

Anesthetic options for Rezūm water vapor therapy

Is minimal sedation tolerable for a minimally invasive procedure?

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ABSTRACT

INTRODUCTION: There has been a rapid expansion of the armamentarium for managing benign prostatic hyperplasia (BPH). Due to the invasiveness and complication risks of traditional surgical management, minimally invasive procedures have emerged. Rezūm water vapor therapy is a safe, effective alternative. Given the minimally invasive nature, there is interest in administering conscious sedation over general anesthesia 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.

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 general anesthetic, 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) is a common urologic 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, and 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 the invasiveness and complication risks of traditional surgical treatments have sparked the innovation of minimally invasive therapies.^{3,4}

Rezūm water vapor therapy is a new minimally invasive surgical treatment for BPH, using convective thermal energy from water vapor 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

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.

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 aimed 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 OSLA or 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, body mass index (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 acetaminophen/oxycodone (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 remifentanyl (0.05 mcg/kg/min) administered by an anesthesiologist. Following anesthetic administration in both cohorts, Rezūm water vapor 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 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, U.S.). 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 postoperatively (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 followup, 92.8% of patients overall would opt for conscious sedation over general anesthesia again if they had to undergo a repeat procedure. 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

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.

to others. Although descriptive differences persisted, these findings were not found to be statistically significant ($p=0.48$) (Table 2).

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).

Postoperative 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 postoperatively 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 postoperatively, whereas one (1/14; 7.1%) reported excess pain. Regardless of sedation received, no patient required postoperative hospital admission, emergency room visits, or family physician visits due to their procedure.

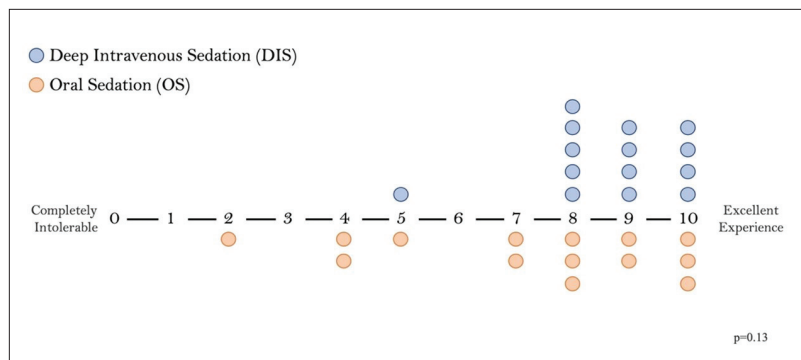


Figure 1. Self-reported tolerability scores reported by patients receiving deep intravenous sedation and oral sedation with local anesthesia. Each circle represents a patient in the specified group. Comparison between cohorts reported using non-parametric Mann-Whitney U testing.

DISCUSSION

Our study aimed to investigate the patient-reported tolerability of Rezūm when performed under two different sedation approaches: OSLA and DIS. Our findings indicate that Rezūm is well-tolerated by most 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 <5, whereas no patients had similarly low scores in the DIS group. This difference in tolerability scores was consistent with the proportion of each group that would select DIS or OSLA sedation over general anesthesia — 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 DIS compared to oral sedation. An added benefit of oral sedation is the decreased need for an anesthesiologist to be present compared to intravenous (IV) 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 OSLA. These findings, combined with reduced costs, make oral sedation an appealing sedation choice for Rezūm not only for the patient but for the public healthcare system as well.

Although intravenous sedation requires an anesthesiologist and is typically more expensive than oral sedation, it remains a reasonable alternative for those who can not tolerate oral sedation.^{13,14} The choice of sedation modalities requires discussion between patients and providers; however, both oral and intravenous sedation appear to be tolerable and are less expensive alternatives to general anesthesia for Rezūm, with previous literature demonstrating the cost of general anesthesia can be over two-fold that of IV sedation.¹⁵

The high self-reported tolerability rates add to the growing body of literature suggesting that Rezūm 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. Gilpin et al 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, the efficacy of a short-acting, minimal sedation method, methoxyflurane, was highlighted and shown to be a rapid, easily administered pain management strategy for Rezūm.¹⁶

Overall, the evidence suggests Rezūm can be safely and efficiently performed without general or spinal anesthesia, providing a viable alternative to traditional surgical interventions. Furthermore, by offering Rezūm 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.

Limitations

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 general anesthetic, which may impact patient preference for conscious sedation over general anesthetic. Despite this limitation, patients were informed about what general anesthetic 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

OSLA and DIS alone are both viable conscious sedation methods for Rezūm water vapor therapy. Almost all patients receiving conscious sedation would choose to undergo Rezūm 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 DIS reported greater subjective tolerability scores and preference for conscious sedation over those receiving OSLA, 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.

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.

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