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Water Vapor Thermal Therapy (Rezum™) for Benign Prostate Hyperplasia: Initial Experience from Turkiye

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What's known on the subject? and What does the study add?

Rezum™ system is a safe minimal invasive treatment modality for benign prostate hyperplasia treatment. This is the first study from Turkiye that reports the initial short-term results of Rezum™ therapy.

Abstract

Objective: Rezum™ system is a safe minimal invasive treatment modality for benign prostate hyperplasia (BPH) treatment. The aim of this study was to evaluate the short-term results of Rezum™ therapy in our center.

Materials and Methods: We retrospectively collected the data of 28 patients with symptomatic BPH who underwent Rezum™ therapy in our center. All patients' pre-operative and post-operative; post-void residual volume (PVR), Q_{max}, international prostate symptom score (IPSS), quality of life (QoL) score, serum total prostate-specific antigen levels were obtained. The number of injections administered during the procedure, operation time, catheter removal time, complications and mean duration of follow-up was recorded.

Results: Our study group consisted of 28 patients with a mean age of 65.1±8.9 years, median prostate volume 64 [interquartile range (IQR) 44.8-89.5] mL. The median procedure time was 12 (IQR 11-13.8) minutes, the median catheter removal time was 6.5 (IQR 5-8.8) days for our study group. None of the patients had experienced Clavien-Dindo 3 complications. Pre-operative median Q_{max} and PVR were 8 (IQR 6-9) mL/s and 110 (IQR 80-187.5) cc and post-operative Q_{max} and PVR were 12.5 (11-14.8) mL/s and 40 (IQR 18.8-70) cc, respectively. We observed a significant increase in IPSS and QoL score at post-operative 3rd month after the Rezum™ therapy.

Conclusion: Rezum™ procedure is an effective and safe treatment for symptomatic BPH in the short term. Rezum™ system provides a significant increase in Q_{max} and significant decrease in PVR and IPSS. QoL scores after the 3rd month of the procedure is significantly lower compared to the pre-operative status.

Keywords: Benign prostate hyperplasia, Rezum™ (water vapor therapy), minimal invasive treatment

Introduction

Benign prostate hyperplasia (BPH) related lower urinary tract symptoms (LUTS) increase with age affects 6% of the male population (1-3). Symptoms, health-related quality of life (QoL) and urinary flow rates worsen and eventually some of the men experience acute urinary retention and need for surgery due to progressive increase in prostate volume (4). In case of pharmacotherapy failure and presence of BPH-related complications surgical treatment modalities such as open adenomectomy, laser enucleation of the prostate and transurethral resection of the prostate (TURP) should be considered (5). TURP has been considered as the gold standard surgical treatment option for BPH (6). Although TURP is a

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valuable option in improving urinary symptoms; risks of acute complication and long-term adverse effects such as ejaculatory and erectile dysfunction, *de novo* incontinence have been demonstrated (7). There are several treatment modalities for BPH with a broad spectrum of cost, invasiveness and efficacy. Rezum™ (Boston Scientific, Marlborough, MA) was a relatively new minimal invasive treatment modality and approved by Food and Drug Administration (FDA) in 2015. Since FDA clearance, Rezum™ system has been adopted by many urologists in Europe and United States (5,8). Clinical improvement in QoL, sustained relief of LUTS and durability of treatment response leads wide adoption of Rezum™ system throughout the world (9). Rezum™ system use a radiofrequency generator that converts water into water vapor. The convective conduction of heat in prostate tissue causes coagulation necrosis of prostate cells (10). Convective thermal energy that stimulates targeted tissue ablation without an effect on outside the targeted zone, offers Rezum™ a strong safety profile when compared to other minimal invasive surgical treatment modalities such as transurethral microwave thermotherapy (TUMT) and transurethral needle ablation of the prostate (TUNA) (10,11). Rezum™ therapy reduces prostate tissue volume associated with BPH, including hyperplasia of lateral, central zone and/or a middle lobe without morphologic limitations (12). Various anatomical variants, such as intravesical prostatic protrusion can be treated without interfering sexual function (13). Moreover, Rezum™ therapy does not have a steep learning curve and relatively easy to perform for the surgeon. Rezum™ procedure can be performed under local or sedoanalgesia in operating room or even in office setting (9). Steam delivered by the needle which is located at the tip of the Rezum™ device dispersed around the prostate tissue by the guidance of a cystoscope for 9 seconds for each injection. This steam leads to cell death and necrosis that in turn results in shrinking of the treated tissue up to 40% (10). This provides the patient; relief of LUTS and improvement in QoL without interfering with sexual function (9). Rezum™ procedure is shown to be effective in treating 30-80 mL prostates (with or without median lobe) for men ≥50 years old and today there are increasing data exists that shows that Rezum™ is a potentially good option for larger prostates or men with urinary retention (14,15). Rezum™ procedure is also applicable for the ablation of median lobe and enlarged central zone which is presented by elevated bladder neck (13). The aim of this study was to report our short-term (3rd month) results of the Rezum™ procedure in our center.

Materials and Methods

Between October 2020 and February 2022; 28 patients with moderate-to severe LUTS underwent Rezum™ (Boston Scientific, Marlborough, MA) procedure in our center. Our study group consisted of patients with IPSS score ≥8 (moderate and severe LUTS) and prostate size ≤130 cc in whom were considered for surgical intervention due to the ineffective pharmacotherapy treatment. Patients with a permanent urinary catheter due to the urinary retention after the trial without the catheter were also included in this study. Four of 28 patients (14.3%) had indwelling foley catheter pre-operatively due to acute urinary retention after the trial without the catheter. Because it was impossible to compare the mean peak urinary flow rate (Q_{max}) before and after the Rezum™ procedure, these 4 patients with pre-operative indwelling catheter due to acute urinary retention parameters excluded in the study. Patients with urinary infection, suspicious digital rectal examination finding, prostate volume >130 mL, history of previous pelvic radiotherapy were excluded. Patient demographic variables, pre-operative, and post-operative 3rd month PSA levels, post-void residual urine (PVR), Q_{max} values, international prostate symptom score (IPSS) and QoL scores were recorded. This study was approved by the Acıbadem Mehmet Ali Aydınlar University Institutional Review Board (İstanbul, Turkiye), (decision number: 2022-09/07) and signed informed consent was collected from all subjects.

The Rezum™ Procedure

All procedures were performed by a dedicated urology team in the operating room under sedoanalgesia. Pre-operative urine cultures and standard pre-operative laboratory examinations were obtained for all patients. Pre-operative prophylactic antibiotherapy according to local practice guidelines was administered to all patients. All procedures were performed in the lithotomy position. After the cleaning of the surgical field and proper draping; Rezum™ device was introduced into the urethra with 30-degree optic cystoscope to access the hyperplastic prostate tissue with the water delivery instrument. Initially, routine cystoscopy was performed to evaluate the bladder and the prostatic lodge. After this step, the vapor needle penetrated the prostate under direct visualization. Subsequently, water vapor was dispersed into the prostate adenoma for 9 seconds. Rapid escalation of the temperature to 70° celcius throughout the adenoma by the dispersion of the heat lead to cell necrosis.

The injections were initiated 1 cm below the bladder neck, downwards to the prostatic urethra to the proximal edge of the verumontanum and performed at each centimeter. In the case of median lobe presence, 1 or more injections may be performed in this lobe. The number of water vapor injections relies on the prostatic urethral length, median lobe presence and prostate volume. During the procedure, the urethral length was measured with a view finder, which is located at the tip of the instrument while retracting from the bladder neck to the verumontanum. The field of view finder used a scale that is 5 mm in diameter. In each 1 cm, a steam injection was performed typically at 9 and 3 o'clock for the lateral lobes and 6 o'clock on the median

lobe. Although we did not expect any bleeding; an 18-F 3-way silicone Foley catheter was placed at the end of the procedure to be at the safe side at the beginning of our experience.

Statistical Analysis

SPSS v.21 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. Shapiro-Wilk tests and probability plots were used to assess normality. Results were presented mean ± standard deviation for normally distributed variables, median [interquartile range (IQR)] for non-normally distributed variables. Categorical variables are presented along together with frequency and percentage. Differences between the two paired groups were tested using the Wilcoxon test. All tests are two-sided and the significance level was set as $p<0.05$.

Results

Rezum™ therapy was performed in 28 patients. Pre-operative characteristics are summarized in Table 1. Mean patient age was 65.1±8.9 years, median PSA level was 2.6 (IQR 1.4-4.4) ng/mL, median prostate volume which was identified with urinary system ultrasonography was 64 (IQR 44.8-89.5) cc. The pre-operative median Q_{max} and Q_{ave} values were 8 (IQR 6-9) mL/s and 4 (IQR 3-5) mL/s respectively. All patients in our study were under alpha-blocker treatment for a median time of 45.5 (IQR 35-50) months and 5 patients were under 5-alpha reductase inhibitors, 4 patients were under phytotherapeutic serenoa repens as well. Preoperative median IPSS and QoL scores were 2 (IQR 2-3) and 5 (IQR 4-5) respectively. The operation time is defined as the time between the transurethral insertion of the instrument to foley catheterization at the end of the procedure. The median operative time was 12 (IQR 11-13.8) minutes. The median number of injections given during the procedure was 6 (IQR 5-7). An 18 F 3-way silicone Foley catheter was positioned at the end of the procedure in the cases. In 2 patients concomitant bladder stone (bladder stones for 1 and 1.5 cm maximal diameter) laser lithotripsy was performed at the same session with Rezum™ therapy. All patients were discharged on post-operative day 1. Alpha-blocker treatment continued for 2 months and then was stopped. Clavien-Dindo grade 1 complications were encountered in 13 (46.4%) patients. Transient hematuria developed in 1 patient after the procedure and resolved spontaneously in a few days without any intervention. Three patients reported catheter-related mild discomfort which was managed conservatively with non-steroidal anti-inflammatory suppositories. Acute urinary retention developed after the catheter removal in 9 (32.1%) patients. In these patients, recatheterization was performed for an additional median 7 (IQR 5.5-9.5) days. For these 9 patients; spontaneous micturition was observed after catheter removal without any adverse event with a median 100 (IQR 60-120) cc PVR at post-operative 3rd month. In 2 patients post-operative urinary tract infection developed (Clavien-Dindo grade 2) which required oral antibiotics for 2 weeks. Clavien-Dindo grade ≥3 complications were not encountered in our study group and none of the patients required definitive TURP or any other surgical intervention for BPH management during the post-operative 3-month follow-up. Three months after the Rezum™ procedure; a significant increase in Q_{max} and Q_{ave} values and reduction in IPSS and PVR was identified (respectively $p<0.001$, $p<0.001$, $p<0.001$, $p<0.001$). The QoL score also showed a significant

Table 1. Characteristics of the study group

Categories	Patient n	n (%)	Mean ± SD	Median (IQR)
Age, year	28		65.1±8.9	65.5 (58.3-72)
BMI, kg/m^2	28		30.8±3.3	31 (28-32.8)
ASA score	28		2.1±0.5	2 (2-2)
Pre-operative urinary ultrasound prostate volume, cc	28		67±26.7	64 (44.8-89.5)
Pre-operative urinary retention	28	4 (14.3%)		
Pre-operative catheterization	28	4 (14.3%)		
Total prostate lobe injection	28		6.2±1.5	6 (5-7)
Operative time, minutes	28		13.6±4.2	12 (11-13.8)
Post-operative foley catheter removal time, day	28		7.3±3.6	6.5 (5-8.8)
Spontaneous micturition after catheter removal	28	21 (75%)		
PMR after catheter removal, cc	28		172.9±178.9	70 (32.5-300)
Post-operative re-catheterization	28	9 (32.1%)		
Post-operative re-catheterization, day	9		7.4±2.2	7 (5.5-9.5)
Spontaneous micturition after removal of re-catheterization	9	9 (100%)		
PMR after catheter removal (for patients that required recatheterization), cc	9		95.7±46.5	100 (60-120)

n (%): Frequency (percentage), BMI: Body mass index, SD: Standard deviation, IQR: Interquartile range

decrease after the Rezum™ procedure (p<0.001) (Table 2, Figures 1, 2). There was no significant difference between PSA values in pre-operative and post-operative 3rd month (p=0.058) (Table 2). Four patients with pre-operative indwelling catheter due to urinary retention were catheter free from the time of catheter removal with a median 80 (IQR 37.5-400) cc PVR at post-operative 3rd month.

Discussion

Recently, surgeons, and patients both shown an interest in minimal invasive methods for BPH management. Many minimal invasive surgical treatment options have emerged over the past decades; but high retreatment rates, procedure related sexual dysfunction and/or patient related anatomical variations like presence of middle lobe, have remained a common obstacle to their wide adoption. Although high-intensity focused ultrasound, TUNA, TUMT, prostate stent implantation, Aqua-ablation and selective prostate artery embolization (PAE) occur in the literature; new methods such as Urolift™ and Rezum™ became more popular in clinical practice. Rezum™ therapy can be performed in the presence of median lobe in contrast to urethral stents and prostatic urolift (PUL) (9). Unlike PAE and aquaablation; Rezum™ procedure can be an appliable in the day-

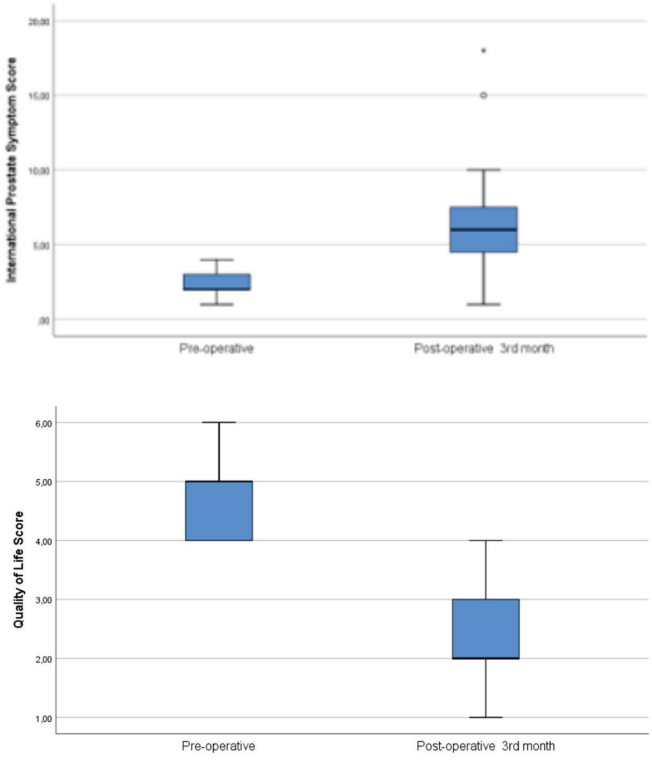

Figure 1. Change in IPSS and QoL score pre-operative and post-operative 3rd month

IPSS: International prostate symptom score, QoL: Quality of life

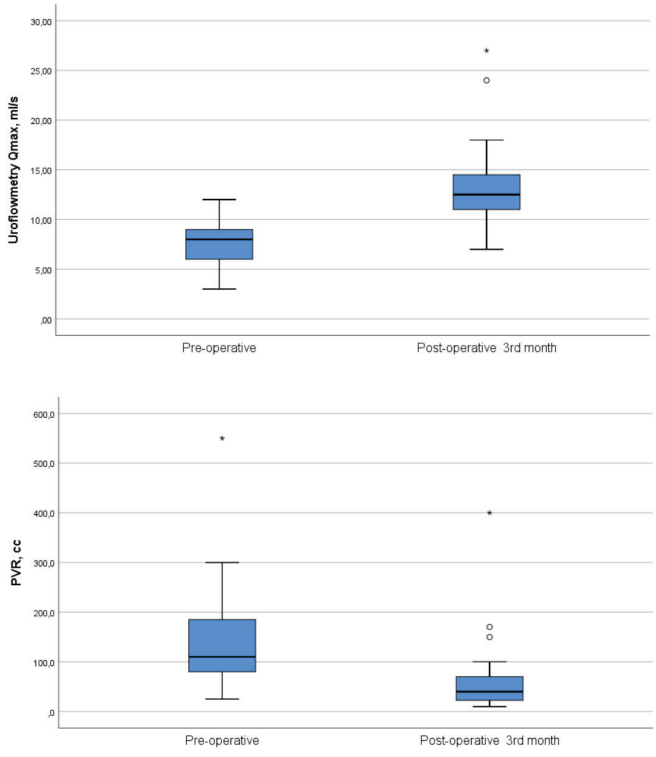

Figure 2. Change in Q_{max} (mL/s) and PVR (cc) score pre-opeative and post operative 3rd month

PVR: Post-void residual volume

Table 2. Comparisons of measures pre-operative and post-operative 3rd month

Categories	Patient n	Pre-operative	Post-operative 3rd month	p[1]
		Median (IQR)	Median (IQR)	
IPSS	28	2 (2-3)	6 (4.3-7.8)	<0.001
QoL score	28	5 (4-5)	2 (2-3)	<0.001
Uroflowmetry Q_{max}, mL/s	24*	8 (6-9)	12.5 (11-14.8)	<0.001
Uroflowmetry Q_{ave}, mL/s	24*	4 (3-5)	7 (5.3-8)	<0.001
PVR, cc	24*	110 (80-187.5)	40 (18.8-70)	<0.001
PSA (total)	28	2.6 (1.4-4.4)	2.3 (1.3-3.6)	0.058

[1]Wilcoxon test; *4 patient had preoperative catheterization, IPSS: International prostate symptom score, QoL: Quality of life, Q_{max}: Peak urinary flow, Q_{ave}: Average urinary flow, PVR: Post-void residual urine, PSA: Prostate-specific antigen

case setting (15-18). Addition to this; operative time is short, and it can be performed in out-patient setting or office and thereby probably reduce the overall cost. Rezum™ procedure improves the clinical outcomes without bleeding or compromising sexual function. Due to the minimal adverse effects of Rezum™; an overall cost-effectiveness was observed in the studies (19,20). Randomized control trials have shown that; Rezum™ provides a mean IPSS improvement of 48% and reduces the LUTS (both storage and voiding symptoms) up to 5 years without negative impact on sexual function (9). To achieve similar results with pharmacotherapy; patient adherence to a combination of many prescription regimens which, which cause sexual dysfunction are required (21-23). Additionally, to produce similar outcome measures with PUL; permanent implants are necessitated, but in this scenario retreatments rates are higher (24). Rezum™ procedure can be also performed in local anesthesia which may be advantageous for older patients with major comorbidity. Moreover, Rezum™ serve as a suitable option in terms of short operative time (9,25). In the European Association of Urology (EAU) guideline, Rezum™ therapy is mentioned as a minimal invasive surgical technique for BPH (5). Today, American Urological Association (AUA) guideline recommend Rezum™ to patients with <80 cc prostate volume (Recommendation Grade: C) (26). However, there are increasing data show that Rezum™ can be used for treating large prostates (15). Coagulative necrosis created by water vapor leads to shrinking of the prostate up to 40% in several weeks (10). This effect is stated in a magnetic resonance imaging study; that showed a one-third decrease in the entire prostate and transition zone volumes (27). Dixon et al. (28) reported their 2 years of follow-up Rezum™ experience in 65 patients. They determined the clinical improvement in IPSS (55.7% reduction), QoL (59% reduction), Q_{max} (44.6% improvement) and benign prostatic hyperplasia impact index (BPHII) (30.5% improvement), PVR (19.8% reduction) and international index of erectile function score as early as post-operative 1-month. They detected the maximal improvement at 3rd month and this improvement was sustained for 24 months (28). Roehrborn et al. (29) conducted a study on 53 patients with 12 months follow-up in 2017. They showed a 36.4% improvement in Q_{max} values compared to the baseline parameters without compromising erectile function. Mollengarden et al. (25) reported their single surgeon Rezum™ experience in 129 patients. In this study, they detected a 51.4% improvement in Q_{max} values and 45.2% reduction in IPSS during the post-operative 6th month (25). Rezum™ can also be performed in patients with urinary catheter due to urinary retention. Johnston et al. (15) reported the first United Kingdom trial in 2020 210 patients and 12-months follow-up. In this study, mean prostate volume was 56.9 cc and 25 of the 210 cases were pre-operatively catheterized. They reported that ultimately 202 men (96%) were catheter free or on intermittent self-catheterisation in their study population and have shown the efficacy of Rezum™ in patients with urinary catheter due to urinary retention (15). Some studies have shown that Rezum™ can be performed in large (≥80 cc) prostates. Bole et al. (14) reported their single center experience in 2020. Their study group consisted of 182 patients and 47 of these patients had prostates ≥80 cc. Addition to this; 59 of the 182 patients had pre-operative urinary retention. They reported the post-operative catheter-free rates 88% for small-sized prostates and 83% for large-sized prostates (14). To date, one multicenter randomized controlled clinical trial was conducted to assess the efficacy of Rezum™ by McVary et al. (9), which reported the 5-year outcomes in 2021. This study consisted of 197 patients from 15 centers in the USA with 5-years follow-up. In this trial, significant improvement of LUTS was noticed <3 months after Rezum™ therapy and this improvement is durable through 5 years. In this study, Q_{max} and IPSS-QoL scores increased 44% and 45%, respectively. However, IPSS and BPHII of the study population both decreased 48%. They stated that; during the 5-years of follow-up alleviation of LUTS secondary to BPH was sustainable without any cases with *de novo* sexual dysfunction. In this randomized controlled trial, surgical retreatment rate at the end of the study was reported 4.4% (9). Moreover, there are several advantages of Rezum™ therapy over other minimal invasive treatment modalities. Unlike TURP or Holmium laser enucleation of the prostate, which has steep learning curves, Rezum™ therapy is a simple procedure to perform and easy to learn. Additionally, Rezum™ therapy can be performed as an alternative to pharmacotherapy to decrease the side effects of medical therapies. Gupta et al. (22) reported their outcomes of Rezum™ therapy compared to the cases with medical therapy of prostatic symptom study treated with doxazosin and/or finasteride for 36 months. In this study, they stated that Rezum™ therapy provides an equivalent, prolonged IPSS improvement compared to the combination therapy (doxazosin + finasteride) and was found to be superior to the monotherapy. Moreover, in the pharmacotherapy arm, clinical progression was 5 times greater compared to Rezum™ (22). Rezum™ can be performed in cases with median lobe and large-sized prostate unlike PUL therapy (30). In the randomized controlled trial conducted by McVary et al. (9), Rezum™ therapy provided similar significant improvement in patients with median lobe (58 patients, 30.1% of the study group) compared to the patients without median lobe with an additional 1.6±0.7 injections to this lobe. Rezum™ therapy has a short operative time with an average of 8 min and can be performed in an out-patient setting (25). Most of the cases do not require general or regional anesthesia. This procedure can be performed using oral or intravenous sedation, urethral local anesthesia with or without prostatic block (9,10,31). One of the most advantageous issues of Rezum™ over other surgical and medical treatment is the preservation of the

ejaculatory and sexual functions. To date, *de novo* erectile or ejaculatory dysfunction has not been reported in the literature after Rezum™ therapy (9). The reported post-operative complications in the literature related to this procedure are generally minor (Clavien-Dindo grade I-II) irritative symptoms. These irritative symptoms may be attributable to the acute inflammatory response in the prostate tissue after Rezum™ therapy. These irritative symptoms subside in 2-3 weeks (9,12,14,15,23,28,29).

Although there are no strict contraindications exist, Rezum™ is not recommended for patients with penile implant, artificial urinary sphincter, and radiation therapy history. Moreover, to date, the effectiveness of Rezum™ therapy for patients with previous invasive treatments (TURP, PVP etc.) has not been clinically tested in the studies. For TURP, resected prostate material can be evaluated for the identification of incidental prostate cancer, which is reported up to 13% in the studies (32,33). The lack of pathological evaluation of the prostate material may be considered a disadvantage of Rezum™. Regarding the existing literature, retreatment rate of Rezum™ therapy (due to missed median lobe, bladder neck contracture etc.) reported with the incidence of 1% to 2.3% (15,25,28).

There is no consensus on the timing of catheter removal time in the literature. Dixon et al. (28) reported an average of 3.8 days for catheter removal time. Johnston et al. (15) reported an average catheter removal time of 3-5 days, but in cases with previous urinary retention and large-sized prostates, they kept the catheter for a longer time. Moreover, Bole et al. (14) reported the catheter removal time for 3 days up to 4 weeks and stated that, catheter removal time should be adjusted according to the prostate volume and presence of previous urinary retention.

Conclusion

Rezum™ procedure (Water vapor therapy) is an effective and safe procedure for symptomatic BPH in the short-term follow-up. Rezum™ system provides a significant increase in Q_{max} values and a significant decrease PVR and IPSS. The QoL scores after the 3rd month of the procedure are significantly lower compared to the pre-operative status.

Ethics

Ethics Committee Approval: This study was approved by the Acıbadem Mehmet Ali Aydınlar University Institutional Review Board (İstanbul, Turkiye), (decision number: 2022-09/07).

Informed Consent: Signed informed consent was collected from all subjects.

Peer-review: Externally and internally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: M.B.T., T.D., Ö.B.A., B.Z.P., İ.T., C.O., A.R.K., Concept: M.B.T., T.D., Ö.B.A., B.Z.P., İ.T., C.O., A.R.K., Design: M.B.T., T.D., Ö.B.A., B.Z.P., İ.T., C.O., A.R.K., Data Collection or Processing: M.B.T., T.D., Ö.B.A., B.Z.P., İ.T., C.O., A.R.K., Analysis or Interpretation: M.B.T., T.D., Ö.B.A., B.Z.P., İ.T., C.O., A.R.K., Literature Search: M.B.T., T.D., Ö.B.A., B.Z.P., İ.T., C.O., A.R.K., Writing: M.B.T., T.D., Ö.B.A., B.Z.P., İ.T., C.O., A.R.K.

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