Rezūm water vapor therapy for catheter-dependent urinary retention: a real-world Canadian experience

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Introduction: *This analysis reported outcomes of treating catheter-dependent urinary retention with Rezūm water vapor therapy.*

Materials and methods: *A prospective registry was established at two high-volume Canadian centers. Patients had baseline medical and benign prostatic hyperplasia (BPH) history documented. The subgroup of patients with refractory, catheter-dependent urinary retention was analyzed. The primary outcome was the proportion of patients who were spontaneously voiding and catheter-free at 6 months.*

Results: *Sixteen patients (age: 68.7 years) with catheter-dependent urinary retention were treated with Rezūm. Average prostate volume was 84.4 mL and 75% had median lobe. All patients had at least one recent failed trial without catheter (TWOC) and 87.5% were on BPH oral therapy. Mean number of vapor injections was 14.5. Visibility and bleeding during procedure were assessed using a 5-point scale, and were rated as 1.4 and 1.3, respectively. Anesthesia was either intravenous propofol sedation (n = 13) or self-administered methoxyflurane inhaler (n = 3). Mean catheter duration until first planned TWOC was 28.4 days. Three patients needed catheter replacement due to initial failed TWOC. One patient was lost to follow up, one patient did not return at 1 month, and one patient did not return at 3 months. At 1 month, 13/14 patients were spontaneously voiding and catheter-free. At 3 months, 14/14 patients were spontaneously voiding, and at 6 months, 15/15 patients were spontaneously voiding and catheter-free (1 patient was lost to follow up).*

Conclusions: *Rezūm water vapor therapy can successfully treat catheter-dependent urinary retention after initial failed TWOC in an outpatient setting.*

Key Words: prostatic hyperplasia, lower urinary tract symptoms, male, prospective study

Introduction

Benign prostatic hyperplasia (BPH) is a urologic condition characterized by a progressive increase in prostate size.[1,2] Patients with BPH will often develop lower urinary tract symptoms (LUTS), and it has been found that healthcare costs attributed to BPH are among the top 10 most prominent and costly diseases in men older than 50 years.[3,4] Urinary retention is one of the most significant complications of BPH and, historically, it has represented an indication for surgery.[5-7] From a socioeconomic perspective, patients with urinary retention present a particular challenge as, in addition to recovery from surgery, these patients have the inability to urinate and increased pain. Consequently, they will eventually require an emergency room visit, catherization, long term physician follow up, and an attempt at catheter removal.[6]

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The American Urological Association (AUA) and Canadian Urological Association (CUA), state that the current management of BPH includes conservative treatment, pharmacologics, and surgery.[1,8-10] Specifically with regards to patients with refractory urinary retention secondary to BPH, surgical intervention is recommended.[8-10] The gold standard surgical option for BPH is transurethral resection of the prostate (TURP); however, this procedure is associated with high rates of hospital readmission and retrograde ejaculation.[1,8,11] In recent years, a novel, minimally-invasive procedure was introduced for the management of BPH patients, the Rezūm System (Boston Scientific Company Inc., Marlborough, MA, USA), which uses water vapor thermal therapy to ablate obstructing prostate tissue.[1,4]

The Rezūm System was approved by the Food and Drug Administration (FDA) in 2015 based on the results of the Rezum II pivotal trial (NCT01912339), a randomized trial that allocated 197 men to either Rezūm therapy or control and demonstrated that Rezūm therapy provides rapid and durable improvements in BPH symptoms.[4,12] Support for Rezūm therapy was also published by the National Institute for Health and Care Excellence (NICE) in June 2020.[13,14] Both the AUA and CUA have now included water vapor thermal therapy in their most recent guidelines as a treatment that may be offered to particular BPH patients; however, the evidence on its use specifically within catheter-dependent urinary retention is limited.[1,8,9] The objective of the current study was to evaluate the efficacy and safety of Rezūm therapy in these patients within a multicenter, real-world setting.

Materials and methods

Study subjects

A prospective registry was established in Canada at two high-volume centers, the University Health Network in Toronto, Ontario and the University of Montreal Hospital Center in Montreal, Quebec. The subgroup of BPH patients who received Rezūm water vapor therapy at these institutions and had catheter-dependent urinary retention were included in this study. In Canada, Rezūm does not have public health coverage nor is it covered by private health insurance. As a result, all patients electing for Rezūm therapy pay out-of-pocket.

Treatment procedure

Rezūm water vapor therapy was performed as previously described.[4,15,16] This system includes a generator containing a radiofrequency power supply, system controls, and a single-use transurethral delivery device that incorporates a standard 4 mm, 30-degree endoscopic cystoscopy lens. Water vapor thermal energy, created by the radiofrequency current against an inductive coil heater in the device handle, is delivered via a retractable needle and saline flush. The water vapor is delivered for 9 seconds, retracted, and then administered to another treatment site at the surgeon's discretion. The goal is to create contiguous, overlapping lesions running parallel to the natural slope of the urethra. The intervention is customized to the shape and location of the gland, including treatment of the median lobe.

Assessments

All patients had baseline medical and BPH history documented. The primary outcome of this study was the proportion of patients who were spontaneously voiding and catheter-free at final follow up (6 months). Adverse events were monitored during study follow up.

Statistical methods

Cohort characteristics and assessments were summarized using descriptive statistics. The proportion of patients who were spontaneously voiding and catheter-free was calculated at 1, 3, and 6 months. Statistical analyses were conducted using R version 3.6.0.

Results

Subject demographics

A total of 16 subjects (mean age 68.7 years) were treated with Rezūm from April 2019 to December 2020, Table 1. The mean prostate volume was 84.4 mL (range: 41-158 mL), and 75% of subjects had a median lobe. The mean number of injections was 14.5 (range: 10-21) and the mean duration of procedure was 6.1 minutes (range: 3.2-10.5). Visibility and bleeding during the procedure were assessed using a 5-point scale, and were rated as 1.4 and 1.3, respectively. Postoperatively, the mean duration of catheterization was 28.4 days (range: 7-30). None of the patients had prior BPH surgery.

Primary outcome

Three patients needed catheter replacement due to initial failed trial without catheter (TWOC). One patient was lost to follow up (i.e., did not attend any follow up visit), one patient did not return at 1 month, and one patient did not return at 3 months. At 1 month follow up, 13/14 (93%) patients were spontaneously voiding and catheter-free, Figure 1. At 3 months, 14/14

TABLE 1. **Baseline characteristics (16 subjects)**

Characteristic	Mean (SD) or n (%)
Age, years	68.7 (11.7)
Prostate volume, mL	84.4 (35.8)
PSA, ug/L	11.1 (8.1)
Median lobe	12 (75%)
Duration of BPH	
< 5 years	6 (38%)
5-7 years	6 (38%)
8-10 years	0 (0%)
> 10 years	4 (25%)
Current BPH medication	
Alpha-blocker	13 (81%)
5ARI	7 (44%)
Cialia/Viagra	0 (0%)
None	2 (13%)
Medical history	
Dyslipidemia	5 (31%)
Hypertension	4 (25%)
Diabetes	3 (19%)
Kidney/bladder stone	0 (0%)
Operative characteristics	
Anesthesia	
Propofol	13 (81%)
Lidocaine gel	8 (50%)
Penthrox/methoxyflurane	3 (19%)
Pain medication/anxiolytic	
Percocet	3 (19%)
Ativan/Lorazepam	2 (13%)
Acetaminophen	1 (6%)
Number of injections	14.5 (3.2)
Saline volume, mL	467.8 (120.0)
Duration of procedure, minutes	6.1 (1.8)
Planned duration of catheter, days	28.4 (5.7)
Postoperative medications	
Antibiotics	16 (100%)
Stool softener	13 (81%)
Pain medications	10 (63%)
Anti-inflammatories	5 (31%)
Bladder	3 (19%)

PSA = prostate-specific antigen
BPH = benign prostatic hyperplasia
5ARI = 5-alpha reductase inhibitor

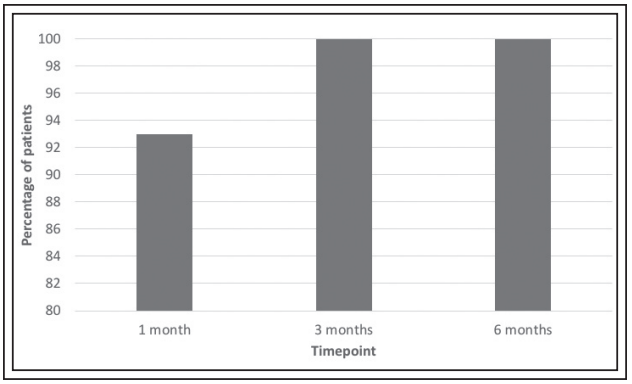

Figure 1. Proportion of patients who were spontaneously voiding and catheter-free over time.

(100%) patients were spontaneously voiding, and at 6 months, 15/15 (100%) patients were spontaneously voiding and catheter-free.

Safety

The procedure was well-tolerated by patients over the course of the study. No grade ≥ III Clavien-Dindo events occurred. Additionally, no patients changed their BPH medication by 1 month; however, at 3 months, 2 patients stopped taking their medication and, at 6 months, another 2 patients ceased their medication consumption.

Discussion

The purpose of this study was to evaluate the efficacy and safety of Rezūm therapy in patients with catheter-dependent urinary retention in a real-world, Canadian setting. A total of 16 patients, with a mean prostate volume of 84.4 mL (range: 41-158 mL), were treated with Rezūm. The mean procedure time was 6.1 minutes (range: 3.2-10.5), and the average catheterization length was 28.4 days (range: 7-30). One patient was lost to follow up. Of the remaining patients, 93% were spontaneously voiding and catheter-free at 1 month and, at 3 and 6 months, 100% of patients were voiding and catheter-free. Three patients needed catheter replacement due to initial failed TWOC. Rezūm therapy was shown to successfully treat catheter-dependent urinary retention after initial failed TWOC in a quick, safe, out-patient setting.

As noted earlier, the evidence on the use of Rezūm therapy for catheter-dependent urinary retention is limited and consists mostly of retrospective evaluations.[1,5,7,17,18] One previous study was a retrospective analysis on 38 catheter-dependent men with complete urinary retention, which found that 70%

of patients voided spontaneously and were catheter-free a median of 26 days (range: 4 to 65) after Rezūm therapy, with infrequent adverse events that were mild and resolved quickly.[5] In another retrospective study on 10 patients who developed urinary retention and subsequently failed their TWOC, treatment with Rezūm resulted in seven (70%) of these patients passing their TWOC at 4 weeks and the other three (30%) passing their TWOC at 6 weeks. Additionally, their post-void residual (PVR) volume significantly decreased from 1100 to 107.2 mL after treatment.[7] In a retrospective evaluation on 136 patients with recurrent urinary retention who underwent Rezūm therapy in an ambulatory setting, Eredics et al found that 78.6% of patients were spontaneously voiding after a median of 31 days and that 93.5% and 91% of patients remained catheter-free after 3 and 12 months, respectively. Additionally, perioperative complications were infrequent and minor (Clavien-Dindo Grade 1-2).[18] A retrospective chart review by Bassily et al on 49 patients with catheter-dependent urinary retention treated with Rezūm revealed similar findings in terms of urinary retention outcomes (i.e., 79.6% of patients were catheter-free following the procedure and 87.8% were catheter-free at 6 months), but also demonstrated that Rezūm therapy results in a statistically significant improvement in IPSS and IPSS-QoL scores, Qmax, and PVR at 6 months.[17] Though these studies support Rezūm therapy as a safe, fast, and effective procedure for patients with catheter-dependent urinary retention, they also emphasized the need for more multi-centered studies with larger sample sizes, comparator treatments, and long term follow up. Though the current study included a relatively smaller sample size of 16 patients, it is one of the first prospective studies with results that are consistent with these prior retrospective evaluations. More evidence is needed evaluating patient symptom and quality of life scores, and uroflowmetry outcomes (i.e., peak urinary flow [Qmax] and PVR) following Rezūm therapy in this particular patient population.[1,5]

Despite its merits, this study is not devoid of limitations. These include a small sample size coupled with no comparator intervention, thus, it is unclear how the Rezūm System performs against other treatment options. Secondly, as treatment allocation was known by both the patient and treating physician, outcomes assessment was unblinded; however, spontaneous voiding and catheter independence is an objective outcome that has less potential of bias. Third, patient-reported outcome measures and uroflowmetry outcomes were not measured, which provides limited information on patient function and quality of life. A strength of this study was that it demonstrated that Rezūm therapy is effective in a real-world setting using an objective outcome. Additionally, improvements occurred early (i.e., 1 month) and were sustained up to 6 months post-intervention, demonstrating that patients do not regress months after treatment; however, longer term follow up data is needed. Last but not least, the population may be skewed to a higher socio-economic class as the procedure is paid out-of-pocket. This may result in a more motivated and compliant patient.

Conclusions

Rezūm water vapor therapy can successfully treat catheter-dependent urinary retention after initial failed TWOC in a quick, out-patient setting. Future research in this area should include the evaluation of this therapy in comparative trials versus other treatment options used for this patient population, and its long term effects on patient quality of life and function.

Disclosures

Drs. Elterman, Bhojani, Chughtai, Zorn are consultants for Boston Scientific. Christopher Vannabouathong received payment for medical writing. □

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