RESEARCH PAPER

Comparison between Convective Radiofrequency Water Vapor Thermal Ablation (REZUM) Versus Tamsulosin in Management of Lower Urinary Tract Symptoms in Patients with Benign Prostatic Enlargement

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Received: 15th Sep, 2026; Revised: 05th Oct, 2026; Accepted: 15th Oct, 2026; Available Online: 28th Oct, 2026

ABSTRACT

Background: Benign prostatic hyperplasia (BPH) is a common condition among aging men and may cause lower urinary tract symptoms (LUTS), negatively affecting urinary function and quality of life. Rezūm water vapor thermal therapy is a minimally invasive treatment that may provide effective symptom relief while reducing treatment-related adverse effects compared with conventional medical therapy.

Aim: To assess the efficacy of REZUM water vapor thermal ablation therapy against the conventional medical treatment for benign prostatic hyperplasia using tamsulosin.

Patients and methods: This randomized controlled trial was conducted at the Urology Departments of Kasr Al-Ainy Hospital and Kobry El-Kobba Military Hospital over 12 months and included 94 patients with BPH. Patients were randomly allocated into two equal groups: the Rezūm group (47 patients), who underwent water vapor thermal therapy, and the tamsulosin group (47 patients), who received medical treatment. All participants underwent clinical assessment, laboratory investigations, ultrasonography, International Prostate Symptom Score (IPSS) evaluation, uroflowmetry, and quality of life (QoL) assessment. Outcomes, including IPSS, maximum urinary flow rate (Qmax), post-void residual (PVR) urine volume, prostate volume, QoL, and complications, were evaluated at baseline and during follow-up.

Results: Baseline clinical characteristics were comparable between the two groups. At 3 months, the Rezūm group demonstrated significantly better IPSS, QoL, Qmax, prostate volume, and PVR outcomes than the tamsulosin group. At 6 months, Rezūm was associated with significantly better QoL, Qmax, and PVR, while IPSS and prostate volume showed no significant between-group differences. At 12 months, the Rezūm group demonstrated significantly better QoL, Qmax, prostate volume, and PVR, whereas IPSS did not differ significantly between groups. Complications were significantly less frequent in the Rezūm group than in the tamsulosin group (55.3% vs. 85%, $p = 0.0017$).

Conclusion: Rezūm water vapor thermal therapy demonstrated favorable outcomes compared with tamsulosin in improving urinary flow, quality of life, prostate volume, and post-void residual urine volume over 12 months. It was also associated with a lower overall complication rate, supporting its role as an effective minimally invasive treatment option for selected patients with BPH.

Keywords: Benign prostatic hyperplasia, Rezūm, Tamsulosin, Lower urinary tract symptoms, Uroflowmetry, Quality of life.

How to cite this article: Elmosalamy H.I.F, Meshref A.W, Abd El-Rassoul M.A, Elsayed A.S, Bassiony M.W, Abdelfattah I.M.S.I, Comparison between Convective Radiofrequency Water Vapor Thermal Ablation (REZUM) Versus Tamsulosin in Management of Lower Urinary Tract Symptoms in Patients with Benign Prostatic Enlargement. 2026; 16(87s): 739-743. DOI: 10.25258/ijddt.16. 87s.72

Source of support: None

Conflict of interest: None

INTRODUCTION

Benign prostatic hyperplasia (BPH) is the most common benign neoplasm of aging men and is present in approximately 8% of men in the fourth decade of life but up to 90% of men in the ninth decade [1].

BPH refers to the change in the size of the prostate and not the potential symptoms that it may cause, which are usually referred to as lower urinary tract symptoms (LUTS). LUTS may be primarily irritative, obstructive, or mixed. Men with BPH may be asymptomatic, respond to lifestyle changes, or require medical or surgical therapy; symptoms are more common as men age. Once primarily treated by urologists, guidelines now emphasize a primary care approach [2].

Men with moderate to severe LUTS from BPH (AUASI score of 8 or higher) or mild LUTS that are deemed bothersome by the patient may be offered pharmacologic treatment. The 2 major classes of medications for BPH are alpha-adrenergic blockers and 5-alpha reductase inhibitors. The PDE-5 inhibitor tadalafil is also approved by the Food and Drug Administration (FDA) for the treatment of BPH.

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Many men also are interested in the use of alternative therapy to treat LUTS [**3**].

Several procedures are available for the treatment of symptomatic BPH. The most commonly performed surgical procedure is transurethral resection of the prostate (TURP), which is considered the gold standard. Men should be screened for urinary tract infection as part of a preoperative evaluation; if present, it should be treated before surgery. Potential complications include retrograde ejaculation, erectile dysfunction, hematuria, urethral stricture, and urinary tract infection. Approximately 5% to 10% of men who undergo TURP will require a repeat procedure with 10 years [4].

A number of less invasive procedures have been developed for the treatment of BPH. In general, these procedures are associated with less morbidity than TURP but are also associated with a higher risk of need for retreatment. Healthy men with low surgical risk are appropriate for TURP, whereas men with higher surgical risk or who cannot tolerate general anesthesia may require less invasive surgical treatment. Examples of these procedures include photoselective vaporization of the prostate, transurethral incision of the prostate, and transurethral laser prostatectomy [3].

The Rezum procedure is a novel minimally invasive therapy for treating BPH. So far, data from available studies point towards good clinical outcomes with a short-term risk of self-limiting minor complications. Its application has demonstrated clinical effectiveness and possesses specific benefits that distinguish it among other treatments. It is applicable to outpatient setting, is effective in preserving sexual function and is versatile in its ability to treat a variety of prostate gland morphologies [5].

Our study aimed to assess the efficacy of REZUM water vapor thermal ablation therapy against the conventional medical treatment for benign prostatic hyperplasia using tamsulosin.

PATIENTS AND METHODS

This study was randomized controlled trial conducted in Kasr Al-Ainy Hospital, Urology Department & Kobbry El Kobba Military Hospital Urology Department, on 94 patients with lower urinary tract symptoms due to benign prostatic hyperplasia were enrolled in the study for 12 months.

Inclusion criteria: The inclusion criteria were men ≥ 50 years old. IPSS of ≥ 13. Maximum flow rate (Q-max) of <15 mL/s. Prostate volume 30-80 ml. Measured post void residual (PVR) urine <250 ml.

Exclusion criteria: Patients were excluded if they Patients with neurogenic bladder or urethral strictures.Patients with sexual or ejaculation disturbance.Patients with previous intervention. Patients indicated for surgical interference or TURP e.g. bladder stones, bilateral hydronephrosis, elevated serum creatinine.

Patient's randomization: The 94 patients with benign prostatic hyperplasia (BPH) were randomly allocated into two independent groups: the Rezūm group, which included 47 patients who underwent Rezūm water vapor therapy, and the tamsulosin group, which included 47 patients who received tamsulosin treatment. Randomization was performed using the closed-envelope technique.

Ethical consideration: The nature of the present study and laboratory or radiological procedures was explained to all participants. Consent was obtained from all participants. At the end of the study, all patients were informed about the results of the examinations performed and received appropriate recommendations, and treatment. The World Health Organization (WHO) and the Declaration of Helsinki recommendations were followed, in terms of protecting the rights and well-being of the studied people.

Methods:

All participants provided written informed consent after being informed about the nature of the study, its expected benefits and outcomes, and possible adverse effects. Detailed history taking and complete general and local examinations were performed for all participants. Routine laboratory investigations, including complete blood count (CBC), renal function tests, and coagulation profile, were conducted. Pelvi-abdominal ultrasonography was performed to assess the urinary tract, including pre-voiding and post-voiding measurements. Total and free prostate-specific antigen (PSA) levels and their ratio were measured. Additionally, the International Prostate Symptom Score (IPSS), uroflowmetry, and quality of life (QoL) score related to urinary symptoms were assessed in all participants.

Results from the REZUM arm were compared to the results of single therapy arm, receiving Tamsulosin, restricted only to those subjects with prostate volume 30cc or lager and IPSS 13 or worse. IPSS, uroflowmetry (Qmax), and PVR were compared at 3 months, 6 months, and 1 year. Propensity score weighting was also performed to eliminate differences in IPSS, QOL and prostate volume between the groups at baseline and outcomes were again assessed at 3 months, 6 months, and 1 year.

RESULTS

Comparative study between the 2 groups revealed non-significant difference as regards all basic clinical data ($p > 0.05$) (Table 1).

Comparative study between the 2 groups revealed; highly significant difference in baseline PVR, in Rezum group; compared to Tamsulosin group ($p < 0.01$).

Comparative study between the 2 groups revealed non-significant difference as regards all the other baseline outcome parameters ($p > 0.05$ (Table 2).

Comparative study between the 2 groups revealed; highly significant decrease in 3-months IPSS score, QOL IPSS score, PVR, and Prostate volume, also revealed; highly significant increase in 3-months Qmax, in Rezum group; compared to Tamsulosin group ($p < 0.01$ respectively) (Table 3).

Comparative study between the 2 groups revealed; highly significant decrease in 6-months QOL IPSS score, and PVR, also revealed; highly significant increase in 6-months Qmax, in Rezum group; compared to Tamsulosin group ($p < 0.01$ respectively).

Comparative study between the 2 groups revealed non-significant difference as regards 6-months IPSS score, and Prostate volume ($p > 0.05$). Regarding change in prostate

volume and PVR especially occurred with tamsulosin group may be due to error in measurement by abdominal US,as it is so high **(**Table 4).

Comparative study between the 2 groups revealed; highly significant decrease in 12-months QOL IPSS score, Prostate volume, and PVR, also revealed; highly significant increase in 12-months Qmax, in Rezum group; compared to Tamsulosin group ($p < 0.01$ respectively). Comparative study between the 2 groups revealed non-significant difference as regards 6-months IPSS score ($p > 0.05$) (Table 5).

Regarding Complications rate; (70.2%) of patients had suffered complications which were mild, tolerated and transient and treated conservatively and no patients shifted from arm one to another.Comparative study between the 2 groups revealed; highly significant decrease in Complications rate in in Rezum group; compared to Tamsulosin group ($p = 0.0017$). (Table **6**).

Table1**:** Comparison between the 2 groups as regards Basic clinical data using Student's t and Chi square tests

Variable	Rezum group (47)	Tamsulosin group(47)	Student's *t* test
	Mean ± SD	Mean ± SD	P value
Age (years)	70.6 ± 4.9	69.5 ± 3.8	= 0.266
BMI	26.1 ± 2.8	26 ± 1.2	= 0.793

* Percentage of Column Total.

Table 2: Comparison between the 2 groups as regards Baseline outcome parameters using Student's t test

Variable	Rezum group (47)	Tamsulosin group (47)	Student's t test
	Mean ± SD	Mean ± SD	P value
IPSS score	25.5 ± 4.6	25.9 ± 4.5	= 0.737
QOL IPSS score	4.7 ± 1.05	4.9 ± 1.09	= 0.389
Qmax (mL/s)	9.1 ± 1.8	9.7 ± 1.6	= 0.089
Prostate volume (ml)	55.7 ± 12.3	54.6 ± 12.5	= 0.654
PVR (mL)	108.7 ± 34.8	174.8 ± 24.6	< 0.001**

Table 3: Comparison between the 2 groups as regards Follow up (3-months) outcome parameters using Student's t test

Variable	Rezum group (47)	Tamsulosin group (47)	Student's *t* test
	Mean ± SD	Mean ± SD	P value
IPSS score	10.2 ± 4.3	15.6 ± 5.7	< 0.001**
QOL IPSS score	2.2 ± 1.1	3.8 ± 1.1	< 0.001**
Qmax (mL/s)	13.9 ± 2.4	10.4 ± 1.1	< 0.001**
Prostate volume (ml)	45.6 ± 9.9	51.4 ± 11.8	0.011*
PVR (mL)	82.4 ± 29.4	147 ± 26.9	< 0.001**

Table 4: Comparison between the 2 groups as regards Follow up (6-months) outcome parameters using Student's t test

Variable	Rezum group (47)	Tamsulosin group (47)	Student's *t* test
	Mean ± SD	Mean ± SD	P value
IPSS score	11.3 ± 5	9.4 ± 4.5	= 0.055
QOL IPSS score	1.9 ± 0.8	3.6 ± 1.1	< 0.001**
Qmax (mL/s)	16.5 ± 2.9	13 ± 1.4	< 0.001**
Prostate volume (ml)	43 ± 8.9	42.2 ± 12.1	= 0.147
PVR (mL)	47.7 ± 14.6	127.7 ± 30	< 0.001**

Table 5: Comparison between the 2 groups as regards Follow up (12-months) outcome parameters using Student's t test

Variable	Rezum group (47)	Tamsulosin group (47)	Student's *t* test
	Mean ± SD	Mean ± SD	P value
IPSS score	9.6 ± 1.8	9.4 ± 4.6	= 0.792
QOL IPSS score	1.9 ± 0.8	2.6 ± 1.1	< 0.001**
Qmax (mL/s)	17.3 ± 3.1	15.2 ± 1.9	< 0.001**
Prostate volume (ml)	36.3 ± 7	42.6 ± 12.5	= 0.003**
PVR (mL)	48.4 ± 13.7	92.4 ± 25	< 0.001**

Table 6: Complications rate and type among 94 BPH patients

Variables		Frequency (%)	
	+ve	Rezum	Tamsulosin
Complications type	Dizziness	0	6 (12.7%)
	Dysuria	9 (19.1%)	5 (10.6%)
	Foreign body floating	1 (2.1%)	0
	Hematuria	5 (10.6%)	2 (4.2%)
	Orthostatic hypotension	0	4 (8.5%)
	Retrograde ejaculation	1 (2.1%)	14 (29.8%)
	Urgency	0	9 (19.1%)
	Urine retention	2 (4.2%)	0
	UTI	8 (17%)	0
Complications rate		26 (55.3%)	40 (85%)

DISCUSSION

Regarding basic clinical data; the mean age of all patients was (70 ± 4.4) years, and the average BMI was (26 ± 2.2). Sterling et al., [6] reported that, the Rezum II trial enrolled men 50 years old or older with an International Prostate Symptom Score of 13 or greater, maximum flow rate of 15 ml/s or less, and prostate size of 30 to 80 cc. Pramana et al., [7] also reported that, their mean age was 62.28±7.3 years old, and an average prostate volume was 36.09±8.3 cc.

Comparative study between the 2 groups revealed; Also, Rezum was better in Qmax improvement with highly significant increase in 3-months Qmax, in Rezum group; compared to Tamsulosin group ($p < 0.001$). Which came in agreement with Madersbacher et al., 2020,. Sterling et al., [6] reported that, the trial showed a decreased IPSS of 11.2 after 3 months compared with a decrease of 4.4 in the control group(sham surgery control arm) an improvement that was sustained at 1 year. Madersbacher et al., [8] also reported that, objective improvement of LUTS was seen as early as 2 weeks after the procedure, which remained consistently durable throughout the follow-up period of 4 years .

In our study: Comparative study between the 2 groups revealed; highly significant decrease in 6-months QOL IPSS score, and PVR, in Rezum group; compared to Tamsulosin group ($p < 0.01$ respectively). Comparative study between the 2 groups revealed; highly significant increase in 6-months Qmax, in Rezum group; compared to Tamsulosin group ($p < 0.001$). Which came in agreement with Sterling et al., [6].

Alegorides et al., [9]. also concluded that, the results were also significant in patients with a median lobe (48.1%; 26/54) with a higher mean decrease in IPSS: −15.4 (± 7.7) points at 6 months ($P < 0.001$) and −13.3 points (± 6.5) at 12 months ($P < 0.001$), i.e. a mean decrease of70.9% and 66.1%, respectively. The Qmax had significantly increased by 6.1 mL/s ($P < 0.001$) after treatment with Rezum.

Barbosa & Antunes, [10]. reported that, available date has demonstrated that, after Rezum, there is an increase in urinary flow rate of up to 6 milliliters per second, as well as a 11-point improvement of symptoms as evaluated with the IPSS. So far, efficacy of the results has been demonstrated at the end of a 2-year follow-up. Furthermore, prostate volume in patients undergoing Rezum ablation has decrease by 17 to 28%. Significantly, sexual function is well preserved after this procedure, with ejaculatory dysfunction occurring in only 3% of subjects; erectile function impairment was noted only among patients with a previous dysfunction.

Regarding Complications for Rezum group , which were mild ,tolerated and transient in the form of UTI (17%) , urine retention (4.2%) , retrograde ejaculation (2.1%), hematuria (10.6%) , floating foreign body intravesically (2.1%) and dysuria (19.1%). Regarding Complications rate for tamsulosin group, which were mild ,tolerated and transient in the form of urgency(19.1%) , retrograde ejaculation (29.8%), orthostatic hypotention (8.5%) , hematuria (4.2%), dysuria (10.6%) and dizziness (12.7%).

Westwood et al., [11]. concluded that, the majority of reported complications have been minor in nature (Clavien I–II). The most common adverse events are dysuria, haematuria, hematospermia, symptoms of urgency and UTIs. Khalil et al., [12]. reported in their literature review which done for patients with refractory urine retention that, post-Rezum PVR was 144 ccs , and a post Rezum Q max of 11.6 ml/sec was reported in three studies. The post-Rezum improvement of lower urinary tract symptoms reported in five studies, the mean post- Rezum IPSS was 6.2 (SD+-2.9) in four studies, while one study used the AUA symptoms score, which was 12.75 post-Rezum.

CONCLUSION

Our study had proven that, REZUM water vapor thermal ablation therapy showed high efficacy in relieving lower urinary tract symptoms (LUTS), in patients with benign prostatic hyperplasia (BPH), in comparison with the conventional medical treatment using Tamsulosin, especially in IPSS score, Qmax, prostate volume, PVR and quality of life assessments through 12 months of regular follow up.

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