Anesthetic options for Rezūm water vapour therapy: Is minimal sedation tolerable for a minimally invasive procedure?

Dhiraj S. Bal[1], Matthew Urichuk[1], Kapilan Panchendrabose[1], Ryan Ramjiawan[2], Jainik Shah[1], Naomi Gebru[3], Alagarsamy Pandian[4], Premal Patel[2]
[1]Max Rady College of Medicine, University of Manitoba, Winnipeg, MB, Canada; [2]Department of Surgery, University of Manitoba, Winnipeg, MB, Canada; [3]Department of Microbiology, University of Manitoba, Winnipeg, MB, Canada; [4]Department of Anesthesiology, University of Manitoba, Winnipeg, MB, Canada.

Cite as: Bal DS, Urichuk M, Panchendrabose K, et al. Anesthetic options for Rezūm water vapour therapy: Is minimal sedation tolerable for a minimally invasive procedure? *Can Urol Assoc J* 2024 January 30; Epub ahead of print. http://dx.doi.org/10.5489/cuaj.8535

Published online January 30, 2024

Corresponding author: Dhiraj S. Bal, Max Rady College of Medicine, University of Manitoba, Winnipeg, MB, Canada; bald@myumanitoba.ca

***

ABSTRACT

Introduction: There has been a rapid expansion of the armamentarium for managing benign prostatic hyperplasia (BPH). Given the invasiveness and complication risks of traditional surgical management, minimally invasive procedures have emerged. Rezūm water vapour therapy is a safe, effective alternative. Given the minimally invasive nature, there is interest in administering conscious sedation over general anesthesia (GA) to decrease procedural times and costs and increase accessibility by completing procedures in an office-based setting. We sought to assess and describe patient-reported tolerability for Rezūm completed under oral and deep intravenous sedation.

Methods: Patients who underwent Rezūm between April and November of 2022 under conscious sedation with oral sedation and local anesthesia (OSLA) or deep intravenous sedation (DIS) were enrolled. Baseline information was collected, and followup interviews were conducted where patient tolerability scores, future anesthetic preferences, and complication data was prospectively obtained.

KEY MESSAGES

- As the management of BPH evolves from traditional surgery to minimally invasive procedures, the anesthetic administered must also transition from heavier, general anesthesia, to lighter conscious sedation.
- We demonstrate high patient-reported tolerability for Rezūm under the administration of conscious sedation through both oral sedation and local anesthesia and deep intravenous sedation alone.
- Most patients had highly rated experiences of Rezūm under conscious sedation.

Results: Fourteen patients were enrolled in each group. The OSLA and DIS cohorts had a median tolerability score of 8 (interquartile range [IQR] 3.5) and 9 (IQR=1.75), respectively, indicating highly tolerable experiences. There was no significant difference between groups (p=0.13). On followup, 85.7% of patients in the OSLA and 100% in DIS groups expressed their future preference for conscious sedation over GA, with no significant difference between the two groups (p=0.46).
Conclusions: Our study demonstrates OSLA and DIS are both viable conscious sedation methods for Rezūm, with patients reporting high tolerability to the procedure regardless of sedation choice. Almost all patients receiving conscious sedation would choose to undergo Rezūm using conscious sedation again and had minimal complications.

INTRODUCTION

Benign prostatic hyperplasia (BPH) refers to the proliferation of stromal and epithelial cells within the transition zone of the prostate surrounding the urethra. This overgrowth can lead to mechanical bladder outlet obstruction and the development of lower urinary tract symptoms. BPH is a common urological condition affecting older men, with an estimated prevalence of 50% in men aged 50-60 years and up to 80% in men over 70.[1] The symptoms of BPH, including urinary frequency, urgency, nocturia and weak urinary stream, can significantly impact a patient's quality of life. Furthermore, long-term consequences of untreated BPH can involve high-pressure retention and overactivity of the detrusor muscle.[2] Although medical therapy with alpha-blockers and 5-alpha reductase inhibitors is often indicated as a first-line treatment for mild-to-moderate disease, some patients require surgical intervention. Concerns regarding traditional surgical treatment's invasiveness and complication risks have sparked innovation and novel, minimally invasive therapies have emerged.[3,4]

Rezūm Water Vapour Therapy is a new minimally invasive surgical treatment for BPH, using convective thermal energy from water vapour to ablate obstructing prostatic tissue.[5] Rezūm has been shown to be a safe and effective procedure, with sustained improvements in urinary flow rate and symptom score for up to five years.[6] However, the optimal anesthetic choice during the procedure is a matter of debate and is often left to the clinician’s discretion with consideration of patient preferences. Reports of general anesthesia, spinal anesthesia, oral sedation, intravenous sedation and prostate block use exist – however, there is a gap in the literature regarding patient-reported outcomes and tolerability under varying anesthetic options.[7–9]

While general and spinal anesthetics provide substantial periprocedural pain relief, they are associated with increased risks in frail patients with multiple comorbidities – an increasingly common population in practice.[10] Conscious sedation provides a safe alternative for patient comfort and can alleviate anxiety during the procedure. Furthermore, conscious sedation results

in decreased procedural costs, anesthetic-related risks and operative time.[11] While a promising alternative, there is no consensus on the optimal sedation for Rezūm Therapy. Moreover, procedural tolerance under conscious sedation may vary, significantly altering procedural outcomes and the subjective patient experience.

This study aims to evaluate and describe patient tolerability of conscious sedation for Rezūm Therapy with either oral sedation and local anesthesia (OSLA) or deep intravenous sedation (DIS) for the treatment of BPH. The primary objective was to assess patient-reported tolerability of OSLA and DIS and to determine if patients would opt for conscious sedation over general anesthesia in the future. Complications of each sedation modality were reported to assess the efficacy and safety of each sedation type. We hypothesized that both OSLA and DIS would be well-tolerated by patients and result in a non-different, low rate of complications consistent with the existing literature.

METHODS

A prospective cohort study was conducted to describe and evaluate patient tolerability of conscious sedation with either oral sedation and local anesthesia (OSLA) or deep intravenous sedation (DIS) during Rezūm Therapy. Approval for this study was obtained from the University of Manitoba's Health and Research Ethics Board (HS25687).

Study population and data collection

Between April and November of 2022, all adult ambulatory patients who underwent Rezūm Therapy at a single outpatient clinic in Winnipeg, MB under OSLA or DIS were enrolled to achieve a similar sample size per group. A single attending urologist (PP) performed all procedures. Baseline demographic information was collected, including patient age, sex, BMI, place of residence and medical comorbidities assessed by the Charlson Comorbidity Index. Patients were enrolled and contacted by phone where verbal informed consent was obtained. A previously validated, standardized questionnaire relating to tolerability was then administered to prospectively assess both anesthetic choices for a future procedure and whether the patient would recommend their conscious sedation over general anesthesia.[12] Additionally, a patient-reported tolerability score was assessed using a Likert scale ranging from 0-10 to assess the overall experience of the procedure and sedation, with 10 representing an excellent experience and 0 representing completely intolerable procedures. Complication data was collected to address our secondary outcome, including self-reported excess pain, infections, hospital admissions, emergency room visits, or family physician visits due to the procedure.

Procedural and sedation protocol

OSLA included Percocet (10 mg/325 mg, 1-2 tabs) and lorazepam (1 mg) administered 30-45 minutes prior to the procedure. Additionally, a local injection of sterile 2% xylocaine jelly with a 20-minute indwell time and a pudendal nerve block with 20 mL of 1% lidocaine and 0.25% bupivacaine was used in this group. DIS included midazolam (5 mg), ketamine (20 mg) and

continuous infusion of propofol (25-50 mcg/kg/min) and remifentanil (0.05 mcg/kg/min) administered by an anesthesiologist. Following anesthetic administration in both cohorts, Rezūm Water Vapour Therapy was performed and patient vitals including heart rate, blood pressure, end-tidal carbon dioxide and oxygen saturation were monitored continuously throughout the procedure. Upon completion of the procedure, patients were transferred to recovery and had an indwelling 16 French Foley catheter placed, remaining for up to 3-5 days.

Statistical analysis and outcomes

Baseline demographic, clinical and questionnaire data was entered into a password-encrypted Microsoft Excel file (Microsoft Office, Microsoft Corporation, Redmond, WA). Data analysis was completed using R software (v. 4.2.2).

Baseline demographic variables, complication data and patient-reported outcomes were compared between the OSLA and DIS groups. Patient-reported outcomes included self-reported tolerability score (ordinal; 0-10), whether the patient would opt for conscious sedation over general anesthesia for a future procedure (binary; conscious sedation or general anesthesia), if the patient would recommend their method of sedation to others (binary; yes or no), and excess pain or infection post-operatively (binary; yes or no). Self-reported tolerability scores were determined using a Likert scale ranging from 0-10, with 0 representing a completely intolerable procedure and 10 representing an excellent experience.

Medians with interquartile ranges (IQR) were used to report descriptive statistics. Mann-Whitney U-tests, a non-parametric analogue of the two-sample T-test, were used to compare baseline characteristics and self-reported tolerability scores between OSLA and DIS groups. Relationships between binary outcomes and the anesthetic received (OSLA or DIS) were assessed using Fisher's exact tests. All statistical analysis was completed with an alpha of 0.05, with a $p<0.05$ being considered statistically significant.

RESULTS

Between April and November of 2022, 28 patients provided verbal consent and were enrolled with 14 patients in the OSLA group and 14 in the DIS group who underwent Rezūm Therapy performed by a single attending urologist (PP). Baseline characteristics of both cohorts, including patient age, Charlson Comorbidity Index, BMI, prostate volume, treatments per lobe and median lobe presence are shown in Table 1. There were no statistically significant differences in any of these parameters between groups. All procedures were successfully tolerated with no intraoperative or perioperative complications reported.

On follow-up, 92.8% of patients overall would opt for conscious sedation again if they had to undergo a repeat procedure over general anesthesia. Specifically, 85.7% of patients receiving OSLA and 100% receiving DIS reported they would opt for the same sedation. Similarly, 85.7% of patients receiving OSLA and 100% of patients receiving DIS would recommend their sedation to others. Although descriptive differences persisted, these findings were not found to be statistically significant (Table 2; $p=0.48$).

Tolerability scores did not significantly differ between patients receiving OSLA compared to those receiving DIS (p=0.13). Descriptively, both groups reported highly tolerable experiences with a median tolerability score of 8 (IQR=3.5) in patients receiving OSLA and a median tolerability score of 9 (IQR=1.75) in those receiving DIS (Figure 1).

Post-operative complication rates, including self-reported excess pain and infection, did not significantly differ between OSLA and DIS groups. In patients receiving OSLA, only one (1/14; 7.1%) had infection 4-6 weeks post-operatively and two (2/14; 14.3%) indicated the presence of excess pain. In patients receiving DIS, two (2/14; 14.3%) had infection 4-6 weeks post-operatively, whereas one (1/14; 7.1%) reported excess pain. Regardless of sedation received, no patient required post-operative hospital admission, emergency room visits, or family physician visits due to their procedure.

DISCUSSION

Our study aimed to investigate the patient-reported tolerability of this emerging therapy when performed under two different sedation approaches – oral sedation with local anesthesia (OSLA) and deep intravenous sedation (DIS). Our findings indicate that Rezūm is well-tolerated by the majority of patients under both OSLA and DIS, with a high proportion of patients indicating they would opt for conscious sedation in the future for both groups. Additionally, under both sedation options, there was a 100% procedural success rate with no hospital admissions or physician visits as a result of procedural complications.

It is important to note that three patients in the OSLA group rated their experience below a five, whereas no patients had similarly low scores in the DIS group (Figure 1). This difference in tolerability scores was consistent with the proportion of each group that would select DIS or OSLA sedation over general anesthesia (GA), 100% and 85.7%, respectively. Although this was not statistically significant, this may be due to the limited sample size, resulting in diminished statistical power. With a larger sample, it is possible that significant differences may have been present. However, the descriptive difference between groups may indicate that ideal patient selection for conscious, oral sedation in urologic procedures is an important consideration that should be studied further, given the limited literature guiding clinical judgement.

Patient preferences in periprocedural pain and anxiety management are significant factors in the selection of optimal sedation, which warrants a discussion between patients and their providers.[9] Another critical consideration for sedation selection is cost, given the higher costs of deep intravenous sedation compared to oral sedation. An added benefit of oral sedation is the decreased need for an anesthesiologist to be present compared to intravenous sedation, further reducing the costs associated with the procedure. The results of the current study suggest that most patients are expected to tolerate Rezūm Therapy under oral sedation with local anesthesia. These findings, combined with reduced costs, make oral sedation an appealing sedation choice for Rezūm for not only the patient but the public health care system. Although IV sedation requires an anesthesiologist and is typically more expensive than oral sedation, it may be a reasonable alternative for those who may not find oral sedation tolerable.[14,15] The decision

between sedation modalities requires discussion between patients and providers; however, both oral and intravenous sedation appears to be tolerable and cheaper alternatives to GA for Rezūm, with previous literature demonstrating GA can be over two-fold the cost of IV sedation.[16]

The high self-reported tolerability rates add to the growing body of literature suggesting that Rezūm Therapy can be effectively administered without the need for general or spinal anesthesia. This finding is particularly significant in regions with limited anesthesiology resources, as it increases accessibility to the procedure while also minimizing potential complications. To optimize the treatment of BPH in the office-based setting, it is crucial to shift away from traditional surgical interventions that require general or spinal anesthetics. Instead, we recommend utilizing minimal sedation for this minimally invasive procedure. Gilpin et al. (2022) provided evidence that IV conscious sedation is tolerable for Rezūm and that an additional prostate block had no significant effect on patient-reported pain.[9] This is consistent with our study, as DIS patients did not receive any nerve blocks while patients in the OSLA cohort did. In a recent study by Elterman et al. (2022), the efficacy of a short-acting, minimal sedation method, methoxyflurane (Penthrox), was highlighted and shown to be a rapid, easily administered pain management strategy for Rezūm.[17] These various approaches, along with our present study, are key in transitioning BPH interventions from the operating room to the office setting. By offering Rezūm Therapy as a day procedure in an office-based setting under conscious sedation, we can also effectively decrease wait times for patients with severe lower urinary tract symptoms awaiting traditional surgical intervention in the healthcare system. Overall, this evidence suggests that Rezūm Therapy can be safely and efficiently performed without general or spinal anesthesia, providing a viable alternative to traditional surgical interventions.

The limitations of our study are mainly attributed to its non-randomized design, which prevented us from considering all potential factors that might have influenced our findings. Furthermore, we did not collect information on whether patients had prior experience with GA, which may impact patient preference for conscious sedation over GA. Despite this limitation, patients were informed about what GA entails and the associated risks. Finally, the current study had limited statistical power, with only 14 patients per group, making it challenging to assess statistical associations between baseline, demographic and clinical variables with future anesthetic choices.

CONCLUSIONS

Oral sedation with local anesthesia and deep intravenous sedation alone are both viable conscious sedation methods for Rezūm Water Vapour Therapy. Almost all patients receiving conscious sedation would choose to undergo the Rezūm Water Vapour Therapy using conscious sedation over general anesthesia. Patients receiving conscious sedation, whether intravenous or oral, reported the procedure to be highly tolerable. Although patients receiving deep intravenous sedation reported greater subjective tolerability scores and preference for conscious sedation over those receiving oral sedation with local anesthesia, these differences were not statistically

significant. Further research is warranted to identify factors that may impact ideal patient selection and administration route of conscious sedation.

REFERENCES

1. Parsons JK. Benign prostatic hyperplasia and male lower urinary tract symptoms: Epidemiology and risk factors. Curr Bladder *Dysfunct Rep* 2010;5:212. https://doi.org/10.1007/s11884-010-0067-2
2. Gomelsky A, Dmochowski RR. Overactive bladder in males. *Ther Adv Urol* 2009;1:209. https://doi.org/10.1177/1756287209350383
3. Elterman D, Aubé-Peterkin M, Evans H, et al. UPDATE - 2022 Canadian Urological Association guideline on male lower urinary tract symptoms/benign prostatic hyperplasia (MLUTS/BPH). *Can Urol Assoc J* 2022;16:245-256. https://doi.org/10.5489/cuaj.7906
4. Elterman DS, Bhojani N, Vannabouathong C, et al. Rezūm water vapor therapy for catheter-dependent urinary retention: a real-world Canadian experience. *Can J Urol* 2022;29:11075-9.
5. Westwood J, Geraghty R, Jones P, et al. Rezūm: A new transurethral water vapour therapy for benign prostatichyperplasia. *Ther Adv Urol* 2018;10:327. https://doi.org/10.1177/1756287218793084
6. McVary KT, Gittelman MC, Goldberg KA, et al. Final 5-year outcomes of the multicenter randomized sham-controlled trial of a water vapor thermal therapy for treatment of moderate to severe lower urinary tract symptoms secondary to benign prostatic hyperplasia. *J Urol* 2021;206:715-24 https://doi.org/10.1097/JU.0000000000001778
7. Das AK, Leong JY, Roehrborn CG. Office-based therapies for benign prostatic hyperplasia: a review and update. *Can J Urol* 2019;26:2-7.
8. Ebbing J, Bachmann A. Anesthesia-free procedures for benign prostate obstruction: Worth it? *Curr Opin Urol* 2015;25:32-39. https://doi.org/10.1097/MOU.0000000000000123
9. Gilpin L, Zekan D, Baugh B, et al. Evaluating the efficacy of employing local anesthetic prostatic blocks during Rezūm procedure. *Cureus* 2022;14:e29598. https://doi.org/10.7759/cureus.29598
10. Bergman H, Beland F, Lebel P, et al. Care for Canada's frail elderly population: Fragmentation or integration? *CMAJ* 1997;157.
11. Mc Cann ME, Greco C. Procedural sedation. Essentials. *Anesth Infants Neonates* 2022:398-404. https://doi.org/10.1017/9781107707016.038
12. Lapere C, Roelofse J, Omar Y, et al. Patient satisfaction during and following procedural sedation for ambulatory surgery. *South African J Anaesth Analg* 2015;21:29-34. https://doi.org/10.1080/22201181.2015.1073451
13. Jain K, Blachman-Braun R, Jain E, et al. Ureteroscopy under conscious sedation: A proof-of-concept study. *Can Urol Assoc J* 2022;16 :E461-7. https://doi.org/10.5489/cuaj.7750
14. Peeler CE, Villani CM, Fiorello MG, et al. Patient satisfaction with oral versus intravenous sedation for cataract surgery: A randomized clinical trial. *Ophthalmology* 2019;126:1212-8. https://doi.org/10.1016/j.ophtha.2019.04.022
15. Hock LE, Kennedy S, Wilson CW, et al. Oral anxiolytics prior to routine resident cataract surgery eliminate need for intravenous sedation at a Veterans Affairs Hospital. *Am J Ophthalmol Case Rep*. 2022;25:101379. https://doi.org/10.1016/j.ajoc.2022.101379

16. Van Sickels JE, Tiner BD. Cost of a genioplasty under deep intravenous sedation in a private office versus general anesthesia in an outpatient surgical center. *J Oral Maxillofac Surg* 1992;50:687-90. https://doi.org/10.1016/0278-2391(92)90097-J
17. Elterman DS, Zorn KC, Bhojani N, et al. Efficacy and safety of methoxyflurane (Penthrox) for pain control during water vapor thermal therapy (Rezūm) for benign prostatic enlargement. *Can J Urol* 2022;29:11355-60.

Competing interests*: Dr. Patel has been a consultant for Boston Scientific. The remaining authors do not report any competing personal or financial interests related to this work.*

FIGURES AND TABLES

Figure 1. Self-reported tolerability scores reported by patients receiving deep intravenous sedation and oral sedation with local anesthesia. Each circle represents a patient in the specified group. Comparison between cohorts reported using non-parametric Mann-Whitney U testing.

Table 1. Baseline characteristics for those receiving oral sedation with local anesthesia or deep intravenous sedation					
	Oral sedation with local anesthesia (OSLA)		**Deep intravenous sedation (DIS)**		**p**
	Median	**IQR**	**Median**	**IQR**	
Age (years)	65.0	(9.0)	70.0	(13.4)	0.28
BMI (km/m^2)	25.6	(2.8)	25.3	(3.6)	0.37
Charlson comorbidity index	0.0	(0)	0	(1)	0.60
Prostate volume (mL)	83.0	(38.0)	75.5	(8.5)	0.92
Injections per lobe (#)	3.0	(0)	3.0	(0.8)	0.83
Median lobe present (%)	0.0	(0)	0	(0)	

Medians and interquartile ranges, representing the spread of the middle 50% of the cohort, are reported. Significance of differences reported using non-parametric Mann-Whitney U testing.

Table 2. Future anesthetic choice for all patients in the oral sedation with local anesthesia and deep intravenous sedation cohorts			
	General anesthesia	**Conscious sedation**	**p**
Oral sedation (OS)	2	12	0.48
Deep intravenous sedation (DIS)	0	14	

Fisher's exact test comparing groups was insignificant.