

Original Article
Clinical Investigation**Two-year follow-up comparing Rezūm therapy versus bipolar transurethral resection of the prostate for treating benign prostatic hyperplasia. A prospective randomized study**

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Abbreviations & Acronyms

AUA = American Urological Association
BPH = benign prostatic hyperplasia
B-TURP = bipolar transurethral resection of prostate
CUA = Canadian Urological Association
DRE = digital rectal examination
EUA = European Association of Urology
IIEF = International Index of Erectile Function
IPSS = International Prostate Symptom Score
LUTS = lower urinary tract symptoms
M-TURP = monopolar TURP
PSA = prostate-specific antigen
PVR = post-void residual urine
Q_{max} = maximum urinary flow rate
QoL = quality of life
RF = radiofrequency
SPSS = Statistical package for Social Science
TUR = transurethral resection
TURP = transurethral resection of the prostate

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Objective: Comparison of the efficacy and safety of Rezūm therapy and bipolar transurethral resection of prostate (B-TURP) for the management of benign prostatic hyperplasia (BPH) of 50–120 g size.

Methods: One hundred patients with BPH who met the inclusion criteria were included and split into two equal groups to undergo Rezūm therapy or B-TURP. The two groups were compared for efficacy using international prostate symptom score (IPSS), quality of life (QoL), maximum urinary flow rate (Q_{max}), operative time, catheter time, hospital stay, post-void residual urine (PVR), prostate-specific antigen (PSA), and residual prostate size and safety using the incidence of complications.

Results: Rezūm significantly ameliorated IPSS from the baseline score by 55.3%, QoL by 50%, Q_{max} by 62.5%, International Index of Erectile Function (IIEF) by 7.1%, PVR by 50%, residual prostate size by 28.1% and PSA by 42% at 2 years. Meanwhile, the improvement in B-TURP was significantly higher than Rezūm group, Rezūm therapy had a significantly shorter duration of operative time and hospital stay. Also, it had fewer complications in comparison with B-TURP.

Conclusions: Rezūm is a minimally invasive procedure that provides significantly improved symptomatic relief of BPH and quality of life with preservation of erectile and ejaculatory functions. However, it is not as effective as B-TURP.

Key words: BPH, B-TURP, LUTS, Rezūm, thermal therapy.

INTRODUCTION

In reference to the European Association of Urology (EUA), the American Urological Association (AUA), and other major guidelines the present treatment of benign prostatic hyperplasia (BPH) is conservative treatment (watchful waiting and lifestyle changes), drug therapy and surgical intervention, but pharmacotherapy has many side effects like runny nose, sexual dysfunction, orthostatic hypotension, and dizziness.¹

For a longtime, transurethral resection of the prostate (TURP) was the gold standard surgical procedure for small and moderate prostates, however it has high morbidity and prolonged hospital stay.² On the other side, monopolar TURP (M-TURP) where prolonged resection carries the risk of transurethral resection (TUR) syndrome, bipolar transurethral resection of prostate (B-TURP), especially with large prostates was a promising procedure for urologists³ but unfortunately, the morbidity rate of B-TURP remains high.⁴ Therefore, newer minimally invasive procedures have been introduced to provide alternative surgical options to TURP.

Rezūm is a radiofrequency made water vapor thermal treatment. It has recently been added to the international guidelines as a choice for medical treatment resistant lower urinary tract symptoms (LUTS).⁵ The AUA and Canadian Urological Association (CUA) guidelines recently added water vapor therapy as a treatment option for BPH patients with small prostate size <80 g and for those wishing to maintain antegrade ejaculation. While they still offer no

clear recommendation to Rezūm use for those having large prostates.^{6,7} Early studies discussing this topic have found promising results.^{8–10}

The EAU guidelines mention that more randomized controlled trials on the Rezūm therapy in comparison with a reference procedure are still required to offer any recommendation for its use in large prostates.¹⁰ So, our aim was to assess the efficacy and safety of Rezūm therapy in BPH patients in comparison with B-TURP.

PATIENTS AND METHODS

Study design and study population

This was a prospective randomized controlled trial, conducted in our tertiary care center between June 2021 and April 2023. Patients aged 50–80 years with prostate volumes of 50–120 mL, sexually active, and have severe LUTS (maximum urinary flow rate [Q_{max}] of <10 mL/s and International Prostate Symptom Score [IPSS] of >20) who were unresponsive to treatment with alpha blockers were included in our study. Patients known to have prostate cancer, neurogenic bladder, urethral stricture, urinary bladder stone or previous prostatic surgery were excluded.

Calculation of the sample size was done using PASS version 15 program, setting type-I alpha error at 0.05 and power at 0.8 and according to “Green et al., 2019” and “Chen et al., 2010”,^{11,12} the expected decrease in IPSS in the Rezūm group was about 55% and in the B-TURP group was about 83%. A sample size of 50 cases per group was required to detect the difference between the two groups.

A total of 246 cases with BPH were examined for eligibility to be included in the study. One hundred forty-six cases were excluded for these reasons: 88 were excluded for not fulfilling inclusion criteria, while 58 were rejected to share in the study. The remaining 100 cases using computer-based software were randomly divided into two equal groups; group A underwent Rezūm procedure and group B underwent B-TURP, see Figure 1.

Preoperative work up for all patients was: IPSS, International Index of Erectile Function (IIEF), quality of life assessment (QoL), digital rectal examination (DRE), uroflow, urine analysis and culture if needed, prostate-specific antigen (PSA), pelvic ultrasound to estimate post void residual urine (PVR) and transrectal ultrasound (TRUS) to estimate prostate size. Erectile dysfunction (ED) was classified according to IIEF into mild (17–25), moderate (11–16) and severe (1–10).¹³

Technique

- Rezūm was employed either under local anesthesia with sedation or under general anesthesia as a day case, while B-TURP received spinal anesthesia and operations were done by the same expert surgical team (each surgeon operated more than 100 cases prior to start of the study). Prophylactic antibiotics were given at the time of induction of anesthesia. After placement of patients in the lithotomy position, diagnostic urethra-cystoscopy was done.

- In Rezūm procedure, the Rezūm System (NxThera Inc., Maple Grove, MN, USA) consists of a radiofrequency (RF) power supply generator and single-use transurethral delivery device. Starting 1 cm distal to the bladder neck, injection was done at 3 and 9 o'clock sites. The needle was inserted for 9 s duration, retracted, and then delivered to another treatment site in 1 cm distance distal to the previous one. The total number of treatments was estimated by the size of the adenoma and are fashioned according to the shape of the prostate including the median lobe. Our Post-procedure urethral catheterization protocol varied from a minimum of 3 days to a maximum of 7 days according to size of the treated prostatic tissue and the duration of preoperative retention.
- In B-TURP, Olympus SurgMaster™ UES-40 bipolar generator (Olympus Europe, Hamburg, Germany) was used. Current's settings used were cut/coag 200/120. Using continuous flow 26Fr resectoscope, first resection of the median lobe from the level of the bladder neck to the apex of the prostate was done without any intention to preserve ejaculation followed by resection of the lateral lobes. Using Ellic evacuator, prostatic chips were removed out from the field. A 22 fr three-way silicon Foley catheter was inserted with traction applied and the balloon inflated by normal saline of 30–80 cc according to the size of the prostate. Continuous bladder irrigation started by normal saline and stopped when the wash became clear.

Outcome measures

The primary outcome was to determine the efficacy, and the secondary outcome was to determine the safety of both procedures. We assessed the efficacy of the approach using: IPSS, QoL, Q_{max} , operative time, catheter time, hospital stay, PSA, PVR, and residual prostate size and safety using incidence of complications. Retrograde ejaculation was diagnosed by history taking and confirmed by examination of post ejaculate urine sample done 6 months post procedure excluding patients with severe ED from the assessment.

Statistical methods

Changes from baseline were expressed using mean, standard deviation, and percent of change. The student's *t*-test was used to evaluate the statistical significance of the difference between the two study group means, Mann–Whitney *U*-test was used to evaluate the statistical significance of the difference of a non-parametric parameters between the two study groups, Chi-squared test was used to assess the relationship between two qualitative parameters, Fisher's exact test for examination the relationship between two qualitative variables when the expected count is <5 in >20% of cells. The collected data was processed using the Statistical package for Social Science (SPSS 25). *p* Value of <0.05 was considered statistically significant.

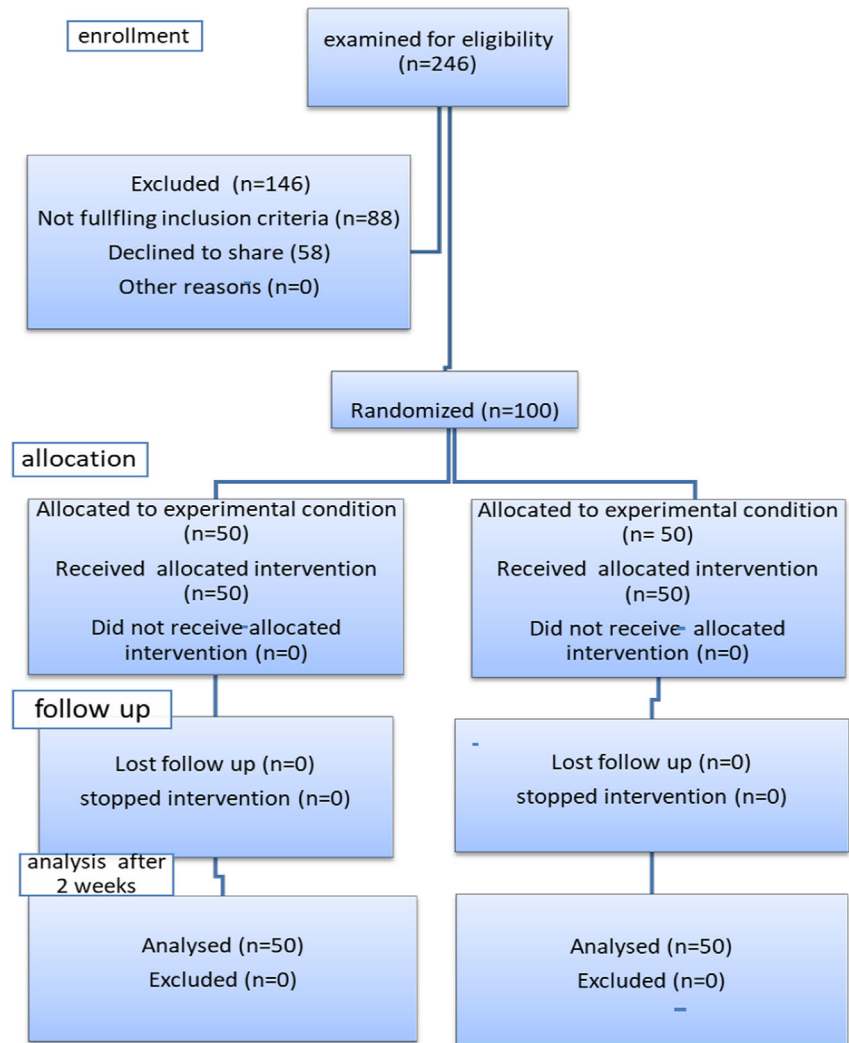


FIGURE 1 CONSORT flow chart. A total of 246 patients with BPH were examined for eligibility to be included in the study. One hundred forty-six patients were excluded for these reasons: 88 were excluded for not fulfilling inclusion criteria, while 58 were rejected to share in the study, as shown in Figure 1. The remaining 100 patients using computer-based software were randomly divided into two equal groups; group A underwent Rezūm procedure and group B underwent B-TURP.

RESULTS

The baseline parameters in the two groups were comparable in terms of age, prostate size, presence of median lobe, pre-operative urinary retention, PSA, Q_{max} , IPSS, QoL, PVR, IIEF and ED severity with no statistically significant difference ($p > 0.05$), see Table 1.

With reference to perioperative data, there was a statistically significant difference between Rezūm and B-TURP groups regarding duration of operation and hospital stay with higher values in the B-TURP, while the catheter duration was longer in the Rezūm group ($p < 0.001$). See Table 2.

Regarding treatment efficacy, there was a higher improvement in B-TURP than the Rezūm group in IPSS, QoL, Q_{max} , PVR, PSA and residual prostate size at 24 months which was statistically significant. Moreover, the mean of each parameter was statistically different after 24 months compared to baseline in each group ($p < 0.001$). Eight-points or greater improvement in IPSS described as marked response was documented in 41 patients (82%) of the Rezūm group versus 45 patients (90%) of the B-TURP group. However, regarding IIEF there was significantly different higher mean

in the Rezūm group at different time intervals and percent of change compared to B-TURP ($p < 0.05$), see Table 3.

The initial spontaneous voiding rate after Rezūm was 96% as two patients failed trial without catheter (TWOC), but all patients in the B-TURP group voided effectively with a success rate of 100%. Eight patients of the Rezūm group continued their alpha blockers usage postoperatively however only two patients of the B-TURP group failed to stop their medication, and this was statistically significant ($p = 0.045$).

When talking about the perioperative complications, there was a statistically significant difference between Rezūm and B-TURP groups regarding incidence of postoperative ED, hematuria and retrograde ejaculation ($p = 0.002$, 0.025 and <0.001 respectively). However, there was no significant difference regarding urinary tract infection (UTI), incontinence, urine retention and retreatment need ($p > 0.05$), see Table 4.

Retreatment was done by the same previous procedure. In the Rezūm group, 4 patients required reintervention representing 8% retreatment rate. Their age was 67.75 ± 5.9 years, the prostate size was 91.5 ± 24.61 g, 3 patients (75%) had median lobe and two patients (50%) were catheter dependent preoperatively. While, in the B-TURP group, two patients

TABLE 1 Baseline parameters of the patients.				
	Group			p-Value
	REZÜM			
	Mean ± SD		Mean ± SD	
Age (Year)	66.7 ± 7.3		63.7 ± 8.9	0.06
Prostate size (g)	71.9 ± 17		74.1 ± 18.6	0.58
Median lobe presence	10 (20%)		13 (26%)	0.47
Preoperative urinary Retention	5 (10%)		5 (10%)	1
PSA (ng/mL)	6 ± 3.3		6.2 ± 1	0.05
PVR (mL)	108.2 ± 35.4		112. 2 ± 32.5	0.44
Q _{max} (mL/s)	8.7 ± 0.6		8.4 ± 0.9	0.26
IPSS	23.7 ± 4.1		23.4 ± 3.3	0.83
QoL	4.6 ± 0.8		4.6 ± 0.9	0.60
IIEF	12.6 ± 5.3		13 ± 6	1
Preoperative erectile dysfunction	No ED	5 (10%)	9 (18%)	0.64
	Mild	20 (40%)	16 (32%)	
	Moderate	10 (20%)	11 (22%)	
	Severe	15 (30%)	14 (28%)	

	Group		p-Value
	REZŪM	B TURP	
	Median (IQR)	Median (IQR)	
Operative time (min)	8 (7–10)	62 (58–75)	<0.001
Hospital stay (h)	4 (4–6)	48 (48–72)	<0.001
Catheter duration (days)	6 (5–7)	2 (2–3)	<0.001

required reintervention representing 4% retreatment rate. Their age was 73 ± 2.82 years, the prostate size was 100 ± 28.28 g, 1 patient (50%) had median lobe, and none was catheter dependent preoperatively.

DISCUSSION

In 2015, the Rezūm therapy was approved by the Food and Drug Administration (FDA) according to the results of the important study (NCT01912339). This was a randomized trial that included 197 patients with prostate size 30–80 mL. Results showed that it caused clinical improvements after 1 month with sustainable improvements of BPH symptoms. Also, in June 2020 its use was accepted by the National Institute for Health and Care Excellence (NICE).¹⁰

It is a minimally invasive modality for treatment of BPH that needs only 2 minutes maximally and can be done under sedation unlike photoselective vaporization of the prostate (PVP) or TURP. It is also easy to learn when compared to the relatively steep learning curve of holmium laser enucleation of the prostate (HoLEP).⁸ Other advantages of Rezūm include mild retrograde ejaculation and preserved erectile function.^{13,14}

With regards to the perioperative data, the operative time and hospital stay were statistically shorter in the Rezūm than in the B-TURP group, while the catheter time was longer in

TABLE 3 Changes in follow-up parameters overtime.					
	Group				p-Value
	REZŪM		B TURP		
	Mean ± SD	% of change	Mean ± SD	% of change	
Q _{max} (mL/s)					
Baseline	8.7 ± 0.6		8.4 ± 0.9		0.26
6 months	10.3 ± 2.3	66.7%	12.6 ± 1.6	77.8%	0.53
12 months	14.8 ± 1.4	75%	15.2 ± 1.4	144.4%	<0.001
24 months	14.1 ± 1.2	62.5%	20.1 ± 2.1	133.3%	<0.001
IPSS					
Baseline	23.7 ± 4.1		23.4 ± 3.3		0.83
6 months	18.5 ± 4.2	−38.7%	12 ± 2.7	−76.0%	<0.001
12 months	13.9 ± 3	−57.1%	5.6 ± 1.1	−76.0%	<0.001
24 months	10.7 ± 1.9	−55.3%	6.4 ± 1.2	−73.5%	<0.001
PVR (mL)					
Baseline	108.2 ± 35.4		109.2 ± 29.7		0.62
6 months	83 ± 28.7	−33.3%	43.5 ± 13.7	−58.8%	<0.001
12 months	74.6 ± 24.6	−55.6%	43.5 ± 13.7	−68.7%	<0.001
24 months	52.6 ± 17	−53.3%	33.9 ± 6.6	−68.8%	<0.001
QoL					
Baseline	4.6 ± 0.8		4.6 ± 0.9		0.6
6 months	2.9 ± 0.5	−25.0%	2.3 ± 0.6	−50.0%	<0.001
12 months	3.1 ± 0.5	−60.0%	2.3 ± 0.6	−60.0%	0.18
24 months	2 ± 0.5	−50.0%	1.6 ± 0.4	−60.0%	<0.001
PSA (ng/mL)					
Baseline	6 ± 3.3		6.2 ± 1		0.05
6 months	4.1 ± 2.1	−30.2%	3.29 ± 0.7	−49.2%	0.21
12 months	3.9 ± 1.9	−33.7%	2 ± 0.6	−67.7%	<0.001
24 months	3.4 ± 1.9	−42%	2 ± 0.6	−67.7%	<0.001
IIEF					
Baseline	12.6 ± 5.3		13 ± 6		1.000
6 months	12.7 ± 2.7	14.3%	7.42 ± 1.9	−40%	<0.001
12 months	15.1 ± 4.8	18.2%	11.5 ± 5.1	−8.3%	<0.001
24 months	13.6 ± 4.6	7.1%	11.5 ± 5.1	−8.3%	0.005
Prostate size					
Baseline	71.9 ± 17		74.1 ± 18.6		0.58
24 months	51.9 ± 13.9	−28.6%	27.7 ± 7	−63.7%	<0.001

TABLE 4 Perioperative complications.

	Group		p-Value
	REZUM	B-TURP	
	N (%)	N (%)	
Postoperative ED			
No ED	6 (12%)	4 (8%)	0.002
Mild	27 (54%)	12 (24%)	
Moderate	16 (32%)	20 (40%)	
Severe	1 (2%)	14 (28%)	
Hematuria			
No	48 (96%)	45 (90%)	0.025
Yes	2 (4%)	5 (10%)	
UTI			
No	44 (88%)	45 (90%)	0.749
Yes	6 (12%)	5 (10%)	
Urine retention			
No	48 (96%)	49 (98%)	1.00
Yes	2 (4%)	1 (2%)	
Retrograde ejaculation			
No	48 (98%)	7 (20%)	<0.001
Yes	1 (2%)	29 (80%)	
Incontinence-urgency			
No	48 (96%)	47 (94%)	1.00
Yes	2 (4%)	3 (6%)	
Retreatment need			
No	46 (92%)	48 (96%)	0.678
Yes	4 (8%)	2 (4%)	

the Rezūm group ($p < 0.001$). In line with the current study, Haroon et al. found that the operative time and hospital stay were significantly longer in B-TURP compared to the Rezūm group resulting in a significant cost saving.¹⁵ Also, the systematic review of Babar et al. showed that the mean Rezūm operative time was 4.4–13.0 min (median = 7 min).¹⁶ In our study, the median duration of postoperative urethral catheter in the Rezūm group was 6 days. In agreement with this, Babar et al. found that the mean duration of postoperative catheter was 3.0–32.2 days, with the higher value for those with urinary retention at presentation.¹⁶

Regarding the efficacy, in this study, B-TURP had a better outcome in: IPSS, QoL, Q_{max} , PVR, PSA and residual prostate size than the Rezūm group. However, the mean of each parameter was improved significantly compared to baseline at 24 months after treatment in the Rezūm group ($p < 0.001$). This outcome was agreed with the results of Tanneru et al., who performed indirect comparison between TURP and Rezūm therapy using 4 randomized controlled trials and found that TURP had more improvement of urinary domain variables than the Rezūm group.¹⁷ Also, Elterman et al., enrolled 83 patients with a prostate size ≥ 80 mL underwent Rezūm procedure and found that there was a significant improvement of all variables at follow-up.¹⁰

The most common sexual side effect of TURP is ejaculatory failure which usually causes a significant bother.¹⁸ Thus, decisions regarding use of new techniques for the management of BPH need investigation for any deleterious effect on sexual quality.¹³ In these regards, Tanneru et al. compared indirectly the outcome of the new minimally invasive

modalities for BPH (Rezūm, Aquablation and UroLift) in terms of urinary and sexual domains. They concluded that patients underwent the resective intervention, that is, Aquablation showed more improvement of the urinary domain (IPSS, QoL, Q_{max} and PVR) in comparison to patients underwent non-resective interventions, that is, UroLift and Rezūm. Their analysis did not find any significant difference regarding urinary and sexual domain outcomes in patients underwent UroLift and Rezūm.¹⁷ However, in comparison to UroLift, Rezūm has no restriction in terms of anatomy, like large-sized prostate or large median lobe.¹⁹

In the present study, IIEF increased by 7% in Rezūm while it decreased by 8% in the B-TURP group. In concordance with our findings, Johnston et al., reported that IIEF improved significantly at follow-ups ($p = 0.001$).²⁰ In contrast, El-Assmy et al., reported that there was no difference or relative improvement in the B-TURP group in the distribution of ED categories compared with baseline and changes in IIEF were statistically stable at 6- and 12-month visits.²¹

With regards to the postoperative complications, B-TURP had a significantly higher incidence of postoperative ED, hematuria and retrograde ejaculation than the Rezūm group while there was no marked difference in the other complications. This is consistent with Babar et al., and Johnston et al., who noted that most adverse effects of Rezūm were temporary and nonserious.^{16,20}

The limitations of our study were the relatively small number of patients and short follow-up duration. So, further multicenter trials with longer follow-up are needed to support our results. However, to the best of our knowledge, it is the first study to compare the efficacy and safety of Rezūm with B-TURP in patients with medium size prostate.

Rezūm therapy is an inferior treatment modality than B-TURP for BPH of 50–120 g size over the course of 2 years. However, it has fewer complications making it a viable alternative to B-TURP, especially in sexually active patients, as it preserves both erectile and ejaculatory functions.

AUTHOR CONTRIBUTIONS

Mohamed Samir: Writing—original draft; Writing—review & editing; Supervision. **Abd Allah Abd Elaal:** Data curation; Supervision. **Khaled Abdel Sattar Gad:** Project administration; Formal analysis; Methodology. **Mohamed Wagieh Basyony:** Investigation; Formal analysis.

CONFLICT OF INTEREST STATEMENT

None declared.

INFORMED CONSENT

All eligible patients signed written informed consent form matching with good clinical practice.

REGISTRY AND THE REGISTRATION NO. OF THE STUDY/TRIAL

NCT 06116370.

ANIMAL STUDIES

N/A.

APPROVAL OF THE STUDY PROTOCOL BY OUR INSTITUTIONAL ETHICAL COMMITTEE

Numbered FMASU MD 244/2021.

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