Research Article

Outcomes of Rezum Water Vapor Therapy for Benign Prostate Obstruction with One-Year Follow-Up: Largest Real-World Data from Türkiye

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Objective: To retrospectively assess the safety and efficacy of Rezum, a promising minimally invasive treatment method for BPH, in patients treated at our clinic.

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) was 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 (Qmax), 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 prostate volume of 60.4±16.6 mL. Preoperatively, IPSS was 21.9±5.2, Qmax 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, Qmax 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, Qmax 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.

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

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Introduction

Benign prostatic hyperplasia (BPH) is a common condition in older men, significantly affecting urinary function and quality of life [1]. The primary goal in treating symptomatic BPH is to alleviate bladder outlet obstruction (BOO) caused by prostate enlargement. This can be achieved through surgical interventions or medications aimed at symptomatic relief. Traditionally, transurethral resection of the prostate (TUR-P) has been considered the gold standard for BPH surgery, despite some controversies surrounding its use [2].

However, TUR-P is associated with significant perioperative and postoperative complications, with rates of approximately 20%. These complications include anejaculation in 65% of patients, erectile dysfunction in 10%, urethral strictures in 7%, and urinary incontinence in 3% [3][4]. Alternative surgical methods for relieving BPH symptoms, with minimal impact on sexual function and lower perioperative risks, include minimally invasive surgical treatments (MIST) [3][4].

Numerous MIST options have emerged for BPH/LUTS therapy. These treatment options are particularly attractive because they generally require minimal anesthesia and can be performed in an office setting [5]. The Rezum System is a novel MIST utilizing water vapor thermal therapy to eliminate obstructive prostatic tissue [6]. It has been demonstrated that the Rezum System, an alternative technology utilizing convective water vapor energy (WAVE) produced by NxThera, Inc, Maple Grove, MN, USA, provides rapid and effective, continuous relief in lower urinary tract symptoms (LUTS) associated with BPH [7].

In recent years, numerous studies have been conducted to evaluate different aspects of the Rezum System. However, comparative randomized studies are scarce. Two recent studies directly comparing Rezum therapy and TUR-P were published in 2024. First, Tayeb et al. evaluated the efficacy of Rezum therapy in catheter-dependent patients with a one-year follow-up period. Consecutive Rezum patients were retrospectively matched with TUR-P patients using propensity score matching. The majority of patients in both groups experienced successful postoperative voiding (90.2% for Rezum vs. 92.7% for TUR-P). While TUR-P patients exhibited significantly better voiding outcomes at one and three months postoperatively, the reduction of LUTS in the Rezum group was comparable after six

and twelve months, in terms of mean International Prostate Symptom Score (IPSS), quality of life (QoL) indices, and maximum urinary flow rate (Qmax) [8].

In contrast, bipolar TUR-P demonstrated greater effectiveness and durability compared to Rezum therapy in a randomized trial with a two-year follow-up period. The re-treatment rate for Rezum therapy was found to be 8%. Re-treated patients typically had larger prostates (91.5 ± 24.61 mL) with half of them being catheter-dependent. While the authors emphasized the superior outcomes of TUR-P over Rezum therapy, they also noted that Rezum therapy remains a viable option, particularly for sexually active men seeking to preserve erectile and ejaculatory functions without sacrificing relief from symptoms [9].

We retrospectively evaluated the safety and efficacy of Rezum, one of the promising minimally invasive treatment methods for BPH, in patients treated at our clinic.

Methods

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 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 and 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 International Prostate Symptom Score (IPSS), Maximum Flow Rate (Qmax), 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.

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 prostate volume, 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 LA 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 and 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 treating physician. Outcome assessments were conducted by an assessor blinded to the procedures, as detailed by Dixon CM et al. [12] and McVary KT 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; peak urine flow (Qmax) ≥15 mL/sec; and prostate volume ≥30-≤120 mL. Exclusion criteria included the following: prostate cancer, Parkinson's disease, neurogenic bladder, overactive bladder, bladder stones, bladder tumor, urinary infection, Alzheimer's disease.

Results

Baseline Characteristics

Out of the 71 patients included in the study, the median age was 62.1±9.3 years, with a median prostate volume of 60.4±16.6 mL. A median lobe was present in 47.8% (34/71) of patients. Preoperatively, IPSS was 21.9±5.2, Qmax 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. The study included patients with varying ASA classifications. The patients were classified as ASA 1 to ASA 4, with 13 classified as ASA 2, 6 as ASA 3, and 1 as ASA 4. Prostate volumes for 52 patients ranged between 30-80 mL, while 13 patients had a prostate volume exceeding 80 mL; there were no patients with a prostate volume below 30 mL. Five patients had indwelling catheters. The middle lobe was present in 34 patients. The average prostate length for the patients was 3.7±1.1 cm. (Table 1.) General anesthesia was administered to 55 patients, while 16 underwent surgery with intravenous sedation. Twenty patients were using aspirin 100 mg and clopidogrel 75 mg as anticoagulants. The drugs were stopped five days before the operation, and low molecular weight heparin was started and continued for one week after the operation; then, the anticoagulants they used were continued. On average, patients received 6.5±2.0 injections, and they were discharged on the same day. The average catheter duration was 4.8±1.9 days. Five (7%) patients failed in the first attempt to remove the catheter; three of these patients were patients with a permanent catheter, the catheters of two patients were removed after a week, and three patients had their catheters removed after ten days, and spontaneous urination was achieved.

Follow-up Results

At the 3-month follow-up, significant improvements were observed in several parameters: the International Prostate Symptom Score (IPSS) decreased to 10.1±5.6, the maximum flow rate (Qmax) increased to 24.5±3.7 mL/sec, and the Quality of Life (QoL) score improved to 1.2±0.51. Additionally, the International Index of Erectile Function (IIEF-5) score increased to 24.5±5.4, total PSA levels decreased to 1.8±0.9 ng/mL, and post-void residual volume (PVR) remained at 177.4±216.5 mL. At the 12-month follow-up, these improvements were maintained, with IPSS further decreasing to 6.0±3.1, Qmax at 18.12±3.7 mL/sec, QoL at 1.2±0.51, IIEF-5 remaining at 24.5±5.4, total PSA at 1.8±0.9 ng/mL, and PVR significantly reduced to 24.9±25.2 mL. (Table 2, Figure 1.)

Complications

The most significant complications reported by patients were as follows: 10 experienced dysuria, 4 had urgency, 7 presented with hematuria, and 5 developed urinary tract infections. In cases of urinary tract infections, cultures revealed Escherichia coli growth, and these infections were successfully treated with outpatient antibiotic therapy. Among patients with dysuria, improvement was observed in 8 individuals six weeks post-operation, while 2 patients continued to experience dysuria for up to 3 months. Patients with urgency complaints showed improvement within the first two weeks, and notably, no cases of incontinence were reported. Postoperative 30-day complications are shown in Table 3.

Discussion

This article represents the first study reporting the Turkish experience with the Rezum® system for BPH treatment. The mechanism of this system involves allowing convective thermal energy to pass through the interstitium of the transitional zone of the prostate, leading to disruption of the cell membrane, cell death, and necrosis [14]. Mynderse and colleagues demonstrated, as shown in magnetic resonance imaging (MRI), that prostatic tissue ablation volume decreased by 91.5% at 3 months and 95.1% at 6 months post-treatment. At 6 months, there was an average reduction of approximately 28.9% in total prostatic volume and a 38% reduction in transition zone volume [11].

Dixon and colleagues, in their 24-month follow-up, demonstrated a decrease in PVR volume from 78.5 mL to 62.8 mL [15]. In our study group, we conducted controls using ultrasound and demonstrated a reduction of 29% at 12 months, indicating a significant ablation of prostatic tissue. Wong and colleagues conducted a study using data from 10 patients who required catheterization due to urinary retention. The results demonstrated that all patients became catheter-free, and PVR volume significantly decreased [4]. In a retrospective analysis, McVary and colleagues studied 38 men with urinary retention and an average prostate volume of 58.5 mL. They found that, on average, after two unsuccessful attempts at voiding, 70.3% of the patients could spontaneously urinate and remain catheter-free following Rezum treatment [16]. The statement "In another study, Rezum was a safe and effective therapy to treat catheter-induced urinary retention in patients with BPH, including patients with middle lobe BPH" suggests that in a different research investigation, Rezum was found to be a reliable and secure treatment for resolving urinary retention caused by catheters in individuals with

BPH, even in cases involving middle lobe BPH [17]. In our study, we observed that three patients who initially had indwelling catheters became completely catheter-free after the operation.

Rezum therapy is generally approved by the FDA for use in prostates with a volume of 80 cc and below. However, some studies have explored the application of Rezum treatment in patients with prostates larger than 80 cc. In one study involving 182 patients, 47 had prostates larger than 80 cc, with an average prostate volume of 119 mL in this cohort. Among them, 55% were catheter-dependent. Post-Rezum treatment, all measurements, including American Urological Association symptom score (AUASS), peak flow, and PVR, showed statistically significant improvement. In patients with larger glands, all postoperative measurements, including AUASS, peak flow rate, and post-void residual, demonstrated statistically significant improvement [18].

In a recent urodynamic study, Martinelli et al. analyzed the pressure-flow data before and after Rezum procedures from 17 patients with proven bladder outlet obstruction. It was the first study to assess the effect of Rezum therapy on urodynamic findings. PVR and bladder outlet obstruction index were significantly reduced, with the prostate size decreasing by approximately 40%. They stressed that Rezum therapy represents a notably robust surgical alternative irrespective of the severity of obstruction [18].

In our study involving 71 patients, 11 had a prostate volume exceeding 80 mL. These patients exhibited significant improvements in IPSS, QoL, Qmax, and PVR. Among our patient group, 5 individuals were catheter-dependent initially, but they became catheter-free after the treatment.

The re-treatment rate is a significant indicator of the effectiveness of surgical interventions. Our study reports a re-treatment rate of 2.1% at 1 year. This rate can be compared with other studies in the literature. For instance, Darson et al. reported a rate of 2% at 1 year, and Roehrborn et al. reported a rate of 3.7% at 2 years [19].

In the Rezum study, 4.4% of patients required surgical retreatment, and 5.2% resumed medical treatment with alpha-blockers after a 4-year follow-up [20]. In our study, TUR-P surgery was performed on two patients due to persistently elevated residual urine volumes and impaired voiding functions.

Studies on sexual function in patients undergoing Rezum treatment have shown that McVary et al. reported preserved sexual function over a 2-year follow-up with no reports of erectile dysfunction [7]. In Dixon's study, there was a 30.5% improvement in IIEF, Roehrborn et al. reported an 18%

improvement, Johnston et al. reported 26.2%, and McVary et al. reported 7.6% [12][19][21]. Retrograde ejaculation or anejaculation is a commonly encountered issue following prostate surgeries. In the treatment of BPH, a meta-analysis comparing TUR-P with Thulium laser prostatectomy found retrograde ejaculation rates of 37.5% and 36.2%, respectively. In a study on holmium laser enucleation of the prostate (HoLEP), the overall retrograde ejaculation rate was reported as 92.5% [22][23][24]. The preoperative IIEF-5 score for these patients was 18.5, and the Male Sexual Health Questionnaire (MSHQ) score was 7.4. This increased to an average IIEF-5 score of 16.4 and an average MSHQ score of 9.62 in a 3-month follow-up. Rezum treatment appears to be effective in preserving sexual function. In a study by Roehrborn et al., convective RF water vapor thermal treatment of prostatic hyperplasia revealed that erectile function was preserved, and concomitant BPH symptoms were permanently relieved in subjects followed for two years [19].

In our study, two patients experienced retrograde or anejaculation, and two patients reported a decrease in ejaculation volume following Rezum surgery. There are only four studies available regarding ejaculation-related issues post-Rezum operation. In our patient group, we noted a postoperative enhancement in erection quality, with a statistically significant improvement observed in IIEF-5 values.

Rezum surgery is brief and can be performed without the need for general anesthesia. Most patients require only oral sedation, while some clinicians prefer to perform a prostate block, and less than 20% require intravenous sedation [7]. Rezum water vapor thermal ablation is a minimally invasive treatment for BPH lasting just over two minutes, and unlike TURP or PVP, it can be performed without general anesthesia [18]. We chose general anesthesia for 77.47% (55/71) of the patients to enhance comfort, as they were in good health with no comorbidities, and the procedure was relatively quick. Conversely, 22.53% (16/71) of the patients underwent surgery with intravenous sedation due to the presence of comorbidities, where the use of general anesthesia was considered risky.

Studies have shown Clavien-Dindo grade I/II complications such as AUR, dysuria, hematuria, urgency, and urinary tract infection in 3-33.8% of patients with prostates < 80 mL [12][25]. In our study, Clavien-Dindo grade I/II complications were found at a rate of 37%. This rate was higher than the literature, but there were patients with prostate volumes above 80 mL.

After 5 years of follow-up data was published by McVary et al., the Rezum system has been delivered to many urological clinics around the world. It may let us evaluate the outcomes of the treatment in

different ethnicities. Obinata et al. reported 3-month outcomes of 25 Japanese patients. Maximum flow rates of the patients significantly improved around 50%, and the amount of residual urine decreased from 185.7 mL ± 195.3 to 80.0 mL ± 87.5. Despite 12 (48%) patients failing the initial trial of catheter removal, 2 (8%) patients remained catheterized at 3 months' follow-up [26]. To our knowledge, there were only two observational studies with a small sample size and short follow-up on the Rezum system in the Turkish population. Our study is the first and largest cohort with unselected BPH patients for a 1-year follow-up in this population [27][28].

Limitations

The retrospective design of the study may impose limitations on data collection and analysis. It is acknowledged that prospective studies could provide stronger evidence. The small sample size of the study may limit the generalizability of the results and decrease statistical power. Conducting studies with larger sample sizes could enhance the reliability of the findings. The absence of a control group in some studies makes it challenging to compare the effectiveness of the treatment with other methods. The short follow-up period in some studies may hinder a comprehensive understanding of the long-term effects. Studies with longer follow-up durations could better evaluate the long-term effectiveness and reliability of the treatment.

Conclusion

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.

Statements and Declarations

Approval of Research Protocol by Institutional Review Board

The ethical review boards at all study sites approved the study protocol and related documentation. Approval number 24-2.

Informed Consent

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.

Registry and the Registration No. of the Study/Trial

ClinicalTrials.gov identifier NCT0625765.

Animal Studies

Not applicable.

Conflict of Interest

The authors declare no conflict of interest.

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Declarations

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