World Journal of Urology (2021) 39:3041–3048
https://doi.org/10.1007/s00345-020-03548-7

ORIGINAL ARTICLE

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

Evan B. Garden[1] · Devki Shukla[1] · Krishna T. Ravivarapu[1] · Steven A. Kaplan[1] · Avinash K. Reddy[1] · Alexander C. Small[1] · Michael A. Palese[1]

Received: 1 July 2020 / Accepted: 30 November 2020 / Published online: 3 January 2021

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,

✉ Michael A. Palese
Michael.Palese@mountsinai.org

[1] Department of Urology, Icahn School of Medicine At Mount Sinai, One Gustave Levy Place, Box 1272, New York, NY 10029, USA

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 prostatic 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 χ^2 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, $p = 0.909$).

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 protrustion (mm)	9.74 (4.29)	(0, 17.1)	9.08 (6.11)	(0, 13)	0.364
	N (%)		*N* (%)		p^e
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* (%)		*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®		4 (2.38%)		0 (0.00%)	
Transurethral microwave Therapy		3 (1.79%)		0 (0.00%)	
Grenlight		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^a
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 χ^2 tests

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 phosphodiesteriase-5

Table 2 Functional and clinical outcomes of patients who underwent Rezum at a single institution between Jan 2017–Feb 2020

Small prostate ($N=168$)						Large prostate ($N=36$)					
(A) Urological parameters of all patients	*N* (%)	Mean (SD)	Range	POD Follow-Up (Median, IQR)	*p**	A) Urological parameters of all patients	*N* (%)	Mean (SD)	Range	POD Follow-Up (Median, IQR)	*p**
Max flow rate (Qmax)						Max flow rate (Qmax)					
Pre-op	128 (75.74%)	9.47 (5.08)	(1.5, 31)	–	–	Pre-op	27 (75.00%)	7.39 (5.57)	(2, 26)	–	–
Post-op	75 (44.64%)	10.90 (6.41)	(3, 34.3)	135 (59.5, 278.5)	0.187	Post-op	21 (58.33%)	14.60 (13.32)	(1.5, 50)	247 (111, 380)	0.039
Post-void residual volume (PVR)						Post-void residual volume (PVR)					
Pre-op	148 (87.57%)	89.51 (106.95)	(0, 640)	–	–	Pre-op	32 (88.89%)	161.09 (140.98)	(0, 550)	–	–
Post-op	142 (84.52%)	62.72 (88.86)	(0, 535)	92.5 (30, 208.25)	0.019	Post-op	33 (91.67%)	80.85. (78.83)	(0, 358)	167 (91, 348)	0.009
AUA-Symptom Score (AUA-SS)						AUA-symptom score (AUA-SS)					
Pre-op	64 (37.87%)	16.59 (6.84)	(2, 30)	–	–	Pre-op	18 (50.00%)	15.22 (5.79)	(2, 25)	–	–
Post-op	38 (22.62%)	11.21 (7.30)	(2, 29)	167.5 (110, 263)	0.003	Post-op	13 (36.11%)	12.46 (6.49)	(0, 21)	147 (72, 259)	0.29
Sexual health inventory for men (SHIM) score						Sexual health inventory for men (SHIM) score					
Pre-op	27 (15.98%)	15.15 (7.83)	(0, 25)	–	–	Pre-op	8 (22.22%)	14.00 (8.78)	(3, 25)	–	–
Post-op	0 (0.00%)	–	–	–	–	Post-op	5 (13.89%)	12.80 (7.36)	(3, 19)	461 (34, 678)	0.825

(B) Urological parameters of patients with longitudinal follow-up	*N* (%)	Mean (SD)	Range	*p*^b	(B) Urological parameters of patients with longitudinal follow-up	*N* (%)	Mean (SD)	Range	*p*^b
Max flow rate (Qmax)	68 (40.48%)	+1.86 (6.35)	(− 15.3, +19.2)	0.025	Max flow rate (Qmax)	13 (36.11%)	+11.46 (14.12)	(+0.3, +42.5)	0.001
Post-void residual volume (PVR)	128 (75.74%)	− 28.52 (107.51)	(− 414, +282)	0.001	Post-void residual volume (PVR)	30 (83.33%)	− 78.73 (120.54)	(− 392, +210)	0.001
AUA-symptom score (AUA-SS)	32 (19.05%)	− 3.31 (7.85)	(− 22, +10)	0.013	AUA-symptom score (AUA-SS)	7 (19.44%)	− 7.71 (+8.10)	(− 22, 0)	0.027

(C) Medication utilization rates	Pre-op *N* (%)	Post-op *N* (%)	*p*^c	(C) Medication utilization rates	Pre-op *N* (%)	Post-op *N* (%)	*p*^c
Alpha-blocker	125 (73.96%)	78 (46.15%)	0.001	Alpha-blocker	34 (94.44%)	22 (61.11%)	0.001
5-Alpha reductase Inhibitor	30 (17.75%)	22 (13.02%)	0.059	5-Alpha reductase Inhibitor	15 (41.67%)	10 (27.78%)	0.096
Anti-spasmodic	17 (10.06%)	31 (18.34%)	0.011	Anti-spasmodic	5 (13.89%)	6 (16.67%)	0.705
Phosphodiesterase-5 Inhibitor	10 (5.92%)	7 (4.14%)	0.317	Phosphodiesterase-5 Inhibitor	5 (13.89%)	5 (13.89%)	1.000

(D) Clinical outcomes	Small prostate *N* (%)	Large prostate *N* (%)	*p*^c	(D) Clinical outcomes	Small prostate *N* (%)	Large prostate *N* (%)	*p*^c
Trial void evaluation				ED visits—90 days	30 (17.86%)	8 (22.22%)	0.542
Passed	157 (93.45%)	34 (94.44%)	0.699	Urinary retention	16 (9.52%)	4 (11.11%)	–
Failed	11 (6.55%)	2 (5.56%)		Fever	3 (1.79%)	2 (5.56%)	–
Post-op complications				Clot retention	2 (1.19%)	1 (2.78%)	–
No documented complications	44 (26.19%)	6 (16.67%)	0.228	Chest pain	1 (0.60%)	1 (2.78%)	–
Urgency	51 (30.36%)	18 (50.00%)	0.024	Dysuria	3 (1.79%)	0 (0.00%)	–
Hematuria	66 (39.29%)	18 (50.00%)	0.236	Urine leakage	2 (1.19%)	0 (0.00%)	–
Frequency	52 (30.95%)	13 (36.11%)	0.547	Malaise	1 (0.60%)	0 (0.00%)	–

Table 2 (continued)

(D) Clinical outcomes	Small prostate *N* (%)	Large prostate *N* (%)	p^c	(D) Clinical outcomes	Small prostate *N* (%)	Large prostate *N* (%)	p^c
Bladder spasms	41 (24.40%)	11 (30.56%)	0.442	Sore throat	1 (0.60%)	0 (0.00%)	–
Dysuria	39 (23.21%)	9 (25.00%)	0.819	Testicular pain	1 (0.60%)	0 (0.00%)	–
Retention	36 (21.43%)	7 (19.44%)	0.791	Readmissions—90 days	8 (4.76%)	3 (8.33%)	0.389
Erectile dysfunction	3 (1.79%)	2 (5.56%)	0.184	Urosepsis	0 (0.00%)	2 (5.56%)	0.002
Fever	7 (4.17%)	3 (8.33%)	0.293	Urinary tract infection	4 (2.38%)	1 (2.78%)	–
Clot retention	3 (1.79%)	1 (2.78%)	0.697	COPD exacerbation	1 (0.60%)	0 (0.00%)	–
Hematospermia	4 (2.38%)	0 (0.00%)	0.350	COVID-19 infection	1 (0.60%)	0 (0.00%)	–
Nausea/vomiting	0 (0.00%)	0 (0.00%)	–	Hematuria	1 (0.60%)	0 (0.00%)	–
Post-op urinary tract infections	17 (10.12%)	7 (19.44%)	0.115	Urinary retention	1 (0.60%)	0 (0.00%)	–

Patients sub-divided as small prostate (i.e., prostate volume < 80 cc) and large prostate (prostate volume ≥ 80 cc). *a* Average measurements of urological parameters for all patients with pre- and postoperative records, *b* Average measurements of urological parameters for all patients with longitudinal follow-up from pre- and postoperative records, *c* Medication utilization rates for patients before and after Rezum, *d* Postoperative clinical outcomes of all patients

[a]Denotes *p* values derived from Mann–Whitney *U* tests. [b] denotes *p* values derived from Wilcoxon Rank Sum tests. [c] denotes *p* values derived from χ^2 tests

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 an 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 Mollengarten et al.'s retrospective study of a single surgeon's experience which demonstrated that 89.5% 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 prostatic 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.

Acknowledgements We would like to acknowledge the following Urologists at the Icahn School of Medicine at Mount Sinai for graciously allowing us to present their patients as part of this research project: Dr. Norman Coleburn, Dr. Mantu Gupta, Dr. Susan Marshall, Dr. Jay Motola, Dr. Craig Nobert, Dr. Rajveer Purohit, Dr. Ardeshir Rastinehad, and Dr. Sovrin Shah.

Author contributions Each person listed as an author has fulfilled the criteria for authorship established by the International Committee of Medical Journal Editors. EBG–protocol/project development, data collection, data analysis, manuscript writing/editing. DS–protocol/project development, data collection, data analysis, manuscript writing/editing. KTR–protocol/project development, data collection, data analysis, manuscript writing/editing. SAK–protocol/project development, data collection, manuscript writing/editing. AR–protocol/project development, data collection, manuscript writing/editing. ACS–protocol/project development, data collection, data analysis, manuscript writing/editing. MAP–protocol/project development, data collection, data analysis, manuscript writing/editing.

Funding This study was performed in its entirety at the Icahn School of Medicine at Mount Sinai. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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.

References

1. Foster HE, Barry MJ, Dahm P, Gandhi MC, Kaplan SA, Kohler TS, Lerner LB, Lightner DJ, Parsons JK, Roehrborn CG, Welliver C, Wilt TJ, McVary KT (2018) Surgical management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA guideline. J Urol 200(3):612–619. https://doi.org/10.1016/j.juro.2018.05.048
2. Girman CJ, Jacobsen SJ, Tsukamoto T, Richard F, Garraway WM, Sagnier PP, Guess HA, Rhodes T, Boyle P, Lieber MM (1998) Health-related quality of life associated with lower urinary tract symptoms in four countries. Urology 51(3):428–436. https://doi.org/10.1016/s0090-4295(97)00717-6
3. Dixon C, Cedano ER, Pacik D, Vit V, Varga G, Wagrell L, Tornblom M, Mynderse L, Larson T (2015) Efficacy and safety of Rezūm system water vapor treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia. Urology 86(5):1042–1047. https://doi.org/10.1016/j.urology.2015.05.046
4. McVary KT, Gange SN, Gittelman MC, Goldberg KA, Patel K, Shore ND, Levin RM, Rousseau M, Beahrs JR, Kaminetsky J, Cowan BE, Cantrill CH, Mynderse LA, Ulchaker JC, Larson TR, Dixon CM, Roehrborn CG (2016) Minimally invasive prostate convective water vapor energy ablation: a multicenter, randomized, controlled study for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia. J Urol 195(5):1529–1538. https://doi.org/10.1016/j.juro.2015.10.181
5. Roehrborn CG, Gange SN, Gittelman MC, Goldberg KA, Patel K, Shore ND, Levin RM, Rousseau M, Beahrs JR, Kaminetsky J, Cowan BE, Cantrill CH, Mynderse LA, Ulchaker JC, Larson TR, Dixon CM, McVary KT (2017) Convective thermal therapy: durable 2 year results of randomized controlled and prospective crossover studies for treatment of lower urinary tract symptoms due to benign prostatic hyperplasia. J Urol 197(6):1507–1516. https://doi.org/10.1016/j.juro.2016.12.045
6. McVary KT, Roehrborn CG (2018) Three-year outcomes of the prospective, randomized controlled Rezūm system study: convective radiofrequency thermal therapy for treatment of lower urinary tract symptoms due to benign prostatic hyperplasia. Urology 111:1–9. https://doi.org/10.1016/j.urology.2017.10.023
7. McVary KT, Rogers T, Roehrborn CG (2019) Rezūm water vapor thermal therapy for lower urinary tract symptoms associated with benign prostatic hyperplasia: 4 year results from randomized controlled study. Urology 126:171–179. https://doi.org/10.1016/j.urology.2018.12.041
8. McVary KT, Gange SN, Gittelman MC, Goldberg KA, Patel K, Shore ND, Levin RM, Rousseau M, Beahrs JR, Kaminetsky J, Cowan BE, Cantrill CH, Mynderse LA, Ulchaker JC, Larson TR, Dixon CM, Roehrborn CG (2016) Erectile and ejaculatory function preserved with convective water vapor energy treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia: randomized controlled study. J Sex Med 13(6):924–933. https://doi.org/10.1016/j.jsxm.2016.03.372
9. Leong JY, Patel AS, Ramasamy R (2019) Minimizing sexual dysfunction in BPH surgery. Curr Sex Health Rep 11(3):190–200. https://doi.org/10.1007/s11930-019-00210-1
10. Dixon CM, Rijo Cedano E, Mynderse LA, Larson TR (2015) Transurethral convective water vapor as a treatment for lower urinary tract symptomatology due to benign prostatic hyperplasia using the Rezūm(®) system: evaluation of acute ablative capabilities in the human prostate. Res Rep Urol 7:13–18. https://doi.org/10.2147/rru.S74040
11. Darson MF, Alexander EE, Schiffman ZJ, Lewitton M, Light RA, Sutton MA, Delgado-Rodriguez C, Gonzalez RR (2017) Procedural techniques and multicenter postmarket experience using minimally invasive convective radiofrequency thermal therapy with Rezūm system for treatment of lower urinary tract symptoms due to benign prostatic hyperplasia. Res Rep Urol 9:159–168. https://doi.org/10.2147/rru.S143679
12. Westwood J, Geraghty R, Jones P, Rai BP, Somani BK (2018) Rezum: a new transurethral water vapour therapy for benign prostatic hyperplasia. Ther Adv Urol 10(11):327–333. https://doi.org/10.1177/1756287218793084
13. Dixon CM, Cedano ER, Pacik D, Vit V, Varga G, Wagrell L, Larson TR, Mynderse LA (2016) Two-year results after convective radiofrequency water vapor thermal therapy of symptomatic benign prostatic hyperplasia. Res Rep Urol 8:207–216. https://doi.org/10.2147/rru.S119596
14. Foster HE, Dahm P, Kohler TS, Lerner LB, Parsons JK, Wilt TJ, McVary KT (2019) Surgical management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA guideline amendment 2019. J Urol 202(3):592–598. https://doi.org/10.1097/ju.0000000000000319
15. Bole R, Gopalakrishna A, Kuang R, Alamiri J, Yang D, Helo S, Ziegelmann M, Kohler T (2020) Comparative post-operative

outcomes of Rezūm prostate ablation in patients with large versus small glands. J Endourol. https://doi.org/10.1089/end.2020.0177
16. Ulchaker JC, Martinson MS (2018) Cost-effectiveness analysis of six therapies for the treatment of lower urinary tract symptoms due to benign prostatic hyperplasia. Clinicoecon Outcomes Res 10:29–43. https://doi.org/10.2147/ceor.S148195
17. Mollengarden D, Goldberg K, Wong D, Roehrborn C (2018) Convective radiofrequency water vapor thermal therapy for benign prostatic hyperplasia: a single office experience. Prostate Cancer Prostatic Dis 21(3):379–385. https://doi.org/10.1038/s41391-017-0022-9
18. Green Z, Westwood J, Somani BK (2019) What's new in Rezum: a transurethral water vapour therapy for BPH. Curr Urol Rep 20(7):39. https://doi.org/10.1007/s11934-019-0903-7
19. Mynderse LA, Hanson D, Robb RA, Pacik D, Vit V, Varga G, Wagrell L, Tornblom M, Cedano ER, Woodrum DA, Dixon CM, Larson TR (2015) Rezūm system water vapor treatment for lower urinary tract symptoms/benign prostatic hyperplasia: validation of convective thermal energy transfer and characterization with magnetic resonance imaging and 3-dimensional renderings. Urology 86(1):122–127. https://doi.org/10.1016/j.urology.2015.03.021
20. Pfitzenmaier J, Gilfrich C, Pritsch M, Herrmann D, Buse S, Haferkamp A, Djakovic N, Pahernik S, Hohenfellner M (2008) Vaporization of prostates of ≥ 80 mL using a potassium-titanyl-phosphate laser: midterm-results and comparison with prostates of <80 mL. BJU Int 102(3):322–327. https://doi.org/10.1111/j.1464-410X.2008.07563.x
21. Shah BB, Tayon K, Madiraju S, Carrion RE, Perito P (2018) Prostatic urethral lift: does size matter? J Endourol 32(7):635–638. https://doi.org/10.1089/end.2017.0855
22. Roehrborn CG, Gange SN, Shore ND, Giddens JL, Bolton DM, Cowan BE, Cantwell AL, McVary KT, Te AE, Gholami SS, Rashid P, Moseley WG, Chin PT, Dowling WT, Freedman SJ, Incze PF, Coffield KS, Borges FD, Rukstalis DB (2015) Durability of the Prostatic Urethral Lift: 2-Year Results of the L.I.F.T study. Urol Practice 2(1):26–32. https://doi.org/10.1016/j.urpr.2014.08.001
23. Ray AF, Powell J, Speakman MJ, Longford NT, DasGupta R, Bryant T, Modi S, Dyer J, Harris M, Carolan-Rees G, Hacking N (2018) Efficacy and safety of prostate artery embolization for benign prostatic hyperplasia: an observational study and propensity-matched comparison with transurethral resection of the prostate (the UK-ROPE study). BJU Int 122(2):270–282. https://doi.org/10.1111/bju.14249
24. Gilling P, Barber N, Bidair M, Anderson P, Sutton M, Aho T, Kramolowsky E, Thomas A, Cowan B, Kaufman RP Jr, Trainer A, Arther A, Badlani G, Plante M, Desai M, Doumanian L, Te AE, DeGuenther M, Roehrborn C (2019) Two-year outcomes after aquablation compared to TURP: efficacy and ejaculatory improvements sustained. Adv ther 36(6):1326–1336. https://doi.org/10.1007/s12325-019-00952-3
25. Madersbacher S, Lackner J, Brössner C, Röhlich M, Stancik I, Willinger M, Schatzl G (2005) Reoperation, myocardial infarction and mortality after transurethral and open prostatectomy: a nationwide, long-term analysis of 23,123 cases. Eur Urol 47(4):499–504. https://doi.org/10.1016/j.eururo.2004.12.010