Efficacy of Rezūm water vapor therapy for the treatment of catheter-dependent urinary retention: A single-center, Canadian experience

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ABSTRACT

Introduction: Urinary retention secondary to benign prostatic hyperplasia (BPH) requiring catheterization is a prevalent and morbid condition. The objective of this study was to evaluate the real-world efficacy and safety of Rezūm as the primary treatment of catheter-dependent urinary retention.

Methods: A single-center, retrospective study analyzed patients with catheter-dependent urinary retention secondary to BPH who were treated with Rezūm between April 2022 and April 2024. Standardized postoperative followup was required for inclusion. Patient demographics, medication use, volume drained at time of urinary retention, catheter-free status, complications, and postoperative International Prostate Symptom Score (IPSS) was collected.

KEY MESSAGES

- Catheter-dependant patients with BPH face significant difficulties accessing traditional surgical treatments in our current healthcare landscape; however, emerging minimally invasive therapies may hold promise for this population.
- In our cohort, we demonstrate 79% of patients with catheter-dependent BPH were able to successful undergo a trial of void post-Rezūm treatment.
- Rezūm is still a valid option for patients with a longer duration of chronic catheterization with a larger prostate size; however, patients with elevated retention volume ≥ 1 L at time of urinary retention episode were found to be significantly more likely to fail post-treatment TOV.
- Further research is warranted to assess the cost-effectiveness of Rezūm as a primary option for the treatment of BPH in the Canadian healthcare system.

Results: A total of 53 patients were included. Mean age was 73.4 years (standard deviation 9.4), and the mean Charlson comorbidity index score was 3.7. The baseline mean prostate volume was 81.7 (range 33–179) mL. Patients were catheter-dependent for an average of 225 (range 30–1821) days prior to surgical intervention. Average followup time was 10.2 months. Of the 53 patients treated, 42 (79%) patients were able to become catheter-free after treatment. Twenty-six (49%) patients failed their initial trial of void at 14 days postoperatively; 11% (n=6) of patients experienced hematuria with one admitted to hospital due to hematuria/clot retention. There were no Clavien Dindo ≥3 complications. Only retention volume ≥1 L was a significant independent predictor of treatment failure on univariate and multivariate logistic regression analysis.
Conclusions: Rezūm effectively treated catheter-dependent urinary retention. Given the simplicity of treatment, accessibility, and minimal anesthetic requirements, providers should consider Rezūm to minimize indwelling catheter-related morbidity for catheter-dependant patients.

INTRODUCTION

Benign prostatic hyperplasia (BPH) is one of the most common conditions affecting the aging male population, the management of which exceeds $1.1 billion annually in the US.[1] Traditionally, the treatment of BPH has consisted of medical management or surgical treatment with transurethral resection of the prostate (TURP) being the mainstay. However, treatment options for BPH have significantly expanded since that time. Minimally invasive surgical treatments (MIST(s)) have begun to emerge in efforts to minimize patient exposure to general anesthesia, and preservation of sexual function.[2] Rezūm Water Vapour Therapy (Rezūm) is a safe and effective transurethral MIST that utilizes convective thermal energy through water vapour to rapidly ablate obstructive prostatic tissue, providing patients with sustained improvements in urinary flow rate and symptom score for up to five years, while preserving sexual function.[3] In a recent economic analysis conducted by Ulchakar et al. of MISTs for BPH, Rezūm warranted consideration as a first-line treatment alternative to medical therapies, offering favourable cost-effectiveness, excellent safety, and favourable tolerability profile compared to other therapies.[4]

In the Canadian healthcare system, surgical wait times for benign urological disease have historically been disproportionately affected when compared to those that are malignant in nature, a trend that has been further exacerbated by the COVID-19 pandemic.[5–8] This has a significant impact on catheter-dependent patients secondary to their progressive BPH leading to potential deleterious outcomes, with studies demonstrating an increased risk of complications when compared to patients receiving immediate surgical management.[9] Currently, the recent Canadian Urological Association (CUA) and American Urological Association (AUA) guidelines recommend the use of Rezūm in patients with prostates less than 80mL in size and

wishing to preserve sexual function.[10,11] However, there is emerging evidence that Rezūm can be performed in patients with >80mL prostates effectively and with low complication rates.[12 28]-A recent systematic review conducted by Spinos et al. evaluating Rezūm in treating patients with chronic indwelling catheters found that the use of Rezūm is feasible, safe, and efficient in this population.[13] However, with the included studies being limited in patient volume, further investigation is warranted as this presents an alternative for those who are catheter-dependent but may not tolerate the general or spinal anesthesia required for traditional BPH surgical options. Additionally, Rezūm can be utilized in an office-based or ambulatory setting, alleviating burden on hospital operating room resources, while possessing favourable cost-effectiveness when compared to other minimally invasive therapies.[4]

This study sought to investigate the utility and safety of Rezūm in the treatment of BPH in catheter-dependent patients. The primary objective was to assess real-world clinical outcomes including the rates of post-treatment catheter-free status, discontinuation of medications, and incidence of post-treatment complications. These findings would be of particular interest for universal healthcare systems, such as Canada, as longer wait times and extended periods of catheter-dependence are frequently encountered.

METHODS

A single centre, retrospective study was conducted including patients who were treated with Rezūm by two staff urologists over a two-year period between April 1, 2022, and April 1, 2024. This study received approval from the University of Manitoba Health and Research Ethics Board (HS25687). Patients were included if they had catheter-dependant urinary retention and had failed at least one trial of void (TOV) prior to initial consultation. Preoperative data including baseline demographic information, urine volume at time of urinary retention episode (determine by bladder scan or drained volume), presence of median lobe, BPH related pharmacotherapy usage, prostate volume measurement (via transrectal/transabdominal ultrasound, prostate MRI, or pelvic CT), time with indwelling urethral catheter, and medical history was obtained via retrospective review of electronic medical records.

All patients received periprocedural intravenous antibiotics prior to Rezūm. For anesthetic, patients either had anesthetist administered intravenous conscious sedation or oral conscious sedation plus local prostatic block as previously described.[14] Rezūm procedure was then performed as previously described.[3] Intraoperative and immediate postoperative adverse events were recorded and collected from the electronic medical record. Patients were given a prescription for either acetaminophen and codeine or nonsteroidal anti-inflammatories for post-procedure oral analgesia.

Routine post-operative follow-up occurred at two weeks for catheter removal and TOV. If patients failed initial TOV, a second attempt occurred one week later. Patients were considered to have passed TOV if measured PVR < 300cc. Routine follow-up for all patients was performed at two weeks, one month, and three months postoperatively. Catheter dependency, International prostate symptom score (IPSS), BPH pharmacotherapy utilization, time to catheter removal

and/or requirement of other BPH surgical interventions were recorded. Any postoperative adverse events including urinary tract infections, hematuria, emergency department visits and hospital admissions were also collected. All adverse events were categorized based on the Clavien-Dindo classification system.

Cohort characteristics and study parameters were summarized using descriptive statistics. Changes in outcomes measures from baseline to follow up were compared descriptively. Primary outcome measure was postoperative catheter-free rate. Secondary analysis to determine predictors of treatment failure was performed for the following variables including age, presence of median lobe, drained volume ≥ 1L, prostate size > 80cc, and time with indwelling catheter > 6 months. Univariates and multivariate logistic regression analysis was performed using SPSS. Two-sided statistical significance was set at p=0.05.

RESULTS

From April 2022 to April 2024, a total of 276 patients underwent Rezūm at a single center. Of these, 53 patients met our inclusion criteria and were enrolled in our study. Demographics of the study cohort is detailed in Table 1. The mean age was 73.4 years (standard deviation [SD] = 9.4) with an average CCI of 3.7 (SD = 1.6). Mean time with indwelling catheter prior to intervention was 225 days (range 30-1821). Monotherapy with alpha-blocker was the most utilized medication regimen followed by combination therapy (a-blocker and 5-ARI), and finally by monotherapy with 5-ARI at 45%, 32%, and 4% respectively. 19% of patients were not on any medications to treat their BPH at time of Rezūm. The mean prostate volume of our cohort was 81.7mL (range 33-179mL), with 28.3% (n=15) of patients with a median lobe visualized at time of procedure. At our institution, patients received Rezūm therapy most commonly under conscious sedation (83%, n=44), followed by oral sedation with local pudendal nerve block (15%, n=8) and spinal anesthetic (2%, n=1). Retention volume at time of urinary retention episode was also captured, with a median volume of 887.5mL (range 340-3000mL). 35.8% (n=19) of patients presented with retention volume equal to or greater than 1L. The average follow-up time for our cohort was 10.2 months (SD = 3.2).

All included patients underwent Rezūm therapy as previously described with no intraoperative complications. Clinical outcomes post-treatment are detailed in Table 2. All patients underwent initial TOV two weeks post-procedure. Of these patients, 49% (n=26/53) failed TOV at this time. Overall, 79% (n=42/53) of patients successful underwent TOV by the 1-month follow-up with an average time to successful catheter removal of 23.9 days (SD=16.6). Of all patients who were catheter free post Rezūm treatment, 1 patient developed recurrence of urinary retention requiring the use of ongoing clean intermittent catheterization. Of the successful patients, 10% (n=4) underwent subsequent procedure for bother some LUTS. Average postoperative IPSS was measured at 3 months for patients successfully undergoing TOV was 10.89 (SD= 6.5). 43 out of the 53 patients were using BPH pharmacotherapy pre-procedurally. The use of pharmacotherapy for BPH related symptoms was able to be successfully eliminated in 86% of patients (n=37/43). Nine patients required the ongoing use of an indwelling catheter or

clean intermittent catheterization despite undergoing Rezūm treatment. Of these patients, 36% (n=4) underwent urodynamic studies demonstrating the presence of bladder atony and 55% (n=6) went on to subsequent BPH surgery to become catheter free (TURP, photoevaporation of the prostate, holmium laser enucleation of the prostate), while 9% (n=1) continued with chronic self-catheter use.

Patient characteristics were analyzed that predicted treatment failure post Rezūm as detailed in Table 3. On univariate logistic regression analysis, only retention volume ≥ 1L was a significant independent predictor of treatment failure (7.515 [1.686 – 33.499]; p=0.008). Other variables analyzed such as age (1.061 [0.983-1.146]; p=0.126), presence of median lobe (0.938 [0.212-4.144]; p=0.932), prostate size > 80cc (1.320 [0.348 – 5.003]; p=0.683), and time with indwelling catheter > 6 months (3.5 [0.875 – 13.995]; p=0.076) were not significant predictors. On multivariate logistic regression analysis, again only retention volume ≥ 1L was a significant independent predictor of treatment failure (10.082 [1.740 – 58.437]; p=0.010).

Complications post-Rezūm treatment are detailed in Table 2. Dysuria/infection were the most common complication seen, occurring in 23% (n=12) of patients. These cases were managed with oral antibiotics with or without oral analgesia and did not require presentation to the hospital. 11% (n=6) of patients experienced hematuria, with none of these patients requiring cystoscopy +/- clot evacuation. Retrograde ejaculation was seen in one patient, however, of note they did continue utilizing an alpha-blocker post-procedure. Two patients (4%) required presentation to the emergency department, with one being hospitalized for hematuria and clot retention. Finally, no Clavien-Dindo ≥ 3 complications were seen in our cohort.

DISCUSSION

Rezūm water vapor therapy has been an emerging office-based MIST option for the management of BPH, with the CUA and AUA guidelines recommending its use for patients with prostate sizes under 80mL and desiring preserve ejaculatory function.[10,11] Recent small retrospective series have shown potential benefit in patients with larger prostates suffering from urinary retention.[13] With the COVID-19 pandemic, surgery for benign diseases have been disproportionately affected, exacerbating an already chronic problem that has long plagued the Canadian health care system.[6–8] The lack of operating room resources has led to further delays for patients with catheter dependency secondary to BPH, resulting in both potential increased direct and indirect costs to both the patient and the healthcare system. Expanding the role of office based Rezūm to patients with larger sized glands and urinary retention offers one potential solution to alleviate the surgical backlog by providing timely and effective care. Our study demonstrated that the use of Rezūm in the catheter-dependent population with larger sized prostates can be an effective option to help patients successfully undergo TOV.

Despite our cohort having significantly longer time with an indwelling catheter compared to the published literature, comparable efficacy rates were seen with 79% of patients becoming catheter free post-procedure.[11,13,15] A systematic review recently published by Spinos et al. of five retrospective studies similarly included patients with prostate size greater than the

recommended 80mL, while showing efficacy rates of 70.3 to 100%.[13] However, studies demonstrating complete efficacy were largely limited to smaller sample sizes (n<16). Of note, three (3/16) of the treatment failures in our series demonstrated bladder atony on post-intervention urodynamic studies, likely signifying that these patients would have remained catheter-dependent regardless of treatment modality. Additionally, the time with urinary catheter until intervention in our cohort was approximately eight months; significantly longer than the reported time in the literature of 51 days to 4.8 months, which is unfortunately the real-world experience for patients in the Canadian system.[7,13,15] Although there is some evidence that delay to BPH debulking surgery of greater than six months may result in higher rates of treatment failure, this is limited to the pre-MIST era.[16] Our study results show that Rezūm treatment of patients with significant time of indwelling catheter may still be a viable option, however, expanding the use of this therapy to provide timely treatment may result in greater treatment success and benefit to the system.

Further analysis was performed to identify predictors of treatment failure. Only elevated retention volume ≥ 1L at time of urinary retention episode was a significant predictor of treatment failure. Previous studies have demonstrated lower rates of successful TOV following urinary retention for patients with ≥ 1L drained at time of catheterization[17]. A possible explanation for this finding is that these patients may be more likely to have a hypotonic bladder, and pre-procedural urodynamics could be considered in these select patients. No significant association was seen between larger prostate size (>80cc) and treatment failure. This is in keeping with the published literature, with good efficacy and safety profile seen for the use of Rezūm in patients with larger glands[18]. Comparative studies looking at treatment outcomes for large and small prostate glands show similar outcomes between groups[19,20], however longer-term follow-up is required. Other variables such as prolonged time with indwelling catheter (> 6 months), age, presence of median lobe, were not found to be significant predictors, however further research is required in this domain.

Although TURP has long been the benchmark for the surgical management of BPH, minimally invasive therapies have continued to rise. No randomized control trials are available comparing the efficacy of TURP vs Rezūm, as only indirect comparisons are available. However, final five-year outcome data by McVary et al. shows durable improvements in voiding and quality of life with a low re-treatment rate of 4.4%.[3] Other potential benefits of Rezūm include preserved ejaculatory function, lower bleeding risk, as well as the ability to offer treatment to more frail patients otherwise unfit for general or spinal anesthesia. Despite our cohort consisting of catheter-dependent patients with larger prostates, our rate of hematuria and serious complications compare favorably to the published literature with no other series reporting grade 3 or higher Clavien-Dindo classified complications.[3,13,21] In an overwhelmed Canadian system, a key benefit would be circumventing lengthy operating room wait times with an office-based approach performed under conscious sedation, oral sedation with local anesthesia, or even self-administered inhaled analgesics.[14,22] A US cost-effectiveness analysis showed that the cost

of Rezūm was approximately $2000 USD less per case compared to TURP, with analysis suggesting that Rezūm should be considered as a first-line alternative to medical therapy for patients with moderate-to-severe lower urinary tract symptoms.[4] Furthermore, cost modelling provided by the National Institute for Health and Care Excellence estimated cost savings of £569-65 per person compared to TURP or holmium laser enucleation of the prostate, due to its ability to be performed in outpatient settings as well as its efficacy.[4]

Contemporary cost benefit analyses have demonstrated that Rezūm is cost-effective for patients with bothersome lower urinary tract symptoms, however, the application of this treatment to the catheter-dependent population may come with further benefit to both the healthcare system and the patient. For our cohort, the average time with catheter until treatment was approximately eight months, a duration that would likely be longer if patient was awaiting a traditional TURP. Majority of patients awaiting surgical treatment with an indwelling catheter longer than three months are at higher risk of developing complications such as hematuria, urinary tract infections, or catheter-related problem (blockage, encrustation, trauma) potentially requiring repeat hospital presentations and possible admission.[9,23] Additionally, prolonged dwelling time of urethral catheters can be problematic with previous literature demonstrating a non-linear incremental increase in the risk of catheter-related urinary tract infections (CAUTIs) with each additional day of catheterization.[24,25] This alone may result in significant cost savings, with the attributable costs of one CAUTI ranging from $876 from $8,398 depending on their severity.[26] Multiple indirect costs are also associated with the delay of treatment for catheter-dependent BPH patients, including homecare services for catheter changes, lost hours of work, as well as reduced quality of life that is difficult to account for in a cost-benefit analysis.[27,28] It is also important to recognize that implementing Rezūm treatment is not without cost, including the cost of the device, increased need for nursing staff for post treatment catheter care, and most provinces still require patients to pay out of pocket for these treatments. However, in our province, Rezūm therapies are currently covered by Manitoba Health, allowing for expanded utilization of this treatment modality. Although formal cost-benefit analyses are required, consideration of insurance coverage for Rezūm may result in net cost savings for the healthcare system while reducing patient morbidity associated with prolonged wait times.

Our study holds important strengths, one of which is being the largest cohort investigating Rezūm for catheter-dependant patients reported in the literature thus far. Expanding the availability of Rezūm therapies may aid in providing expedited treatment for catheter dependent BPH patients, both reducing cost to the system as well as morbidity to the patients. However, certain limitations exist mainly attributable to the retrospective nature and inherent limitations. Given our limited sample size, our logistic regression modelling is likely underpowered, however we do feel that our study offers valuable insights in implementing Rezūm in real world clinical practice. Important variables such as post-void residual volume, post procedure uroflow/PVR, QoL and sexual function assessments, medications prescribed for complications, duration of pharmacotherapy use prior to treatment, and number of injections

were unable to be assessed. Additionally, the limited temporal follow-up of our data set is an important limitation. TOV was also performed at two weeks post-procedure as was stated in the initial trial by McVary et al., however, this may differ from previous studies in the literature. Although our rate of patients becoming catheter-free post-Rezūm was 79%, we note that 49% of patients failed their initial TOV at two weeks. We felt it was still reasonable to consider these patients as successfully becoming catheter-free if they subsequently passed a future TOV, as the mean time to successful TOV was approximately one month. Prostate size was estimated by multiple modalities including CT abdomen/pelvis, transabdominal ultrasound, MRI, or transrectal ultrasound, which may have inaccurately quantified the size of the gland. To further validate the efficacy of this potential solution, future directions from our group include performing larger-scale prospective studies of MISTs and performing formal cost benefit analyses.

CONCLUSIONS

Our study demonstrates that Rezūm in catheter dependent BPH patients is both safe and effective. Patients with elevated retention volume ≥ 1L at time of urinary retention episode were found to be significantly more likely to fail post-treatment TOV. Increased implementation of Rezūm in the Canadian landscape may be beneficial in alleviating the surgical backlog for catheter dependent BPH patients, while reducing cost to both the system and to the patient. Further research is warranted to assess the cost-effectiveness of Rezūm as a primary option for the treatment of BPH in the Canadian health care system.

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FIGURES AND TABLES

Table 1. Baseline demographics	
Total number of patients	**N=53**
Age (mean ± SD)	73.4±9.4 years
Charleston comorbidity index (mean ± SD)	3.7±1.6
Time with indwelling catheter (mean [range])	225 (range 30–1821) days
Prostate volume (mean [range])	81.7 (range 33–179) mL
Prostate size >80 cc	49.1% (n=26)
Pre-treatment medications	
Alpha-blocker monotherapy (%[n])	45% (24)
5-ARI monotherapy (%[n])	4% (2)
Combination therapy (%[n])	32% (17)
None (%[n])	19% (10)
Followup time (mean ± SD)	10.2±3.2 months
Presence of median lobe	28.3% (n=15)
PVR retention volume ≥1 L	35.8% (n=19)
PVR retention volume (median [range])	887.5 (range 340–3000)
Anesthetic choice	
Spinal (%[n])	2% (1)
Conscious sedation (%[n])	83% (44)
Oral sedation with local block (%[n])	15% (8)

ARI: 5α-reductase inhibitors; PVR: postvoid residual; SD: standard deviation.

Table 2. Outcomes post-Rezūm treatment	
Clinical outcomes	
Initial failed TOV at 2 weeks (%[n])	49% (26)
Successful TOV at 1 month (%[n])	79% (42)
Patients remaining catheter free at 3 months (%[n])	98% (41)
Time to successful TOV (mean ± SD)	23.9±16.6 days
Successful patient undergoing subsequent procedure (%[n])	10% (4)
Procedure undertaken	
Rezūm (%[n])	50% (2)
TURP (%[n])	25% (1)
Green Light PVP (%[n])	25% (1)
Reason for failure	
Bladder Atony on UDS (%[n])	36% (4)

Underwent subsequent procedure with successful TOV (%[n])	55% (6)
Continued with catheterization (%[n])	9% (1)
Postop elimination of pharmacotherapy (%[n])	83% (37/43)
Postop IPSS (mean ± SD)	10.89±6.5
Complications	
Dysuria/infection (%[n])	23% (12)
Hematuria (%[n])	11% (6)
Hospitalization/ED visit (%[n])	4% (2)
Retrograde ejaculation (%[n])	2% (1)
Clavien-Dindo ≥3 complications (%[n])	0% (0)

ED: emergency department; IPSS: International Prostate Symptom Score. PVR: postvoid residual; SD: standard deviation; TOV: trial of void; TURP: transurethral resection of the prostate.

Table 3. Predictors of persistent catheter dependency post-Rezūm treatment

Variable	**Univariate**		**Multivariate**	
	OR (95% CI)	**p**	**OR (95% CI)**	**p**
Age (y)	1.061 (0.983–1.146)	0.126	1.037 (0.950–1.130)	0.417
Presence of median lobe	0.938 (0.212–4.144)	0.932	0.885 (0.152–5.163)	0.892
PVR ≥1 L	7.515 (1.68633.499)	**0.008**	10.082 (1.740–58.437)	**0.010**
Size >80 cc	1.320 (0.348 – 5.003)	0.683	0.924 (0.183–4.624)	0.923
Time with catheter >6 months	3.5 (0.875–13.995)	0.076	4.856 (0.910–25.931)	0.064

CI: confidence interval; OR: odds ratio; PVR: postvoid residual.