ORIGINAL PAPER

FUNCTIONAL UROLOGY

Outcomes of Rezum water vapor therapy for benign prostate obstruction with 1-year follow-up: Largest real-world data from Turkey

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Introduction The study aimed to retrospectively assess the safety and efficacy of Rezum, a promising minimally invasive treatment method for BPH, in patients treated at our clinic.

Material and methods From January 1, 2022, to December 31, 2022, a cohort of 71 patients presenting with moderate to severe lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH) were enrolled in the study. These individuals opted for Rezum therapy as their treatment approach. Primary outcome measures included the International Prostate Symptom Score (IPSS), maximum flow rate (Q_{max}), post-void residual volume (PVR), Quality of Life (QoL), prostate volume (PV), prostate-specific antigen (PSA), and the International Index of Erectile Function (IIEF) questionnaire.

Results The median age of the 71 patients was 62.1 ±9.3 years, with a median PV of 60.4 ±16.6 ml. Preoperatively, IPSS was 21.9 ±5.2, Q_{max} was 9.67 ±3.2, QoL was 3.35 ±0.61, IIEF-5 was 23.9 ±5.4, total PSA was 2.43 ±1.27 ng/ml, and PVR was 177.4 ±216.5 ml. At the 3-month follow-up, IPSS improved to 10.1 ±5.6, Q_{max} to 24.5 ±3.7, QoL to 1.2±0.51, IIEF-5 to 24.5 ±5.4, total PSA to 1.8 ±0.9 ng/ml, and PVR remained at 177.4 ±216.5 ml. At the 12-month follow-up, IPSS was 6.0 ±3.1, Q_{max} was 18.12 ±3.7, QoL was 1.2 ±0.51, IIEF-5 was 24.5 ±5.4, total PSA was 1.8 ±0.9 ng/ml, and PVR was 24.9 ±25.2 ml.

Conclusions Rezum therapy is a safe, effective, and minimally invasive option for the treatment of men with moderate to severe lower urinary tract symptoms (LUTS).

Key Words: BPH ‹› minimally invasive ‹› prostate ‹› surgery ‹› Rezum

INTRODUCTION

Benign prostatic hyperplasia (BPH) is a prevalent condition in older men, significantly impairing urinary function and quality of life [1]. The primary treatment objective for symptomatic BPH is to alleviate bladder outlet obstruction (BOO) caused by prostate enlargement, which can be achieved through surgical interventions or medical therapies targeting symptom relief. Traditionally, transurethral resection of the prostate (TUR-P) has been regarded as the gold standard for BPH surgery, although its use has sparked some debate [2].

Despite its efficacy, TUR-P is associated with considerable perioperative and postoperative complications, reported at approximately 20%. These include anejaculation (65%), erectile dysfunction (10%), urethral strictures (7%), and urinary incontinence (3%) [3, 4]. These challenges have spurred interest in minimally invasive surgical treatments (MIST) as alternative approaches for BPH/LUTS therapy. MIST options are especially appealing because they often require minimal anesthesia and can be performed in outpatient settings, offering a more patient-friendly approach [5]. The Rezum System is a novel MIST that utilizes water vapor thermal therapy to ablate obstructive

prostatic tissue [6]. This system delivers convective water vapor energy (WAVE), providing a unique mechanism to effectively and continuously relieve lower urinary tract symptoms (LUTS) associated with BPH. Studies have demonstrated its safety and efficacy, positioning Rezum as a promising alternative to traditional surgical interventions [7].

In recent years, numerous studies have explored various aspects of the Rezum System; however, comparative randomized trials remain scarce. Two studies published in 2024 compared Rezum therapy with TUR-P. The first, conducted by Tayeb et al. [8], assessed the efficacy of Rezum therapy in catheter-dependent patients over a one-year follow-up. Using propensity score matching, Rezum patients were compared with TUR-P patients. Both groups achieved high rates of successful postoperative voiding (90.2% for Rezum vs 92.7% for TUR-P). Although TUR-P showed superior voiding outcomes at one and three months, LUTS reduction in the Rezum group became comparable at 6 and 12 months in terms of International Prostate Symptom Score (IPSS), Quality of Life (QoL) indices, and maximum urinary flow rate (Q_{max}) [8].

In contrast, a randomized trial with a two-year follow-up demonstrated greater effectiveness and durability for bipolar TUR-P compared to Rezum therapy. The re-treatment rate for Rezum therapy was reported as 8%, primarily among patients with larger prostates (91.5 ±24.61 ml) or catheter dependency. Nonetheless, the study highlighted Rezum's advantages for sexually active men seeking to preserve erectile and ejaculatory functions while achieving symptom relief [9].

This study retrospectively evaluates the safety and efficacy of Rezum therapy, a promising minimally invasive treatment for BPH, in a real-world clinical setting at our institution.

MATERIAL AND METODS

Study design and patients

Between January 1, 2022, and December 31, 2022, a cohort of 71 patients presenting with moderate to severe LUTS associated with BPH was enrolled in the study. The study was recorded on the website ClinicalTrials.gov (NCT06257654). These individuals opted for Rezum therapy as their selected treatment approach. Primary outcome measures employed for BPH diagnosis and follow-up included the IPSS, Q_{max}, post-void residual volume (PVR), QoL, prostate volume (PV), prostate-specific antigen (PSA), and the International Index of Erectile Function (IIEF) questionnaire.

Outcome measures

The IPSS, which is scored between 0 and 35, with higher scores indicating more frequent BPH symptoms, served as a key diagnostic and follow-up tool [10]. Additionally, parameters such as PV, PSA values, postoperative complications (Clavien-Dindo classification), anesthesia types, anesthesia durations, and catheter durations were assessed.

Thermal treatment procedure

The thermal treatment procedure utilized the previously described Rezum System for lower urinary tract symptoms/benign prostatic hyperplasia, as outlined in detail by Mynderse et al. [11]. In brief, thermal energy in the form of water vapor was generated using radiofrequency current against an inductive coil heater in the device handle. The system delivered water vapor (at 103°C) through a retractable needle, accompanied by saline flush irrigation to enhance visualization and cool the urethral surface. The vapor needle was deployed, and a 9-second delivery of water vapor was administered.

The radiofrequency (RF) thermal therapy employed the Rezum System, comprising an RF power supply, a generator, and a single-use transurethral delivery device with a standard 4 mm, 30-degree endoscopic cystoscopy lens. The instrument delivered RF water vapor thermal energy into the prostate through a retractable needle, with saline flush irrigation used to enhance visualization and cool the urethra. The needle tip was positioned and inserted starting approximately 1 cm distal to the bladder neck into the transition and central prostate adenoma. The total number of treatments in each lobe of the prostate was determined by the length of the prostatic urethra and could be customized to the gland's configuration, including the median lobe.

For blinding purposes, a surgical drape prevented subjects from visualizing the device and the treating physician. Outcome assessments were conducted by an assessor blinded to the procedures, as detailed by Dixon et al. [12] and McVary et al. [13].

Patient follow-up

After catheter removal, all patients were administered alpha-blockers for approximately one month, and antiplatelet therapies were continued. For one week postoperatively, patients were provided with antibiotics and anti-inflammatory therapy. Patients were reevaluated at 3 and 12 months during follow-up assessments. Inclusion criteria included the following: age ≥45 years; IPSS ≥14; Q_{max} ≥15 ml/s;

and PV ≥30–≤120 ml. Exclusion criteria included the following: prostate cancer, Parkinson's disease, neurogenic bladder, overactive bladder, bladder stones, bladder tumor, urinary infection, and Alzheimer's disease.

Bioethical standards

The study was approved by the Hisar Intercontinental Hospital Local Ethics Committee according to the ethical principles of the Declaration of Helsinki and the Health Insurance Portability and Accountability Act (approval number 24-2).
For surviving patients who had routine visits to the study site, evidence of a personally signed and dated informed consent document was obtained. Evidence of oral or written informed consent was obtained for surviving patients who had been transferred to another hospital. Deceased patients fulfilling the above inclusion criteria were also included in this study unless patients' families opted out of inclusion.

RESULTS

Baseline characteristics

Out of the 71 patients included in the study, the median age was 62.1 ±9.3 years, with a median PV of 60.4 ±16.6 ml. Among these, 52 patients had PV ≤80 ml, and 13 had volumes >80 ml.
The average operative time was 15.6 ±3.2 minutes. General anesthesia was utilized in 77.47% (55/71) of the procedures, while 22.53% (16/71) were performed under intravenous sedation due to comorbidities.
Preoperative baseline parameters included:
- IPSS: 21.9 ±5.2,
- Q_{max}: 9.67 ±3.2 ml/s,
- QoL: 3.35 ±0.61,
- IIEF-5: 23.9 ±5.4,
- total PSA: 2.43 ±1.27 ng/ml,
- PVR: 177.4 ±216.5 ml.

Patients; comorbidities were assessed using the American Society of Anesthesiologists (ASA) classification: 13 patients were classified as ASA 2, 6 as ASA 3, and 1 as ASA 4. The cohort included 34 patients (47.8%) with middle lobe enlargement, and the average prostate length was 3.7 ±1.1 cm (Table 1).
Anticoagulation protocol: Twenty patients were on aspirin (100 mg) and clopidogrel (75 mg). These medications were discontinued five days before surgery and replaced with low molecular weight heparin, which was continued for one week postoperatively. Afterward, patients resumed their regular anticoagulant regimen.
Catheterization details: Patients were discharged on the same day as the procedure, with an average catheter duration of 4.8 ±1.9 days. Five patients (7%) experienced initial catheter removal failure:
- 2 patients: catheters were removed after one week,
- 3 patients: catheters were removed after ten days.

All 5 patients achieved spontaneous urination following catheter removal.

Table 1. *Descriptive data of benign prostate hyperplasia cases*

	BPH (before treatment)
Age (year)	62.1 ±9.3
PV (cc)	60.4 ±16.6
30–80 cc	52
>80 cc	13
Prostate length (cm)	3.7 ±1.1
Prostate Middle Lobe	47.8% (34/71)
ASA classification	
ASA 2	13
ASA 3	6
ASA 4	1
General anesthesia	55
Intravenous sedation	16
Number of injections	6.5 ±2.0
Catheter duration (day)	4.8 ±1.9

ASA – American Society of Anesthesiologists; BPH – benign prostate hyperplasia; PV – prostate volume

Follow-up results

At the 3-month follow-up, significant improvements were observed across several parameters:
- IPSS: decreased to 10.1 ±5.6,
- Q_{max}: increased to 24.5 ±3.7 ml/s,
- QoL: improved to 1.2 ±0.51,
- IIEF-5: increased to 24.5 ±5.4,
- total PSA: reduced to 1.8 ±0.9 ng/ml,
- PVR: unchanged at 177.4 ±216.5 ml.

At the 12-month follow-up, the most substantial improvements included:
- IPSS: reduced further to 6.0 ±3.1,
- Q_{max}: stabilized at 18.12 ±3.7 ml/s,
- QoL: maintained at 1.2 ±0.51,
- PVR: significantly decreased to 24.9 ±25.2 ml ($p < 0.05$).

These outcomes confirm the sustained efficacy of Rezum therapy over 12 months in alleviating symptoms associated with BPH (Table 2, Figure 1).

Complications

Clavien-Dindo grade I/II complications were reported in 37% of patients, with a higher incidence (45%) among those with PVs >80 ml. Table 3 provides a detailed summary of these complications, including dysuria (14%), hematuria (10%), and urinary tract infections (UTIs; 7%).

The most common complications observed were dysuria, urgency, hematuria, and UTIs:

- dysuria: reported in 10 patients, with 8 resolving by 6 weeks post-operation; the remaining

Table 2. *Third and twelfth month data after Rezum treatment in benign prostate hyperplasia cases*

	Before treatment	After treatment		p1	p2	p3
		3 months later	12 months later			
QoL	3.35 ±0.61	1.22 ±0.51	1.08 ±0.44	0.000	0.000	0.058
IEFF	23.9 ±5.4	24.5 ±5.3	24.8 ±5.4	0.000	0.001	0.481
Q_{max}	9.67 ±3.2	18.12 ±3.7	22.84 ±20.3	0.000	0.000	0.065
PVR	177.4 ±216.5	52.6 ±61.5	24.9 ±25.2	0.000	0.000	0.000
IPSS	21.9 ±5.2	10.1 ±5.6	6.0 ±3.1	0.000	0.000	0.000
PV [ml]	60.4 ±16.6	–	42.9 ±11.8	–	0.000	–
PSA [ng/ml]	2.43 ±1.27	–	1.8 ±0.9	–	0.000	–

Paired Samples Tests: significance p ≤0.05
p1: difference between before treatment and 3 months after treatment
p2: difference between before treatment and 12 months after treatment
p3: difference between 3 months and 12 months after treatment
IIEF – International Index of Erectile Function; IPSS – International Prostate Symptom Score; Q_{max} – maximum flow rate; QoL – Quality of Life; PSA – prostate-specific antigen; PV – prostate volume; PVR – post-void residual volume

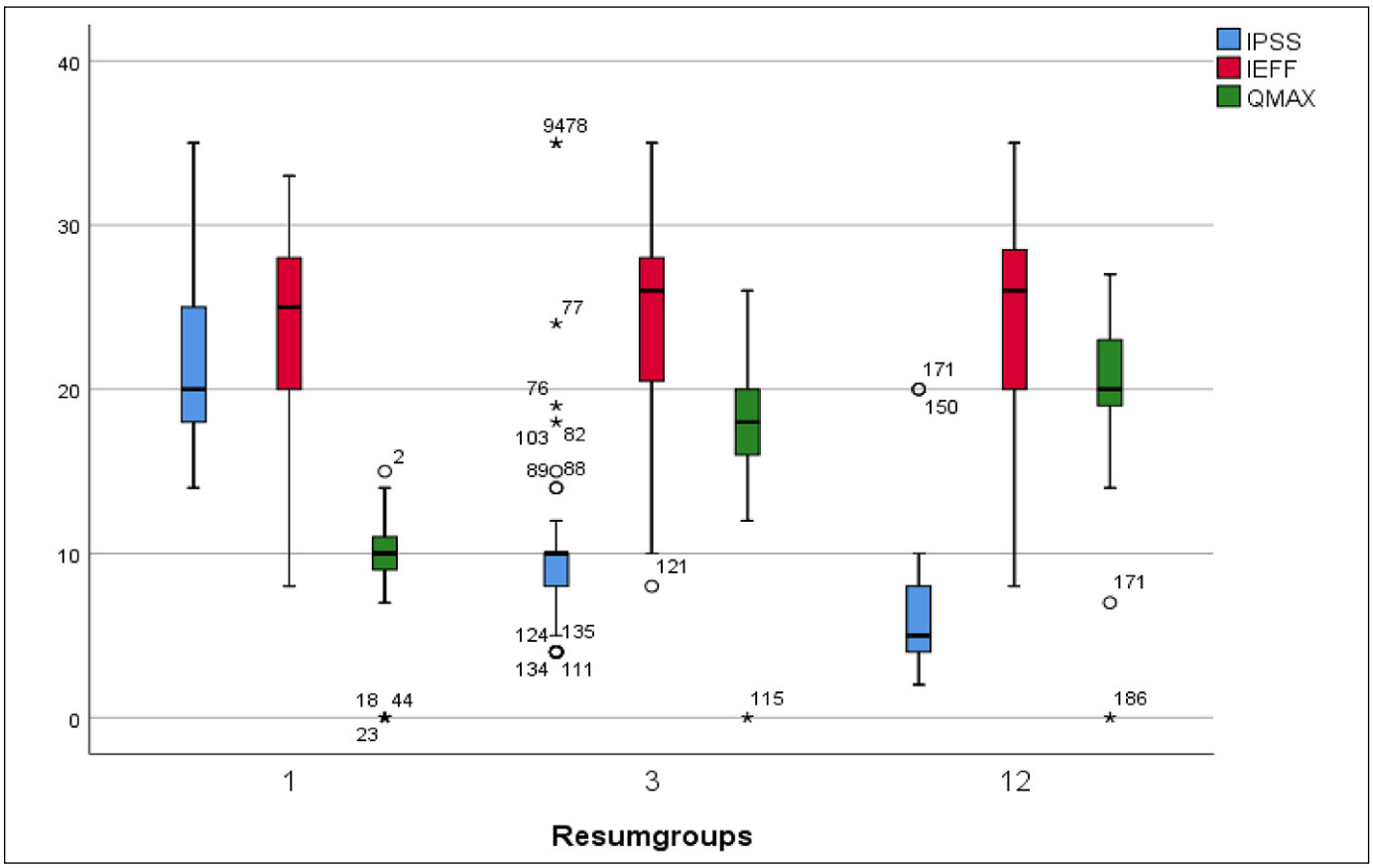

Figure 1. *Box plots of the data of BPH cases before Rezum treatment and at the 3rd and 12th months after treatment.*

2 patients experienced persistent dysuria for up to three months before eventual resolution;
- urgency: it was reported in 4 patients, all of whom experienced symptom resolution within the first 2 weeks post-treatment;
- hematuria: occurred in 7 patients, resolving spontaneously within the first week without additional intervention;
- UTIs: 5 patients developed UTIs, with *Escherichia coli* identified as the causative organism in all cases; these infections were effectively managed with outpatient antibiotic therapy.

Notably, no cases of urinary incontinence were observed in the cohort.

Postoperative 30-day complications are further detailed in Table 3, highlighting the safety profile of Rezum therapy even in patients with larger PVs.

DISCUSSION

This study represents the first report on the Turkish experience with the Rezum® system for the treatment of benign prostatic hyperplasia (BPH). Rezum utilizes convective thermal energy to ablate obstructive prostatic tissue by disrupting the cell membrane, leading to cell death and necrosis [14]. Mynderse et al. [11] demonstrated that magnetic resonance imaging (MRI) revealed a 91.5% reduction in ablation volume at three months and a 95.1% reduction at 6 months post-treatment. Additionally, there was a 28.9% reduction in total prostatic volume and a 38% reduction in transition zone volume at 6 months [11].

In long-term follow-up studies, Dixon et al. [15] reported a reduction in post-void residual (PVR) volume from 78.5 ml to 62.8 ml at 24 months [15]. In our cohort, ultrasound follow-up at 12 months showed a comparable 29% reduction in prostatic volume, demonstrating significant tissue ablation.

Wong et al. demonstrated that all 10 patients requiring catheterization due to urinary retention became catheter-free following Rezum therapy, with a significant reduction in PVR [4]. Similarly, McVary et al. [16], in their analysis of 38 catheter-dependent patients, showed that 70.3% achieved spontaneous urination after two unsuccessful voiding attempts and remained catheter-free post-treatment. Our findings align with these studies, as all three patients with indwelling catheters in our cohort became catheter-free after Rezum therapy.

Rezum therapy is FDA-approved for prostates ≤80 ml [17]; however, its efficacy in larger prostates has also been explored. Bole et al. [18] analyzed 182 patients, including 47 with prostates >80 ml, reporting significant improvements in AUASS, peak flow rate, and PVR post-treatment. Similarly, Martinelli et al. [19] demonstrated significant reductions in bladder outlet obstruction index and prostate size (approx. 40%) in patients with larger prostates, underscoring the potential of Rezum therapy as a robust surgical alternative [18]. In our study, 11 patients with PVs >80 ml showed significant improvements in IPSS, QoL, Q_{max}, and PVR.

The re-treatment rate is a critical measure of the effectiveness of surgical interventions. Our study reports a re-treatment rate of 2.1% at one year, consistent with rates reported in the literature, including 2% by Darson et al. [20] and 3.7% by Roehrborn et al. at two years [21]. Two patients in our study required TUR-P due to persistently elevated residual urine volumes and impaired voiding.

Preservation of sexual function is a notable advantage of Rezum therapy. McVary et al. [7] reported no erectile dysfunction at two years post-treatment, while other studies observed improvements in IIEF scores ranging from 7.6% to 30.5% [12, 18, 22–26]. In our cohort, two patients experienced retrograde ejaculation or reduced ejaculation volume, but most patients showed a statistically significant improvement in IIEF-5 scores. This suggests that Rezum effectively preserves sexual function while providing symptomatic relief.

The safety profile of Rezum therapy is well-documented. Clavien-Dindo grade I/II complications such as dysuria, hematuria, urgency, and UTIs are reported in 3–33.8% of patients with prostates <80 ml [12, 27]. In our study, the overall complication rate was 37%, with higher rates observed in patients with PVs >80 ml.

The minimally invasive nature of Rezum therapy is another key advantage. Most patients tolerate the procedure well under oral sedation or local anesthesia, with only a minority requiring intravenous sedation [7]. In our cohort, 77.47% of patients underwent the procedure under general anesthesia for enhanced comfort, while 22.53% received intravenous sedation due to comorbidities.

Table 3. *Clavien-Dindo grade*

Safety outcomes of Rezum	Rezum patients (n = 71)
I	21
II	5
IIIa	0
IIIb	0
IVa	0
IVb	0
V	0

Recent studies have also highlighted the importance of understanding Rezum outcomes across different ethnicities. Obinata et al. reported on 25 Japanese patients, showing significant improvements in Q_{max} and PVR at three months, although 8% remained catheterized [28]. To our knowledge, this is the first and largest cohort study evaluating Rezum outcomes in the Turkish population.

While our study provides valuable insights into the effectiveness and safety of Rezum therapy in a Turkish population, its retrospective design limits the ability to establish causal relationships [29, 30]. The absence of a control group and the relatively small sample size may reduce the generalizability of our findings. Larger, prospective studies with long-term follow-up are needed to confirm these results.

CONCLUSIONS

Rezum therapy is regarded as a safe, effective, and minimally invasive option for treating lower urinary tract symptoms in men with benign prostatic hyperplasia. However, future research should focus on further understanding the efficacy and reliability of this treatment.

For surviving patients who had routine visits to the study site, evidence of a personally signed and dated informed consent document was obtained. Evidence of oral or written informed consent was obtained for surviving patients who had been transferred to another hospital. Deceased patients fulfilling the above inclusion criteria were also included in this study unless patients' families opted out of inclusion.

CONFLICT OF INTERESTS

The authors declare no conflict of interest.

FUNDING

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ETHICS APPROVAL STATEMENT

The study was approved by the Hisar Intercontinental Hospital Local Ethics Committee (approval number 24-2).

REGISTRY AND THE REGISTRATION NUMBER OF THE STUDY

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