

A SHORT TERM EVALUATION OF TRANSURETHRAL
ABLATION OF THE PROSTATE AS A TREATMENT OPTION
FOR BENIGN PROSTATIC HYPERPLASIA AT THE
UNIVERSITY TEACHING HOSPITAL, LUSAKA.

BY

DR OMEGA CHITUWO Bsc Hb, MBCChB (UNZA)

THESIS
M.MED
CHI
2003
C.I

A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT
OF THE REQUIREMENTS FOR THE AWARD OF THE
MASTER OF MEDICINE (SURGERY) DEGREE OF THE
UNIVERSITY OF ZAMBIA.

SCHOOL OF MEDICINE
UNIVERSITY OF ZAMBIA

2003


SUPERVISORS PAGE

The dissertation of Dr Omega Chituwo is ready for examination.

Signed (Supervisor) 

Signature

DR M.A. LABIB MD (UROLOGY)
SENIOR LECTURER IN SURGERY
UNIVERSITY OF ZAMBIA
SCHOOL OF MEDICINE

Signed (Co-supervisor) 

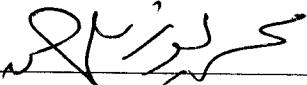
Signature

Dr K Bowa
MSc(Glasgow), Mmed Ch (UNZA), FRCS(Glasgow)
LECTURER IN SURGERY
UNIVERSITY OF ZAMBIA
SCHOOL OF MEDICINE

COPYRIGHT DECLARATION

I hereby declare that the work presented in this study for the Degree of Master of Medicine (Surgery) represents my work and has not been presented either wholly or in part for any other degree and is not being currently submitted for any other degree at the University of Zambia or any other University.

Signature of Candidate _____ Date _____

Signature of Supervisor  _____ Date 4/10/04

APPROVAL

This dissertation of Dr. Omega Chituwo is approved in partial fulfillment of the requirements for the award of the Master of Medicine in Surgery by the University of Zambia.

Signature

Date

AKNOWLEDGEMENT

I am greatly indebted to Dr M.A. Labib, Consultant Urological Surgeon and Lecturer in Surgery, University of Zambia, School of Medicine; for his assistance, encouragement and guidance in developing the research, which was born out of my time spent in Urology.

I would also like to thank Mr K Bowa, Consultant Surgeon and Senior Registrar (Urology), for his assistance in the preparation of this dissertation.

Abbreviations

AUA	American Urological Association
BPE	Benign Prostatic Enlargement
BPH	Benign Prostatic Hyperplasia
IPSS	International Prostate Symptom Score
LUTS	Lower Urinary Tract Symptoms
Q-max	Peak flow rate of urine
TEAP	Transurethral ethanol ablation of the Prostate
TURP	Transurethral resection of the Prostate
UTH	University Teaching Hospital

Table of figures

FIGURE	PAGE
Table 1 – Age Distribution	33
Table 2 – Intraoperative procedure findings	34
Table 3 – Postoperative findings – initial	35
Table 4 – TEAP postoperative findings – months	36
Table 5 – Postoperative requirements/costs	37
Figure 1 – Change in IPSS over time pre and postoperatively	38
Figure 2 – Peak flow rate (Q-max) over time	39

Table of Contents

Subject	Page
1. Abstract	x
2. Introduction	1
3. Objectives	3
4. Rationale	3
5. Literature Review	4
Introduction	4
Epidemiology	5
Prevalence	6
Aetiology	6
Anatomy	8
Pathophysiology	10
Symptoms and Complications	11
Diagnosis	14
Treatment	17
6. Patients and methods	22
7. Results	30
8. Discussion	38
9. Conclusion	43
10.Recommendations	44
11.References	49
12.Appendices	54

Abstract

A prospective study evaluating the procedure, Transurethral ethanol ablation of the prostate (TEAP), as a treatment option in the University Teaching Hospital, Lusaka.

Twenty-five patients from the Urology clinic, UTH, were included in the study. The patients had mild to moderate BPH, determined by symptoms and on examination. Other factors taken into consideration were in the inclusion and exclusion criteria e.g. No history of urinary retention or other related complications, pelvic surgery or trauma etc.

The details of each patient were collected and included name, age, file number, date of admission, date of discharge, preoperative prostate size, IPSS, operating time, intraoperative complications, and postoperative assessment.

The mean age was 68 years. Preoperatively, the patients had a mean of IPSS of 22 with a range of 18 – 25. The average operating time was ten minutes. Simple analgesia was used to relieve any discomfort postoperatively.

Patients were kept overnight and discharged with a catheter. This was removed after 5 days. Two patients went into acute retention following catheter removal. They were catheterized for a further 5 days and did not develop any problems thereafter.

Postoperatively, mean IPSS reduced from 18 at one month to 11 at six months indicating an improvement in symptoms of patients. Ease of voiding improved with time as was evidenced by the increase in mean peak flow rate of urine (Q-max) of 11ml/s at one month to a mean of 19ml/s at 6 months. In terms of cost, TEAP was found to be much cheaper than the traditional forms of treatment at UTH, i.e. TURP and open prostatectomy

TEAP was found to be a feasible, safe and cost effective method of treating mild to moderate BPH at UTH. Guidelines for its use have been set down.

INTRODUCTION

Benign prostrate hyperplasia (BPH) consists of about 40% (2,978 patients out of a total of 7,500 urology pathologies) of the cases seen in the Urology clinic at the university teaching hospital (UTH)(1). Benign prostratic hyperplasia commonly affect the aging male population resulting in significant morbidity (2).

The patient normally presents with symptoms signs and sequelae of bladder outlet obstruction (BOO) such as poor flow, hesitancy and poor bladder emptying (2). Possible sequelae are increased: residual urine, recurrent urinary tract infection, stone formation and renal impairment (3,4). However, not all clinical symptoms are due to obstruction but due to age induced detrusor dysfunction (5).

There are different treatment modalities for BPH worldwide, which can basically be divided into conservative management such as watchful waiting or medical therapy (Alpha blockers or androgen suppressors) and surgical treatment such as open prostatectomy transurethral resection of the prostate (TURP) etc.

Watchful waiting in Zambia is usually not a suitable option as many present at an advanced stage requiring active management rather than conservative treatment. Medical treatment on the other hand is quite expensive for the average Zambian. In addition, such medicines are not catered for under the already strained government medical health system.

This leaves surgical treatment as the most common treatment modality at UTH.

Surgical treatment has its own associated complications and is quite expensive in terms of expertise (staff) and money spent by health sector on hospital stay, theatre time and materials. The commonest type of surgical treatment performed at UTH is open prostatectomy and transurethral resection of the prostate. Unfortunately, there is a long waiting list for operation (6-18 months) due to the large number of patients and the small number of experienced staff. Whilst awaiting surgery, patients normally have indwelling catheters for long periods of time. They are changed every 4-6 weeks. Prolonged use of indwelling catheters may lead to urinary tract infections (UTI's), urethral strictures and bladder stones.

An alternative treatment modality has been explored in North America and Europe with favourable results but has not been used in Africa. Studies have shown differences in prostate size, LUTS (Lower Urinary Tract Symptoms), severity and bothersomeness of symptoms in different races hence the need to take these differences into consideration in studies (6). It is a minimally invasive treatment modality known as transurethral ethanol injection or ablation of the prostate (TEAP). Injection of the prostatic adenoma results in lysis of the adenoma with subsequent tissue reduction and widening of the prostatic urethra. Ethanol

has proved to be an effective medium for chemoablation (7). It has proved to be safe, inexpensive and effective with a short postoperative hospital stay and a low incidence of complications in comparison to other treatment modalities in Europe and America (7). However, no comparisons have been made in Africa since its inception, neither have any guidelines for its use in Africa been made.

OBJECTIVES

1. To evaluate the feasibility, safety and efficacy of transurethral ethanol ablation of the prostate (TEAP) in a selected group of patients with benign prostatic hyperplasia at the University Teaching Hospital.
2. To set down guidelines for the use of TEAP in BPH patients in the Zambian setting.

RATIONALE

Transurethral ethanol ablation of the prostate is a minimally invasive and relatively cheaper and quicker method of treating BPH. It does not require expensive equipment and results in short hospital stay (hence cutting down costs) with reduced morbidity.

The only documented information available on TEAP is about North America and Europe whilst there is no information on it in Africa. This is a pioneer study seeking to document the feasibility, safety and efficacy in a Zambian setting whilst seeking to evaluate any complications. The study also seeks to lay down guidelines for its use in Zambia. And possibly even Africa. Minimal training is required and is much cheaper and less complicated than other forms of treatment for BPH. Since it is not a complicated procedure, once the guidelines are in place, not only can urologists perform it but general surgeons too. The reduced time of the procedure means that more patients can be attended to much quicker by the limited number of staff. This will result in reducing the long waiting list.

LITERATURE REVIEW

INTRODUCTION

Benign prostatic hyperlasia is one of the commonest pathologies affecting the prostrate gland in the aging male (8,11,13). Patients with benign prostate hyperlasia make up about 40% of the patients seen in the urology clinic at the University teaching Hospital (1). A study done by Arbo M.I showed that BPH tends to progress more, with a measurable progression

in urinary symptom severity, in African American men in comparison to white men (11). It has been shown that symptomatology is reported in nearly 50% of men over 50 years of age (8).

EPIDERMIOLOGY

BPH is the most common benign tumour in men (9,10). Estimates of BPH prevalence depend on the definition of the disease. It has been defined in various ways as benign prostatic enlargement (BPH), histologic hyperplasia, lower urinary tract symptoms (LUTS, diminished uroflow or urodynamic obstruction (bladder outflow obstruction – BOO) or Benign prostatic enlargement (BPE).

1. Benign prostatic hyperplasia or histologic hyperplasia denotes the histological entity.
2. Benign prostatic enlargement (BPE) denotes the clinical finding on digital rectal examination.
3. Bladder outflow obstruction (BOO), diminished uroflow or urodynamic obstruction (loosely banded together as benign prostatic obstruction) describes the urodynamic state and symptoms associated with the pathology.
4. Lower urinary tract symptoms (LUTS) are basically descriptive of the symptoms seen in the disease.

PREVALENCE

At the end of puberty, the prostate reaches approximately 26 grams and is maintained at that weight unless BPH develops. At the beginning of the fourth decade, only 8% of men have BPH (11). 50% of men aged 50 – 60 and 90% of men over 80 years have histologic BPH (11). BPH increases with age and is present in almost all men by the 80s or 90s (4,7,12). The odds of moderate to severe symptoms (rated according to the International Prostate Symptom Score (IPSS), >20) increases with age from 1.9 for men 50-59 years old, to 3.4 for men 70-79 years of age. Results from the Baltimore Longitudinal study of aging study suggests the proportion of the male population with the clinically recognizable LUTS by a given age is about the same proportion with pathological evidence of BPH despite the poor correlation between symptoms and prostate size of histology in individual patients (13).

It is more prevalent in the West in comparison to the Far East (9,10). However, Asians who migrate to the West acquire a higher rate of BPH than their counterparts remaining on the East.

AETIOLOGY

The major aetiological risk factors that have been established are:

1. Increasing age: The aging process induces a block in the maturation process thereby lowering the overall rate of cell

death. This leads to cellular accumulation. There is also an observed increase in cellular number due to epithelial and stromal proliferation. (4)

2. Normal male androgen hormone status (4,13,14):

Dihydrotestosterone (DHT) is derived from testosterone. It is the major intracellular androgenic prostatic metabolite and the main stimulant of prostatic growth. It had been postulated that with aging, the prostate becomes more sensitive to androgens. These have a supporting role in established BPH (10). Androgen withdrawal leads to partial involution of established BPH. The disease is not seen in 20year old men or in men castrated before puberty because these men have a reduction in the male androgen hormone.

3. Genetic factors: BPH has been demonstrated to be an inheritable disease (10). Those with a family history of BPH have been shown to have a more severe form of BPH. However, the specific gene or genes have yet to be elucidated.

4. Other risk factors: Oestrogens, growth factors stromal epithelial interaction and neurotransmitters either singly or in combination are thought to play a role in the aetiology of BPH (10).

ANATOMY

The prostate is a firm glandular and partly fibromuscular body surrounding the commencement of the urethra in the male. It is somewhat conical in shape with base, apex, posterior, and two lateral surfaces, which make up the right and left lateral lobes, a median lobe and anterior lobes. The prostate extends from the bladder neck to the superior aspect of the sphincter urethra and the transverses profundus. The urethra passes through the gland. This part of the urethra is known as the prostatic urethra.

Histologically, Mc Neal (1972) divided it into 4 well-defined zones of glandular tissue as follows:

1. The Peripheral Zone: This accounts for 70% of the volume of the adult prostate and contains about 75% of the total glandular tissue (15). It is also the region of the prostate in which the majority of the carcinomas arise (15).
2. The Central Zone: It comprises about 20% of the total mass of the prostate and 20% of the prostate glandular tissue (16). It extends from the base of the prostate to the verumontanum. McNeal distinguishes the central zone from the peripheral zone by the differences in glandular architecture and cytological detail (16).
3. The Transitional Zone: This comprises 10% of the total mass of the prostate but only 5% of the total glandular tissue. It is prone to

hyperplasia and accounts for the increase in size of the prostate in BPH (15). As it increases in size it compresses the peripheral zone producing a distinct 'capsule' that provides a cleavage plane during enucleation.

4. The Anterio-fibromuscular Zone: This makes up about a third of the total mass of the prostate. It does not contain glandular tissue (16).

From birth to puberty, there is slow and continuous increase in the size of the prostate. At puberty there is a rapid increase to twice its original size. These changes are probably due to an increase in the secretion of testosterone into the blood stream by the testis. After the age of forty-five to fifty the prostate may either undergo benign hypertrophy so that its size increases gradually until death or undergoes progressive atrophy. However, hypertrophy of the prostate is much more common than atrophy.

In advanced life, the prostate often becomes considerably enlarged and projects into the bladder impeding the passage of urine, elongating and distorting the prostatic urethra. In some cases when the median lobe enlarges, it acts as a valve of sorts over the internal urethral orifice. This prevents the passage of urine and the more the patient strains the more it

blocks the opening of the bladder. The longer the patient remains untreated the more the bladder will become hypertrophied.

PATHOPHYSIOLOGY

BPH results in symptoms associated with bladder outflow obstruction.

1. Firstly, there is mechanical or anatomical obstruction of the bladder outlet by an enlarged prostatic adenoma, which is secondary to the enlargement of the transurethral zone in the periurethral area of the prostate.
2. The bladder outflow obstruction may be due to an increase in the smooth muscle tone in the bladder neck and prostatic capsule (4,17). These smooth muscle fibres are richly innervated by alpha-1-adrenergic receptors. Stimulation leads to an increase in tension of the smooth muscle fibres with resultant increase in urinary resistance to outflow. Blockage on the other hand relaxes the smooth muscle resulting in and improvement of the patient's signs and symptoms (6,14,17).

LUTS associated with BPH presents as bladder outflow obstruction (BOO) and is affected by detrusor function, which declines with age.

Bladder outflow obstruction due to any cause results in two types of obstruction induced changes in the bladder. Firstly, there must be resultant detrusor instability or decreased compliance, which are

clinically associated with symptoms of frequency, urgency, nocturia and urge incontinence. These are known as irritative or storage symptoms. Secondly, there are changes associated with deterioration in the force of urinary stream, hesitancy, intermittency, increased residual urine and terminal dribbling. These are known as obstructive or voiding symptoms (17). There are minimal correlations or none at all between IPSS and the degree of obstruction as assessed by pressure flow urodynamics (15).

SYMPTOMS AND COMPLICATIONS

It is difficult to identify a clinical indicator that might be useful in predicting which patients will develop serious BPH complications without bothersome symptoms. Silent BPH, a rare condition, is described in men with histology hyperplasia and urodynamic obstructive but without bothersome symptoms.

Although mortality from BPH is rare and complications are uncommon, the symptoms of LUTS are bothersome to many patients. The reported death rate for men over 45 years in East Germany to 0.5 per 100,000. However lack of uniformity in criteria for attributing deaths to BPH limits the usefulness of these data. A study by Napalkov et al (1995) clearly demonstrates that the death rate for BPH is significantly lowered by management strategies employed in developing countries (7). When symptoms interrupt normal daytime activities or sleep, create anxiety or reduce perception of general health, the quality of life can decline

significantly. Yet the degree of bothersomeness may be dramatically different for different patients with the same degree of symptom severity (6).

Complications of BPH are acute urinary retention, chronic urinary retention, urinary tract infection, renal impairment, bladder decomposition and detrusor instability.

1. ACUTE URINARY RETENTION: 25% to 30% of men undergoing prostatectomy studies had an acute episode of acute retention (6). Risk factors resulting in acute urinary retention are acute prostatic infraction (6), acute urinary tract infections, renal impairment, infection, age and medical problems (3, 18).
2. CHRONIC URINARY RETENTION: This complication may occur with upper tract dilation and renal impairment, which may be reversible (4, 6).

Detrusor pressure normally rises to 15mmH₂O or less in full bladder. This is higher in patients with chronic retention. Those with pressures of less than 25mmH₂O are classified as having high-pressure chronic retention (19). This division enables accurate prediction of the outcome of prostate surgery. Patients with high bladder pressures tend to do well after adequate prostate surgery whilst those with low bladder pressures have less satisfactory results. It is important to identify these men early, a point in favour of routine measurement of

residual urine in order to identify those at risk. Large residual urine is a sign of detrusor failure (3).

3 URINARY TRACT INFECTIONS (UTI): A fraction of patients have UTIs when they present with BPH. This may be in part due to the residual urine or chronic urinary retention. Internationally, between 20% and 50% of men undergoing prostate surgery have urinary retention (16). However, the likelihood that a patient with a given symptom complex will progress to complete urinary retention over a given time span is not certain, but is probably in the range of 1% per year.

4. BLADDER STONES: Residual urine, chronic urinary retention, foreign bodies (such as a fragment of a catheter balloon) and dietary factors favour the formation of bladder stones. The prevalence of bladder stones in men undergoing surgery for BPH is approximately 1% to 2% (16).

5. BLADDER DECOMPOSITION, DETRUSOR INSTABILITY AND IMPAIRMENT: All these may be due to chronic outlet obstruction in untreated BPH in some patients. Anatomical changes such as trabeculations and diverticula formations are seen (6). Histological studies of trabeculated human bladder show fibrosis in the muscle of the obstructed bladder (6). About 50% to 60% of men

with bladder outflow obstruction have systematic evidence of inhibited contract actions of the detrusor, so called detrusor instability (3,6). This correlates with the irritative symptoms of prostatism such as frequency and urgency. However, impaired detrusor contractility may occur and is associated with deterioration in the force of the urinary system, hesitancy, intermittency, increased residual urine and detrusor failure (in minority cases).

DIAGNOSIS

MEDICAL HISTORY

There must be a detailed medical history focusing on the urinary tract, previous surgical procedures, general health and fitness issues for possible surgical procedures that must be performed (16).

PHYSICAL EXAMINATION

A full physical examination must be done with emphasis on focused neurological examination and digital rectum examination (16). In addition, examination of the external genitalia must be done.

Rectal examination establishes the approximate size of the prostate gland, however, the size of the gland should not be considered in deciding whether active treatment is required. Prostate size does not correlate with symptom severity, degree of undynamic obstruction, or treatment outcomes (20, 21, 22). If a more precise measurement of the prostate size

is needed in decision making transrectal ultrasonography is more accurate intravenous urography or urethro-cystoscopy.

INVESTIGATIONS

URINALYSIS

A urinalysis must be done to rule out urinary tract infection and haematuria, either of which strongly suggests non-BPH pathology as a cause of symptoms (6).

SERUM CRETININE

Measurement of serum creatinine should be performed on all patients with LUTS to exclude renal sufficiency due to the presence of obstructive uropathy (23).

SYMPTOM ASSESSMENT

The IPPS, which is identical to the AUA symptom index, is recommended as the symptom-scoring instrument to be used for the baseline assessment of symptom severity in each patient presenting with LUTS (6). The IPPS cannot be used to establish the diagnosis of BPH. However, the IPPS is the ideal instrument to grade baseline symptom severity, assess the response to therapy and detect symptom progression in those men managed by watchful waiting.

UROFLOWMETRY

It is the electronic recording of the urinary flow rate throughout the course of micturation. Flow rate recording is the single best non-invasive

urodynamic test to detect lower urinary tract obstruction. The peak flow rate (Q-max) more specifically identifies patients with BPH than does the average flow rate. Flow rate measurements are inaccurate if the voided volume is less than 125ml to 150ml. Patients With a Q-max greater than 15ml/second appear to have somewhat poorer treatment outcome after prostatectomy than patients with a Q-max less than 15ml/second. A Q-max of less than 15ml/second does not differentiate between obstruction and bladder decomposition (6).

POSTVOID RESIDUAL URINE

This is the volume of fluid remaining in the bladder immediately following micturation. Residual urine volume has significant intra-individual variability that limits its clinical usefulness. Residual urine can be measured with a sufficient accuracy non-invasively by a bladder scan. Residual urine volume does not correlate with other signs or symptoms of BPH. It is uncertain whether residual urine volume predicts the outcome of surgical treatment (6).

URETHROSCOPY

Urethroscopy is not recommended to determine the need for treatment (6). The test is recommended for men with LUTS who have a history of microscopic or gross haematuria, urethral stricture disease or risk factors (arthritis or urethral injury).

IMAGING OF THE URINARY

Upper Urinary tract imaging is not recommended in the routine evaluation of men with LUTS unless they also have one or more of the following: haematuria, UTIs, renal insufficiency, a history of urolithiasis or a history of urinary tract surgery (6). The presence of the previously mentioned symptoms and signs increases the likelihood that intravenous urography or ultrasonography will demonstrate clinically significant findings (24,25,26,27,28).

TREATMENT

The aims of treatment are to relieve urinary symptoms, improve quality of life and to reduce complications of bladder outflow obstruction.

1. WATCHFUL WAITING

This strategy is optional for the patients with mild to moderate symptoms. Patients with mild symptoms (IPPS<8) and without recurrent urinary retention, urinary tract infections, gross haematuria, bladder stones or renal insufficiency are strongly recommended for watchful waiting (WW). Moderate indication for WW would be a patient with IPPS>8 and <20, but not bothersome symptoms, higher peak urinary flow rate and low post-void urinary residual (29). WW does not imply a total absence of intervention. The severity and distress due to symptoms can be improved through simple measures such as decreasing total fluid intake, especially just before going to sleep, moderating alcohol intake and

intake of caffeine containing products; and following a timed voiding schedule.

2. MEDICAL TREATMENT

Medical treatment is an acceptable alternative for individuals. It is associated with fewer, less serious and reversible side effects. It is suitable for individual who so not wish to undergo surgery, those deemed unfit for surgery and those with mild to moderate symptoms.

The ideal candidate has mild to moderate symptoms that are mildly bothersome and does not negatively affects the quality of life.

Contraindications to drug therapy are patients with recurrent urinary tract infections, recurrent or chronic urinary retention, renal insufficiency, bladder calculi and haematuria (30).

Pharmacotherapy works by reducing the prostatic smooth muscle tone (which contributes to the dynamic components of BPH) or by reduction of gland volume. The main types of drugs are as follows:

- 1) Alpha Blockers: The rationale for the use of alpha-blockers in the treatment of BPH is based on the hypothesis that clinical BPH is, in part due to prostatic smooth muscle mediated bladder outlet obstruction. Smooth muscle accounts for 40% of the prostate in BPH (31). The smooth muscle relaxes in the presence of alpha-adrenergic blockers and in particular alpha-1 adrenoceptor drugs

with a significant reduction in symptoms (31,32). Alpha-blockers also lower blood pressure significantly in hypertensives (30). This is an advantage as 30% of BPH patients have hypertension for various reasons and both disease processes can be treated with a single drug (30). The primary contraindication is a history of orthostatic hypertension. Examples are indoramin, terazosin, alphazosin and tamsulosin.

2) Androgen Suppressors: The rationale is based on observations that prostatic development is dependant on androgen dihydrotestosterone (DHT). Genetic deficiency of 5-alpha reductase results in a rudimentary prostate and feminization of the external genitalia (33). Androgen suppression results in reduction in prostate volume. Finistride is a competitive inhibitor of the enzyme 5-alpha reductase. It lowers serum and intraprostatic DHT levels by decreasing the conversion of testosterone to dihydrotestosterone (33). Several studies have demonstrated long-term efficacy in relieving symptoms and improving uroflow (33). Use of finistride is limited to patients who have contraindications to, or do not respond to, alpha-blockers. Impotence and decreased ejaculatory volumes are the primary treatment related adverse experiences.

MINIMALLY INVASIVE TREATMENT

1.STENTS

There are a variety of different intraprostatic stents on the market. They can be divided into the first and second generation of temporary stents. The first generation is indicated only as an alternative for an indwelling catheter for short-term relief of prostatic obstruction or as a treatment for patients not fit for surgery. Second generation stents seem to have fewer complications with the same indications as first generation stents. Studies on these stents are still lacking (33).

2.TRANSURETHRAL LASER INCISION OF THE PROSTATE (TULIP)

It is possible to deliver laser wavelengths suitable for urological applications through small semi-flexible fibres, which pass through standard endoscopes. The tissue effect to laser energy usually involves almost instantaneous attainment of temperatures greater than 60 degrees Celsius to create coagulation, or to greater than 100 C to create vaporisation. The laser represents shorter surgeries, fewer complications, is an outpatient treatment, and gives results approaching those seen after TURP. Disadvantages to laser prostatectomy include: lack of tissue (except the Ho.YAG laser), prolonged catheter time post operatively, dysuria (which can last up to two months), and overall lower perk flow

rates than for TURP. However it cannot be used on patients taking anticoagulants (35).

3. TRANSURETHRAL NEEDLE ABLATION (TUNA)

Transurethral needle ablation (TUNA) of the prostate utilises radio frequency energy to create temperatures up to 60-100 C, and treatment times of 5-7 minutes to produce zones of coagulation necrosis. The results with TUNA showed significant improvement in peak flow and in symptom score (34). However, it does not treat median lobe hypertrophy effectively. It is suitable for patients with mild to moderate symptoms that wish to experience minimal discomfort and treatment bother. Sexual function is preserved unlike in some procedure.

4. TRANSURETHRAL MICROWAVES THERMOTHERAPY (TUMT)

Microwaves are electromagnetic radiation and oscillating electrical and magnetic field in the range of 300-3000 MHz. The heat is produced when the tissue absorbs the microwaves. Coagulative necrosis of the transitional zone is achieved by transurethral microwave thermotherapy (TUMT) at 915 and 1296 MHz as soon as the temperature threshold over 44 C is reached (37,38).

5. TRANSURETHRAL ETHANOL ABLATION OF THE PROSTATE (TEAP)

Dehydrated alcohol causes tissue lysis and nerve blockade in the prostate. This causes improvement in peak flow and symptom score (37).

SURGICAL TREATMENTS

1) TRANSURETHRAL RESECTION OF THE PROSTATE (TURP)

It is often referred to as the “golden standard” for the treatment of BPH. In BPH this is no longer appropriate. TURP is the standard in that its efficacy is currently the highest that can be achieved by BPH treatment, and therefore the standard by which new intervention therapies for BPH should be compared. TURP continues to be associated with low but significant morbidity, even when performed by experienced urologists. The TUR syndrome was recognised in 0.8% and there was 2.5% transfusion rate. At less than one year the re-operation rate was 6.3% and urethral strictures were noted in 6.5%. Twenty five percent of patients experienced initial urinary incontinence and 2.5% required continuing use of a urinary pad. There was 4.8% acute urinary retention after the procedure and febrile urinary infections occurred in 2.1% (42). There are also occurrences of retrograde ejaculation and impotence in 40% of patients.

2. OPEN PROSTATECTOMY

This is an alternative in patients with large glands (100gms) or concurrent diverticulum or a large bladder stone (43).

METHODS

STUDY DESIGN

This was a descriptive and prospective longitudinal study carried out in the Urology Unit, Department of Surgery, UTH.

STUDY POPULATION

This consisted of patients presenting at the Urology clinic, UTH, from various parts of the country. 25 patients with LUTS or mild to moderate BPH, diagnosed by history examination and investigations, randomised to undergo TEAP. The patients who were picked for the various procedures had similar symptoms and were picked based on the inclusion criteria.

INCLUSION CRITERIA

1. Mild to moderate BPH diagnosed digitally.
2. IPSS score < 19 (See IPSS score sheet attached to document).
3. No history of acute urinary retention or other related complications.
4. Patients without suspected prostatic or bladder malignancy.
5. No history of previous surgical management for BPH.
6. Patients without a previous history of pelvic surgery or trauma.

ASSESSMENT

All patients underwent the following:

1. Pre-operative assessment including IPSS, peak urinary flow rate (Q-max), ultrasound study and post void residual urine (PVR).
2. Intra-operative information including operating time, irrigant requirements and intra-operative complications.
3. Post-operative assessment including IPSS peak urinary flow rate (Q-max), ultrasound study, PVR and post-operative complications at a period of 1 month, 3 months and 6 months.

PROCEDURE

The patient is anaesthetized using spinal anaesthesia. An ordinary continuous flow cystoscope and a stainless steel needle are the only instruments used with irrigation fluid. The cystoscope was introduced into the urethra until the prostatic urethra was visualised and identified. The needle was positioned in the cystoscope and advanced under vision into the prostatic urethra. The needle was advanced about 0.5 cm in the adenoma and 3.5 ml of ethanol is slowly injected into the tissue. Continuous irrigation occurs throughout the procedure. Each lateral lobe was injected, and in cases of median lobe enlargement, and injection was made into the median lobe. A urethral balloon catheter is inserted after completion of the procedure.

The patient was then kept overnight and allowed to go home with the catheter. The patient was then reviewed after 5 days at which point the

catheter was removed. The patient was then allowed to void normally and went home. Subsequently, the patient is reviewed after 1, 3 and 6 months or at any point he felt he has problems in between review dates.

ETHICAL CONSIDERATIONS

Informed consent was obtained and confidentiality was observed throughout the study. Ethical approval was sought from the Research Ethics committee.

BUDGET

All the equipment and materials used were present in the hospital. The Budget is on an appendix.

RESULTS

1. AGE

25 patients were seen. The ages of the patients ranged from 50 to 85 years with a median age of 68 years. The largest percentage (23.3%) came from patients within the 65 to 69 years age range whilst the smallest came from those ranging from 80 to 85 years of age. The age distribution is on Table 1, page 30.

2. PREOPERATIVE ASSESSMENT

a) Prostate Size

This was assessed digitally by the doctors in the Urology Clinic i.e Consultant, Senior Registrar, Registrar or Senior House

Officer. A senior doctor makes confirmation of mild to moderate BPH if a much junior doctor assesses the patient.

b) International Prostate Symptom Score

The majority of the patients had an IPSS of 22 or less, indicative of slight or moderately bad urinary symptoms. Most presented with a history of incomplete emptying, frequency, intermittency, urgency, weak stream, straining or nocturia, of varying severity. The mean symptom score of 22 was found initially and ranged from 18-25. This is demonstrate on table 5, page 36.

c) Peakflow Rate (Q-Max)

This was done on the 25 patients seen. The baseline for the patients for whom Q-max was measured, was a mean flow of 11ml/s with a range of 8ml/s to 13ml/s. There was an improvement of mean Q-max over the months to 14ml/s at 6 months with a range of 13ml/s to 22ml/s. Over time, the patients were able to pass urine with increasing ease. This is shown on Fig 3, page 32.

3. Intraoperative Assessment

- a) Operating time averaged ten minutes.
- b) The only intraoperative complications relating to this procedure was intraoperative mild bleeding after injections.

Anaesthesia meant the procedure was pain free intraoperatively. Simple analgesia was required postoperatively. This is unlikely in open prostatectomy and TURP, which require stronger analgesia postoperatively.

4. Post Operative Assessment And Follow Up

a) International Prostate Symptom Score (IPSS)

The mean baseline IPSS preoperatively was 22 and ranged from 14-28. A decrease in mean IPSS is an indicator of improved symptoms and quality of the patient's life. At one month IPSS reduced to 14 at 3 months assessment and 12 at 6 months follow up. This is shown in Fig 2, page 33.

b) Peak Flow Rate (Q-Max)

There was an improvement of mean Q-max from baseline i.e initial visit to 6 months later from a mean flow of 11 ml/s to a mean of 19 ml/s at 6 months. This is shown in Fig 2, page 33 and is indicative of the improvement in ease with which the patients were able to pass urine.

c) Catheter Use

The urethral catheter was kept in situ postoperatively for 5 days for all the patients who underwent the procedure. No fluids were required for irrigation postoperatively as there was minimal or no bleeding. This was then removed on the 5th day. There

were no problems passing urine per urethra. This is in comparison to open prostatectomy in which the catheter is kept for a much longer period of 7-10 days and irrigation is required to wash out blood clots and prevent blockage of the urethral catheter. TURP on the other hand whilst requiring irrigation postoperatively only need catheter use for 2-3 days (44). This is shown on Table 5, page 36.

d) Hospital Stay

Post TEAP, all the patients were kept overnight and discharged. None were kept longer than 24 hours. This has an advantage over TURP in which hospital stay ranged from 3 to 5 days and over open prostatectomy that had a range of 7-10 days. This is due to possible postoperative complications such as bleeding, blockage of catheter and infection. The comparisons of hospital stay for the various procedures are shown on Table 5, page 34. This makes TEAP popular with patients (and hospital administrators) as they do not have to spend long periods in the hospital. This reduces, to the delight of hospital administration and the medical staff, the congestion in the hospital and allows more patients to be attended to.

e) Postoperatively

There were mild postoperative complications. Postoperative discomfort was minimal and could be managed with mild analgesics. There were no difficulties in voiding once the catheter was removed. Patient's symptoms improved. This is unlike open prostatectomy and TURP which may result in catheter blockage resulting in urinary retention, abdominal fistula, bleeding, epididymitis, septic shock, urethral stricture, wound infection and intraoperative/postoperative haemorrhage. There have been instances of mortality at UTH (3.5%) and reoperation in study done by Kachimba (44). In addition, unlike in open prostatectomy, there are no instances of impotence, retrograde ejaculation or incompetence.

5. COSTS

The costs of the procedure took into consideration hospital stay, antibiotic use, analgesia use, irrigant requirements, surgical procedure, equipment and anaesthesia. Open prostatectomy is the most expensive at five hundred United States dollars (US \$500), whilst TURP costs four hundred and fifty United States dollars (US \$450). TEAP has been evaluated as the cheapest at fifty United States dollars (US \$50). Open prostatectomy does not need a lot of fluid intraoperatively but uses a lot of fluid postoperatively and increased hospital care. TURP needs a lot of fluid intra and

postoperatively with increased hospital care. TEAP on the other hand only needs fluids intraoperatively for irrigation and has a 24-hour period stay in hospital. The only real cost is the needle for injection which though re-usable needs replacement once in a while.

Table 1

AGE DISTRIBUTION

AGE	NO. OF PATIENTS	PERCENTAGE %
50 – 54	5	20
55 - 59	4	16
60 – 64	1	4
65 – 69	6	24
70 –74	4	16
75 – 79	3	12
80 – 84	2	8
TOTAL	25	100

TABLE 2

INTRAOPERATIVE PROCEDURE FINDINGS

PROCEDURE	TEAP	TURP	OPEN PROSTATECTOMY
OPERATING TIME (MINUTES)	10	15 - 20	30 - 60
IRRIGATIVE REQUIREMENTS	3 - 5	3 - 5	6 - 15
COMPLICATIONS	Slight haemorrhage	Varied	Varied

TABLE 3**POSTOPERATIVE FINDINGS - INITIAL**

PROCEDURE	TEAP	TURP	OPEN PROSTATECTOMY
CATHETER USE (DAYS)	5	3 - 5	7 - 10
ANALGESIA USE (HRS)	NONE	24	> 24
COMPLICATIONS			
A. Bleeding	YES	YES	YES
B. Urinary Tract Infection	NO	NO	NO
C. Retrograde Ejaculation	NO	YES	YES
D. Impotence	NO	NO	YES
E. Urethral Stricture	NO	YES	NO
F. Incontinence	NO	NO	YES
G. Retention	YES	YES	YES

TABLE 4

TEAP POSTOPERATIVE FINDINGS – MONTHS

TIME (MONTH)	1	3	6
CATHETER USE	NIL	NIL	NIL
Q – MAX	14ml/s	16ml/s	19ml/s
IPSS	18	14	12
COMPLICATIONS	NIL	NIL	NIL

TABLE 5 POSTOPERATIVE REQUIREMENTS/COSTS

PROCEDURE	TEAP	TURP	OPEN PROSTATECTOMY
HOSPITAL STAY (DAY)	1	3 - 5	7 - 10
ANTIBIOTICS	1 DOSE	3 DAYS	5 DAYS
IRRIGATION FLUIDS (LITRES)	3	3	5
CATHETER USE (DAYS)	5	2 - 3	7 - 10
OPERATION COSTS(USDOLLARS)	50	450	500

FIGURE 1.

CHANGE IN INTERNATIONAL PROSTATE SYMPTOM SCORE OVER
TIME PRE AND POST OPERATIVELY

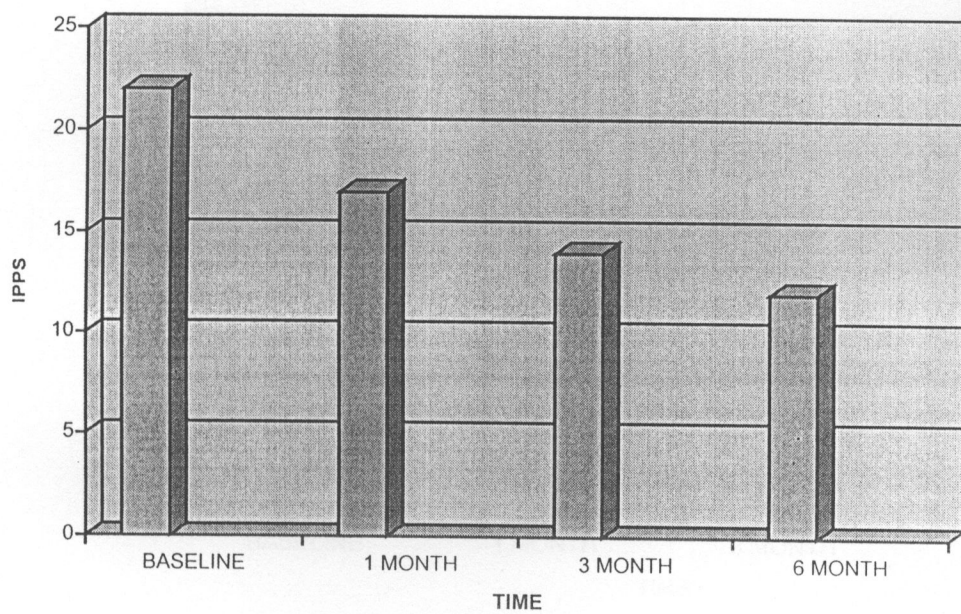
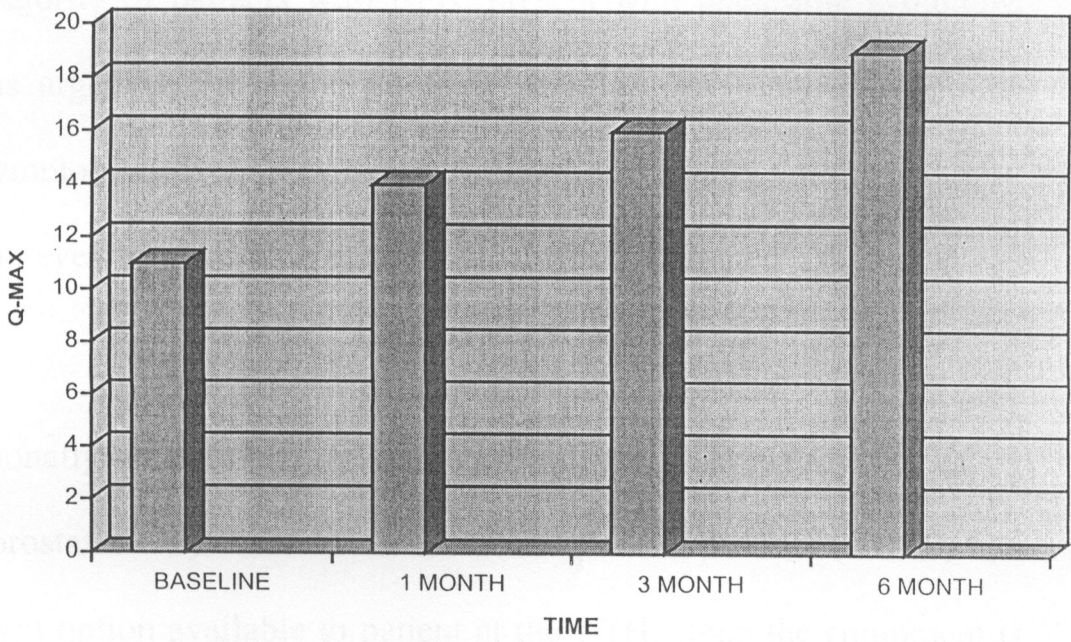


FIGURE 2

PEAK FLOW RATE (Q-MAX) OVER TIME



DISCUSSION

As previously mentioned, BPH is a common prostatic disease in Zambia. The majority of patients with BPH, present with disturbing symptoms such as urgency, frequency, dribbling of urine, straining, nocturia etc. The symptoms may be disabling, affecting the quality of life and may result in even more disable complications if left untreated.

Traditionally, at the UTH, the patients with BPH are mainly treated by open prostatectomy. Transurethral resection of the prostate (TURP) is a treatment option available to patient at the UTH, when the equipment is available. Both of these options are costly and associated with relatively long hospital stay, 6-10 days for open prostatectomy and 3-5 days for TURP as shown by Kachimba, 1998 (44). One of intraoperative complications associated with the two procedures are intraoperative bleeding especially during open prostatectomy. This was shown in a study by Mallaya that there was a high rate of transfusion during and after open prostatectomy, reflecting the amount of bleeding during open surgery (29). Kachimba, in a study at the UTH, showed that open prostatectomy resulted in significant intraoperative bleeding in 1.9% of complications seen with both are clot retention, abdominal fistula formation, epididymitis, wound infection, postoperative urethral strictures

and acute urinary retention. Reoperation following only TURP has shown to be a complication with varied studies showing different percentages from 0.4% (Muguti and Woluhau-Wanambwa) to 4.5% by Mackenzie (45). As previously mentioned, medical treatment is not a variable option due to cost and it is difficult for the patient to continue buying it.

AGE

Previous studies have shown that men from the 5th decade upwards have a significant increase in urinary symptoms associated with BPH. Di Triolio, in a TEAP study, treated patients ranging from 50 years to 83 years with a median age of 68.2 years (39). This is similar to the age range seen in this study of 50 years to 85 years. The median age is 68 years. Another study of BPH showed that BPH was most common in men over 60 years (46).

PREOPERATIVELY

The patients selected had a higher IPSS than targeted. Digitally, they had mild to moderate BPH. Other criteria were strictly adhered to i.e no history of acute urinary retention, no previous pelvic surgical management for BPH, no suspected bladder or prostate malignancy or previous pelvic trauma.

The 25 patients had their peak urinary flow rate measured from baseline to 6 months. Due to the breakdown of the uroflowmetre, the targeted number of patients could not be reached, hence a study population of 25 rather than 50.

The other limitations that the breakdown of the uroflowmetre presented is the long term follow up of the patients, which would have been ideal but was not possible. Other parameters such as IPSS, which are quite subjective, were depended on.

INTRAOOPERATIVELY

a) Operating Time

The procedure of TEAP is much shorter in comparison to open prostatectomy and TURP. The shortened operative time reduces the cost of anaesthesia. In addition, this means more patients can be treated in the limited operating time of 6 hours per week available to the Urology doctors for elective procedures. This in turn would result in a reduction in the long waiting list for BPH patients before operation. TURP is much quicker than open prostatectomy as shown in Table 2. This does not include time taken to anaesthetize and reverse anaesthesia.

b) Irrigant Requirements

As indicated in Table 5, the fluids are required only intraoperatively for TEAP. The other two common procedures at UTH require quite a lot of fluid either and or intra and postoperatively, and this adds to the cost of both procedures. TEAP does not have this added postoperative cost to be considered, thereby being a more suitable procedure in an institution like UTH where materials and money are in short supply.

c) Antibiotic use

Patients for open prostatectomy and TURP were given antibiotics for 5 and 3 days respectively. This does not include the cost of other disposables such as needles, syringes and water for injection all of which add to the cost.

d) Complications

There only intraoperative complications related to the procedure were bleeding following injection of the prostate. The bleeding is minimal and does not need any intervention intra or postoperatively. The bleeding was noted in a few patients and did not occur in all. Bleeding is common in most of the surgical procedures related to the prostate. This may occur either or both intraoperatively and postoperatively but measures are taken to

ensure that bleeding is not uncontrollable. It can occur as a complication. The same is true of TURP.

POSTOPERATIVELY

a) Analgesia

Slight discomfort was experienced by some of the patients after the procedure. However, the majority of the patients did not require any analgesia immediately postoperatively or subsequently. If any were needed, simple analgesics were used.

b) Catheter use

The urethral catheter was inserted after the procedure. This was kept in about 5 days and then removed. Most patients showed no problems with voiding following its removal. Patients actually reported an improvement in the ease of voiding urine after catheter removal. As revealed by the IPSS and Q-max, symptoms reduced quite substantially as time went on and catheter use was not needed again in the follow up period. This is unlike a study done at UTH by Kachimba in which acute urinary retention lead to readmission in 6.9% of patients following TURP and 3.8% in open prostatectomy cases (37).

This is comparable to a study done in America in which more than 90% of 200 patients were able to void 4 days following the procedure (43).

CONCLUSION

TEAP is a feasible, safe and efficacious procedure for the treatment of BPH in a selected group of patients. It has been shown to have minimal requirements and equipments intra and postoperatively with costs reduced in comparison to other surgical procedures used at the University Teaching Hospital. There is also the factor of reduced hospital stay. The incidence of few complications both intra and postoperatively is a factor in its favour.

Apart from the advantages, most of the patients were able to carry on with their lives postoperatively the catheter was removed with no subsequent problem or complications leading to a reduction in loss of work time and an increased quality of life unlike the other procedures.

This is a procedure that has worked well at the University Teaching Hospital and would do well in other Zambian hospitals.

RECOMMENDATIONS

1. The TEAP study needs to be followed up for a much longer period of time i.e follow up of patients postoperatively.
2. TEAP can be done on an outpatient basis.
3. Teach general surgeons how to perform TEAP on patients (when all materials are available eg needles,cystoscope etc).

GUIDELINES FOR TEAP

Patients who can undergo this procedure, should have:

a) Preoperatively

1. IPSS score < 22
2. Mild to moderate BPH determined by digital rectal examination
3. No history of
 - I. Acute urinary retention
 - II. Previous pelvic trauma
 - III. Previous surgical management for BPH

b) Intraoperative

1 dose of IV antibiotics

c) Postoperatively

1. Indwelling urethral catheter for 5 days then removal.
2. Follow up at 1, 3 and 6 months.

Reference

1. UTH records, Urology Clinic, UTH, Lusaka (1998 – 2001).
2. Campbell's Textbook of Urology, Seventh Edition 1985, Volume 2. Edited by Walsh P.C., Retik A.B., Vaughan D.E., Weir A.J. 1998: 1411 – 13
3. Neal D.E., Bladder Outflow Observation and Outcome Surgery. Recent advances in Urology/Andrology. Number 5. Edited by Hendry W.F., Edinburgh, Churchill, Livingstone 1991; 41, (2): 149-165.
4. Paulson D., Disease of the prostate. Clinical symposia, New Jersey Ciba-Geigy 1989: 41, (2): 2-32.
5. Bruskewits et al. Proceedings 4th International Consultation on Benign Prostatic Hyperplasia.
6. Barry M.J., Fawler F.J., O'Leary M.P., et al The AUA Measurement Committee. The American Urological Association Symptom Index for Benign Prostatic Hyperplasia. Journal of Urology. 1992a; 148:1549.
7. Di Trolis J.U., Chemoablation of the prostate with dehydrated ethanol for the treatment of BPH, 5th International Consultation of BPH, 2000.
8. Barry M.Y., Epidemiology and Natural History of Benign Prostatic Hyperplasia. Urological Clinic of North America, August 1990; 17:241.
9. Flingelstone L., Davies A.H., Essential Postgraduate Surgery, 2001: 177.
10. Campbell's Urology. Volume 2, Seventh edition. Edited by Walsh P.C., Retik A.B., Vaughan D.E., Weir A.J. 1998:1385.
11. Girman C.J., Jacobsen S.J., Gness H.A. et al. The cumulative prevalence of prostatism matches the autopsy prevalence of benign prostatic hyperplasia. Prostate 1990; 17:241.
12. Grist E. Benign Prostatic Hyperplasia. Medicine Digest March 1990, 16 (3): 3 – 7.

13. Guess H.A., Arrigh H.M., Metter E.J., et al: The cumulative prevalence of prostatism matches the autopsy prevalence of benign prostatic hyperplasia. *Prostate*, 1990; 17: 24.
14. Sherwood L.M. Benign prostatic hyperplasia: Natural history, endocrine pathogenesis and medical treatment with Finasteride. *The Mount Sinai Journal of Medicine*, January 1996, 63, (1): 1-9.
15. *Campbell's Urology*. Volume 2, Seventh Edition. Edited by Walsh P., Retik A.B., Vaughan J.D.E., Weir A.J. 1998: 1385.
16. Yalla S.V., Sullivan M.P., Lecomwasam H.S., et al: Correlation on American Urological Association of Symptom Index with obstructive and non-obstructive prostatism. *Journal of Urology*, 1995; 153: 674.
17. McNeal J.E: Origins and evolution of benign prostatic enlargement, *Invest Urology*. 1978: 1540.
18. Neal S.E., Ramsden P.D., Powell P.H., Styles R.A., Webb R.J., Sharpes L and Smith A. Outcome of elective prostatectomy. *Journal of Urology*. 1989; 496 – 497.
19. Abrams P.J., Farrar D.J., Warwick R.T., Whiteside C.G and Fenely R.C.L. The results of prostatectomy: A symptomatic and urodynamic analysis of 152 patients. *Journal of Urology*. May 1979, 121: 640 – 642.
20. Meyhoff H.H., Ingemann L, Nordling I, Hald I: Accuracy in preoperative estimation of prostatic size. A comparative evaluation of rectal palpation, intravenous pyelography, urethral closure pressure profile recording and cystourethrography. *Journal of Urology and Nephrology*. 1981: 15; 45.
21. Rehrborn C.G., Chinn H.K., Fulgham P.F., et al: The role of transabdominal ultrasound in the preoperative evaluation of patients with benign prostatic hypertrophy. *Journal of Urology*. 1986: 135: 1190.
22. Simonsev O, Moller-Madsen B, Dorflinger I, et al: The significance of age on symptoms, urodynamic and cystoscopic findings on benign prostatic hyperplasia. *Journal of Urology*. 1992; 142: 1298.

23. Campbell's Urology, Volume 2, Seventh Edition. Edited by Walsh P.C., Retik A.B., Vaughan J.D.E., Weir A.J. 1998: 1443.
24. Campbell's Urology, Volume 2, Seventh Edition. Edited by Walsh P.C., Retik A.B., Vaughan J.D.E., Weir A.J. 1998: 1444.
25. Kreel L, Elton A, Habershon R et al. Use of intravenous urography. *British Medical Journal*. 1974; 4:31.
26. Morrison J.D. Help or Habit? Excretion urography before prostatectomy. *British Journal of Clinical Practice*. 1980, 34:239.
27. Wasserman N.F., Lapointe S, Eckman D.R., Rossel P.R: Role of intravenous urography. *Radiology* 1987; 831.
28. Juul N, Torp-Pedersen S, Neilson H: Abdominal Ultrasound in obstructed males. *Scandinavian Journal of Urology and Nephrology*. 1989; 23:89.
29. Madsen F.A., Bruskewit R.C: Textbook of Benign prostatic hyperplasia. 1996; 4:16.
30. Stoner E and the Finasteride study group: The clinical effects of 5-alpha reductase inhibitor, finasteride on benign prostatic hyperplasia. *Journal of Urology*. 1992: 147:12989.
31. Lepor H, Auerbach S, Puras-Benz A et al: A randomised multitherapeutic placebo controlled study of efficacy and safety of teragodin in the treatment of benign prostatic hyperplasia. *Journal of Urology*. 1992; 148:1487.
32. Lepor H: The treatment of BPH with alpha 1 blockers. *Current Opinion Urology*. 1994; 3:16.
33. Campbell's Urology, Volume 2, Seventh Edition. Edited by Walsh P.C., Retik A.B., Vaughan J.D.E., Weir A.J. 1998:1480-90.
34. Nording J: Temporary stents. Textbook of benign hyperplasia. 196: 443.
35. Campbell's Urology, Volume 2, Seventh Edition. Edited by Walsh P.C., Retik A.B., Vaughan J.D.E., Weir A.J. 1998: 1480-91.

- 36.Schulman C.C., Lotta A.R: Transurethral needle ablation of the prostate (TUNA): Clinical experience with two year follow up in patients with benign prostatic hyperplasia. *Journal of Urology* 1997; 157:A380.
- 37.Trachtenberg J: High temperature thermotherapy of the prostate creates TOR defects without anaesthesia. *Journal of Urology* 1994; 151:416A.
- 38.Larson T.R., Corilea A, Bostwich D: Extent of thermal cell death correlated to accurate interstitial temperature of ten pathologic prostate specimen using uroloix 73 microwave transurethral thermal therapy unit. *Proceedings of the Xth Congress of the European Association of Urologist, Berlin 1994:335.*
- 39.Di Trilo J.U: Chemoablation of the prostate with dehydrated ethanol for the treatment of BPH, 5th International Consultation on BPH, June 2000.
- 40.Plante M.K., South Bulington V.T., Palmer J.U.K., Martinez-Sagarra J, Span et al. Complications amounted with transurethral ethanol ablation of the prostate for treatment of Benign Prostatic Hyperplasia: A world-wide experience. *The Journal of Urology*, 1997, Vol 146, No. 4, Supp: 392, No. 1466.
- 41.Gutierrez-Aceves J. Guadalajara, Mexico, Gilling P, Tauranga, New Zealand, Manilo S, Romo, Italy et al. Transurethral ethanol ablation of the prostate (TEAP), initial long-term report of two prospective multicentre study. *The Journal of Urology*. Vol 169, No. 4 Supp; 466, No. 1747.
- 42.Chilton C.P., Morgan R.J., England H.R., Paris A.M.I and Blandy J.P. A critical evaluation of the results of transurethral resection of the prostate. *British Journal of Urology*, 1978, 50: 542- 46.
- 43.McConnell J.D., Barry M.J., Bruskewits R.C et al. Benign prostatic hyperplasia, diagnosis and treatment. Clinical practise guidelines.1998, No. 8, APHCR, Publication No. 94-0582. Rockville, MD, Agency for Health Care Policy and Research, Public Health Services, US Department of Health and Human Services.

Appendix 1

DATA ENTRY FORM-TEAP STUDY

Personal Details:

Name Hospital No.

Age

Date of admission

Date of discharge

Pre-operative Assessment

PROSTATE SIZE IPSS Q-Max

Post Operative Assessment

Operating time

Complications

Post Operative Assessment and Follow-up

1 Month 3 Months 6Months

IPSS

Q-MAX

Catheter use

Complications

Appendix 2

CONSENT FORM

Iofhereby consent to the operation of transurethral ablation of the prostate as a treatment option for the treatment of benign prostatic hyperplasia be performed on

The effects and nature has been explained to me. I also consent to the administration of local or any other anaesthesia for the above purpose.

I understand that an assurance has not been given that the operation will be performed by a particular surgeon

Signed

Witness

Date

Appendix 3

TEAP STUDY BUDGET

A. REQUIREMENTS FOR EACH PATIENT (without instruments)

1. Drugs	
a) Distilled water (3 litres) @ K 1000/litre	K 3,000
b) Anaesthesia (Xylocaine 2%) 10mls	K 3,000
c) Gentamycin (80mg)	K 5,000
2. Needle x1 & Syringe x1	K 1,500
3. Catheter x1	K 10,000

B. INSTRUMENTS

1. Cystoscope (Reusable) : Provided by U.T.H
2. Urethral needle (Reusable) : As above

C. OTHER COSTS

Nursing care, Theatre fees, staff fee per patient	K 225,000
TOTAL PER PATIENT PER PROCEDURE	K 247,500

TOTAL FOR 50 PATIENTS **K12,375,000**

C. TYPING, PRINTING AND BINDING OF PROJECT

K 200,000

TOTAL

K12,575,000

International Prostate Symptom Score (I-PSS)

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

		None	1 Time	2 Times	3 Times	4 Times	5 Times or more	
7. Nocturia Over the past month, how many times did you most typically get up to urinate from the time you went to bed at night until the time you get up in the morning?	0	1	2	3	4	5		
Total I-PSS Score								

		Delighted	Pleased	Mostly Satisfied	Mixed - about equally satisfied and dissatisfied	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 that?	0	1	2	3	4	5		

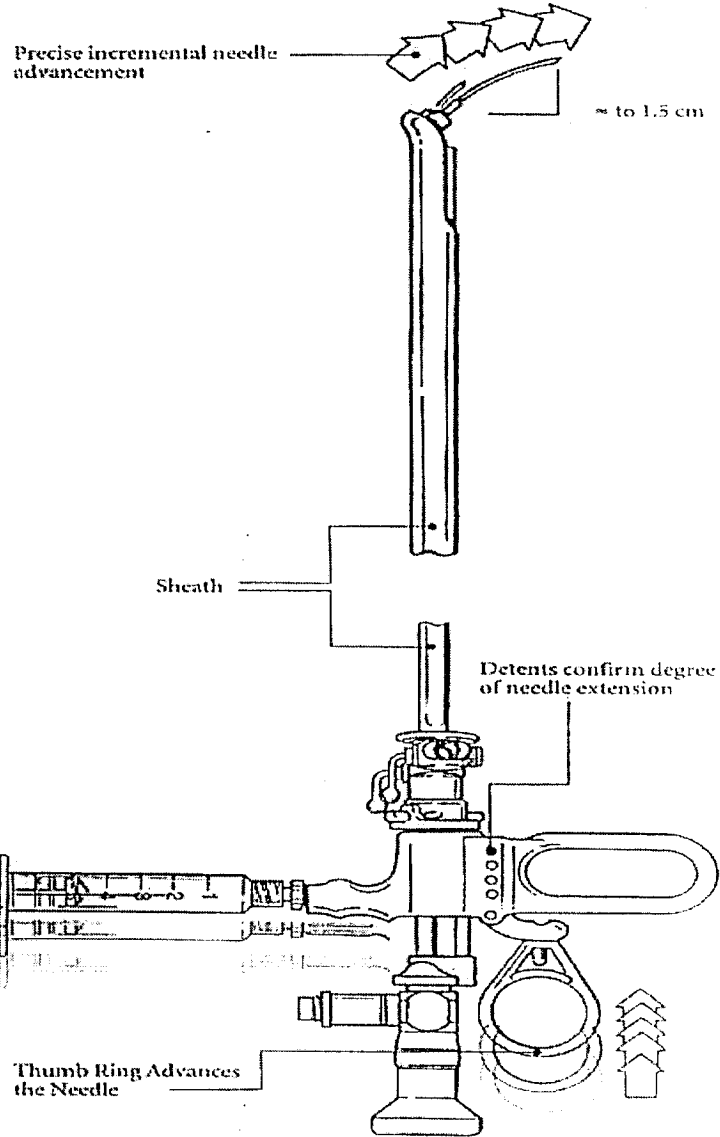
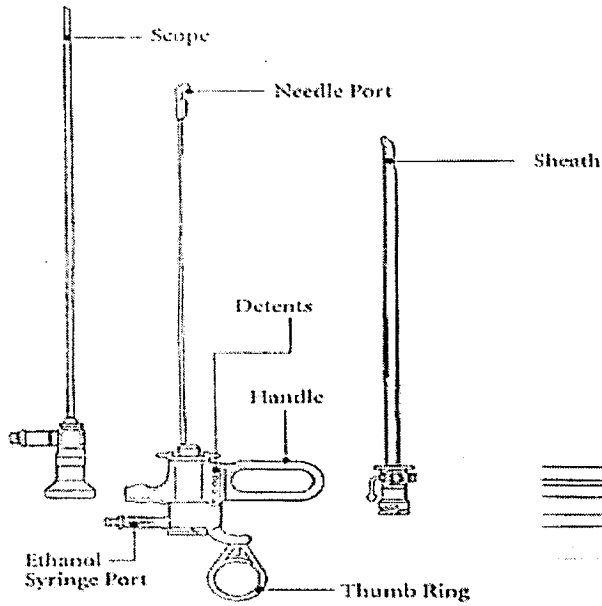
The International Prostate Symptom Score (I-PSS) is based on the answers to seven questions concerning urinary symptoms. Each question is assigned points from 0 to 5 indicating increasing severity of the particular symptom. The total score can therefore range from 0 to 35 (asymptomatic to very symptomatic).

Although there are presently no standard recommendations on grading patients with mild, moderate or severe symptoms, patients can be tentatively classified as follows: 1 - 7 = mildly symptomatic; 8 - 19 = moderately symptomatic; 20 - 35 severely symptomatic.

The International Consensus Committee (ICC) recommends the use of only a single question to assess a patient's quality of life. The answers to this question range from "delighted" to "terrible" or 0 to 6. Although this single question may or may not capture the global act of BPH symptoms on quality of life, it may serve as a valuable starting point for a doctor - patient conversation.

The ProstaJect System

The ProstaJect System is compatible with the most-commonly used cystoscopes and sheaths to create an ethanol delivery system that allows transurethral access to the lateral and median lobes with good visualization of the prostatic access points. The ProstaJect System features a unique curved stainless steel needle that provides a targeted pass through the urethra wall. The needle positioning system features detents, designed for precise needle advancement through auditory, visual and tactile confirmation of needle-tip position in the lobe.



1. DiTolias, IV, Transurethral Ethanol Ablation of the Prostate, presented AUA 91th Annual Meeting, March, 1999.
2. DiTolias, IV, Chemical Ablation of the Prostate with Dehydrated Ethanol for Treatment of BPH, 5th International Consultation on BPH, June, 2000.

