



Change in Prostate Volume and Symptom Improvement in Men Treated With Rezūm Water Vapor Therapy

Dean Elterman, Naeem Bhojani, Bilal Chughtai, and Kevin C. Zorn

OBJECTIVE	To evaluate the change in prostate volume (PV) and relationship to improvement in urinary symptom scores following Rezūm therapy.
METHODS	Quality of life outcomes and PV were assessed at baseline and 12 months postprocedure. Percent change from baseline in outcomes and PV were calculated, as was the number of Rezūm injection to baseline PV ratio. Association between total number of injections and changes in outcomes and PV were evaluated using linear regression models.
RESULTS	A total of 49 men (mean age = 67.8; standard deviation = 9.4) underwent the procedure between April 2019 and September 2020, with a median baseline PV of 71.5 cc (range 24-150) and median number of vapor injections of 11.0 (range 4-21). At 12 months, the median percent change in PV was -34.0% (interquartile range: -49.2%, -16.7%), with 45/49 (91.8%) patients having reduced volume. Among the 45 patients with reduced volume at 12 months, every 10% increase in volume reduction was associated with a 7.5% (95% confidence interval, 1.4%-13.6%; $P = .02$) improvement in the International Prostate Symptom Score. There was no significant association between total number of injections or injection to baseline volume ratio and change in PV.
CONCLUSION	In this cohort of men treated with Rezūm therapy for benign prostatic hyperplasia, it was demonstrated that there is a correlation between greater PV reduction and greater symptomatic improvement. This study showed no association between more injections or the ratio of injections to PV changes, refuting the claim that more injections are better. UROLOGY 177: 142-147, 2023. © 2023 Elsevier Inc. All rights reserved.

Benign prostatic hyperplasia (BPH) is a urologic condition characterized by a progressive, age-related increase in prostate size.^{1,2} Patients with BPH will often develop lower urinary tract symptoms, and it has been found that healthcare costs attributed to BPH are among the top 10 most prominent and costly diseases in men older than 50 years.^{3,4} Urinary retention is one of the most significant complications of BPH and, historically, it has represented an indication for surgery.⁵ From a socioeconomic perspective, men with urinary retention present a particular challenge and burden for the health care system. In addition to waiting for elective surgery, with inherent delays during the COVID epidemic for non-oncology surgery, especially in socialized medical systems, these patients who are unable to void

have increased Foley-related pain and bladder spasms, increased emergency room visits for hematuria and infection, need of re-catheterization, long-term physician follow-up, and, often, several attempts at catheter removal.⁵

In recent years, a novel, minimally invasive procedure was introduced for the management of BPH, the Rezūm System (Boston Scientific Company Inc., Marlborough, MA), which harnesses convective radiofrequency water vapor thermal energy stored in 0.42 mL of steam to slowly ablate obstructing prostate tissue.^{1,3} The initial pilot studies, conducted at 3 sites (Dominican Republic, Czech Republic, and Sweden) involving 65 consented cases with Rezūm, demonstrated >90% magnetic resonance imaging resolution of treatment lesions by 3-6 months along with an overall mean prostate volume (PV) reduction of 28.9% at 6 months.⁶

In short, the Rezūm procedure entails use of a retractable needle injected at 1 cm intervals into the lateral lobes followed by 9-second water vapor delivered at a temperature of 103 °C. The needle can be administered to multiple treatment sites (up to 15 injections per disposable device) as needed, including median lobes.³ The Rezūm System was approved by the Food and Drug

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From the Division of Urology, University Health Network, University of Toronto, Toronto, Ontario, Canada; the University of Montreal Hospital Center, Université de Montréal, Montreal, Quebec, Canada; and the Department of Urology, Weill Cornell Medical College, New York Presbyterian, New York, NY

Address correspondence to: Dean Elterman, M.D., M.Sc., F.R.C.S.C., Toronto Western Hospital, Room 317, 8th Floor, Main Pavilion, 399 Bathurst St, Toronto, Ontario M5T 2S8, Canada. E-mail: dean.elterman@uhn.ca

ORCID ID: 0000-0003-1507-7783

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Administration (FDA) in 2015 based on the results of the pivotal randomized trial (NCT01912339), which demonstrated that Rezūm therapy provides rapid and durable improvements in BPH symptoms relative to controls.^{3,7} Support for Rezūm therapy was also published by the National Institute for Health and Care Excellence (NICE) in June 2020.^{8,9} Additionally, the American Urological Association (AUA), European Association of Urology (EAU), and Canadian Urological Association (CUA) have now included water vapor thermal therapy in their most recent guidelines as a treatment that may be offered to some BPH patients.^{1,10,11} Clinical evidence, including real-world data, have demonstrated the efficacy and safety of Rezūm therapy across a range of different BPH subgroups (eg, large glands, urinary retention, or median lobe involvement).¹²⁻¹⁴

BPH progression and its negative outcomes have been shown to be related to baseline PV, which can be predictive of treatment response. Disease progression includes worsening of BPH symptoms, negative impact quality of life, urinary retention or infection, and the need for surgery.¹⁵⁻¹⁷ Prior research using diagnostic imaging has demonstrated reductions in PV following Rezūm therapy, though evidence on this topic is lacking, especially with regard to the impact of more or less treatments per a given prostate size.⁶ Additionally, there is currently no consensus on the optimal number of injections required during the Rezūm procedure.¹⁸ Up to 15 injections can be administered with each device and the number of injections given may vary based on the anatomy of the patient. Guidance on injection frequency is available, but, ultimately, this decision is at the discretion of the treating physician.^{18,19} Determining the ideal number of injections will ensure that patients achieve adequate symptomatic relief while limiting the risk of treatment-related adverse events and healthcare resource use. As such, we sought to evaluate the change in PV and its relationship to improvement in symptoms scores following Rezūm therapy, as well as the association between the number of vapor injections and changes in outcomes and PV.

METHODS

Study Subjects

A prospective registry was established in Canada at two high-volume centers, the University Health Network in Toronto, Ontario and the University of Montreal Hospital Center in Montréal, Québec, to follow BPH patients receiving Rezūm therapy at these institutions. Institutional ethics board approval was obtained at each center. Data from all consecutive Rezūm cases were prospectively collected following treatment and retrospectively reviewed.

Total 151 patients underwent the procedure between April 2019 and September 2020, while 49 patients had both baseline and 1-year post-Rezum PV. This manuscript analyzed paired-value data of these 49 patients who had both baseline and 1-year post-Rezum PV. As the study was observational in nature and was conducted during COVID pandemic, most of

the follow-ups were virtual visits of which limited the data collection. The numbers of paired-value data for International Prostate Symptom Score (IPSS), International Index of Erectile Function (IIEF), Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD) Bother, and MSHQ-EjD Function were 29, 18, 20, and 20, respectively.

Treatment Procedure

Rezūm water vapor therapy was performed as previously described.^{3,6,20} This system includes a generator containing a radiofrequency power supply, system controls, and a single-use transurethral delivery device that incorporates a standard 4 mm, 30-degree endoscopic cystoscopy lens. Water vapor thermal energy, created by the radiofrequency current against an inductive coil heater in the device handle, is delivered via a retractable needle and saline flush. The water vapor is delivered for 9 seconds, retracted, and then administered to another treatment site at the surgeon's discretion. The goal is to create contiguous, overlapping lesions running parallel to the natural slope of the urethra. The intervention is customized to the shape and location of the gland, including treatment of the median lobe.

Assessments

All men had baseline medical and BPH history documented. Patients completed the following validated questionnaires at baseline and 12 months following the procedure:

- The International Prostate Symptom Score (IPSS)²¹
- The International Index of Erectile Function (IIEF-15)²²
- The Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD) function and bother domains²³

PV was also measured at baseline and at 12 months using transrectal ultrasound and standard ellipsoid formula calculation. Adverse events were monitored during study follow-up.

Statistical Methods

Patient demographics and treatment characteristics were summarized using descriptive statistics. Predictors and outcomes were modeled as continuous variables to minimize loss of information that results from categorizing data. The percent reduction from baseline to 12 months in PV, and percent change in functional outcomes (IIEF-15, IPSS, MSHQ-EjD Function, and Bother) were calculated for patients with nonmissing data at baseline and 12 months. The relationship between the total number of injections and percent reduction in PV, and the injection to baseline volume ratio and percent reduction in PV were quantified using linear regression models and visualized using scatterplots. Injection to baseline volume ratio was divided by 100 for the regression analysis. The relationships between percent reduction in PV and percent improvement in functional outcomes were analyzed in the same manner. Statistical analyses were conducted using R version 4.0.0, and *P*-values less than .05 were considered statistically significant.

RESULTS

Baseline Characteristics and 12-Month Outcomes

A total of 49 men underwent the procedure between April 2019 and September 2020 with a median (interquartile range

[IQR] age of 67.4 (60.6, 72.2) years, prostate-specific antigen of 3.5 (1.7, 5.4) ng/mL, peak urinary flow (QMax) of 7.5 (4.0, 10.0) mL/s, post-void residual volume of 114 (36, 297) mL, PV of 71.5 (51.0, 95.0) cc, and 11^{8,13} total injections (Table 1). Thirty-six men (73.5%) had an injection in their median lobe.

Median changes from baseline to 12 months across functional outcome measures are presented in Table 2. The median PV at 12 months was 43 (IQR: 32, 65) cc and the median percent change in PV was -34.0% (IQR: -49.2%, -16.7%), with 45/49 (91.8%) patients overall having reduced PV.

PV and Number of Injections

Figure 1 displays the relationship between the total number of injections, injection to baseline PV ratio, and percent reduction in PV. The association between the total number of injections and percent reduction in PV (Fig. 1A, 0.92, 95% confidence interval [CI] - 1.52 to 3.37, $P = .45$), and injection to baseline PV ratio and percent reduction in PV (Fig. 1B, -0.21, 95% CI - 2.19 to 1.76, $P = .83$) were not statistically significant.

PV and Functional Outcomes

Figure 2 displays the relationship between percent reduction in PV (restricted to patients who had a reduction in PV at 12 months) and percent improvement in functional outcomes. Reduction in PV was associated with a statistically significant increase in IPSS score improvement (Fig. 2A, 0.75, 95% CI 0.14-1.36, $P = .02$). There was no statistically significant association seen for IIEF (Fig. 2B, -0.54, 95% CI - 1.21 to 0.13, $P = .11$), MSHQ-EjD Bother (Fig. 2C, -0.17, 95% CI - 2.74 to 2.40, $P = .88$), and MSHQ-EjD Function (Fig. 2D, 4.42, 95% CI - 3.06 to 11.9, $P = .23$).

DISCUSSION

Presently, there is limited evidence on the ideal number of injections administered during Rezūm therapy in patients with BPH. Additionally, it has been shown that there is a relationship between PV and treatment response in this patient population. The objective of this study was twofold: (1) to evaluate the change in PV and its relationship to symptomatic improvement following treatment with Rezūm and (2) to determine if there is an association between the number of Rezūm injections and changes in outcomes and PV. A total of 49 patients were included in this analysis, who had a median number of injections of 11.0 and median percent change in PV from baseline to 12 months of -34.0%. Of these patients, 45 (91.8%) had reduced PV at 12 months; the remaining 4 patients had increases in PV of 3%, 7%, 38%, and 44%. Among the 45 patients with reduced PV in the current study, there was a statistically significant relationship between PV reduction and decreases in the IPSS, demonstrating that for every 10% increase in PV reduction, there was a 7.5% (95% CI, 1.4%-13.6%; $P = .02$) improvement in the IPSS; however, there were no statistically significant associations between changes in PV and the other functional outcome measures (ie, IIEF, MSHQ-EjD Bother, and MSHQ-EjD). The relationships between the total number of injections or injection to

Table 1. Baseline characteristics (49 subjects).

Characteristic	
Age	
Mean (SD)	67.8 (9.4)
Median (Q1, Q3; Min, Max)	67.4 (60.6, 72.2; 50.9, 100.7)
Prostate-specific antigen, ng/mL	
Mean (SD)	4.9 (5.0)
Median (Q1, Q3; Min, Max)	3.5 (1.7, 5.4; 0.5, 26.9)
Prostate volume, cc	
Mean (SD)	73.2 (27.9)
Median (Q1, Q3; Min, Max)	71.5 (51.0, 95.0; 24, 150)
Median lobe injection n (%)	36 (73.5%)
Peak urinary flow (QMax), mL/s	
Mean (SD)	7.4 (4.3)
Median (Q1, Q3; Min, Max)	7.5 (4.0, 10.0; 0.5, 19.0)
Post-void residual volume, mL	
Mean (SD)	175.7 (166.4)
Median (Q1, Q3; Min, Max)	114 (36, 297; 0, 580)
IPSS	
Mean (SD)	21.7 (6.7)
Median (Q1, Q3; Min, Max)	22 (18, 26; 6, 31)
IPSS QoL	
Mean (SD)	4.5 (1.0)
Median (Q1, Q3; Min, Max)	5 (4, 5; 2, 6)
IIEF	
Mean (SD)	49.6 (16.1)
Median (Q1, Q3; Min, Max)	50.5 (38.5, 66.0; 15, 71)
MSHQ-EjD Bother	
Mean (SD)	2.4 (1.6)
Median (Q1, Q3; Min, Max)	3 (2, 3; 0, 5)
MSHQ-EjD Function	
Mean (SD)	8.6 (4.0)
Median (Q1, Q3; Min, Max)	9 (6, 11; 1, 15)
Number of vapor injections—Right	
Mean (SD)	4.6 (1.7)
Median (Q1, Q3; Min, Max)	4 (3, 5; 2, 11)
Number of vapor injections—Left	
Mean (SD)	4.5 (1.4)
Median (Q1, Q3; Min, Max)	5 (3, 5; 2, 9)
Number of vapor injections—Median lobe	
Mean (SD)	1.7 (1.5)
Median (Q1, Q3; Min, Max)	1 (0, 3; 0, 5)
Number of vapor injections—Center no median lobe	
Mean (SD)	0.2 (0.6)
Median (Q1, Q3; Min, Max)	0 (0, 0; 0, 3)
Total number of vapor injections	
Mean (SD)	11.0 (3.5)
Median (Q1, Q3; Min, Max)	11 (8, 13; 4, 21)

IIEF, International Index of Erectile Function; IPSS, International Prostate Symptom Score; Max, maximum; Min, minimum; MSHQ-EjD, Male Sexual Health Questionnaire for Ejaculatory Dysfunction; Q1, quartile 1; Q3, quartile 3; QoL, quality of life; SD, standard deviation.

baseline volume ratio and changes in PV were also not statistically significant.

Changes in PV and functional outcome measures following Rezūm therapy in this study were consistent with prior studies on this procedure using the traditional injection technique.^{3,6,9,24} Additionally, Aladesuru et al published a retrospective cohort (52 men) in 2022 evaluating a “less is more” treatment approach with Rezūm therapy, consisting of

Table 2. Functional outcomes at 12 months.

Outcome	12 Months Absolute	Change From Baseline
Peak urinary flow (QMax), mL/s (n = 3)	23.0 (20.4, 27.0)	13.0 (8.3, 17.0)
Post-void residual volume, mL (n = 25)	54 (11, 145)	- 84 (- 243, 0)
IPSS (n = 30)	7 (3, 13.2)	- 16 (- 20, - 9)
IPSS QoL (n = 30)	1 (0, 3)	- 3 (- 4, - 2)
IIEF (n = 19)	56.0 (39.5, 68.5)	1.0 (- 4.5, 4.8)
MSHQ-EjD Bother (n = 22)	1.5 (0, 3)	0 (0, 0)
MSHQ-EjD Function (n = 22)	8.5 (3.5, 12.8)	- 0.5 (- 3.2, 0.5)

Values are presented as median (Q1, Q3).

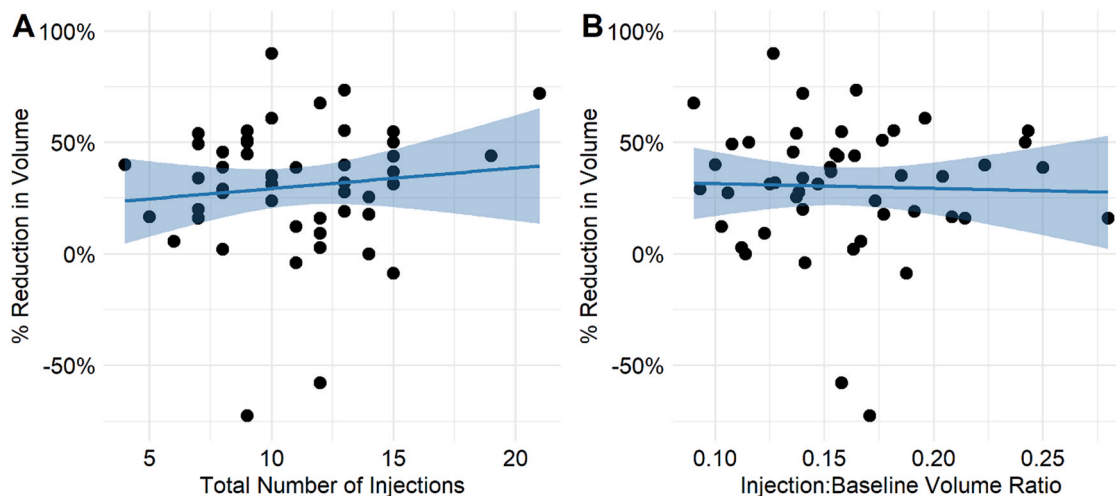


Figure 1. Relationship between percent reduction in prostate volume, (A) total number of injections and (B) injection to baseline volume ratio. (Color version available online.)

a single water vapor injection per prostate lobe.¹⁸ The authors found that this approach significantly improved IPSS scores (- 11.63 points; $P = .006$) and QMax (5.36 mL/s; $P = .008$) at 12 months postprocedure. They concluded that this method is both safe and effective, and comparable to outcomes seen following the traditional approach of multiple injections based on baseline PV. Taken together with the results of the current study, such findings indicate that more Rezūm injections do not necessarily lead to greater symptom improvement. Furthermore, though the current study provides only 12-month results, previously published trials have demonstrated that the beneficial effects of Rezūm therapy are also evident in the short-term (ie, as early as 2 weeks) and at long-term (ie, up to 5 years) follow-up visits, demonstrating rapid and durable symptom relief, including within different BPH subgroups.^{3,6,12-14,25}

The median change in PV in the current study was - 34.0%, and reduction in PV was significantly associated with IPSS score improvement. Earlier studies on this topic have demonstrated variable results.²⁶⁻³⁰ Additional research in this area is needed to determine if certain clinical or patient characteristics may influence the relationship between PV and IPSS.

Despite its merits, this current study has some limitations. These include a small sample size coupled with no comparator intervention; thus, it is unclear how the Rezūm System performs against other treatment options. Second, as treatment allocation was known by both the patient and treating physician, outcomes assessment was unblinded. Though PV is an objective outcome, IPSS, IIEF-15, and MSHQ-EjD are patient-reported measures that are subject to bias when outcomes assessment is unblinded. Third, the number of paired values available for evaluation at 12 months was low due to patient dropout, missed follow-up, or missing data points; however, these patterns reflected what occurs in typical urology practice. A strength of this study was that it demonstrated that Rezūm therapy is effective in a real-world setting and results were consistent with prior published evidence on Rezūm. Additionally, improvements were shown to be maintained at long-term follow-up (ie, 12 months). This study demonstrates that patients with BPH can achieve symptomatic relief with Rezūm therapy while reducing the risk of adverse events and healthcare resource use associated with more Rezūm injections.

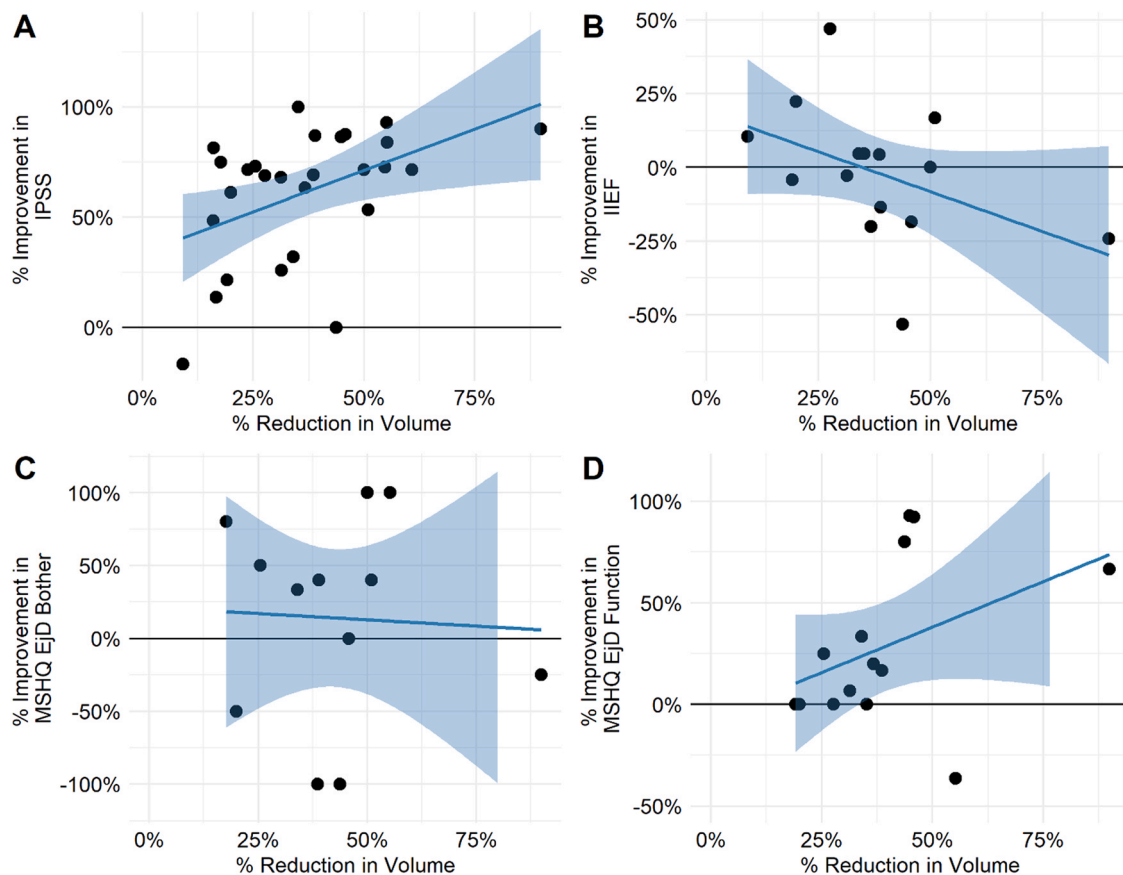


Figure 2. Relationship between percent reduction in prostate volume and percent improvement in (A) International Prostate Symptom Score, (B) International Index of Erectile Function, (C) Male Sexual Health Questionnaire for Ejaculatory Dysfunction Bother, and (D) Male Sexual Health Questionnaire for Ejaculatory Dysfunction Function. (Color version available online.)

CONCLUSION

In this cohort of patients treated with Rezūm convective water vapor thermal therapy for BPH, it was demonstrated that there is a correlation between greater PV reduction and greater symptomatic improvement. Additionally, this study showed no association between more injections or the ratio of injections to PV changes, refuting the claim that more injections are better.

DECLARATION OF COMPETING INTEREST

Drs. Elterman, Bhojani, Chughtai, Zorn are consultants for Boston Scientific.

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