Feasibility of Suprapubic Transvesical endoscopic prostatectomy

Protocol for a thesis submitted for partial fulfillment of M.D. degree in urology

BY

Moustafa Hosny Mohamed

Assistant Lecturer of urology, Beni-Suef University

Supervised by:

Dr/ Ahmed Mahmoud Hasan Abd el Bary

Professor of urology Beni-Suef university

Dr/ Rabiee Mohamed Abdallah

Associate Professor of urology Beni-Suef university

Dr/ Amr Mohamed Lotfy

Associate Professor of urology Beni-Suef university

Dr/ Ahmed Gamal Mohamed

Lecturer of urology Beni-Suef university

Faculty of Medicine

Beni–Suef University

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❖ Introduction:

Lower urinary tract symptoms (LUTS) are highly prevalent in men older than 50 years and represent a large epidemiological and financial burden **[1].** Benign prostatic obstruction (BPO) is one of the most common causes of LUTS in middle-aged and older men. Benign prostatic hyperplasia (BPH) is a histological diagnosis that increases in prevalence with age, and autopsy studies have shown that 80–90% of men will have evidence of BPH in their 70s or 80s. However, not all of these men will develop LUTS with symptoms typically arising when the prostatic enlargement results in obstruction **[2].**

Epidemiological data suggest a lifetime prevalence of LUTS suggestive of BPO of 26.2% and this increases with age **[3].** With a globally aging population, the incidence of BPO is continuing to increase and it's treatment estimated $73.8 billion annual cost burden **[4].**

LUTS also have substantial impact on the quality of life (QoL) of patients, with one study reporting that severe LUTS produce a similar impact on QoL to a heart attack or stroke. BPO mostly is a progressive condition and factors associated with clinical progression include increased age, increased prostate volume, elevated PSA and low peak urinary flow rate (Qmax) **[2]**. Fortunately, numerous treatment options are available to manage LUTS secondary to BPO including both medical and surgical **[5].**

In men with LUTs alpha1 adrenoreceptor antagonists can be offered as first line medical therapy **[6].** Over time, various surgical techniques have emerged for BPO treatment, each with distinct strengths and weaknesses. The transition from open simple prostatectomy to monopolar or bipolar transurethral resection of the prostate (M/B-TURP) marked a pivotal moment, enhancing safety and reducing

invasiveness, maintaining its gold standard status for prostatic volumes from 30 to 80 cm3 **[7,8].** Techniques such as thulium or holmium laser enucleation of the prostate (HoLEP) and robot-assisted simple prostatectomy (RASP) are widely used **[9,10].**

Prostatic uretheral lift (UroLift), convective water vapor energy (Rezum) and prostatic arterial embolization can be performed with local anesthesia . Although the literature currently suggest that minimally invasive procedures are associated with higher rates of clinical failure requiring secondary interventions **[6].**

Despite significant improvements in surgical techniques, the incidence of late complications such as urethral stricture after TURP has not decreased. Reports of urethral stricture rates vary widely, ranging from 1% to as high as 10–12%, depending on the surgical technique and the series analyzed **[11,12].**

Mechanical stress exerted on the external urinary sphincter during transurethral procedures can result in transient urinary incontinence (UI) which may adversely affect patient QoL **[13]**. The treatment of choice for patients with past history of previous surgery for uretheral stricture who present with of obstruction due to BPH is still a matter of discussion **[14].**

The debate is about whether the feasible insertion of the resectoscope in previously operated urethera carries a high risk of multiple microtrauma that in turn can lead to scar formation and repeat stricture development **[15].**

In patients who had previously undergone dorsal onlay urethroplasty for urethral strictures The need to protect the delicate urethral graft in these patients justified a suprapubic approach **[13].**

In patients with penile prosthesis, any transurethral procedure could place the implant at risk. The use of long or extra-long resectoscope can be of some assistance;

however, these are not available in many institutions **[14]**. So suprapubic transvesical endoscopic prostatectomy is newly developed to bypass the anterior urethra.

❖ Aim of the work:

To determine safety and efficacy of Suprapubic Transvesical endoscopic prostatectomy.

❖ Patients and methods:

This prospective clinical study will be conducted at the department of urology, Beni suef university Hospital on selected 60 Men indicated for surgical treatment of benign prostatic hyperplasia fulfilling the inclusion criteria. The study will be conducted for 6 months starting from July 2025 (The date of ethical committee approval).

Inclusion criteria

Male patients with moderate to severe lower urinary tract symptoms (IPSS score ≥ 8) indicated for surgical intervention with prostate size less than 120 cc.

Exclusion criteria

History of previous pelvic surgery, urothelial cancer, kidney transplantation, uncontrolled coagulopathy, and significant central fat accumulation that could potentially increase the risk during transvesical access(body mass index not exceeding 27 kg/m2)

Preoperative Assessment

All patients will undergo a thorough preoperative evaluation, including:

- **History mainly IPSS score and Physical Examination**
- **Laboratory Tests:**

Complete blood count , Kidney function tests (serum creatinine, serum electrolytes , Liver function tests, Coagulation profile , Prostatic specific antigen (PSA), Urine analysis & urine culture

- **Imaging:**

* Pelvi–abdominal ultrasonograghy to assess post voiding residual urine (PVR).

* Trans rectal ultrasound (TRUS) for accurate estimation of the prostate size.

* Preoperative Uroflowmetry.

* A preoperative urodynamic study (UDS) was performed in patients with a chronic indwelling catheter , patients with post voiding residual urine more than 150 cc and in those clinically suspected of neurological problems

Surgical Technique

Cysto-uretheroscopy will be done to evaluate the urethera , detect any bladder pathology and to visualise steps of insertion of laparoscopic port. The patient will be in supine position, and the surgeon will stand beside the patient .The bladder is filled with normal saline until it is completely full . Using Ultrasound A 18 G puncture needle is inserted 4 cm above the upper margin of the symphysis pubis to gain access to the bladder. then track is formed through single step dilation using a 30 Fr amplatz dilator and 10 mm laparoscopic port over it. Before starting the procedure, the ureteral orifices must be identified.

Sample size calculations:

The sample size calculation was performed using G*Power 3.1.9.7 for a paired samples t-test (difference between two dependent means). A priori power analysis was conducted to determine the required sample size. Based on the previous study (Bucca et al., 2024) **[13]**, IPSS score showed mean difference of 26.5 which is considered an effect size (dz). Given an alpha error probability of 0.05 and a desired power of 0.95, the analysis revealed that a total sample size of 4 participants is needed to achieve the specified power level. The actual power achieved with this

sample size was 0.95, slightly exceeding the target. Additionally, the previous study **[13]** did not show a sample size calculation and just recruited a total of 44 patients. Hence, a sample size of 80 patients is suggested for this study, considering about the double of the previous study sample size.

Statistical analysis

The collected data will be revised for accuracy and completeness then coded, entered, and analysed using Statistical package for Social Science (SPSS version 25) program. Suitable analysis will be done

Descriptive statistics:

o Qualitative data will be presented in the form of numbers and percentages (proportions).

o Quantitative data will be presented in the form of mean and standard deviation (mean ± SD).

Analytical statistics:

Differences will be considered significant at p-value less than or equal to 0.05.

Analysis of relations will be done using the appropriate statistical tests according to the type of data obtained for each parameter.

Ethical considerations:

Patients will be informed that procedure is an innovative procedure in its standardization phase and written consent for treatment and data publication Will be obtained .

Ethical approval will be obtained from the Research Ethical Committee (REC) in the Faculty of Medicine – Beni Suef University, Beni Suef, Egypt.

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