

Rezūm™ Water Vapor Therapy vs. Medication for BPH/LUTS Patients

Editorial Commentary by Kevin T. McVary, MD, FACS
Director, Center for Male Health, and Professor of Urology at Stritch School of Medicine, Loyola University Medical Center,
Maywood, Illinois

As urologists, most of my colleagues and I take a "shared decision-making" approach to patients with lower urinary tract symptoms secondary to benign prostatic hyperplasia (LUTS/BPH). We counsel our patients on their options for intervention, which can include behavioral or lifestyle modifications, medical therapy, and interventional procedures. Together, physician and patient decide which therapy to pursue, an approach supported by the American Urological Association Guidelines for shared decision making.¹

While medication and interventional therapy are the main treatments for LUTS/BPH, some physicians try a "step therapy" where medication is tried first—because many patients prefer to avoid surgery, viewing medication as less intrusive and less expensive than surgical intervention.^{1,2} Often, men stay on medications for years until side effects or waning effectiveness cause them to consider interventional therapy.¹⁻³

However, the introduction of minimally invasive surgical therapies (MISTs), such as Rezūm™ Water Vapor Therapy, offer physicians and their patients a safe, effective, durable, in-office treatment for LUTS/BPH that can improve quality of life and preserve sexual function.³⁻⁵ Thus, adding another option to consider in the shared decision-making discussion.

As a result, in my practice, my patients are increasingly more comfortable discussing MISTs as a possible first choice of BPH treatment. And many of them are opting for a MIST first. Furthermore, according to a four-year single-center study of 255 men, 97% of patients would recommend Rezūm Therapy to a friend.⁶

Why the change? Although medications may be seen as less intrusive and less expensive, most medications, specifically the commonly used alpha blockers, do not induce changes in the size of the prostate and can be associated with various side effects, such as headache, postural hypotension, fatigue, and dizziness. They can also negatively affect sexual function, and some can lead to decreased libido, impotence, and ejaculatory dysfunction.

Meanwhile, Rezūm Therapy also has side effects. Most notably, a time limited dysuria, hematuria, hematospermia, urinary frequency, retention, urinary tract infection (UTI), decrease in ejaculatory volume, and urgency.⁵ Following is an overview of the indications, contraindications, and adverse effects of both Rezūm Therapy and some common medications used to treat BPH.

Rezūm Therapy⁸

The Rezūm System is intended to relieve symptoms, obstruction, and reduce prostate tissue associated with BPH. It is indicated for men ≥ 50 years of age with a prostate volume 30cm³ ≤ 80cm³. The Rezūm System is also indicated for treatment of prostate with hyperplasia of the central zone and/or a median lobe. The use of the Rezūm System is contraindicated for patients with a urinary sphincter implant, patients who have a penile prosthesis, patients who have an active urinary tract infection. Possible adverse events include dysuria, hematuria (gross), hematospermia, urinary frequency, decrease in ejaculatory volume, urinary retention, UTI (suspected), urinary urgency, anejaculation, terminal dribbling, UTI (culture proven), epididymitis, erectile dysfunction (worsening), pain/discomfort (pelvic), prostatitis, urethral stricture, gross hematuria with clots, pain/discomfort with ejaculation, pain/discomfort (penile), poor stream, splayed stream, gross hematuria with retention, hematuria (intermittent uncomplicated), hematuria (micro), incomplete voiding, urinary incontinence (urge), urinary tract infection (UTI).

Alpha Blockers9

Alpha blockers are indicated to treat BPH (Selective Alpha-1 Blockers) and pheochromocytoma (Nonselective Alpha-blockers). They are contraindicated in individuals with hypersensitivity to alpha-blockers or any other component of the drug formulation and in those men with cataracts or plans for future cataract surgery. Adverse effects for selective alpha-1 blockers include hypotension, weakness, tachycardia, tremulousness.

5-Alpha Reductase Inhibitors¹⁰

5-alpha reductase inhibitors are indicated to treat BPH and androgenic alopecia. They are contraindicated for children, women who are pregnant or planning on getting pregnant. The 5-alpha-reductase inhibitors should also be avoided in any persons who have had a hypersensitivity to these medications. Adverse effects include erectile dysfunction, decreased ejaculatory volume, a decrease in libido, gynecomastia, orthostatic hypotension, and decreased fertility.

Research shows that Rezūm Therapy provides effective and durable improvements with lower observed clinical progression rates compared to daily medications. ¹¹ The American Urological Association (AUA) guidelines support the consideration of MIST as a first-line treatment in certain clinical scenarios when the therapy choice is made as part of a shared decision-making process. ¹

Following are some of the considerations when evaluating treatment options, such as Rezūm Therapy, for BPH:

Safety: Both Rezūm Therapy and medications have a strong safety profile.^{5,12}

Side effects: As a minimally invasive procedure, typically done in the physician's office with local anesthesia, Rezūm Therapy's side effects are typically short-term and late-related adverse events were rare. Some of the common side effects associated with Rezūm Therapy are dysuria, hematuria, hematospermia, urinary frequency, retention, urinary tract infection (UTI), decrease in ejaculatory volume, and urgency. A complete list of side effects is provided in the labeling supplied with the device.

Medications side effects include hypotension, weakness, tachycardia, tremulousness, erectile dysfunction, decreased ejaculatory volume, a decrease in libido, gynecomastia, orthostatic hypotension, and decreased fertility depending on the specific medication chosen.^{9,10}

Efficacy: Rezūm Therapy treats the cause of BPH symptoms and lasts over time.⁵ In the Rezūm Therapy pivotal trial, outcomes improved from the first visit three months post-procedure and were maintained through 60 months after a single Rezūm Therapy procedure (IPSS reduced 48%, QOL increased 45%, Qmax improved 44%, BPHII decreased 48%) with preservation of sexual function.⁵ Several clinical trials have reported that medications, such as alpha blockers, can be efficacious over both the short and long term. Yet, these drugs (alpha blockers) do not induce changes in the size of the prostate.⁷ Therefore, eventually, a patient may need to progress to a MIST. Plus, many patients on medications are inconsistent about staying on their regimen.¹³

Durability: According to one study, BPH clinical progression rates are slower with Rezūm Therapy than with medical therapy.*¹¹ Rezūm Therapy has been demonstrated to have long-term, effective symptom relief and improved quality of life that remains durable for at least five years.⁵ Prolonged use of many of the medical therapies may lead to a greater number of older patients with larger prostates and decompensated bladders needing intervention.¹⁴

Sexual function and quality of life: Some BPH medications can impair sexual function and reduce libido.^{9,10} These side effects are usually resolved with discontinued treatment. Rezūm Therapy preserves sexual function and quality of life out to at least five years, with no clinically meaningful impact to erectile or ejaculatory function.^{5,15}

Cost effective: Rezūm Therapy is less expensive than combination drug therapy. ¹⁶ It also provides quality of life benefits to the patients and is a cost-saving treatment for BPH compared to the medical therapy. ¹⁶ Re-treatment rates in particular are low with Rezūm Therapy, which reduces costs to the health care system. ⁵

In my opinion, when choosing an initial therapy, patients with LUTS/BPH should consider Rezūm Therapy as a treatment option—especially when compared to a potential lifetime of managing medications and their possible side effects.^{5,10} Rezūm Therapy offers significant and durable symptom relief, is safe, preserves sexual function, and is a minimally invasive, in-office procedure.⁵ In my experience, when discussing treatment options with patients, the most compelling reason to pursue Rezūm Therapy as a first-line therapy is that it can enhance the patient's quality of life.⁵

*Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.

References

- 1. Lerner LB, McVary KT, Barry MJ, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA Guideline 2021. J Urol. 2021 Oct;206(4):806-26.
- 2. Mayo Clinic. Benign prostatic hyperplasia (BPH). https://www.mayoclinic.org/diseases-conditions/benign-prostatic-hyperplasia/diagnosis-treatment/drc-20370093#:~:text=ease%20without%20treatment.-,Medication,Alpha%20blockers. Accessed Sept. 1, 2022.
- 3. Bortnick E, Brown C, Simma-Chiang V, Kaplan SA. Modern best practice in the management of benign prostatic hyperplasia in the elderly. Ther Adv Urol. 2020 May 27;12:1756287220929486.
- 4. Christidis D, McGrath S, Perera M, et al. Minimally invasive surgical therapies for benign prostatic hypertrophy: The rise in minimally invasive surgical therapies. Prostate Int. 2017 Jun;5(2):41-6.
- 5. McVary KT, Gittelman MC, Goldberg KA, et al. Final 5-year outcomes of the multicenter randomized sham-controlled trial of Rezüm water vapor thermal therapy for treatment of moderate-to-severe lower urinary tract symptoms secondary to benign prostatic hyperplasia. *J Urol.* 2021 Sep;206(3):715-24.
- 6. Mooney R, Goldberg K, Wong D, Roehrborn C. Convective radio frequency thermal therapy for treatment of benign prostatic hyperplasia: Single office experience with 255 patients over 4 years. *Urol Pract.* 2020 Jan:7(1):28-33.
- 7. Yu ZJ, Yan HL, Xu FH, et al. Efficacy and side effects of drugs commonly used for the treatment of lower urinary tract symptoms associated with benign prostatic hyperplasia. Front Pharmacol. 2020 May 8;11:658.

 8. Data on file with Boston Scientific. Directions for Use. 50998296-01A
- 9. Nachawati D, Patel JB. Alpha Blockers. [Updated 2022 Jul 4]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK556066/.
- 10. Salisbury BH, Tadi P. 5 Alpha Reductase Inhibitors. [Updated 2022 Jun 11]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK555930/.
- 11. Gupta N, Rogers T, Holland B, et al. Three-year treatment outcomes of water vapor thermal therapy (Rezūm System) compared to doxazosin, finasteride and combination drug therapy for men with benign prostatic hyperplasia: cohort data from the Medical Therapy of Prostatic Symptoms (MTOPS) Trial. J Urol. 2018 Aug; 200(2): 405-13.
- 12. Yuan JQ, Mao C, Wong SY, et al. Comparative effectiveness and safety of monodrug therapies for lower urinary tract symptoms associated with benign prostatic hyperplasia: a network meta-analysis. *Medicine* (Baltimore). 2015 Jul;94(27):e974.
- 13. Cindolo L, Pirozzi L, Sountoulides P, et al. Patient's adherence to pharmacological therapy for benign prostatic hyperplasia (BPH)-associated lower urinary tract symptoms (LUTS) is different: Is combination therapy better than monotherapy? BMC Ural. 2015 Sep 21:15:96.
- 14. Elkoushy MA, Elshal AM, Elhilali MM. Changing patients' profile presenting for surgical management of benign prostatic hyperplasia over the past 16 years: A single-centre perspective. Can Urol Assoc J. 2015 Nov-Dec;9(11-12):372-8.
- 15. McVary KT, El-Arabi A, Roehrborn C. Preservation of sexual function 5 years after water vapor thermal therapy for benign prostatic hyperplasia. Sex Med. 2021 Dec;9(6):100454.
- 16. Chughtai B, Rojanasarot S, Neeser K, et al. A comprehensive analysis of clinical, quality of life, and cost-effectiveness outcomes of key treatment options for benign prostatic hyperplasia. *PLoS One*. 2022 Apr 15;17(4):e0266824.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device or at www.iFU-BSCl.com. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.

IMPORTANT INFORMATION: These materials are intended to describe common clinical considerations and procedural steps for the use of referenced technologies but may not be appropriate for every patient or case. Decisions surrounding patient care depend on the physician's professional judgment in consideration of all available information for the individual case.

Boston Scientific (BSC) does not promote or encourage the use of its devices outside their approved labeling. Case studies are not necessarily representative of clinical outcomes in all cases as individual results may vary.

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

 $Results from \ different \ clinical \ investigations \ are \ not \ directly \ comparable. \ Information \ provided \ for \ educational \ purposes \ only.$

For information purposes only. The content of this article/publication is under the sole responsibility of its author/publisher and does not represent the opinion of BSC.

Kevin T. McVary, MD, FACS, is a Boston Scientific consultant and was compensated for his contribution to this article. Dr. McVary was the Principal Investigator of the pivotal clinical trial.

All trademarks are the property of their respective owners.

© 2022 Boston Scientific Corporation or its affiliates. All rights reserved. URO-1396805-AA OCT 2022