Rezum therapy for patients with large prostates (≥ 80 g): initial clinical experience and postoperative outcomes

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Abstract
Purpose Rezum is a minimally invasive surgery for benign prostatic hyperplasia. Current guidelines recommend Rezum for prostates < 80 cc, but little data exist describing outcomes in patients with prostates ≥ 80 cc. We compare outcomes after Rezum between men with small < 80 cc (SP) and large ≥ 80 cc prostates (LP).
Methods Patients undergoing Rezum between Jan 2017–Feb 2020 were subdivided by prostate volume (< 80, ≥ 80 cc). Outcomes were documented pre- and postoperatively. Descriptive analyses of urodynamics data (Qmax, PVR), symptom scores (AUA-SS, SHIM), disease management (medications, catheterization, retreatments), and clinical outcomes were conducted.
Results 36 (17.6%) men had prostates ≥ 80 cc (LP mean prostate size 106.8 cc). LP men had improved Qmax and PVR postoperatively; those with longitudinal follow-up exhibited improved Qmax, PVR, and AUA-SS. After one year, alpha-blocker usage decreased significantly (LP 94.44–61.11%, p = 0.001, SP 73.96–46.15%, p = 0.001); other medication usage and self-catheterization rates remained unchanged. Compared to SP patients, differences in passing trial void (LP 94.44%, SP 93.45%), postoperative UTI (LP 19.44%, SP 10.12%), ED visits (LP 22.22%, SP 17.86%), readmissions (LP 8.33%, SP 4.76%), and retreatment (LP 8.33%, SP 4.76%) were insignificant. However, mean days to foley removal (LP 9, SP 5.71, p = 0.003) and urosepsis rates (LP 5.56%, SP 0.00%, p = 0.002) differed.
Conclusion In select LP patients, Rezum provided short-term symptomatic relief and improved voiding function comparable to SP patients. Postoperatively, though alpha-blocker usage decreased significantly, use of other medications did not change, and nearly two-thirds of patients still needed alpha-blockade. Further efforts should explore the possibility of expanding Rezum’s inclusion criteria.

Keywords Rezum · Transurethral radiofrequency thermal ablation · Benign prostatic hyperplasia · Lower urinary tract symptoms

Introduction
Symptomatic benign prostatic hyperplasia (BPH) presents clinically when the enlarged prostate and increased prostatic smooth muscle tone compress the prostatic urethra, causing bladder outlet obstruction with ensuing lower urinary tract symptoms (LUTS) ranging from urinary storage to voiding issues [1]. Chronic obstruction can cause acute urinary retention (AUR), urinary tract infection (UTI), bladder stones, and renal failure. BPH-associated LUTS are burdensome on quality of life for many men and are predicted to climb as the population ages [2]. Emerging minimally invasive surgical treatments (MISTs) offer the possibility of symptom improvement when medical or traditional surgical interventions fail.

Several procedures are available to manage BPH surgically. Recently developed MISTs such as convective water vapor thermal therapy (Rezum System, NxThera Inc., Maple Grove, MN, USA) offer effective treatment of BPH while minimizing sexual side effects, anesthetic needs, lengthy hospitalizations, and other inherent risks of more-invasive approaches [3–9]. Rezum utilizes heated steam injections within the prostatic transition zone to thermally ablate hyperplastic tissue while limiting treatment to targeted areas,
representing an evolution of thermal ablative techniques like transurethral needle ablation and microwave therapy [10–12]. Several studies have demonstrated long-term reduction of LUTS and improved urinary flow metrics following Rezum [5–7, 13].

Although Rezum is attractive for these reasons, it is currently only recommended for prostates < 80 cc (i.e., small prostates, SP), whereas the suggested treatment options for prostate glands ≥ 80 cc (i.e., large prostates, LP) include laser enucleation procedures or simple prostatectomy [14]. However, Rezum can theoretically also be a viable option for men with LP, though this is a largely unexplored area of interest. Bole et al. recently published the first report on the use of Rezum for prostates ≥ 80 cc, preliminarily demonstrating its short-term safety and efficacy for LP men [15].

Further data are required to understand the outcomes of Rezum in this expanded population and how they compare to those currently eligible for Rezum. To this end, we present our institutional experience with Rezum for symptomatic BPH in men with prostates ≥ 80 cc and compare their outcomes to men with prostates < 80 cc.

Materials and methods

Rezum delivers thermal energy to prostatic tissue via radio frequency-generated convective water vapor, inducing prostatic ablation. Energy is delivered in 9 s bursts to either lateral prostatic lobe or the median prostatic lobe in varying quantities, depending on patient pathology.

All patients were counseled on Rezum preoperatively and expectations were managed accordingly. LP patients were informed that Rezum for prostates ≥ 80 cc is not recommended by AUA guidelines; still, most elected to proceed with Rezum due personal preferences for a less invasive procedure, an alternative to further medical management, and a desire to mitigate risk of sexual side effects associated with alternative treatment options (i.e., retrograde ejaculation, erectile dysfunction).

In Rezum for LP patients, the same safety principles are followed including avoiding the bladder neck, ureteral orifices, and ejaculatory ducts. The technique for large gland Rezum requires more thermal energy deliverance. Thus, a minimum of ~1 treatment/10 cc of prostate tissue is recommended (i.e., 100 cc prostate should require ≥ 10 treatments). Procedures are often performed as outpatient utilizing conscious sedation, monitored anesthesia care, or modified prostatic nerve blocks for analgesia. Patients require postoperative catheterization, with scheduled follow-up typically 3–7 days later. A subset of these LP Rezums should have prolonged catheterization of ≥ 2 weeks.

This retrospective analysis was IRB approved. 206 patients who underwent Rezum between Jan 2017–Feb 2020 at our institution were queried from an internal database. Patients were subdivided based on preoperative prostate size, as determined via MRI, CT scan, or transrectal ultrasound. Two patients were subsequently excluded: one prematurely aborted his procedure due to discomfort; another had undergone two Rezums within a four-month timeframe and patient records could not delineate which outcomes were attributable to either procedure.

For the remaining 204 patients, the following data were recorded: patient age and BMI, number of total and median lobe injections, pre- and post-operative BPH management (i.e., medication regimens and instances of self-catheterization ≤ 1 year before and after surgery, past and subsequent procedures), pre- and post-operative clinical metrics of disease, and post-operative clinical outcomes. Clinical metrics included prostate size, extent of intravesicular prostate protrusion (IPP, in mm), AUA-Symptom Score (AUA-SS), Sexual Health Inventory for Men (SHIM) questionnaire score, maximum flow rate (Qmax), post-void residual volume (PVR), and total prostate specific antigen (PSA) levels. Clinical outcomes included trial void evaluation (TOV), nausea, vomiting, fever, hematuria, hematospermia, urgency, frequency, AUR, clot retention, bladder spasms, erectile dysfunction, UTI, and details of emergency department (ED) visits and/or readmissions within 90 days.

In cases where multiple data points were available for metrics of disease, we used data furthest removed from the procedure to best evaluate for long-term outcomes. For each metric we report postoperative day of follow-up (POD) with median and interquartile range (IQR).

Analyses were performed using IBM SPSS Statistics 26.0 (IBM, Armonk, NY, USA). Descriptive analyses, tests of normality, and group comparisons through Mann–Whitney U tests for nonparametric samples, Wilcoxon signed-rank tests for continuous variables, and χ² tests for categorical variables were conducted utilizing a two-tailed alpha of 0.05.

Results

36/204 patients (17.65%) had prostates ≥ 80 cc (mean 106.8 cc) (Table 1a). LP men were significantly older (LP 67.31, SP 65.41, p = 0.021), and more likely to have a history of intermittent catheterization (LP 22.22%, SP 5.95%, p = 0.002) and prostate cancer (LP 8.33%, SP 1.18%, p = 0.038); there were no significant differences in BMI, baseline PSA, or IPP. Neither group had a significantly greater history of BPH surgery, nor were they more prone to surgical retreatment after Rezum (Table 1b). The difference in mean time to retreatment was statistically insignificant between groups (LP 367 days, SP 364 days, p = 0.909).
LP men, on average, received more total (LP 9.61, SP 4.76, \(p = 5.30E-13\)) and median lobe injections (LP 2.06, SP 1.14, \(p = 1.04E-11\)) (Table 1c). Four LP procedures surpassed the standard 15 maximum treatments (16, 16, 17, and 18 injections).

Analyzing LP men as a whole, significant improvements were seen in postoperative measurement of Qmax (7.39–14.60, \(p = 0.039\)) and PVR (161.09–80.85, \(p = 0.009\)), but not in AUA-SS (15.22–12.46, \(p = 0.29\)) nor SHIM (14.00–12.80, \(p = 0.825\)). In contrast, SP men showed improved PVR (89.51–62.72, \(p = 0.027\)) and AUA-SS (16.59–11.21, \(p = 0.003\)), but not in Qmax (9.47–10.90, \(p = 0.187\)) (Table 2a). Longitudinally, both cohorts showed significant improvements in all clinical metrics of disease, including Qmax (LP: + 11.46, \(p = 0.001\); SP: + 1.86, \(p = 0.025\)), PVR (LP: − 78.73, \(p = 0.001\); SP: − 28.52, \(p = 0.001\)), and AUA-SS (LP: − 7.71, \(p = 0.027\); SP: − 3.31, \(p = 0.013\)) (Table 2b). Additionally, when comparing longitudinal improvements head-to-head, changes in Qmax and PVR were significantly more profound for LP men (\(p = 0.004\) and 0.024, respectively), while average longitudinal changes in AUA-SS were not significantly different between groups (\(p = 0.296\)). Remaining analysis of overall and longitudinal SHIM scores was hindered by limited data.

In the 25% of LP men and 8.3% of SP men with postoperative imaging, prostate size decreased by 10.4 and 14%, respectively, though these were statistically insignificant (LP: \(p = 0.779\), SP: \(p = 0.333\)). Both cohorts significantly decreased alpha-blocker (AB) usage postoperatively (LP: 94.44–61.11%; SP: 73.96–46.15%, both \(p = 0.001\)), with insignificant changes in 5-alpha reductase inhibitor (5ARi) and phosphodiesterase-5 inhibitors.

### Table 1

Characteristics and surgical details of Rezum performed at a single institution between Jan 2017–Feb 2020.

(A) Baseline patient characteristics

|                      | Small prostate (N=168) | Large prostate (N=36) | \(p^d\) |
|----------------------|------------------------|-----------------------|---------|
| Mean (SD)            | Range                  | Mean (SD)             | Range   |         |
| Age (years)          | 65.41 (9.05)           | (43, 85)              | 67.31 (7.17) | (54, 82) | 0.021 |
| BMI                  | 27.71 (5.21)           | (17.59, 45.71)        | 26.23 (3.42) | (18.65, 33.02) | 0.129 |
| Pre-op prostate size (cc) | 45.33 (14.53) | (9.4, 78.6)           | 106.77 (37.57) | (80, 276) | 2.80E-05 |
| Pre-op total PSA     | 2.67 (3.42)            | (0.07, 23.2)          | 5.63 (3.79) | (1.05, 13.7) | 0.056 |
| Intravesicular prostatic protrusion (mm) | 9.74 (4.29) | (0, 17.1)           | 9.08 (6.11) | (0, 13) | 0.364 |
| **N (%)**            |                        |                       |         |         |
| History Prostate Cancer | 2 (1.19%)       |                       | 3 (8.33%) |         | 0.038 |
| History Intermittent Catheterization | 10 (5.95%) |                       | 8 (22.22%) |         | 0.002 |

(B) BPH surgical history + follow-up

|                      | N (%) | \(p^e\) |
|----------------------|-------|---------|
| Prior BPH surgery     | 11 (6.55%) | 2 (5.56%) | 0.825 |
| TURP                 | 2 (1.19%) | 1 (2.78%) |         |
| Prostatic arterial Embolization | 0 (0.00%) | 1 (2.78%) |         |
| UroLift^b             | 4 (2.38%) | 0 (0.00%) |         |
| Transurethral microwave Therapy | 3 (1.79%) | 0 (0.00%) |         |
| Greenlight            | 1 (0.60%) | 0 (0.00%) |         |
| Transurethral needle Ablation | 1 (0.60%) | 0 (0.00%) |         |
| Follow-up BPH surgery | 8 (4.76%) | 3 (8.33%) | 0.293 |
| TURP                 | 6 (3.57%) | 2 (5.56%) |         |
| Greenlight            | 0 (0.00%) | 1 (2.78%) |         |
| Rezum                 | 1 (0.60%) | 0 (0.00%) |         |
| RALP                  | 1 (0.60%) | 0 (0.00%) |         |

(C) Procedure details

|                      | Mean (SD) | Range | Mean (SD) | Range | \(p^c\) |
|----------------------|-----------|-------|-----------|-------|---------|
| Total injections     | 4.76 (1.79) | (2, 10) | 9.61 (3.99) | (3, 18) | 5.30E-13 |
| Median lobe injections | 1.14 (0.47) | (0, 2) | 2.06 (1.39) | (0, 6) | 1.04E-11 |

Patients sub-divided as small prostate (i.e., prostate volume < 80 cc) and large prostate (prostate volume ≥ 80 cc)

\(^a\) Baseline characteristics of patient cohort, \(^b\) BPH-related surgical history and follow-up of patients, \(^c\) Surgical details of Rezum procedures performed

\(^d\) Denotes \(p\) values derived from Mann–Whitney U tests

\(^e\) Denotes \(p\) values derived from \(\chi^2\) tests
|                              | Small prostate (N=168) | Large prostate (N=36) |
|------------------------------|------------------------|-----------------------|
| (A) Urological parameters of all patients |                        |                        |
| **Max flow rate (Qmax)** |                        |                        |
| Pre-op                      | 128 (75.74%)           | 27 (75.00%)           |
| Post-op                     | 75 (44.64%)            | 21 (58.33%)           |
| **Post-void residual volume (PVR)** |                    |                        |
| Pre-op                      | 148 (87.57%)           | 32 (88.89%)           |
| Post-op                     | 142 (84.52%)           | 33 (91.67%)           |
| **AUA-Symptom Score (AUA-SS)** |                    |                        |
| Pre-op                      | 64 (37.87%)            | 18 (50.00%)           |
| Post-op                     | 38 (22.62%)            | 13 (36.11%)           |
| **Sexual health inventory for men (SHIM) score** |                    |                        |
| Pre-op                      | 27 (15.98%)            | 8 (22.22%)            |
| Post-op                     | 0 (0.00%)              | 5 (13.89%)            |
| (B) Urological parameters of patients with longitudinal follow-up |              |                        |
| **Max flow rate (Qmax)** |                        |                        |
| Pre-op                      | 68 (40.48%)            | 13 (36.11%)           |
| Post-op                     | 128 (75.74%)           | 30 (83.33%)           |
| **AUA-symptom score (AUA-SS)** |                    |                        |
| Pre-op                      | 32 (19.05%)            | 7 (19.44%)            |
| (C) Medication utilization rates |                        |                        |
| Alpha-blocker               | 125 (73.96%)           | 34 (94.44%)           |
| 5-Alpha reductase Inhibitor | 30 (17.75%)            | 15 (41.67%)           |
| Anti-spasmodic              | 17 (10.06%)            | 5 (13.89%)            |
| Phosphodiesterase-5 Inhibitor | 10 (5.92%)        | 5 (13.89%)            |
| (D) Clinical outcomes Small prostate (N%) |              |                        |
| **Trial void evaluation** |                        |                        |
| Passed                      | 157 (93.45%)           | 30 (17.86%)           |
| Failed                      | 11 (6.55%)             | 8 (22.22%)            |
| **Post-op complications** |                        |                        |
| No documented complications | 44 (26.19%)            | 2 (1.19%)             |
| Urgency                     | 51 (30.36%)            | 3 (1.79%)             |
| Hematuria                   | 66 (39.29%)            | 2 (1.19%)             |
| Frequency                   | 52 (30.95%)            | 1 (0.60%)             |
| **Large prostate (N%)**    | 34 (94.44%)            | 22 (61.11%)           |
| **Post-op N (%)**           | 7 (4.14%)              | 5 (13.89%)            |
| **Frequency**               | 13 (36.11%)            | 5 (13.89%)            |
| **Urgency**                 | 61 (37.87%)            | 15 (41.67%)           |
| **Phosphodiesterase-5 Inhibitor** |            | 5 (13.89%)            |
| **Hematuria**               | 27 (16.77%)            | 5 (13.89%)            |
inhibitor (PDE5i) use (Table 2c). Anti-spasmodic (AS) usage did not change for LP patients (13.89–16.67%, $p = 0.705$), but significantly increased for SP patients (10.06–18.34%, $p = 0.011$). Changes in catheterization rates after Rezum were statistically insignificant for both groups.

Table 2d shows postoperative clinical outcomes. Though both groups passed TOV at similar rates (LP: 94.44%, SP: 93.45%, $p = 0.699$), LP patients did so at a significantly later date (LP: POD 9, SP: POD 5.71, $p = 0.003$). Aside from urgency (LP: 50.00%, SP: 30.36%, $p = 0.024$), there were no differences in rates of minor postoperative complications within one month of surgery. Both groups exhibited similar rates of postoperative UTIs, ED visits, and readmissions within 90 days; however, sub-analysis of urosepsis-related readmissions found statistically significant differences between groups (LP: 5.56%, SP: 0.00%, $p = 0.002$). On average, neither group visited the ED (LP: POD 7.75 vs. SP: POD 16.4, $p = 0.379$) or was readmitted (LP: POD 8 vs. SP: POD 30.5, $p = 0.309$) sooner, and differences in readmission lengths were similarly insignificant (LP: 2.67 vs. SP: 5.50 days, $p = 0.729$). Neither group experienced a Clavien grade ≥ III complication.

**Discussion**

Rezum’s clinical trial found that, between 3 and 48 months postoperatively, patients demonstrated sustained symptomatic relief related to LUTS, incontinence, and overactive bladder, as well as consistent improvements in Qmax. Furthermore, in sexually active patients, no changes in erectile or ejaculatory function were noted at similar intervals [4–7]. Additionally, Rezum touts a minimally invasive and simple option for managing BPH-related symptoms that is more cost-effective than similar MISTs like the UroLift® System (i.e., prostatic urethral lift) [16]. As such, it is not surprising that Rezum has been rapidly adopted as a key component of the urologist’s armamentarium.

This series represents the second study documenting outcomes of patients with large (≥ 80 cc) prostates following Rezum. Bole et al. reported 3 months outcomes in LP patients who underwent Rezum [15]. For the present study, of the 36 patients that met inclusion criteria, mean preoperative prostate size was 106.8 cc, 22% were catheter-dependent at the time of procedure, and 97% were being managed medically with AB, 5ARi, AS, PDE5i, or some combination thereof.

This analysis presents a conflicting picture on the efficacy and safety of Rezum for large prostates. Consistent with Bole et al.’s findings, in the subset of LP patients with sufficient follow-up, the observed changes in metrics of disease suggest that LP patients can experience symptomatic relief and improved voiding after Rezum. Further, median follow-up
for these metrics exceeded 90 days, offering a glimpse at potential durability of these improvements. Conversely, Rezum did not significantly reduce rates of intermittent catheterization, which contrasts Bole et al.’s findings [15].

This is also the first study to report on the medical management of LP men after Rezum. Our findings suggest that, for these patients, Rezum can aid in reducing reliance on AB, but ultimately is unlikely to do so for other medication classes. Yet still, nearly two-thirds these patients continued to take daily AB after Rezum, lying in contrast to Molliengarten et al.’s retrospective study of a single surgeon’s experience which demonstrated that 89.9% of patients—with an average prostate volume of 52.6 cc (max 85.9 cc)—ceased pharmacological management after undergoing Rezum [17]. Although LP men exhibited a 5.49% greater decrease in AB usage compared to SP men, the data presented contradicts the notion that Rezum may effectively lower the burden of polypharmacy and its accompanying side effects in patients with large prostates [18].

Rezum did not significantly decrease prostate size for either cohort, which contrasts previously reported findings of reductions in prostate volume approaching 30% within 6 months after Rezum [19]. However, this conclusion is limited by the small sample (LP 25%, SP 8.3%) of patients that were reimaged postoperatively.

The favorable sexual side effect profile associated with Rezum is an oft-cited advantage when evaluating BPH surgical options [9]. Multiple studies have reported no changes in sexual or ejaculatory function at long-term follow-up [7, 11, 13], while smaller retrospective series have described retrograde ejaculation in 3–6% of patients [17]. However, the limited SHIM data available hinders the conclusions that can be drawn regarding sexual function in LP men after Rezum.

Our retreatment data appears consistent with the existing body of literature for BPH-related surgeries. Our SP retreatment rate of 4.76% is similar to the two- and four-year retreatment rates reported in Rezum’s original clinical trial (3.7 and 4.4%, respectively) [5, 7]. Moreover, though our LP cohort had a higher retreatment rate (8.33%), it is not uncommon for retreatment rates to increase for patients with larger prostates. In their analysis of outcomes after Greenlight therapy, Pfitzenmaier et al. report retreatment rates of 10.4 and 23.1% for patients with prostates <80 and ≥80 cc, respectively [20]. Meanwhile, Shah et al. reported retreatment after UroLift was 10% for SP men and 13% for LP men (median time to reintervention: 289 days) [21]. For broader context on retreatment after BPH MISTs, UroLift’s original clinical trial had a two-year retreatment rate of 7.5%, while retreatments following prostatic arterial embolization have approached 20% [22, 23]. Conversely, a recent study of AquaBeam® aquablation reported a one-year retreatment rate of 1.7%, and one-year retreatment rates of TURP can range between 0–5.8% [24, 25]. A caveat to our findings is the possibility that our retreatments are underestimated due to interruptions in patient follow-up resulting from the COVID-19 pandemic.

Postoperative complications reported in this study largely agree with previous analyses of Rezum. Clavien–Dindo grade I/II complications such as AUR, dysuria, hematuria, urgency and UTI have been recorded anywhere between 3–33.8% for patients with prostates <80 cc; aside from slightly higher rates of urgency and hematuria (both 50%) in our LP cohort, these are largely comparable with our overall institutional experience [3, 4, 6, 11]. Further, the LP cohort’s readmission rate for IV antibiotics was higher in this study than previously reported for large prostates (8.3 vs 2.1%); however, all three patients were discharged within 4 days of admission and recovered fully. Additionally, no patients in this study experienced Clavien–Dindo grade III/IV complications, whereas previous studies have reported up to a 3.8% occurrence [3].

Interestingly, though there were no differences in UTI rates, LP patients were at a higher risk for urosepsis after Rezum. Of the two men, one had a concomitant history of bladder stones, and his urosepsis-related readmission occurred 7 days after he underwent cystoscopy with unsuccessful removal of an 8 mm bladder stone, which likely elevated his risk for readmission. LP men may be at increased risk for this complication due to their prolonged Foley placement. However, this may warrant preoperative urine cultures or more extensive antibiotic prophylaxis. For comparison, Rezum’s original clinical trial’s 2 years follow-up reported one case of urosepsis in a sample of 197 men [5].

This study is not without limitations. The retrospective design adds selection bias that may underestimate negative outcomes. In addition, there is variability in patient follow-up, many of whom have incomplete or missing data; in particular, there were insufficient measurements of prostate median lobe size to sufficiently analyze any impact this pathology may have on outcomes and responsiveness to Rezum. Furthermore, given that a minority of patients followed-up at regularly scheduled intervals, the longitudinal data is limited. Retreatment rates may also have been underreported due to the cancelation of planned subsequent procedures by the COVID-19 pandemic. The sample size of our LP cohort is small, making it difficult to draw large conclusions from this data. This highlights the need for future prospective studies with larger cohorts and more complete data to further elucidate Rezum outcomes for patients with large prostates.

**Conclusion**

This study evaluated outcomes after Rezum for men with prostates ≥ 80 cc compared to patients with prostates <80 cc. For select patients with sufficient longitudinal follow-up, we
found that Rezum effectively improved Qmax and PVR in patients with large prostates while offering short-term symptomatic relief and reducing the need for AB usage post-operatively. Rates of postoperative complications were largely comparable between groups, though men with large prostates were at increased risk for urosepsis. Further investigation is necessary to explore the potential to expand inclusion criteria for Rezum.

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Compliance with ethical standards

Conflict of interest Dr. Steven A. Kaplan is a consultant for Boston Scientific.

Ethics approval This study was approved by the Institutional Review Board at the Icahn School of Medicine at Mount Sinai.

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