

**Prospective study comparing Convective radio-frequency  
water vapor energy with trans-urethral enucleation of  
prostate for management of benign prostatic hyperplasia**

**Protocol for Thesis  
Submitted for Partial Fulfillment of The Doctor of Medicine (MD)  
in urology**

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## **Introduction**

Over the years, many treatments have been devised to treat benign prostatic hyperplasia (BPH). Initial medical therapy may be effective for mild to moderate symptoms. However, in patients with moderate to severe symptoms, with objective measurements indicating a greater degree obstruction surgical intervention may be necessary. Previously, trans-urethral resection of the prostate (TURP) was the most performed procedure, considered the gold standard for treating BPH. However, this resulted in high levels of morbidity including sexual dysfunction, urethral strictures, stress incontinence, bleeding, and a longer length of hospital stay (**Mynderse et al., 2015**).

Transurethral enucleation and resection of the prostate (TUEP) is a procedure created by Liu et al. in which the prostate is transurethrally enucleated and resected using a bipolar plasma kinetic resectoscope (**Liu et al., 2010**).

Bipolar transurethral enucleation of the prostate also showed its efficacy on variable prostate sizes ranged from 20 g to 250 g. It has been well recognized and developed for many years with satisfactory result and low morbidity (**Liu et al., 2010**)

The advent of minimally invasive treatments for lower urinary tract symptoms secondary to benign prostatic hyperplasia (LUTS/BPH) allows the urologist to tailor therapy in a continuum of medical management to more invasive surgical procedure approaches. Although minimally invasive procedures such as transurethral needle ablation (TUNA) of the prostate and transurethral microwave thermotherapy (TUMT) are alternatives to surgical intervention, their use is declining (**Malaeb et al.,**

**2012).**

Thermal therapy using convective radiofrequency (RF) water vapor energy has emerged to treat men with moderate-to-severe LUTS, providing early and durable relief of bothersome symptoms and with minimal transient perioperative side effects. This perspective provides an explanation and validation of the technology and clinical evidence supportive of convective RF thermal therapy for LUTS associated with BPH **(Gupta et al., 2017).**

Convective RF water vapor energy (Rezūm System; NxThera, Inc., Maple Grove, MN, USA) was introduced as a minimally invasive, radio-frequency thermal energy-based treatment, designed to convectively deliver sterile water vapor, or steam for targeted ablation limited to the transition and central zones in men with clinical BPH **(Dixon et al., 2015).**

The procedure was performed with the technology of convective radiofrequency (RF)-generated water vapor energy to ablate obstructive prostatic tissue including the median lobe. This therapy provides significant, and durable relief of LUTS as well as preservation of sexual function **(McVary & Roehrborn 2018)**

## **Aim of the work**

To compare Convective RF water vapor energy (Rezüm) with trans-urethral enucleation of the prostate (TUEP) regarding efficacy in terms of lower urinary tract symptoms (LUTS) improvement, international prostatic symptoms score (IPSS), improving of the maximum flow rate ( $Q_{max}$ ), worsening of erectile and ejaculatory function, and safety regarding post operative complications & hospital stay.

## **Patients and methods**

- **We will analyze a total of 140 patients:**

1. Group A: 70 patients who will undergo Convective RF water vapor energy (Rezum)
2. Group B: 70 patients who will undergo transurethral enucleation of prostate (TUEP).

prospective randomized study comparing Convective radio frequency (RF) water vapor energy (Rezum) with trans-urethral enucleation of the prostate (TUEP) , in which the choice of the procedure for patients will be based on the patient preference depending on the Physician - patient discussion about the two procedures in the period between May 2025 and May 2026, in Urology department, Beni-Suef University hospital

- **Inclusion Criteria:**

Male aged > 50 yrs.

International Prostate Symptom Score (IPSS) >12

Maximum flow rate ( Qmax ) < 15 ml/s for 125ml voided volume

Post-void residual volume <350 ml

Prostate volume 80-120 g

- **Exclusion criteria:**

Active urinary tract infection at time of treatment.

Prostate-specific antigen (PSA) more than 10 ng/l.

history of prostate or bladder cancer.

Anticoagulants within 3d of the index procedure

- **The preoperative evaluation included:**

history, physical examination, laboratory investigations [ urinalysis, urine culture and sensitivity, prostatic specific antigen (PSA), serum creatinine, prothrombin time

(PT), prothrombin concentration (PC), international normalized ratio (INR)], radiological investigations (pelvi-abdominal ultrasonography) and uroflowmetry.

- **Procedure techniques:**

1. **The Convective RF water vapor energy ( Rezum ) (group A):** procedure consists of a handheld delivery device and generator that utilizes convective water vapor energy ablation to reduce prostatic tissue and subsequently alleviate obstructive urinary symptoms. The vapor needle resides within the insulated lumen of the delivery device until it is deployed into the prostatic tissue. The needle is a flexible braided silicone tubing with 12 small emitter holes spaced around its tip at 120-degree intervals to allow a controlled, uniform circumferential dispersion of water vapor.
2. **The trans-urethral enucleation of the prostate (TUEP) (group B):** The first step of surgery is to create a groove at the 12 o'clock position, followed by two additional grooves at the 5 and 7 o'clock positions, laterally to the verumontanum. Next, the lateral lobes and the middle lobe, when present, are bluntly dissected circumferentially from the prostate apex towards the bladder following the plane of the capsule. This allows for the enucleation of the adenoma.

- **The post operative evaluation (follow up) includes:**

history taking (lower urinary tract symptoms, international prostatic symptoms score (IPSS), erectile & ejaculatory function), physical examination, pelvi-abdominal examination ultrasound to check residual urine (PVR) and uroflowmetry for maximum flow rate (Q max). The IPSS-Total was chosen as the primary outcome, while IIEF-EF, MSHQ-EjD, and postoperative complications CD grade  $\geq$  III were selected as the secondary outcomes.

- **Sample size:**

Sample size calculated using G-Power© software (Institute of experimental psychology, Heinrich Heine University, Dusseldorf, Germany). Minimal sample size of patients was (70) patients in each group. Effect size 0.9 Depending on previous research results. Two-sided (two tails) type I error 0.05 and power of 0.95

- **Statistical analysis;**

Data will be collected, tabulated and analyzed using SPSS (statistical program for social science) version 25. Data will be expressed as number and percentage for qualitative variables or mean and standard deviation for quantitative ones. Comparison between groups will be performed through the Chi square or Fisher's exact test for qualitative variables and independent sample t-test (if parametric) or the Mann Whitney test (if non-parametric) for quantitative ones. The correlation will be done to correlate between quantitative variables. The correlation coefficient at  $\leq 0.3$  will be considered a weak correlation, 0.3-0.6 was considered a moderate correlation, and  $>0.6$  was considered a strong correlation. P-values  $<0.05$  will be considered significant.

- **Ethical considerations:**

Ethical approval will be sought from Research Ethical Committee (REC), Beni-Suef University. Informed consents will be signed from the participants, after explanation of the study to all participants.

- **Keywords:**

benign prostatic hyperplasia, transurethral enucleation of prostate, water vapor therapy, lower urinary tract symptoms, international prostate symptom score, minimally invasive procedures

## References

1. Dixon CM, Edwin Rijo Cedano, Dalibor Pacik , Viteslav Vit, Gabriel Varga, Lennart Wagrell , Magnus Tornblom, Lance Mynderse , Thayne Larson: Efficacy and safety of Rezūm system water vapor treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia. *Urology*. 2015;86(5):1042–1047.
2. Guo RQ, Wei Yu, Yi-Sen Meng, Kai Zhang, Ben Xu, Yun-Xiang Xiao, Shi-Liang Wu, Bai-Nian Pan: Correlation of benign prostatic obstruction-related complications with clinical outcomes in patients after transurethral resection of the prostate. *Kaohsiung J Med Sci*. 2017, 33:144-51. 10.1016/j.kjms.2017.01.002.
3. Gupta N, Köhler TS, McVary KT, Holland B, Delfino K: Convective radiofrequency water vapor energy ablation (Rezūm®) effectively treats lower urinary tract symptoms due to benign prostatic enlargement regardless of obesity while preserving erectile and ejaculatory function. *J Urol*. 2017;197(Suppl 4): e609
4. Liu Chunxiao, Shaobo Zheng, Hulin Li, Kai Xu.: Transurethral enucleation and resection of prostate in patients with benign prostatic hyperplasia by plasma kinetics. *J Urol* 2010; 184:2440–5.
5. Bahaa S Malaeb, Xinhua Yu, A. Marshall McBean and Sean P Elliott.: National trends in surgical therapy for benign prostatic hyperplasia in the United States (2000-2008). *Urology*. 2012;79(5):1111–1117.
6. McVary KT, Roehrborn CG. Three-year outcomes of the prospective, randomized controlled Rezūm System study: Convective radiofrequency thermal therapy for treatment of lower urinary tract symptoms due to benign prostatic hyperplasia. *Urology* 2018; 111:1-9.
7. Mynderse LA, Dennis Hanson, Richard A Robb , Dalibor Pacik , Viteslav Vit, Gabriel Varga, Lennart Wagrell , Magnus Tornblom , Edwin Rijo Cedano , David A Woodrum. Rezūm system water vapor treatment for lower urinary tract symptoms/benign prostatic hyperplasia: Validation of convective thermal energy transfer and characterization with magnetic resonance imaging and 3-dimensional renderings. *Urology*. 2015;86(1):122–127.