

Rezūm water vapor thermal therapy for large-volume, symptomatic benign prostatic enlargement

Large, multicenter, real-world cohort with two-year followup

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ABSTRACT

INTRODUCTION: Water vapor thermal therapy (WVTT), Rezūm, is a minimally invasive therapy that uses water vapor to ablate benign prostatic tissue. This study aimed to present the prospective, multicenter outcomes of the largest cohort of prostates ≥ 80 mL treated with Rezūm.

METHODS: This study involved a prospective, WVTT registry that collated information from two high-volume centers between April 2019 and August 2024. Baseline medical histories, uroflowmetry (peak flow rate [Qmax], postvoid residual [PVR]), and validated questionnaires (International Prostate Symptom Score [IPSS], IPSS quality of life (QoL), Benign Prostatic Hyperplasia Impact Index [BPHII], International Index of Erectile Function [IIEF-15], Male Sexual Health Questionnaire for Ejaculatory Dysfunction [MSHQ-EjD]) were recorded. The main outcomes assessed included symptom scores, functional improvement, and safety at baseline, six, 12, and 24 months.

RESULTS: A total of 259 patients with a prostate volume ≥ 80 mL were treated with Rezūm. The median prostate volume was 105 mL, with 207 patients (81.2%) exhibiting a median lobe. The IPSS improved from 21.8 at baseline to 5.7 at 24 months. The IPSS QoL score improved from 4.5 at baseline to 1.1 at 24 months. At baseline, the Qmax rate was 8.2 mL/s, increasing to 14.9 mL/s at 24 months. PVR volume decreased from 132.5 mL at baseline to 90 mL at 24 months. The BPHII decreased from 7.5 at baseline to 2.3 at 24 months. There was no significant change in sexual function as measured by IIEF and MSHQ.

CONCLUSIONS: Rezūm therapy is a safe, effective, and minimally invasive option for managing large prostates (≥ 80 mL), providing significant and sustained improvements in urinary symptoms with minimal impact on sexual function.

INTRODUCTION

Among the lower urinary tract symptoms (LUTS) attributed to benign prostatic hyperplasia (BPH), the management of large-volume prostates, defined by glands ≥ 80 mL, remains the most challenging. This is mainly due to the higher complication rates of the surgical treatments available.¹ A large spectrum of treatments can be offered to patients suffering from LUTS secondary to BPH, from the non-invasive to the most invasive.²

Recommendations for patients with large glands are usually limited to invasive tissue-resecting surgical interventions, such as simple prostatectomy (open, laparoscopic, or robotic), bipolar transurethral resection of the prostate (B-TURP), Aquablation, and laser enucleation of the prostate.^{2,3} Most of those options are only suitable for patients who accept anesthesia- and surgical-related risks and who have access to highly trained surgeons in expert centers. Water vapor thermal therapy (WVTT) is a minimally invasive surgical therapy (MIST) that uses heated water vapor to slowly ablate obstructive prostate tissue over 4–8 weeks and alleviate LUTS.⁴

Despite recent series showing a significant symptomatic improvement in patients with large-volume prostates,⁵ international urological society guidelines are still recommending WVTT only for average prostate sizes (30–80 mL) in patients concerned about their erectile and ejaculatory function (evidence level: Grade C).^{2,3}

KEY MESSAGES

- Rezūm produced significant and durable improvements in IPSS, QoL, Qmax, PVR, and BPHII over a 24-month followup.
- Erectile function and ejaculatory function remained stable throughout the study, with no meaningful decline, highlighting preservation of sexual health.
- Rezūm was safely performed in an outpatient setting without the need for general anesthesia, demonstrating a favorable safety profile and convenience for patients.

In 2023, the European Association of Urology (EAU) guidelines considered WVTT as a technique still under investigation that needs more randomized controlled trials against a reference technique to confirm its mid- and long-term efficacy and safety.⁶ The small number of long-term studies certainly explains the guidelines' caution. Nevertheless, health-related financial costs, country-specific healthcare systems, and long wait times are regularly omitted in guidelines.⁷ Furthermore, an increasing number of patients are more concerned about their ejaculatory and sexual function rather than the long-term durability of treatment, especially in patients aware of MIST alternatives.⁸ Thus, some patients consciously choose an alternative technique knowing it might not be their final treatment.

In our last study, we demonstrated that in 83 patients with large-volume BPH (median 100 mL [88.5–115 mL]), WVTT therapy could offer early and sustained improvements at 12 months on International Prostate Symptom Score (IPSS) by 59%, IPSS quality of life (QoL) by 70%, BPH Impact Index (BPHII) by 71%, peak flow rate (Qmax) by 59%, and postvoid residual (PVR) by 62%, with no major adverse events and a very low risk of anejaculation (3.6%).⁹ Those results were similar to the results seen in the pivotal WVTT trial for average-size prostates.¹⁰

Most recently, a single-arm, multicenter, prospective study in the U.S. showed that in a cohort of 47 patients with a large prostate (median 92.9 mL [80.8–148.1]), 72% of patients at six months and 69% of patients at 12 months had an improvement in IPSS of at least eight points compared to the baseline.¹¹

Herein, we assess the safety and efficacy of WVTT therapy for LUTS secondary to BPH in patients with

a prostate volume ≥ 80 mL in a multicenter study with 24-month followup.

METHODS

Study subjects

This is a retrospective analysis of a prospectively collected registry from two high-volume centers performing WVTT (Rezūm) in Canada and Italy. Institutional ethics board approval was obtained at each center. The cohort comprises patients who underwent WVTT between April 2019 and August 2024. Eligibility was restricted to patients with a prostatic volume ≥ 80 mL.

The WVTT procedures were conducted following the methods outlined in previous studies.⁹ Each application of water vapor ablates contiguous regions of the prostatic tissue following the urethra's natural gradient. The number of injections was decided at the surgeon's discretion after analyzing the patient's prostatic anatomy and desire to preserve ejaculation. In general, the aim was to provide one treatment for every 1 cm length per lateral lobe, followed by dedicated injections for any median lobes. Patients were discharged the same day with a Foley in-situ. The duration of Foley catheterization varied from 7–30 days based on the presence of urinary retention.

Data collection and outcomes of interest

Patients were followed at baseline, six, 12, and 24 months, and yearly thereafter. Patients' characteristics, prostatic volume, IPSS, IPSS QoL subscale, International Index of Erectile Function (IIEF-15), Qmax, PVR, prostate-specific antigen (PSA), number of Rezūm injections, complications, and BPH medication usage were evaluated at baseline and followup. The primary outcome of this study was to assess the effectiveness of WVTT in improving urinary function, as measured by IPSS, IPSS QoL, BPHII, and uroflowmetry parameters. Secondary outcomes were evaluation of overall functional and sexual outcomes. Adverse events were monitored during study followup.

Statistical analysis

Patients' characteristics and assessments were reported descriptively. Continuous variables were analyzed using either the Student's t-test or rank sum tests, based on their distribution. Categorical variables were compared using Fisher's exact test. All statistical analyses were performed using Stata 18BE, and a two-sided p-value < 0.05 was considered statistically significant.

RESULTS

A total of 259 patients with a mean age of 68.3 years (range 62.9–73.9) and prostate size ≥ 80 mL were treated with Rezūm. The median prostate volume was 105 mL (interquartile range 91–122.5 mL), with 207 patients (79.9%) exhibiting a median lobe. Urinary retention was present in 86 patients (33.2%) at the time of the procedure. On average, 13.2 \pm 3.8 injections were administered per procedure, which lasted an average of 6.9 \pm 10.1 minutes. A total of 112 patients (43.2%) were taking preoperative alpha blockers, while 65 patients (25.1%) were taking 5- α reductase inhibitors (5-ARI) (Table 1).

Urinary status

The IPSS improved from a baseline of 21.8 \pm 6.7 (n=212) to 9.1 \pm 7.1 at six months (n=131), 9.9 \pm 6.6 at 12 months (n=107), and 8.4 \pm 5.7 at 24 months (n=68), reflecting improvements of 57.5%, 54%, and 59.5%, respectively (Figure 1A). The IPSS QoL score decreased from a baseline of 4.5 \pm 1.1 (n=212) to 1.7 \pm 1.4 at 6 months (n=131), 1.8 \pm 1.3 at 12 months (n=107), and 1.4 \pm 1.1 at 24 months (n=68), corresponding to improvements of 61.1%, 59.1%, and 66.7%, respectively (Figure 1B).

At baseline, the Qmax was 8.2 \pm 6.8 mL/s (n=198), which increased to 14.6 \pm 6.8 mL/s at six months (n=45), 14.1 \pm 7.2 mL/s at 12 months (n=46), and 14.9 \pm 6.1 mL/s at 24 months (n=33), showing improvements of 46.6%, 50.7%, and 42%, respectively (Figure 2A).

The baseline PVR volume was 142.7 \pm 132.5 mL (n=196), which decreased to 40.6 \pm 72 mL at six months (n=42), 47.6 \pm 60 mL at 12 months (n=93), and 51.8 \pm 90 mL at 24 months (n=38), with reductions of 62.2%, 63.5%, and 57.1%, respectively (Figure 2B).

The BPHII decreased from 7.5 \pm 3 at baseline (n=171) to 2.4 \pm 3.3 at six months (n=86), 2.7 \pm 2.9 at 12 months (n=65), and 1.9 \pm 2.3 at 24 months (n=35), with improvements of 67.4%, 62.7%, and 72.8%, respectively. All of these scores showed statistically significant improvements (p<0.0001) at each time point, indicating a significant reduction in symptoms across the study period.

After the analyzed period following WVTT, 16 patients (6.3%) required a secondary surgical intervention. Of these, 11 underwent GreenLight photovaporization, two underwent a second Rezūm, one underwent holmium laser enucleation of the prostate (HoLEP), one underwent prostatic artery embolization (PAE), and one underwent TURP. In addition, only nine patients (4.4%) continued using BPH medications after

Characteristic	Value
Age, years (IQR)	68.3 (62.9–73.9)
Prostate volume, mL (IQR)	105.0 (91–122.5)
PSA, ng/mL (IQR)	4.8 (3.0–7.8)
Presence of median lobe	207 (79.9%)
Duration of BPH	
<5 years	53 (20.5%)
5–7 years	69 (26.7%)
8–10 years	24 (9.3%)
>10 years	113 (43.6%)
Previous BPH surgery	
TURP	7 (2.7%)
Urolift	4 (1.5%)
PAE	7 (2.7%)
Rezūm	7 (2.7%)
Current medication	
Alpha-blocker	112 (43.2%)
5-ARI	65 (25.1%)
PDE5 inhibitors	26 (10.0%)
None	105 (40.5%)
History	
Hypertension	69 (26.6%)
Diabetes	19 (7.3%)
Kidney/bladder stone	19 (7.3%)
Urinary retention	86 (33.2%)
Anesthesia	
Propofol	163 (62.9%)
Lidocaine gel	38 (14.7%)
Prostate block	1 (0.4%)
Spinal	10 (3.9%)
Penthrox (methoxyflurane)	5 (1.9%)
Acetaminophen	6 (2.3%)
Percocet	3 (1.2%)
Ativan/Lorazepam	3 (1.2%)
Oxycodone	1 (0.4%)

5-ARI: 5-alpha reductase inhibitor; BPH: benign prostatic hyperplasia; IQR: interquartile range; PAE: prostatic artery embolization; PDE5: phosphodiesterase type 5; PSA: prostate-specific antigen; SD: standard deviation; TURP: transurethral resection of the prostate.

Table 1 (cont'd). Baseline characteristics

Characteristic	Value
Number of injections (SD)	13.2 (±3.8)
Saline volume used, mL (SD)	444.5 (±141.8)
Duration of procedure, minutes (SD)	6.9 (±10.1)
Postoperative medication	
Antibiotics	257 (99.2%)
Stool softener	207 (79.9%)
Pain medications	184 (71.0%)
Anti-inflammatories	239 (92.3%)
Bladder-specific medications	182 (70.3%)

5-ARI: 5-alpha reductase inhibitor; BPH: benign prostatic hyperplasia; IQR: interquartile range; PAE: prostatic artery embolization; PDE5: phosphodiesterase type 5; PSA: prostate-specific antigen; SD: standard deviation; TURP: transurethral resection of the prostate.

the procedure. Among the 86 patients who were catheter-dependent at baseline, only two (2.3%) remained catheter-dependent after the procedure (Figures 1, 2).

Sexual function

The mean IIEF score at baseline was 42.1 ± 20.7 (n=186). At six months, the score slightly decreased to 41.2 ± 21.5 (n=90) and remained relatively stable at 41.2 ± 21.6 at 12 months. By 24 months, the score was 35.8 ± 20.3 (n=49) (Figure 3A). The Male Sexual Health Questionnaire (MSHQ)-Function score at baseline was 8.2 ± 3.8 (n=151). At six months, the mean score decreased to 7.7 ± 4.6 . At 12 months, the score was 9 ± 4.1 , and at 24 months was 9.4 ± 4.1 . The MSHQ-Bother score at baseline was 2.4 ± 1.7 (n=151). At six months, the mean score decreased to 2.2 ± 1.7 (n=59). At 12 months, the score remained stable at 2.0 ± 1.4 (n=47), and at 24 months, it slightly decreased to 1.5 ± 1.2 , showing no significant change (Figure 3). Overall, these changes were small and characterized by overlapping confidence intervals, suggesting no clinically significant trends over time. Retrograde ejaculation was observed in 10 patients (3.8%). No statistically significant changes in erectile or ejaculatory function were identified throughout the study period (Figure 3, Table 2).

Safety

The WVTT was administered in a single session, either in the office or an outpatient clinic. Management of

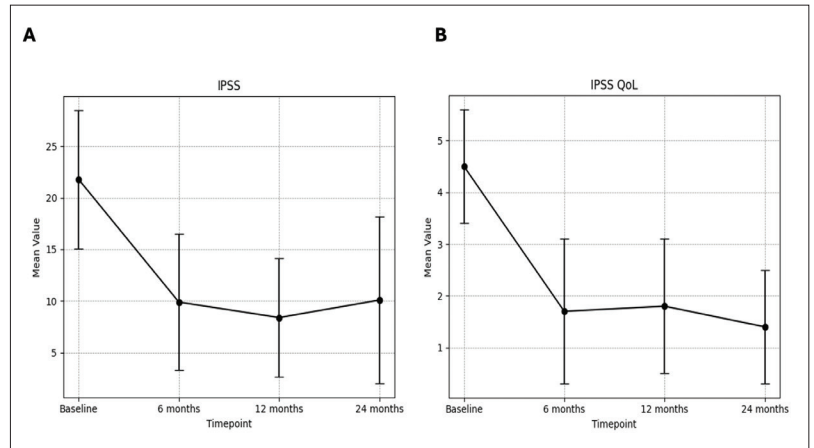


Figure 1. (A) International Prostate Symptom Score (IPSS) and (B) IPSS quality of life (QoL) scores (95% confidence interval) over time.

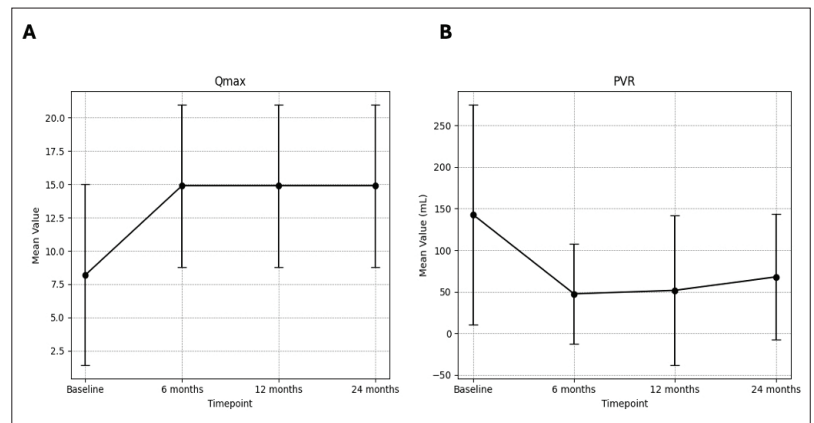


Figure 2. (A) Peak urinary flow (Qmax) and (B) postvoid residual volume (PVR) values (95% confidence interval) over time.

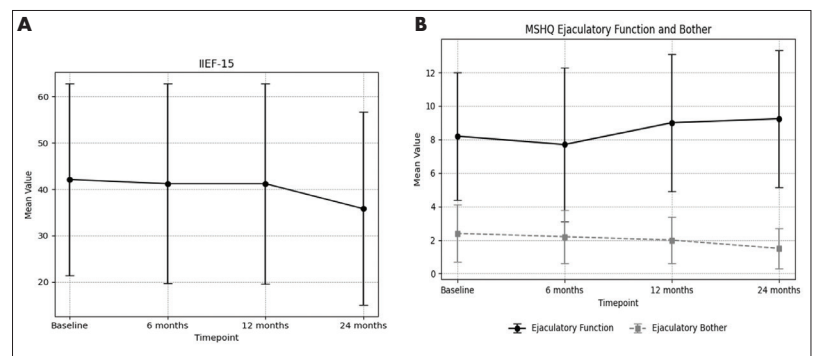


Figure 3. (A) International Index of Erectile Function (IIEF-15) and (B) Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD).

potential discomfort, pain, and anxiety was tailored according to the urologist's preference and discretion, with no need for general anesthesia. All procedures were successfully completed without intraoperative complications. Postoperative complications included acute urinary retention (AUR) in 34 patients (13.1%), urinary tract infections (UTIs) in 47 patients (18.1%),

Table 2. Changes in outcomes from baseline to 24 months

	Baseline	6 months	12 months	24 months
Qmax, mL/sec				
Number analyzed	198	45	46	33
Baseline	8.2±6.8	10±11.5	9.3±11.5	10.4±13
Followup		14.6±6.8	14.9±7.2	14.9±6.1
Change		4.6±13.5	4.7±12.7	4.5±14.5
% change		46.6	50.7	42.8
p		<0.001	<0.001	<0.001
PVR, mL				
Number analyzed	196	42	93	38
Baseline	142.7±132.5	107.6±125.9	130.6 ±117.1	120.8±126.7
Followup		40.6±72	47.6±60	51.8±90.2
Change		-67±132.4	-83±116.9	-69±143.7
% change		-62.2	-63.5	-57.1
p		<0.001	<0.001	<0.001
IPSS				
Number analyzed	212	131	107	68
Baseline	21.8± 6.7	21.4±7	21.5±7.1	20.9±6.7
Followup		9.1±7.1	9.9±6.6	8.4±5.7
Change		-12.3±7.9	-11.6±8.3	-12.4±7.4
% change		-57.5	-54	-59.6
p		<0.001	<0.001	<0.001
IPSS QoL				
Number analyzed	212	131	107	68
Baseline	4.5±1.1	4.4±1.2	4.4±1.2	4.3±1.1
Followup		1.7±1.4	1.8±1.3	1.4±1.1
Change		-2.7±1.7	-2.6±1.6	-2.9±1.4
% change		-61.1	-59.1	-66.7
p		<0.001	<0.001	<0.001
IIEF 15				
Number analyzed	186	90	82	49
Baseline	42.1±20.7	38.6±21.7	38.4±21	35.9±21.3
Followup		41.2±21.5	41.2±21.6	35.8±20.8
Change		2.6±11.7	2.8±8	-0.1±8.8
% change		6.6	7.2%	-0.3
p		0.044	0.004	0.229
MSQH-EjD function				
Number analyzed	151	59	48	23
Baseline	8.2±3.8	8.6±3.9	8.6±3.9	10±3.1
Followup		7.7±4.6	9±4.1	9.24±4.1
Change		-0.8±4.9	0.4±3.4	-0.7±3.7
% change		-9.5	4.6	-6.5
p		0.228	0.566	0.354
MSQH-EjD bother				
Number analyzed	151	59	47	23
Baseline	2.4±1.7	2.2±1.7	2.1±1.8	1.7±1.4
Followup		2.2±1.6	2±1.4	1.5±1.2
Change		0±1.7	-0.2±1.7	-0.1±1.6
% change		0	-8.9	-7.9
p		0.871	0.593	0.586
BPHII				
Number analyzed	171	86	65	35
Baseline	7.5±3	7.5±3	7.3±3.4	6.9±2.7
Followup		2.4±3.3	2.7±2.9	1.9±2.3
Change		-5±3.6	-4.6±3.6	-5.1±3.3
% change		-67.4	-62.7	-72.8
p		<0.001	<0.001	<0.001

BPHII: Benign Prostatic Hyperplasia Impact Index; IIEF-15: International Index of Erectile Function; IPSS: International Prostate Symptom Score; MSQH-EjD: Male Sexual Health Questionnaire for Ejaculatory Dysfunction; PVR: postvoid residual volume; Qmax: peak urinary flow; QoL: quality of life; SD: standard deviation.

and hematuria in 22 patients (8.5%). Only six patients required hospitalization due to a urinary infection and urinary retention.

DISCUSSION

Historically, the gold standard for treating BPH has been TURP, which has shown significant clinical improvement in patients with LUTS; however, the primary drawback of TURP is its associated complications, particularly bleeding and sexual dysfunction.¹² Although BPH patients who adhere to medical treatments, such as 5-ARI and phosphodiesterase inhibitors, may observe symptomatic relief, they often experience side effects that reduce long-term adherence.¹³ Additionally, the same study demonstrated greater efficacy of WVTT compared to doxazosin and finasteride. Moreover, among all MIST procedures, WVTT is the only technology to have a significant change and reduction in prostate volume.¹⁴

In this study comparing pharmaceutical treatment with a single thermal therapy procedure, significant improvements in IPSS QoL and BPHII scores were observed, with statistically significant differences favoring WVTT.¹⁵ These findings underscore the effectiveness of Rezūm in not only improving urinary symptoms but also offering a good safety profile compared to other treatments. The relatively low incidence of complications observed in our study suggests that WVTT is a well-tolerated therapy for patients with BPH, with durable and clinically significant outcomes. This supports its use as a safe and effective alternative to pharmacologic therapies, such as doxazosin and finasteride, which may not achieve the same level of symptom relief.

This series provides the largest and most up-to-date followup on the effectiveness of WVTT in treating bothersome LUTS and its impact on sexual function in patients with large prostates (≥80 mL). Significant and lasting improvements were observed over a two-year followup period in symptoms, including both storage and voiding functions, quality of life, urinary flow rates, and incontinence measures. Although most studies do not focus on prostates >80 mL, we observed beneficial effects on sexual and urinary function in this group.

In 2016, the pivotal study randomizing patients with prostate volumes between 30–80 mL and a control group conducted over five years, demonstrated significant symptom improvement after WVTT, with reductions in BPHII, PVR, and increases in Qmax.¹⁵ The results from this study in smaller prostates are comparable to our outcomes in patients with prostates >80 mL. For example, the mean Qmax at 24 months in the trial

was 14.0 ± 6.4 mL/s, compared to our 14.9 ± 6.1 mL/s. Additionally, the BPHII score at 24 months in the trial was 2.3 ± 2.7 , while our score was 1.9 ± 2.3 . The PVR at 24 months in the trial was 84.6 ± 92.0 mL, whereas in our study it was 51.8 ± 90 mL. These comparable results suggest that our findings in larger prostates align with the positive outcomes observed in smaller prostates, supporting the efficacy of the treatment across a wide range of prostate sizes.

McVary et al recently conducted a meta-analysis focusing on patients with large prostates, >80 mL ranging from $94\text{--}127$ cm³ (median 107 cm³). Their analysis included 15 studies, with the number of analyzed patients ranging from 3–83. The total number of patients in all studies combined was 471, demonstrating statistically significant improvements in the IPSS across 15 studies. The mean change in IPSS reported was -11.0 (95% confidence interval [CI] $-12.2, -9.7$, $p < 0.001$) between before and after the Rezūm procedure. Additionally, the mean change in the IPSS QoL score was -2.9 (95% CI $-3.5, -2.4$, $p < 0.001$).⁵

Similarly, in our study, we observed the same level of improvements in IPSS scores. Our baseline IPSS score was 21.8 ± 6.7 , which decreased by 9.1 ± 6.7 at six months and by 9.9 ± 6.6 at 12 months ($p < 0.0001$), with the overall mean change of -11.3 ± 8.3 . The baseline IPSS QoL score was 4.5 ± 1.1 , which decreased to 1.7 ± 1.4 at 6 months and 1.8 ± 1.3 at 12 months, with the mean change being -2.6 ± 1.6 . The meta-analysis followed patients for a similar duration, reinforcing the observed improvements in both IPSS and QoL scores after the Rezūm procedure.

This meta-analysis also reported significant improvements in Qmax and PVR volume after Rezūm. The weighted mean change in Qmax was 6.5 mL/s (95% CI $4.8, 8.2$ mL/s, $p < 0.001$), and the weighted mean change in PVR volume was -101 mL (95% CI $-145, -57$, $p < 0.001$).⁵ In our study, we similarly observed substantial improvements in both Qmax and PVR volume, but with less difference. Our baseline Qmax was 8.2 ± 6.8 mL/s, which increased to 14.6 ± 6.8 mL/s at six months and 14.1 ± 7.2 mL/s at 12 months, with a mean change of 4.7 ± 12.7 mL/s. For PVR volume, the baseline was 142.7 ± 132.5 mL, which reduced with a mean change of -83 mL ± 116.9 mL.

In 2021, a clinical trial compared the outcomes of the Rezūm procedure in patients with prostates <80 mL ($n=168$) vs. >80 mL ($n=36$), with an average prostate size of 106.8 cc. The study demonstrated significant postoperative improvements for both groups over a one-year period. The Qmax increased from 7.39 to

14.60 ($p=0.039$), and the PVR decreased from 161.09 to 80.85 ($p=0.009$).¹⁶ These results indicated statistical improvement in both Qmax and PVR, with no significant difference in outcomes between the two groups.

A randomized controlled trial involving patients with prostate volumes between $30\text{--}80$ mL conducted over two years demonstrated significant symptom improvement, with reductions in BPHII, PVR, and increases in Qmax.¹⁷ The results from this study in smaller prostates are comparable to our outcomes in patients with prostates >80 mL. For example, the mean Qmax at 24 months in the trial was 14.0 ± 6.4 mL/s, compared to our 14.9 ± 6.1 mL/s. Additionally, the BPHII score at 24 months in the trial was 2.3 ± 2.7 , while our score was 1.9 ± 2.3 . The PVR at 24 months in the trial was 84.6 ± 92.0 mL, whereas in our study it was 51.8 ± 90 mL. These comparable results suggest that our findings in larger prostates align with the positive outcomes observed in smaller prostates, supporting the efficacy of the treatment across a wide range of prostate sizes.

With respect to sexual function, a study conducted across 15 centers in the U.S involving 197 participants with a five-year followup evaluated the outcomes of the Rezūm procedure. The participants were divided into groups based on the presence or absence of erectile dysfunction and ejaculatory dysfunction. The results showed no significant differences in the IIEF, MSHQ-Bother, and MSHQ-Function scores across the groups over the five-year period. Specifically, there were no significant changes in the IIEF-EF (change of -2.4 ± 8.9 , $p=0.1414$) or MSHQ-EjD Bother (change of -0.5 ± 1.6 , $p=0.1107$) in patients who did not have erectile or ejaculatory dysfunction at baseline; however, MSHQ-EjD Function did show a significant improvement in this group at the five-year mark (change of 1.6 ± 3.2 , $p=0.0083$).¹⁸ These results are comparable to our study. One explanation could be the discontinuation of prostatic medication, such as 5-ARI and alpha-blockers, and their sexual side effects.

In 2021, a randomized controlled prospective crossover study with a two-year followup demonstrated, no significant differences in MSHQ-EjD Function change (-0.5 ± 4.2 , $p=0.3601$) and IIEF change (-1.1 ± 7.5 , $p=0.2068$); however, the MSHQ-Bother score showed a significant change of 2.2 ± 0.018 over the two years, indicating evidence of patient-reported bother.¹⁷ In our study, no statistically significant differences were detected in sexual health scores.

Postoperative complications in our study were lower than those reported in other trials. In 2015, an initial study evaluating the efficacy and safety of Rezūm

reported 33.8% rate of AUR, compared to 13.1% in our study; 20% of patients experienced UTIs compared to 18.1% in ours; and 9% reporting hematuria compared to 8.5% in ours.¹⁹ Only six patients required hospitalization due to a urinary infection and urinary retention in our study. Better selection of patients, optimization of the patients' perioperative management, and a few years of experience in the technique are possible reasons to account for our safety results.

Strengths and limitations

Lastly, a strength of our study is that it includes the largest series of patients and length of followup assessing the efficacy and safety of WVTT in large-volume prostates. The limitations of our study include the lack of comparison with a randomized control group. Additionally, there is an inherent risk of bias in the study population, and patient losses during followup limited the ability to continue evaluating functional and sexual scores or to assess postoperative complications in these individuals. Many patients did not complete followup, likely due to the geographic distribution of the study population, as both centers serve patients from distant regions, making return visits for long-term assessment more difficult. Another limitation is the absence of a standardized definition for complications and the lack of use of validated classification systems, such as the Clavien-Dindo or Accordion grading systems.

CONCLUSIONS

This study demonstrates that WVTT therapy is a safe and effective treatment for patients with large prostate volumes, providing significant improvements in LUTS, QoL, and urinary flow rates over a 24-month period. WVTT therapy delivered to large prostate glands demonstrated similar outcomes to glands <80 mL evaluated in other studies, making it an excellent choice for patients seeking relief from LUTS without compromising sexual function. Further long-term followups are needed to confirm the sustainability of these outcomes.

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This paper has been peer-reviewed.

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