS ACCORDING TO SURGERY

39% of the patients underwent TURP while 61% underwent open prostatectomy.



MEAN DISTRIBUTION OF PERIOD OF SYMPTOMS, LENGTH OF STAY IN HOSPITAL AND LENGTH OF CATHETERISATION

(Months) (days) (days)



- **TURP**
- **OPEN**

FIGURE V

THE 1PSS RESULTS

TABLE IV

can IPSS (sd)	Pre-op	l" month	month	6 month
urp	25.97(3.5)	7.62**(094)**	6.25(1 8)	5.54**(2 13)**
pen method	29.27**(4**.5)	1066**(1 78)**	8.31**(2.3)**	9.19**(13 6)**

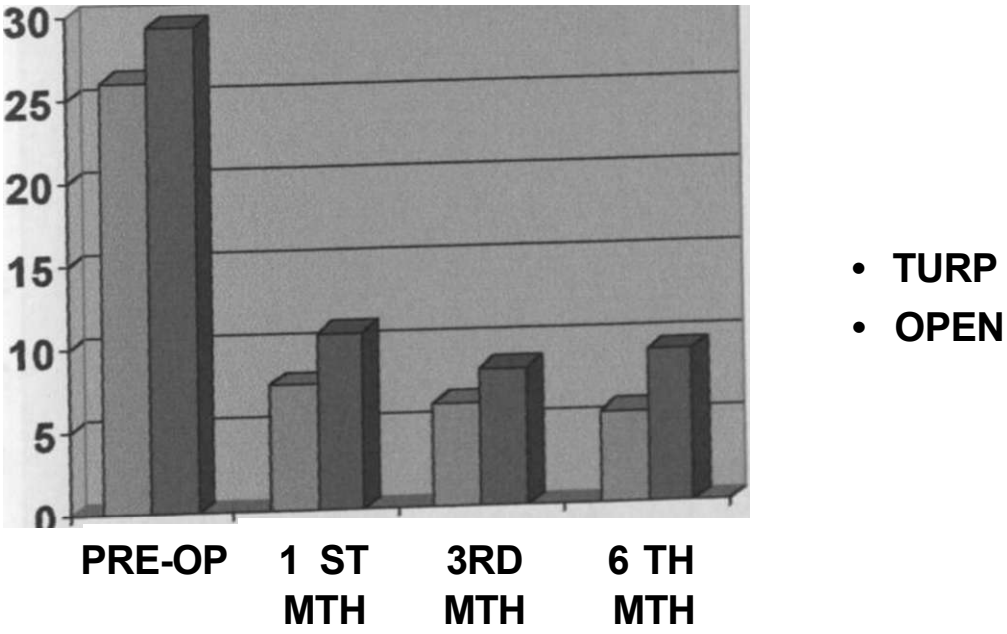


FIGURE VI THF. l-PSS DISTRIBUTION

TABLE V THE QUALITY OF LIFE INDEX fffoi |

QOL (SD)	Pre-op	l" month	3 * month	month
Turp	5.14(0.69)	1.55 (0.57)	0.75 (0 59)	0 57(0 57)
Open	5.33 (0.6)	2.4 (0.50)	1 29(071)	0 75 (0 69)

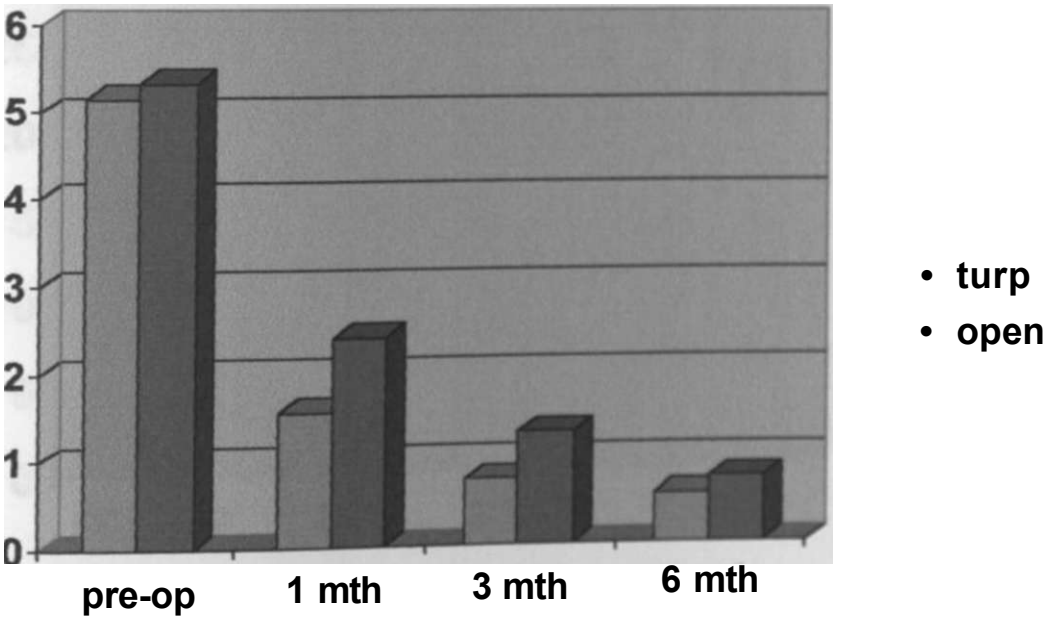
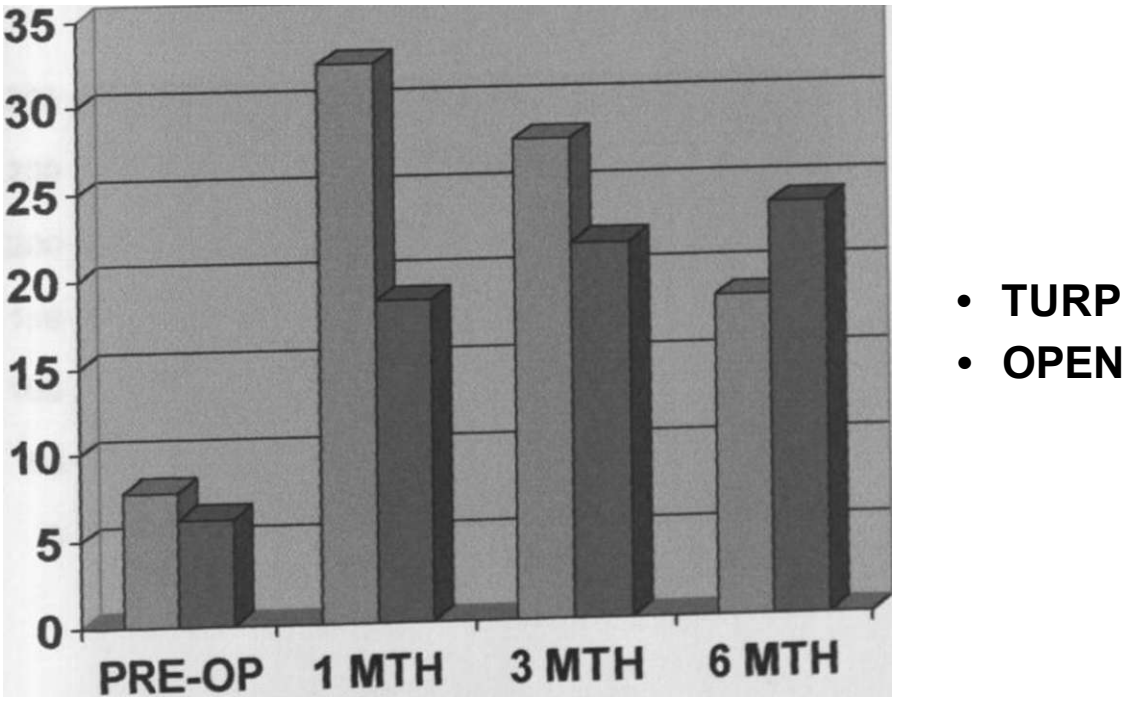


FIGURE VII
THE QUALITY OF LIFE niSTRIBl TION

TABLE IV
THE 0 MAX VARIABLE

Qmax (sd)		Pre-op	l" month	3* month	6* month
	Turp	7.82(1.6)	32.29(38.6)	27.74(42.6)	18.46(3.8)
	Open method	6.16(2.35)	18.58(5.6)	21.73(4.5)	23.85(5.8)



FIGl'RE VIII Q^{max} **distribution before and after surgery**

TABLE VII THE VOIDED VOLfME VARIABLE

Mean voided volume (sd)	**TIME**	**Pre-op**	**1 "month**	**3 month**	**6 * month**
	Turp	**100.3(47 45)**	**274.7(139)**	**246.6(74 4)**	**225.4 (63)**
	Open method	**90.3(49)**	**191.6(107)**	**244.5(93)**	**281.7(116)**

FIGURE IX

VOIDED VOLUME DISTRIBUTION

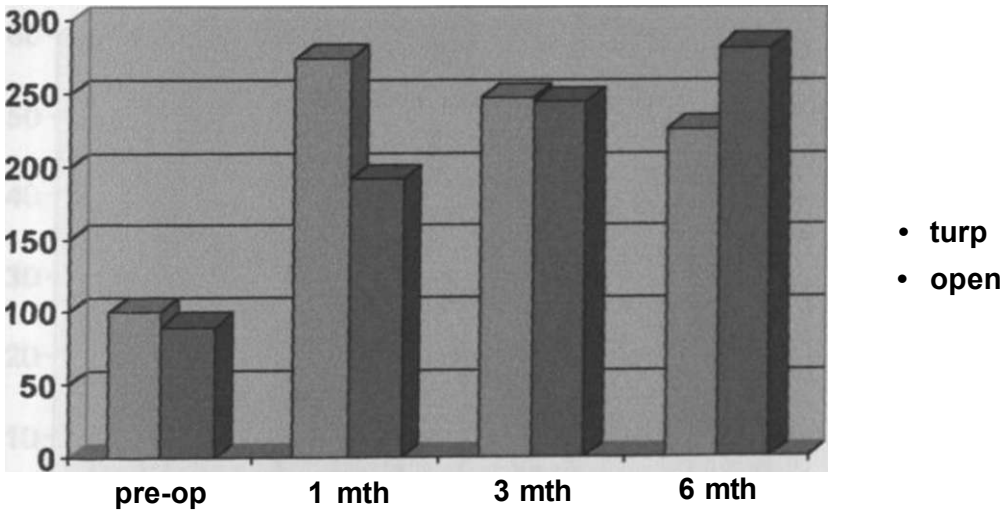


TABLE V THE VOIDED TIME V ARIABLE (SECONDS)

Mean voided time (sd)	TIME	Pre-op	1 " month	3 month	6 * month
	Turp	**27.3(13 8)**	**13.6(5!)**	**18.3(4 4)**	**20.2(4 l)**
	Open method	**52.8(99)**	**25.3(11.3)**	**16.8(83)**	**14.6(5 6)**

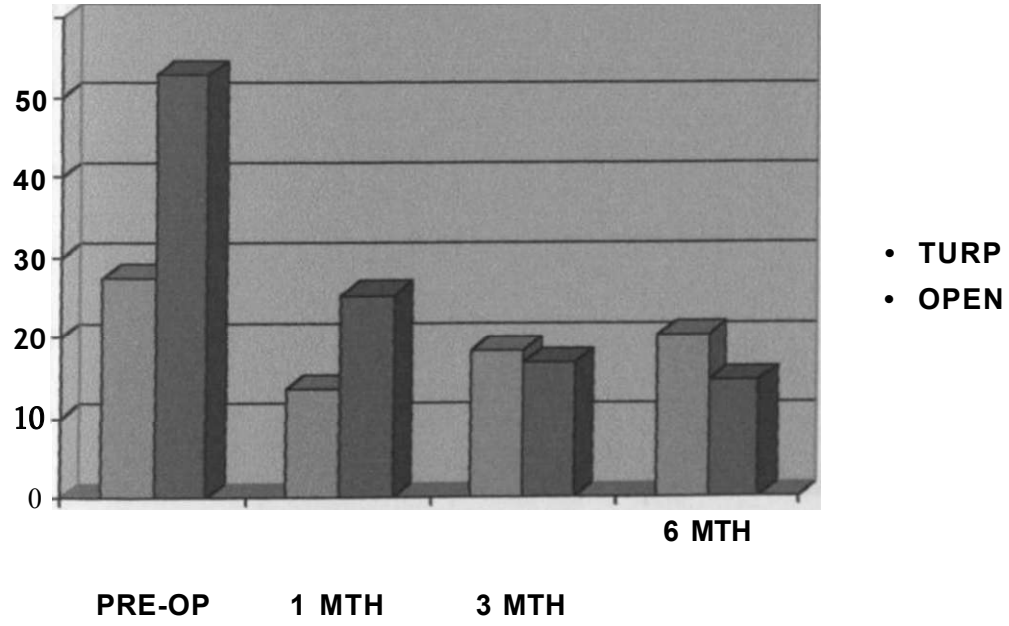


FIGURE X VOIDED TIME DISTRIBUTION

TABLE VI THE POST-VOID RESIDUAL VOLUME (PVR) IN MLS

Mean PVR (SD)	TIME	Pre-op	I " month	3 [w] month	**6 *** month
	TURP	**27.3(138)**	**13.6(5.1)**	**18.3(4 4)**	**20.2(4 I)**
	Open method	**52.8(99)**	**25.3(11.3)**	**16.8(83)**	**14.6(5 6)**

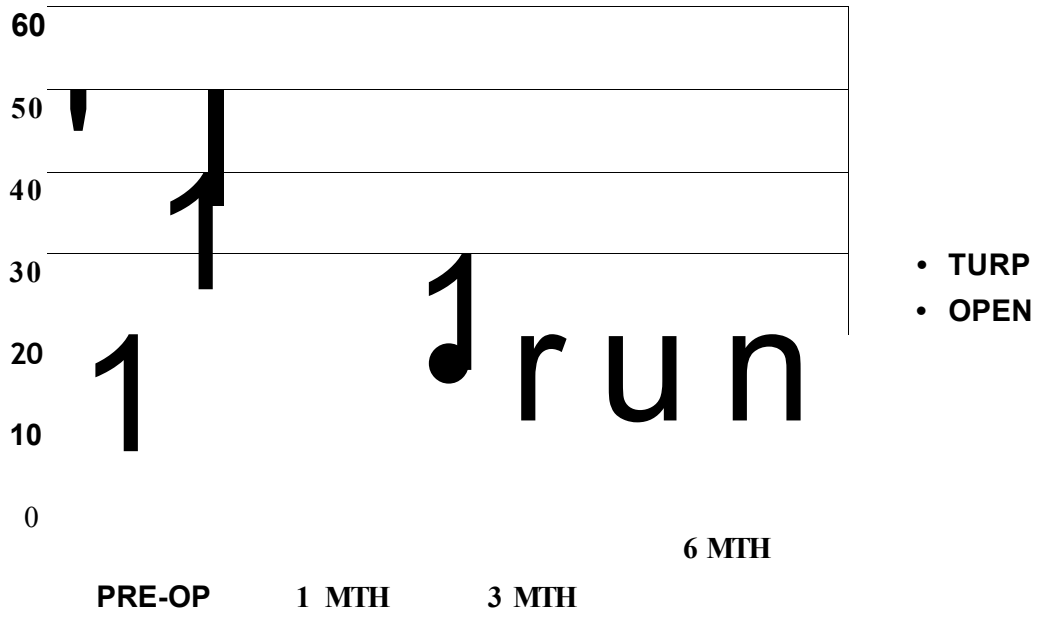


FIGURE XI PVR DISTRIBUTION

TABLE X

THE T TEST PROCEDURE

VARIABLE; Q MAX

Q nuu(mean)||> \alue|	PRE-OP	~5T I MONTH	TSD 3 MONTH	~TH 4 MONTH	
TURP	7.8	32.3	27.7	IL5	
OPEN	**6.16**	**18.6**	21.7	23.9	1
P-VALUE	0 0868	0 000	0.000		**002**

DISCUSSION

The clinical need to test surgical procedures and the desire to avoid post-operative complications as v i as reduce the cost of treatment demands constant re-evaluation of the management of BPH.

In the developed world TURP remains the "gold standard" treatment of BPH due to its supposed low cost, reduced hospital stay and low rates of complications However in our own set-up TURP is still i •I affordable to many patients who may benefit from it. The cost of acquiring and maintaining the equipment is too exorbitant to many hospitals and urologists /surgeons. Open prostatectomy on the ot hand, though it is an invasive procedure, is still much cheaper comparatively. In this study, however. Were not able to tabulate the different costs of the two procedures.

In this study we have compared the two common modalities of surgical treatment in patients prescnti with moderate to severe symptoms of BPH using validated symptom scores as well as uroflowmetric assessments.

The mean age of all the patients recruited was 68years. This compared well with studies elsewhere ***Lytton et al*** in his epidemiological study in New Haven, USA from 1952-63 his mean of ages was 67 Years. (38)

In the "ICS-BPH" study by ***Donovan, Schafer et al*** the mean age was 66.5 years. (44)

22.5%(18) of the patients were aged below 59 years. 25%(20) were aged between 60and 69 years whii 52.5% were aged over 70 years.

There was no significant age difference between the two groups [p-value 0.0571]. The mean age for TURP group was 67.6 years as compared to open method with a mean of68.44 years In this study se Up the surgeon's choice for TURP procedure was largely on evaluation of the prostatic size on DRE. i It is now known that the rate of prostate growth is not entirely age dependent. ***McNeal*** has suggested An inducer mechanism termed epithelial "re-awakening" which stimulates prostatic stroma to induce

Growth The glandular budding and branching mechanism is an expression of re awakening of the embryonic capacity of the tissue in adult life. These phenomenon need an inducer and current now towards specific mediators such as paracrine growth factors These factors are not age dependent(45)

There was a significant difference in the duration of symptoms before operation [p-value 0.0001).

I

The mean period of symptoms for TURP group was 7.62 months compared with 8.66 months in the open method group. The prostate size would invariably be related to the duration since onset of symptoms. The larger the size of prostate, the higher the possibility to perform open prostatectomy as opposed to TURP. There is no documented literature, however, in support of this finding

The length of stay in hospital was remarkably short for TURP group with a mean stay of 3.17 days as compared with the open method with mean stay of 6.22 days The less invasive nature of TURP procedure means less postoperative complications to warrant longer stay in hospital Inherently this reduces hospital care costs to the patient. This is the most positive fact of the TURP procedure

The postoperative length of catheterization was markedly reduced in the TURP group with a mean Duration of 2.17 days while the open method was 3.89 days.

For both groups the mean l-PSS improved after surgery Within the first month after surgery the TUR[1] group improved by 70.5%(a mean of 25.97 pre-op to 7.62) while the open group by 63 5 %< 29.27 to 10.66). At three months post surgery the mean I-PSS for the TURP group was 6.25 while the open gri' was 8.31 recording a change of 21% and 18% respectively However at six months while the Turp grc continue to improve, the open method group resurged to a mean of 9.19 due to recorded complains ol Irritative symptoms

The QOL index score correlated equally for both groups. Before prostatectomy both groups were

Unhappy with their quality of their life they were leading. One month after surgery both groups were Mostly satisfied with their unnary condition. Thereafter they were generally pleased with the outcom< of the operations. I

Both groups had low flow rate velocities below 15-ml/sec. before any intervention. Turp group had a mean velocity of 7.82 ml/sec compared to open group with 6.16 ml/sec. Qmax for both groups improi Significantly after prostatectomy to 32.29 ml/sec (a change of 300%) and 18.58 ml/sec (a change of 200%) for TURP and Open groups respectively. By the third month both Qmax were comparable in ti values. However by the sixth month the TURP group had a lower mean velocity of 18 46ml/sec compared to 23.85 ml/sec of the open method.

It is a known fact that the urethral pain following TURP would make patients expel their unne faster as to be free of the pain. In essence their flow rates will be higher However as healing occurs their pa subsides and their urine flow velocity too decrease. On the other hand, open prostatectomy especially Transvesical type would inherently interfere with bladder contraction mechanisms. The flow velocity urine is dependent on the pressure exerted by the bladder wall (law of Laplace). As healing occurs on the bladder wall they are able to achieve adequate flow rates.

The intraindividual variation of post void residual volume, voiding time and voiding volume was grea j and correlated poorly with symptom scores as well as the maximum flow rates.

When the maximum flow rate velocity was subjected to student-t -test procedure, there was no Significant difference between the two groups before surgery [p-value 0 0868]

After surgery there was significant difference in outcome between the two groups with a p-value of 0.000 at one month, and three months. At six months the p-value was 0.0288

CONCLUSION

- While uroflowmetry cannot replace pressure-flow studies in the diagnosis of BOO, it can prov valuable improvement over using symptoms/signs alone in the diagnosis of the cause of lower urinary tract dysfunction in men presenting with LUTS. At Kenyatta National Hospital patients presenting with LUTS are diagnosed by symptoms This study provides performance statistics for Qmax with respect to BOO. Since statistics may be used to define more accurately tf presence or absence of BOO in men presenting with LUTS, so avoiding the need **for formal** prcssi flow studies in everyday clinical profile, while improving the likelihood of a successful outcome form prostatectomy. Uroflowmetry is a simple, non-invasive, well accepted by patients and easily used as an office tool. This study also show that uroflowmetry is very useful for follow-up of patients after prostatectomy. Indeed if Qmax is still low below 15 ml/sec after prostatectomy, thei there is need for re-evaluation of urethral blockade.

- International Prostate symp6tom score (I-PSS) and Quality of Life (QOL) indices have been show in this study to be very useful validated indices and they are internationally recognized and approved.

Without these parameters it is difficult to assess outcome of surgical treatment in patients with BP Follow-up symptom indices provide useful information on the state of urethral blockage

The intra-individual variation of post-void residual volume, voided volume and voiding time was great. This correlated poorly with symptom score and maximum flow rate. These parameters ma?[1] be of limited use in patients with BOO.

- TURP procedure has been show to be superior to open prostatectomy in terms of outcome Th Length of hospital stay and duration of post-operative catheterization were remarkably low. The Qmax and symptom scoring were equally impressive in comparison. The mean age of presentatio

of our patients was 68 years. More proportion presented after 70 years (5.7%) compared to westei **figures (3.6%)**

RECOMMENDATION

All patients presenting with LUTS suggestive of BOO at Kenyatta National Hospital surgical outpatient clinics should undergo uroflowmetry evaluation to complement clinical argument in the diagnosis of BPH. Post-operatively all patients should be followed up with flow rates

The UrodynR 1000 equipment remain un-utilized in the minor theatre room of the surgical outpatient clinic.

All patients should also be subjected to international prostate symptom score (IPSS) and quality ol life assessment indices of course I know it is difficult to memonze the long charts. The least Kenyatta National Hospital can do is put-up the IPSS at QOL charts in all surgical consultation rooms for easier reference. There should be a Kenyatta National Hospital Prostate Management Protocal. At present, a patient presenting with BOO, whatever the category of symptoms, is booke for prostatectomy.

The following guideline flow chart is recommended (SEE NEXT PAGE)

FLOW C HART GUIDELINE FOR MANAGEMENT OF BPH

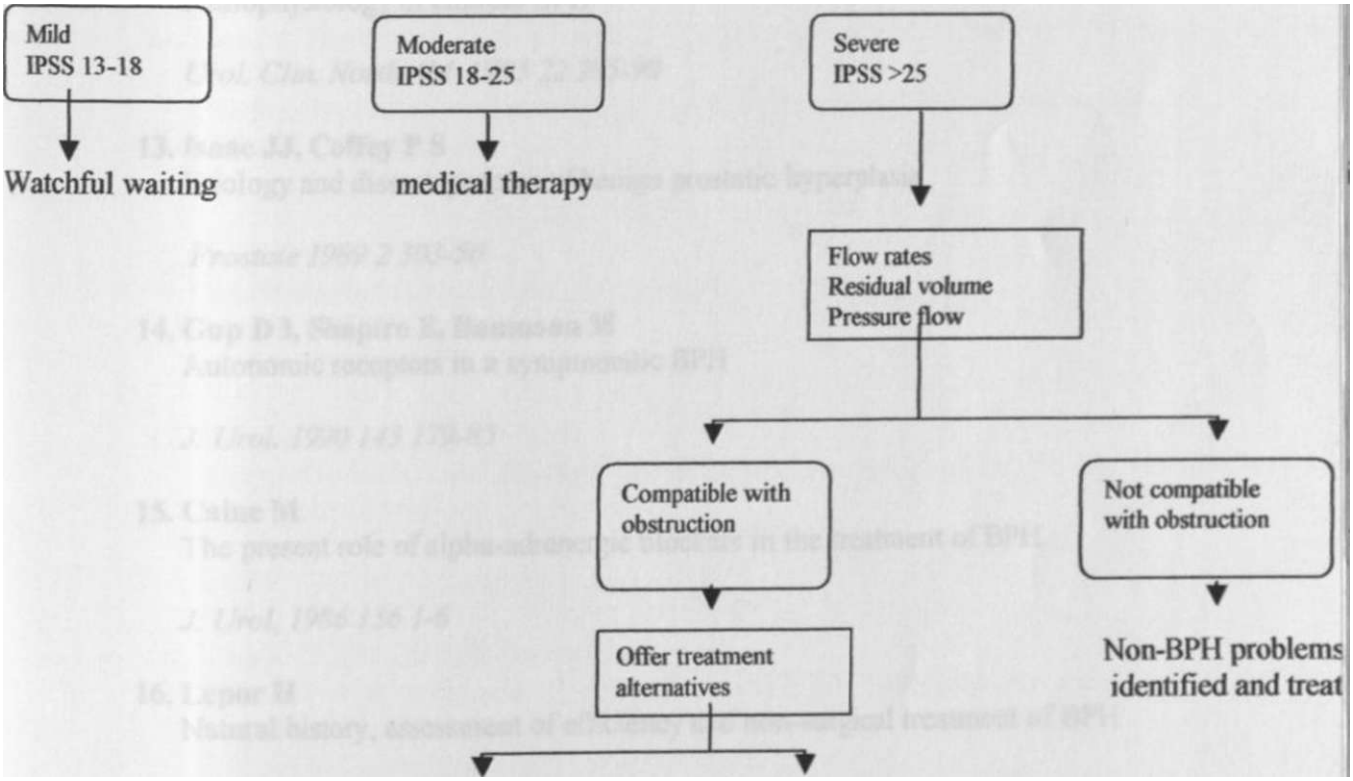
Initial evaluation

- **History**
- **DRE**
- **Urine analysis**
- **Creatinine**
- **PSA**

£

Objective symptom assessment
IPSS, QOL

1



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TURP, open

Balloon
Dilatation

Others

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APPENDIX I

INFORMED CONSENT - Explanation

Title of Study:

The role of uroflowmetry in benign prostatic hyperplasia

Institutions;

Kenyatta National Hospital, University of Nairobi

Principal Investigator:
Dr. Florentius K. Koech MBchB(Nrb)

It is very important that you understand the following general principles that apply to all participants i our studies:

Participation is voluntary.

You may withdraw from this study or any part of this study at any time. Refusal **to** participate will involve no penalty or loss of benefits to which you are otherwise entitled.

After the explanation, please feel free to ask any questions that will allow you to clearly understand **t!** nature of this study.

Introduction

In the past years diagnosis of benign prostatic hyperplasia has been entirely on clinical grounds. However confusion has arisen whereby patients presenting with lower urinary symptoms (LUTS) are booked for surgical procedures without objective definition of Bladder Outlet Obstruction (BOO).

Uroflowmetry assesses the state of bladder outlet obstruction and its severity.

In this study we hope to objectively prove beyond doubt the cause and severity of bladder obstruction patients presenting with LUTS and compare with the results after starting treatment

This will help the institutions of KNH and University of Nairobi in planning future treatment protoco in patients with LUTS.

Procedure to be followed:

Questionnaire:

If you agree to participate in this study you will answer some questions about your symptoms

Clinical Examination:

You will then be requested to have a thorough body examination including a digital rectal e (DRE)

Lab tests

You may be requested to perform some laboratory tests like Prostatic specikfic antigen (PSA) to rule • or confirm the state of your disease.

Uroflowmetry:

With a full bladder you shall be requested to void into a diaphragm, which will record your urine flow

Treatment:

Your options of treatment shall be fully explained to you. You shall be able to understand the benefit and risks of each option.

Follow up:

Upon the definitive treatment given, you shall be required to undergo further uroflowmetry tests after one, three and at six months.

Risks:

The risks from participating in this study are minimal. There is the possibility of mild discomfort on urethral catheterization.

Benefits:

Participation in this study provides benefits to the individual volunteer and the community.

Individual with LUTS shall objectively be assessed for BPH and treatment arranged as soon as possib Individuals with suggestive findings of carcinoma of the prostate shall be required to undergo PSA te: and early treatment arranged.

The community shall benefit from the results of the study for future planning.

NUMBER OF VOLUNTEERS IN THE STUDY

80 patients were recruited

ASSURANCE OF CONFIDENTIALITY OF VOLUNTEERS IDENTITY

Records relating to your participation in the study will remain confidential. The supervisor of the stm

may review the records as part of their responsibility to oversee the research. Your name will not be

Used in any report resulting from this study.

FOR INFORMATION OR ANSWERS TO QUESTIONS CONCERNING YOUR RIGHTS AS A RESEARCH SUBJECT YOU MAY CONTACT;

The chairman of Kenyatta National Hospital ethical committee

IF THERE IS ANY PORTION OF THIS CONSENT/EXPLANATION THAT YOU DO NOT UNDERSTAND, ASK THE INVETIGATOR BEFORE SIGNING.

I acknowledge receipt of this informed consent explanation.

SUBJECT'S NAME:

SUBJECT'S SIGNATURE

STUDY NUMBER

DATE

APPENDIX II

INFORMED CONSENT AGREEMENT

I.....(Subject's nameO having full capacity to corisen; for myself and having attained my.....Birth day, do hereby consent to my participating in the research study the value of uroflowmetry in Benign prostatic hyperplasia at Kenyatta National Hospital' under the direction of Dr F. K. Koech.

The implication of my participation, the nature, duration and purpose, the methods and means by whi it will be conducted and the inconveniences and hazards which may be reasonably expected have beei explained to me by

I have been given the opportunity to ask questions concerning this investigational study, and any such questions have answered to my full and complete satisfaction. Should any questions arise, I may cont Dr. F. Koech at Telephone Number 072-714397, Box 2783 KNH Nairobi.

I understand that I may at any time during the course of this study revoke my consent and withdraw myself from the study without prejudice; however, I may be requested to have myself undergo further examinations if in the opinion of the doctor such an examination is necessary for my well being

SUBJECT'S NAME

SUBJECT'S SIGNATURE

STUDY NUMBER

DATE

APPENDIX 111

QUESTIONNAIRE

(A)

NAME:

AGE:

SEX:

STUDY NUMBER:

TRIBE:.....\

(B) PAST MEDICAL/TREATMENT HISTORY

History of diabetes mellitus Yes/No

History of any Neorological disease Yes/No
If yes, specify

History of previous surgery
On bladder, prostate or urethra Yes/No

History of reccnt mcdication active
On the lower urinary tract
e.g. alpha adrenergic blockers Yes/No

History of urinary instrumentations
e.g. catheters within the past one month Yes/No

Currently on an in dwelling catheter Yes/No

(C) INTERNATIONAL PROSTATE SYMPTOM SCORE
(I-PSS)

	Never	About 1 time in 5	About I Time in	About Time in 2	About 2 Times in 3	Almost always

			3			
Incomplete emptying: Over the past month, how often have you had a sensation of not emptying your bladder completely after you have finished urinating?	0	1	2	3	4	5
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
Intermittency: Over the past month, how often have you found you stopped and started again several times when you urinated	0	1	2	3	4	5
Urgency: Over the past month, how often have you found it difficult to postpone urination?	0	1	2	3	4	5
Weak stream: Over the past month, how often have you noticed a reduction in the force of your urinary stream	0	1	2	3	4	5
Straining: Over the past month, how often have you had to push or strain to begin urination	0	1	2	3	4	5
Nocturia: Over the past month, how many times did you most typically get up to urinate from the time you went to bed until the time you got up in the morning	**None**	**1 time**	**2 times**	**3 times**	**4 times**	**5 or more times**
TOTAL IPSS SCORE OUT OF A TOTAL OF 35			«;TH 'i 1—	LIBRA'		

OF

	Delighted	Pleased	Mostly satisfied	Mixed	Mostly dissatisfied	**Unhappy/terrible**
Quality of life due to urinary symptoms: If						

you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about it	0	1	2	3	4	5

(D) EXAMINATION FINDINGS

The state of the prostate on DRE

(1) Consistency	soft/firm/hard?
(2) Surface mucosa	smooth/irregular?
(3) Mobility	free/fixed?
(4) Median sulcus	Present/obliterated?
(5) Size	small/moderate/Iarge?

(E) UROFLOWMETRY FINDINGS

1. voiding time in seconds
2. Time to maximum flow TQ max
3. Maximum (peak) flow rate in mis/sec
   Q max.
4. Total voided volume in mis
5. Residual urine volume in mis

(F) PSA LEVELS