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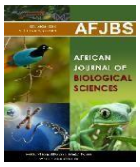

Transurethral bipolar enucleation and resection of the prostate versus open prostatectomy for the treatment of benign prostatic hyperplasia: a randomized clinical trial

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Abstract:

Goal: Benign prostatic hyperplasia (BPH) is a common condition among older men that often leads to bladder obstruction. This study aims to compare the safety and surgical outcomes of two treatment options for BPH patients with large prostates (>80 g): open prostatectomy (OP) and transurethral bipolar enucleation and resection of the prostate (TBERP).

Methods: A randomized, prospective clinical trial was conducted on BPH patients over 50 years old with a prostate volume >80 mL, maximum flow rate (Qmax) >15mL/s, and International Prostate Symptom Score (IPSS) >8, meeting established surgical indications. Patients were randomly assigned to either OP or TBERP. Intraoperative blood loss, operation time, resected prostatic tissue weight, postoperative catheterization, and hospital stay period were recorded. Patients were also assessed for IPSS, post-voiding residual urine, prostate volume, and complications (including catheterization, urinary retention, urinary tract infection, irritative symptoms, urinary incontinence, urethral stricture, and bladder neck contracture) over a three-month follow-up period.

Results: The study enrolled 64 patients with a mean age of 62.6 and 61.8 in the OP and TBERP groups, respectively. TBERP resulted in significantly less bleeding (p=0.139) and shorter catheterization and hospital stay periods (p<0.001 and <0.001, respectively), but no significant difference in operation time, resected tissue weight, or post-operative IPSS (p=0.214, 0.219, and 0.956, respectively). During the three-month follow-up period, OP and TBERP had statistically equivalent outcomes regarding early and late complications.

Conclusion: TBERP is a safe and effective alternative to OP for BPH patients with large prostates, with less bleeding and a quicker recovery period.

Keywords:BPH, Transurethral Bipolar Enucleation; prostate resection; Urology; Surgical Outcomes, Open Prostatectomy.

INTRODUCTION

Benign prostatic hyperplasia (BPH) is a prevalent condition among older men, often leading to

bladder outlet obstruction (BOO) and necessitating the exploration of various endoscopic treatments. The management of BPH traditionally revolves around three transurethral surgery concepts: resection, vaporization, and enucleation [1]. Open prostatectomy, the historical gold standard for large BPH cases (>80 ml), is associated with significant morbidity [2], driving the search for less invasive alternatives.

Monopolar transurethral resection of the prostate (TURP) is frequently avoided due to the heightened risk of complications associated with prolonged procedures, including TUR syndrome, blood transfusions, fluid absorption, extended catheterization, urethral stricture, and bladder neck contracture [3]. As a result, there is a growing demand for technological advancements to mitigate the risks inherent in traditional TURP [4].

In recent years, several minimally invasive procedures have emerged as viable alternatives, including transurethral microwave thermotherapy, transurethral needle ablation, bipolar transurethral resection in saline (TURis), and LASER operations. Holmium LASER enucleation of the prostate (HoLEP) has demonstrated promising long-term clinical improvements with a low complication rate [5]. However, the limited widespread adoption of LASER techniques is often attributed to perceived learning curves and high associated costs [6].

A notable recent development in the field is the introduction of a mushroom-shaped electrode and a bipolar plasma kinetic vaporization device, which has yielded a safe and effective alternative known as TURis plasma vaporization for managing lower urinary tract symptoms caused by BOO [7].

This study introduces a novel hybrid approach, termed transurethral bipolar enucleation and resection of the prostate (TBERP), which combines the advantages of enucleation and resection techniques for the management of large prostatic enlargement. TBERP utilizes the same cutting current and technology setup, aiming to provide enhanced efficacy with reduced morbidity [8].

PATIENTS AND METHODS

Study Design: This prospective, randomized comparative study was conducted from October 2020 to October 2022 at Badr Hospital, Helwan University, and MUST University hospitals. The study protocol was approved by the Faculty of Medicine at Helwan University (IRB: [51-2020]) and registered on ClinicalTrials.gov (NCT05416606). All participants provided written informed consent after receiving detailed information about the study's risks, benefits, compensation, and right to withdraw.

Patient Selection: Our study enrolled male patients aged over 50 with prostate sizes exceeding 80 ml. We specifically included individuals experiencing clinically significant lower urinary tract symptoms (LUTS), indicated by an IPSS score of 8 or higher. While classified as "moderate," these symptoms significantly impacted their quality of life and remained unresponsive to medical therapy. This aligns with current guidelines acknowledging that moderate symptoms alone can justify surgery when they substantially affect patient well-being.

Furthermore, the Qmax cut-off of 15 ml/s was not solely considered in isolation. We exclusively included patients with established surgical indications such as refractory retention, bladder stones, recurrent gross hematuria, recurrent infections, and persistent bothersome symptoms despite medical management. This ensured our study population encompassed individuals with objective evidence of bladder outlet obstruction (BOO) or other compelling reasons for surgical intervention, even if their Qmax fell within the borderline range. By carefully selecting patients with both significant LUTS and objective evidence justifying surgery, we aimed to ensure our study population represented individuals who would genuinely benefit from the procedures investigated.

Patients with uncorrectable coagulopathy, active infection, small prostate (<80ml), severe comorbidities, neurogenic bladder, or prostate cancer were excluded, as were those with prior prostate or bladder surgery minimizing confounding factors that could affect both TBERP and OP outcomes by altering anatomy, bladder function, or prostate characteristics.

Randomization: Patients were randomly allocated to two groups (TBERP and OP) using a computer-generated random number list created with Med Calc version 18.2.1.

Preoperative Assessment: Preoperative assessment included detailed medical history, IPSS scoring, clinical examination with digital rectal examination (DRE), laboratory tests (complete blood count, coagulation profile, renal function tests), midstream urine analysis with culture and sensitivity, total and free prostate-specific antigen (PSA) levels, and pelvic/abdominal ultrasound for prostate volume and post-void residual (PVR) urine measurement.

Surgical Procedures: Group A (TBERP): Transurethral bipolar enucleation of the prostate (TBERP) was performed using a 26 Fr continuous flow resectoscope equipped with the plasmakinetic system's enucleation and resection loops (KARL STORZ HF Generator AUTOCON® III 400) under general or spinal anesthesia with physiologic saline irrigation. Following verumontanum, bladder neck, and ureteral orifice identification (figure 1), the middle lobe was meticulously resected using the resection loop. Subsequently, a mucosal incision was made at the 5 and 7 o'clock positions at the apical adenoma (figure 2), deepened to reach the surgical capsule (figure 3,4). The left and right lobes were then separated from the capsule in a retrograde fashion from apex to bladder using a bipolar enucleation loop, with meticulous hemostasis maintained throughout (figure 5). The bipolar enucleation loop mimicked the surgeon's index finger during open prostatectomy, and the bipolar resection loop fragmented the devascularized prostatic lobes into smaller chips while preserving their connection to the bladder neck via a narrow pedicle.

Group B (OP): Transvesical open prostatectomy was performed using the classical approach [9].

Postoperative Management: Both groups received comprehensive postoperative care, including insertion of a 22Fr triple-lumen catheter with irrigation. Data collected included intraoperative bleeding, operative time, tissue weight, postoperative hemoglobin level, catheterization duration, and mean hospital stay.

Regular follow-up assessments at specified intervals postoperatively included IPSS score measurement, post-void residual urine volume evaluation, and monitoring for early and late complications such as re-catheterization, acute urinary retention, irritative symptoms, urinary tract infections, urinary incontinence, urethral strictures, and bladder neck contracture.

Statistical Analysis:

Data was coded and entered into SPSS version 28. Descriptive statistics were employed, and a range of statistical tests (unpaired t-tests, Mann-Whitney tests, Chi-square tests, etc.) were used for comprehensive analysis as outlined in the methods section. Statistical significance was set at $p < 0.05$[10, 11].

Results

Patient Characteristics: A total of 64 male participants were enrolled in the study, with 32 randomized to transurethral enucleation (TBERP) and 32 to simple prostatectomy (OP). There were no significant differences between the groups in terms of baseline characteristics, including mean age (62.63 vs. 61.82 years), International Prostate Symptom Score (IPSS), hemoglobin, International Normalized Ratio (INR), serum creatinine, prostate-specific antigen (PSA) levels, prostate volume, and post-void residual urine volume (Table 1).

Primary Outcome: The primary outcome measures included catheterization period, hospital stay, operative time, and resected prostatic tissue weight. Patients undergoing TBERP experienced significantly shorter catheterization (mean 5.09 days vs. 7.31 days, $p < 0.001$) and hospital stay (mean 2.13 days vs. 4.94 days, $p < 0.001$) compared to the OP group. Operative time was similar between groups (121.88 vs. 115.31 minutes, $p = 0.214$), and there was no significant difference in the weight of resected tissue ($p =$

0.219) (Table 1).

Secondary Outcomes and Adverse Events (Table 2)**:** Following catheter removal, a small number of patients experienced complications. In the transurethral enucleation (TBERP) group, 1 (3.1%) required recatheterization and 1 (3.1%) experienced acute urine retention. The simple prostatectomy (OP) group had 2 (6.3%) patients with recatheterization and 2 (6.3%) with acute retention. The incidence of irritative symptoms and urinary tract infections (UTIs) was similar between groups at one week ($p = 0.708$ and $p = 1.000$, respectively).

No significant differences were observed in recatheterization, acute retention, irritative symptoms, or UTI at one and three months postoperatively. Additionally, no significant differences were found in the incidence of urinary incontinence, urethral stricture, or bladder neck contracture at three months.

Both TBERP and OP demonstrated comparable improvements in International Prostate Symptom Score (IPSS) and post-void residual (PVR) at all follow-up time points. At one week, there were no significant differences in IPSS ($p = 1.000$) and PVR ($p = 0.984$). Similar findings were observed at one month (IPSS: $p = 0.939$; PVR: $p = 0.903$) and three months (IPSS: $p = 0.793$; PVR: $p = 1.000$) postoperatively.

The majority of participants in both groups did not require blood transfusions (93.8% in TBERP, 87.5% in OP, $p = 0.672$).

Table 1. pre- and intra-operative data.

	transurethral enucleation(N=32)		**simple prostatectomy(N=32)**		**P**
	Mean	**SD**	**Mean**	**SD**	
Age	62.63	5.56	61.82	5.48	0.946
IPSS score preoperative	21.75	7.12	22.84	6.45	0.956
hemoglobin preoperative (g/dl)	12.46	0.97	12.77	0.94	0.979
INR preoperative	1.05	0.07	1.06	0.08	0.755
Serum creatinine preoperative (mg/dl)	0.97	0.19	0.97	0.19	0.895
Total PSA preoperative (ng/ml)	2.97	1.49	3.09	1.52	1.000
prostate volume preoperative (g)	102.66	15.14	101.78	14.84	0.974
PVR preoperative (ml)	204.69	196.07	198.19	190.71	0.989
catheterization period (day)	5.09	0.59	7.31	0.64	< 0.001
hospital stay (day)	2.13	0.34	4.94	0.50	< 0.001
operative time (minutes)	121.88	21.54	115.31	20.24	0.214
weight of resected prostatic tissue (g)	43.94	10.30	46.91	8.77	0.219
hemoglobin drop	1.10	0.50	1.31	0.51	0.139

Table 2 post-operative data.

	transurethral enucleation(N=32)		**simple prostatectomy(N=32)**		**P**
	Count	**%**	**Count**	**%**	

blood transfusion (ml)	0	30	93.8%	28	87.5%	0.672
	500	2	6.3%	4	12.5%	
one week post catheter removal						
Recatheterization	positive	1	3.1%	2	6.3%	1
	negative	31	96.9%	30	93.8%	
acute urine retention	positive	1	3.1%	2	6.3%	1
	negative	31	96.9%	30	93.8%	
irritative symptoms	positive	5	15.6%	3	9.4%	0.708
	negative	27	84.4%	29	90.6%	
urinary tract infection	positive	3	9.4%	3	9.4%	1
	negative	29	90.6%	29	90.6%	
one month post operative						
Recatheterization	negative	32	100.0%	32	100.0%	------
acute urine retention	negative	32	100.0%	32	100.0%	------
irritative symptoms	positive	3	9.4%	3	9.4%	1
	negative	29	90.6%	29	90.6%	
urinary tract infection	positive	1	3.1%	1	3.1%	1
	negative	31	96.9%	31	96.9%	
3 months post operative						
Recatheterization	negative	32	100.0%	32	100.0%	------
acute urine retention	negative	32	100.0%	32	100.0%	------
irritative symptoms	positive	2	6.3%	3	9.4%	1
	negative	30	93.8%	29	90.6%	
urinary tract infection	positive	1	3.1%	1	3.1%	1
	negative	31	96.9%	31	96.9%	
urinary incontinence	positive	2	6.3%	2	6.3%	1
	negative	30	93.8%	30	93.8%	
urethral stricture	negative	32	100.0%	32	100.0%	------
bladder neck contracture	negative	32	100.0%	32	100.0%	------
		Mean	**SD**	**Mean**	**SD**	P
one week post catheter removal						
IPSS score		13.00	4.35	13.00	4.35	1.000
PVR		33.31	43.78	40.66	63.73	0.984
one month post operative						
IPSS score		9.41	3.43	9.34	3.03	0.939
PVR		17.19	10.77	16.50	9.54	0.903
3 months post operative						
IPSS score		7.22	1.95	7.09	1.86	0.793
PVR		12.91	7.19	12.91	7.19	1

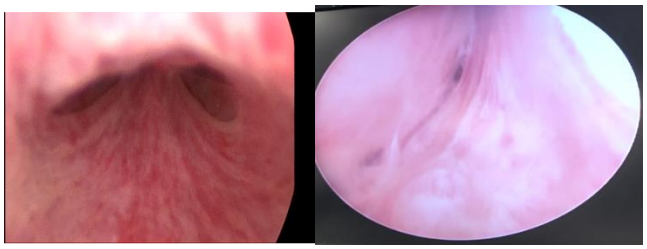

Figure (1): Cystoscopic view of the verumontanum.

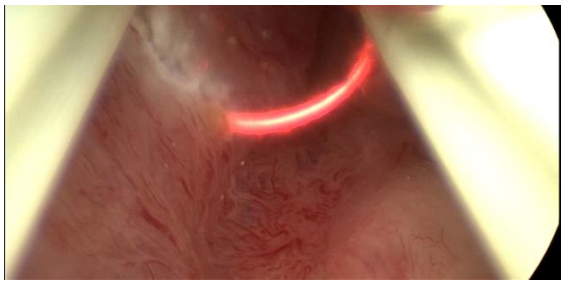

Figure (2): Apical adenoma was incised close to the verumontanum.

Figure (3): Deepening the incision to the level of the surgical capsule.

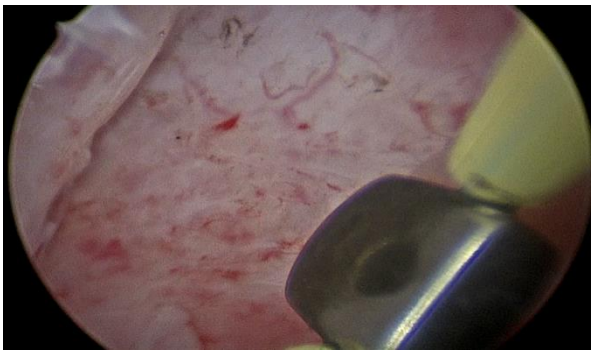

Figure (4): Inner surface of the surgical capsule.

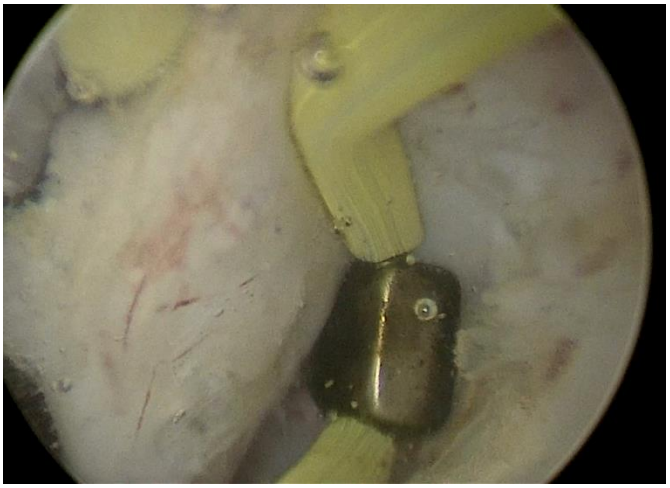

Figure (5): Left lobe was dissected off the surgical capsule in a retrograde fashion from the apex toward the bladder.

Discussion

This study offers a comprehensive comparison between transurethral bipolar enucleation of the prostate (TBERP) and open prostatectomy (OP) for treating prostate adenomas larger than 80cc in patients with lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH). The findings reveal a lack of significant differences between the two groups regarding bladder neck contracture, urethral strictures, and urinary incontinence, affirming comparable safety profiles. Both TBERP and OP exhibit similar functional outcomes at the 1- and 3-month follow-up, demonstrated by equivalent mean post-void residual (PVR) and International Prostate Symptom Score (IPSS) values.

The clinical relevance of this study lies in its affirmation of TBERP as a viable alternative to OP for large prostates. Notably, TBERP presents advantages with a significantly shorter catheterization period and hospital stay, indicating potential benefits for post-operative recovery and healthcare resource utilization. These results resonate with existing literature, including studies by Geavlete et al. and Giulianelli et al., strengthening the evidence that TBERP is a valid option with favorable outcomes at three months. The study contributes valuable insights to the expanding body of evidence supporting minimally invasive techniques for large prostates [12, 13].

However, the unexpected result of no significant difference in the weight of resected prostatic tissue prompts a critical evaluation of factors influencing tissue weight, contrasting with findings from Rao et al. and Xiong et al. This discrepancy highlights the importance of standardized metrics for reporting surgical outcomes and prompts further investigation into the clinical implications of this variation in tissue removal. Future research should explore the impact of tissue weight on long-term outcomes and consider the influence of surgical technique and patient characteristics[14, 15].

The study's outcomes underscore the comparable safety profiles of TBERP and OP, aligning with previous research by Geavlete et al. and Rao et al. Notably, both procedures exhibit low rates of long-term complications, including urethral strictures, urinary incontinence, and bladder neck contracture, supporting the safety of endoscopic enucleation techniques. The observed peri-operative bleeding risks further favor TBERP, as indicated by its lower mean hemoglobin level drop compared to OP. These results align with existing literature, emphasizing the favorable safety profile of endoscopic procedures and contributing to the growing body of evidence supporting their use[13, 15].

TBERP demonstrates several advantages over OP in terms of immediate recovery parameters, including a significantly shorter catheterization period and hospital stay, as also reported by Geavlete et al. These outcomes align with the broader goal of minimizing post-operative discomfort and promoting faster recovery. Additionally, the study findings emphasize the comparability of short and long-term functional outcomes between TBERP and OP, with both procedures demonstrating positive results in IPSS score and PVR at various follow-up points. The study contributes to the evolving evidence supporting the feasibility and efficacy of TBERP in achieving favorable functional outcomes, reinforcing the findings of Geavlete et al. and Giulianelli et al. [12, 13, 16].

Comparisons with existing literature reveal consistent outcomes, with a significant difference in favor of TBERP regarding catheterization period and hospital stay, as reported by Geavlete et al. This study adds to the collective evidence supporting the role of TBERP in the surgical armamentarium for large prostates, emphasizing its potential for a favorable balance between safety, efficacy, and recovery. The findings align with studies assessing bipolar transurethral enucleation of the prostate (B-TUEP) and Holmium Laser Enucleation of the Prostate (HoLEP), contributing to a comprehensive understanding of the available surgical options[13, 16].

The study underscores the favorable bleeding profile of TBERP, consistent with existing literature on the advantages of bipolar vaporization. This aligns with the findings of studies on the plasma kinetic vaporization of the prostate (PKVP), emphasizing the potential benefits of TBERP in minimizing peri-operative bleeding risks. The comparison with OP, known for higher-level drops and associated blood

transfusion rates, further supports the safety profile of TBERP. The study's findings contribute to the ongoing discourse on the safety and efficacy of endoscopic procedures, emphasizing the bleeding-related advantages of TBERP[17, 18].

The study indicates a reduced blood transfusion rate with TBERP compared to OP, consistent with findings by Giulianelli et al., Shah et al. and Rao et al. This reinforces the safety advantages associated with the endoscopic approach, supporting the assertion that TBERP presents a lower risk of significant bleeding requiring blood transfusion. The discussion underscores the importance of considering bleeding-related outcomes in surgical decision-making, particularly in patients at higher risk for complications [12, 15, 19]. The study acknowledges the learning curve associated with TBERP, consistent with findings by Xiong et al. and Hirasawa et al. It highlights the crucial steps involved in TBERP, such as identifying the avascular plane and preserving a distance distal to the bladder neck. The discussion emphasizes the importance of surgeon experience in achieving proficiency, aligning with the findings of Xiong et al. and Hirasawa et al. These insights contribute to the broader understanding of the procedural nuances associated with TBERP, offering valuable guidance for surgeons considering its adoption[14, 20].

Regarding late complications, the study reveals comparable outcomes between TBERP and OP for urethral strictures, urinary incontinence, and bladder neck contracture. These findings are consistent with prior research, highlighting the durability and sustainability of positive outcomes associated with endoscopic enucleation techniques. The study aligns with studies outlining similar rates for plasma-button technique and OP concerning bladder neck sclerosis, urethral strictures, and urinary incontinence. The discussion reinforces the notion that TBERP offers a favorable long-term complication profile comparable to established surgical approaches, echoing the results of Geavlete et al. and Rao et al[13, 15, 16].

Acknowledging the study's limitations is crucial for a comprehensive interpretation of the results. The relatively small sample size and single-center design may limit the generalizability of the findings. Additionally, the absence of long-term follow-up data restricts the assessment of durable treatment effects. Despite these limitations, the study provides valuable insights, laying the groundwork for larger, multicenter studies with extended follow-up periods.

Building on the study's findings, future research should aim to validate outcomes in larger, multicenter cohorts, considering diverse patient populations. Long-term follow-up assessments are essential for understanding sustained benefits and potential complications associated with both TBERP and OP. Standardization of reporting metrics, including a detailed analysis of resected tissue characteristics, could enhance result comparability across studies. Further exploration of the economic implications of observed differences in catheterization and hospital stay durations would provide additional insights into the overall cost-effectiveness of these surgical approaches. Continued research is imperative for refining our understanding of the long-term benefits and potential variations in clinical practice, guiding surgical decision-making for large prostates.

Conclusion:

Transurethral Bipolar Enucleation of the Prostate proves to be a viable and lower-morbidity alternative to open prostatectomy for the treatment of large Benign Prostatic Enlargement. This procedure offers several advantages, including reduced catheterization time, hospital stay, and perioperative bleeding risks. TBERP demonstrates comparable safety, functional outcomes, and long-term sequelae when compared to the traditional approach. However, it is crucial to consider factors such as individual surgeon expertise and patient characteristics when selecting the most suitable method for treating large BPH.

Authors contribution: Mohamed Hassan Ali Soliman, Tarek Abd Al-Majied Salem, Mohammed Fawzy El Syaad, and Mohamed Mahmoud Abd Al-Fatah Zaza were involved in the conception and design of the study. Mohamed Fawzy El Syaad, Tarek Abd Al-Majied Salem, and Mohamed Hassan Ali Soliman

contributed to protocol development, gaining ethical approval, patient recruitment, and data analysis. Mohamed Fawzy El Syaad, Tarek Abd Al-Majied Salem, and Mohamed Hassan Ali Soliman wrote the first draft of the manuscript. All authors reviewed and edited the manuscript and approved the final version.

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List of abbreviations:

- B-TUEP: Bipolar Transurethral Enucleation of the Prostate
- BPH: Benign Prostatic Hyperplasia
- BOO: Bladder Outlet Obstruction
- CT: Computer Tomography
- DRE: Digital Rectal Examination
- EDTA: Ethylenediaminetetraacetic Acid
- HoLEP: Holmium Laser Enucleation of the Prostate
- INR: International Normalized Ratio
- IPSS: International Prostate Symptom Score
- IRB: Institutional Review Board
- LASER: Light Amplification by Stimulated Emission of Radiation
- LUTS: lower urinary tract symptoms
- MRI: Magnetic Resonance Imaging
- OP: Open Prostatectomy
- P-value: Probability Value
- PKVP: Plasma Kinetic Vaporization of the Prostate
- PSA: Prostate-Specific Antigen
- PVR: Post-Void Residual Urine
- Qmax: Maximum Urinary Flow Rate
- SD: Standard Deviation
- SPSS: Statistical Package for the Social Sciences
- TBERP: Transurethral Bipolar Enucleation and Resection of the Prostate
- TURis: bipolar transurethral resection in saline
- TURP: Transurethral Resection of the Prostate
- UTI: Urinary Tract Infection

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