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ORIGINAL PAPER

Evaluation of Rezum therapy as a minimally invasive modality for management of Benign Prostatic Hyperplasia: A prospective observational study

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Summary *Objective: To evaluate safety and efficacy of Rezum therapy as a minimally invasive modality for management of benign prostatic hyperplasia in patients with prostate volume < 80cc and those with prostate volume > 80cc.*

Methods: Between June 2020 and February 2023, A total of 98 patients diagnosed with BPH and managed by Rezum were included in this study. Patients were divided based on their prostate volume of either less than 80 cc or greater than 80 cc. We evaluated several parameters related to their condition, including prostate volume, post-voiding residual (PVR) before and after surgery, number of treatments received, maximum urine flow rate (Q_{max}) before and after surgery and mean follow-up periods.

Results: The mean age was 68 years (SD 11.2). The median prostatic volume was 62 cc (IQR 41, 17). A maximum of 9 treatments were administered. Six months was determined to be the average post-operative follow-up period (IQR: 3.5-7.2). The mean preoperative total PSA was 2.7 (IQR 1, 2), preoperative mean PVR was 79.8 cm^3, preoperative mean Q_{max} was 8.2 ml/s (IQR 4.7-10.5), and median post-operative days until catheter removal was four days (IQR 3,1). Post-operative PVR was 24.7 cm^3 (IQR 18.2, 29.4) and the mean post-operative Q_{max} was 18.3 ml/s (SD 6.3). Q_{max} levels significantly increased, by an average of 8.2 ml/s (SD 7.13) ($p < 0.001$). Similarly, a decrease of average PVR of 97.28 cm^3 (SD 95.85) ($p < 0.001$) was detected, which is a substantial reduction. Between prostates less 80cc and those over 80cc, there were no appreciable differences in Q_{max} or PVR (p-values: 0.435 and 0.431, respectively).

Conclusions: From our study, we conclude that Rezum water vapor thermal therapy, as a minimally invasive modality, is an effective and safe surgical option for management of benign prostatic hyperplasia of men with moderate to severe lower urinary tract symptoms (LUTS). This procedure has been shown to be effective in patients with varying larger prostate volumes.

KEY WORDS: *Hyperplasia; Prostate; Rezum.*

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INTRODUCTION

Benign prostatic hyperplasia (BPH) is a disease of high prevalence and its natural history shows that 25% of men are affected by bothersome *lower urinary tract symptoms* (LUTS) caused by bladder outflow obstruction during their lifetime (1, 2). There are many devised treatment options to treat BPH. Initial medical therapy may be effective for mild to moderate symptoms. Patients with moderate or severe symptoms may still require surgical intervention in presence of objective measurements that indicate greater obstruction. In the past, *transurethral resection of the prostate* (TURP) was considered the gold standard procedure for BPH treatment. TURP was associated with high rates of morbidity, including bleeding, sexual dysfunction, stress incontinence, urethral strictures, and longer length of stay (3, 4). Recently, many innovative surgical procedures using thermal energy steam, or prostate artery embolization or mechanical dilation with UroLift have been introduced (5, 6). The aim of all of them is to maintain a strategic distance from the complications associated with TURP whereas keeping comparable results. *Rezum* is recommended for men ≥ 50 year of age with BPH and prostate volumes extending from 30 cm^3 to 80 cm^3. Its use is suggested for the treatment of enlargement of the central zone and/or a middle lobe. In general, the prostate is ablated through convective warm water vapor, produced through radiofrequency (7, 8). This procedure has been detailed within the literature to result in a significant reduction in LUTS in patients with BPH, with high safety profile (9). *Rezum* has too illustrated advancement in symptoms scores compared to medical therapy (10, 11). Another recognized key advantage of *Rezum* treatment is the low rate of sexual affection post-operatively, which may be a watched key complication of other treatments for BPH, such as TURP (10). The aim of this study is to evaluate safety and efficacy of *Rezum* therapy as a minimally invasive modality for management of benign prostatic hyperplasia in patients with prostate volume < 80cc and those with prostate volume > 80cc.

Materials and methods

Between June 2020 and February 2023, a total of 98 patients diagnosed with BPH and managed by *Rezum* on the urology department of the institution of the Authors were included in this prospective observational study.

All procedures performed in this study complied with institutional and/or national research council ethical standards as well as the 1964 Declaration of Helsinki and its subsequent amendments or similar ethical standards. Protocols and written informed consent for all participants were approved by the *Research Ethics Committee of Thumbay University Hospital* (affiliated with *Gulf Medical University, REC #: 432/2020*).

Written informed consent was obtained from the patients for their anonymized information to be published in this article.

The *Rezum* procedure utilizes the flow of water vapor to deliver heat to the prostate tissue in short bursts of 9 seconds. At our hospital, patients underwent *Rezum* therapy in the operating room under general anesthesia. Following the procedure, all patients had catheters of varying sizes inserted. The data collected included basic demographic information such as age and ethnicity, as well as preoperative and postoperative values. Additionally, we recorded the number of treatments administered, the time taken for catheter removal (TWOC), the average follow-up time, and any complications that arose. Due to non-compliance from some patients, it was not feasible to utilize standardized symptom questionnaires for assessment purposes. Furthermore, we categorized patients into two groups based on their prostate volume of either less than 80 cc or greater than 80 cc.

Statistical methods

The IBM *Statistical Package for the Social Sciences* (SPSS) software, version 25.0 (*IBM Corp., Armonk, NY*), was used to enter and analyze the data. Pre- and postoperative values of parameters as PSA, Q_{max}, and PVR were compared. The Wilcoxon signed-rank test was applied since the change was negatively skewed and the data were paired. Statistics were judged significant at a 0.05 p-value. Additionally, we used a non-parametric Mann-Whitney U test to examine if the preoperative prostatic volume was connected to the change in Q_{max} and PVR.

Results

This prospective observational study comprised 98 patients with benign prostatic hyperplasia who underwent *Rezum* surgery at *Thumbay University Hospital* (affiliated to *Gulf Medical University*) between June 2020 and February 2023. The mean age was 68 years (SD 11.2) (Table 1). Overall, 54.2% (51/96) of the patients had prostate gland volumes that were less than 80 cc and 45.8% (45/96) of the patients had prostate gland volumes that were more than 80 cc. The mean prostatic volume was 69 cc (SD 34.19), while the median prostatic volume was 62 cc (IQR 41,17). A maximum of 9 treatments were administered, with a mean of 4.2 treatments into the median lobe. Six months was determined to be the average post-operative follow-up period (IQR: 3.5-7.2). The mean preoperative total PSA in our sample was 2.7 (IQR 1,2), mean preoperative PVR was 79.8 cm^3, mean preoperative Q_{max} was 8.2 ml/s (IQR 4.7-10.5), and the median post-operative days until catheter removal was four days (IQR 3.1). Mean post-operative PVR was 24.7 cm^3 (IQR 18.2, 29.4) and mean post-operative Q_{max} was 18.3 ml/s (SD 6.3) (Table 1). Q_{max} levels significantly increased, by an average of 8.2 ml/s (SD 7.13) ($p < 0.001$). Similarly a decrease of average PVR by 97.28 cm^3 (SD 95.85) ($p < 0.001$) was detected, which is a substantial reduction (Table 2). Between prostates less 80cc and those over 80cc, there were no appreciable differences in Q_{max} or PVR (p-values: 0.435 and 0.431, respectively) (Table 3). Our study's complications included two occurrences of *urinary tract infections* (UTI), which were treated with oral antibiotics, and five instances of hematuria, which resolved on its own. Due to the catheter's temporary post-operative presence, several patients experienced slight discomfort. None of the patients who underwent this treatment reported any sexual difficulties. Regarding the use of post-operative med-

Table 1.
General demographical data.

	Mean/median	SD/IQR
Age	68	11.2
Prostate volume	62	41, 17
Preoperative PSA total	2.7	1,2
Preoperative Q_{max}	8.2	4.7, 10.5
Preoperative PVR	79.8	42.4, 115.0
TWOC	4	3,1
Post-Op Q_{max}	18.3	6.3
Post-Op PVR	24.7	18.2, 29.4

Q_{max}: peak urinary flow; PSA: prostate-specific antigen; PVR: post-void residual; TWOC: time to removal of catheter.

Table 2.
Mean changes in Q_{max} and PVR.

	Mean	SD	Median	Percentile 25	Percentile 75	p-value
Change in Q_{max}	8.2	7.13	5.60	3.42	11.90	< 0.001
Change in PVR	-97.28	95.58	-71.50	-142.00	-31.10	< 0.001

Q_{max}: peak urinary flow; PVR: post-void residual.

Table 3.
Mean changes in measures of Q_{max} and PVR in relation to prostate volume between the studied groups.

		Mean	SD	Median	Percentile 25	Percentile 75	p-value
Change in Q_{max}							
Prostate volume	<=80	7.65	5.66	6.62	2.80	12.30	0.435
	>80	12.88	13.10	6.10	3.20	28.10	
Change in PVR							
Prostate volume	<=80	29.3	25.8	22.2	15.8	28.4	0.431
	>80	31.2	21.7	27.6	17.8	46.7	

Q_{max}: peak urinary flow; PVR: post-void residual.

ications, patients stopped using their medications within three months of the procedure.

Discussion

Benign prostatic obstruction (BPO) is one of the most frequently diagnosed conditions of the male genitourinary tract. Globally, BPO results in 1,2 million surgical procedures annually. The range of interventions available to treat BPH has broadened in recent years. *Quality of life* (QOL) and healthcare spending may be impacted in ageing men because of LUTS due to enlargement of the Prostate (LUTS) (12). *Rezum* presented itself as a new surgical innovation, providing satisfactory clinical results while offering a safe and low-risk side effect profile (3). Its recommended by the the *American Urological Association* (AUA) and the *European Urological Association* (EUA). In addition to the existing interventions of prudent waiting and lifestyle modifications, pharmacotherapy, and surgical management for LUTS, it has historically been difficult for patients with BPH to remain compliant with the medical treatments offered (e.g. 5-alpha reductase, phosphodiesterase, etc.). These treatments provide symptomatic relief but at the expense of side-effects that threaten compliance (3). In this study, we have highlighted the effectiveness of *Rezum* therapy through comparing the pre- operative and post-operative outcomes in our institution among different patients with enlarged prostate including volumes greater than 80cc. Our study showed no significant difference in Q_{max} or PVR among prostate volumes of less than 80cc versus greater than 80cc. Historically, TURP has been the gold standard of BPH treatment. TURP provided patients with clinically meaningful improvements in LUTS. However, TURP's major disadvantage is its complications, particularly bleeding and sexual dysfunctions (12). *Rezum* has several advantages over TURP. First, it improves clinical outcomes while maintaining sexual function. Second, it has minimal bleeding. Third, it can be performed without general anesthesia. This may be beneficial for some elderly patients. Fourth, it has been studied for cost-effectiveness in the USA compared to TURP long term follow-up, demonstrating that *Rezum* is comparable in health and cost-effectiveness (13, 14). While clinical improvement with TURP was increased, the literature has shown an overall cost reduction with *Rezum* due to the lower adverse effects (14, 15). Randomized control trials have also shown a reduction in symptomatic LUTS at four years with an average IPSS improvement with *Rezum* therapy of 47% (10). Lastly, due to COVID-19 and the benefit of reducing operative time, *Rezum* has proven to be a good choice with each procedure being reported to take about 17.5 minutes compared with 60-90 minutes for TURP (16). The efficacy of *Rezum* in the Arab population has not been extensively studied since the introduction of this novel therapy. However, in the UK it has been reported on the preoperative experience of *Rezum*, as described in the study of *Maximilian et al.* (17). Our study has demonstrated the benefit of *Rezum* therapy amongst the Arab population, based on improvements in Q_{max}, PVR, and patient symptom reporting. Our population did not have any patient with catheter dependency, 29 of whom were on medical treatment (30.2%). Within 90 days' post-operatively, our patients had discontinued their previous medications, this results going in line with the single office experience of *Mollengarden et al.* (18). Our study focused on postoperative changes in PVR and Q_{max} as objective measures of improvement in postoperative outcomes. At three months follow up, we observed a significant average increase in Q_{max} and a significant decrease in PVR, in line with other internationally published papers (17, 19). We also looked at the relationship between preoperative prostatic volume and changes in Q_{max} and PVR. In our sample, there was no statistically significant relationship. This was in contrast to *Garden et al.*, who found that men with larger (> 80cc) prostates showed more profound Q_{max} and PVR changes than men with smaller prostates (< 80cc) (19). Medication side-effects can lead to patients not adhering to treatment for BPH; for example, *Cindolo et al.* (20), showed that adherence was 29% after one year of treatment with at least 6 months of therapy in a population based cohort study of 1,5 million men. In our experience, patients have only needed medical treatment temporarily after surgery, while no medications were needed for symptom control after 90 days from the procedure. This alone may increase the acceptance of the procedure and increase the adoption rate. In addition to reducing the need for medication and improving quality of life, *Rezum* is also a well-tolerated procedure (21). One of the main drawbacks of temporary catheterization after surgery is that it can take an average of 4 days to heal, and our patients have reported discomfort during this time. In our study, complications have included UTI that was managed with antibiotics only, as well as four cases of spontaneous resolving hematuria. No patients needed to be readmitted for any reason, and no patients reported sexual dysfunction up to the most recent follow-up. This is consistent with published data, as *Dixon et al.* found no clinically relevant changes in sex function over 2 years. *McVary et al.* reported a single treatment of water vapor therapy with no adverse effects on sex function over a 3-year period, which is in contrast to medical treatment that results in worsening erectile dysfunction and libido (9, 10). Lastly, the population that requires surgery for BPH includes an older group of men, many of whom may be on anti-coagulants and have multiple underlying conditions. *Rezum* is an excellent choice as it does not require the interruption of anticoagulants and does not require general anesthesia.

Limitations.

In our study median lobe size was not sufficiently measured to adequately evaluate the effect of this measurement on outcome and response to *Rezum*. Our small sample size of patients with prostate size > 80cc emphasizes the need for larger, more robust prospective studies to elucidate *Rezum* outcomes in patients with larger prostates.

Conclusions

From our study, we conclude that *Rezum* water vapor thermal therapy as a minimally invasive modality is effective and safe surgical option for management of benign prostatic hyperplasia of men with moderate to severe

LUTS. This procedure has been shown to be effective in patients with varying larger prostate volumes.

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References

1. Speakman M, Kirby R, Doyle S, Ioannou C. Burden of male lower urinary tract symptoms (LUTS) suggestive of benign prostatic hyperplasia (BPH) - focus on the UK. BJU Int. 2015; 115:508-519.

2. Lee SWH, Chan EMC, Lai YK. The global burden of lower urinary tract symptoms suggestive of benign prostatic hyperplasia: a systematic review and meta-analysis. Sci Rep. 2017; 7:7984.

3. Foster HE, Dahm P, Kohler TS, et al. Surgical management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA Guideline Amendment 2019. J Urol. 2019; 202:592-8.

4. Guo RQ, Yu W, Meng YS, et al. Correlation of benign prostatic obstruction-related complications with clinical outcomes in patients after transurethral resection of the prostate. Kaohsiung J Med Sci. 2017; 33:144-51.

5. Jones P, Rai BP, Nair R, Somani BK. Current status of prostate artery embolization for lower urinary tract symptoms: review of world literature. Urology. 2015; 86:676-81.

6. Jones P, Rajkumar GN, Rai BP, et al. Medium-term outcomes of urolift (minimum 12 months follow-up): evidence from a systematic review. Urology. 2016; 97:20-4.

7. Green Z, Westwood J, Somani BK. What's new in rezum: a transurethral water vapour therapy for BPH. Curr Urol Rep. 2019; 20:39.

8. Mynderse LA, Hanson D, Robb RA, et al. Rezum 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. 2015; 86:122-7.

9. Dixon CM, Cedano ER, Pacik D, et al. Two-year results after convective radiofrequency water vapor thermal therapy of symptomatic benign prostatic hyperplasia. Res Rep Urol. 2016; 8:207-16.

10. McVary KT, Rogers T, Roehrborn CG: Rezum water vapor thermal therapy for lower urinary tract symptoms associated with benign prostatic hyperplasia: 4-year results from randomized controlled study. Urology. 2019; 126:171-9.

11. Gupta N, Rogers T, Holland B, et al. Three-year treatment outcomes of water vapor thermal therapy compared to doxazosin, finasteride and combination drug therapy in men with benign prostatic hyperplasia: cohort data from the MTOPS trial. J Urol. 2018; 200:405-13.

12. Aboutaleb H, Ali TA, Zaghloul A, Amin MM. Efficacy of bipolar 'button' plasma vaporisation of the prostate compared to green laser vaporisation for benign prostatic obstruction. Journal of Clinical Urology. 2018; 11: 350-356.

13. Arezki A, Sadri I, Couture F, et al.: Reasons to go for Rezum steam therapy: an effective and durable outpatient minimally invasive procedure. World J Urol. 2021; 39:2307-13.

14. Ulchaker JC, Martinson MS. Cost-effectiveness analysis of six therapies for the treatment of lower urinary tract symptoms due to benign prostatic hyperplasia. Clinicoecon Outcomes Res. 2018; 10:29-43.

15. Darson MF, Alexander EE, Schiffman ZJ, et al. Procedural techniques and multicenter postmarket experience using minimally invasive convective radiofrequency thermal therapy with Rezum system for treatment of lower urinary tract symptoms due to benign prostatic hyperplasia. Res Rep Urol. 2017; 9:159-68.

16. Johnston M, Shah T, Emara A, et al. Rezum water vapour ablation therapy for benign prostatic hyperplasia: Preoperative results from the United Kingdom. J Urol. 2019; 201: e1-e2.

17. Johnston MJ, Noureldin M, Abdelmotagly Y, et al. Rezum water vapour therapy: promising early outcomes from the first UK series. BJU Int. 2020; 126:557-8. 10.1111/bju.15203.

18. Mollengarden D, Goldberg K, Wong D, Roehrborn C. Convective radiofrequency water vapor thermal therapy for benign prostatic hyperplasia: a single office experience. Prostate Cancer Prostatic Dis. 2018; 21:379-85.

19. Garden EB, Shukla D, Ravivarapu KT, et al. Rezum therapy for patients with large prostates (≥ 80 g): Preoperative clinical experience and postoperative outcomes. World J Urol. 2021; 39:3041-8.

20. Cindolo L, Pirozzi L, Fanizza C, et al. Drug adherence and clinical outcomes for patients under pharmacological therapy for lower urinary tract symptoms related to benign prostatic hyperplasia: population-based cohort study. Eur Urol. 2015; 68:418-25.

21. McVary KT, Holland B, Beahrs JR. Water vapor thermal therapy to alleviate catheter-dependent urinary retention secondary to benign prostatic hyperplasia. Prostate Cancer Prostatic Dis. 2020; 23:303-308.

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