Office-based therapies for benign prostatic hyperplasia: a review and update

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DAS AK, LEONG JY, ROEHRBORN CG. Office-based therapies for benign prostatic hyperplasia: a review and update. *Can J Urol* 2019;26(Suppl 1):2-7.

Introduction: *Lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH) is one of the most common conditions affecting the aging man. Over the years, various treatment modalities with distinct efficacy and safety profiles have emerged in experimental and clinical use. However, only a handful have gained in popularity and stood the test of time.*

Materials and methods: *We provide an update on minimally invasive treatment modalities for BPH, specifically focused on office-based procedures namely the prostatic urethral lift (UroLift) and the convective water vapor ablation therapy (Rezūm).*

Results: *Both the UroLift and Rezūm have demonstrated excellent efficacy and durability in relieving LUTS in the BPH patient. When compared to the gold standard TURP, these novel therapies can also be performed as an outpatient procedure under local anesthesia, which allows for decreased hospitalization, operative and catheterization times, subsequently allowing for increased cost savings. Moreover, these procedures have no discernable adverse effects on postoperative sexual function, making it a desirable treatment option for many patients.*

Conclusions: *Both the UroLift and Rezūm are minimally invasive treatment options capable of providing rapid, significant and durable relief of LUTS secondary to BPH. They demonstrate comparable efficacy to TURP with the added advantage of preserving sexual function and decreasing patient morbidity and healthcare costs.*

Key Words: UroLift, Rezūm, BPH, LUTS, minimally invasive therapy

Introduction

The goal of developing novel treatment alternatives for lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH) is to achieve similar clinical outcomes to the gold standard transurethral resection of the prostate (TURP) while minimizing incontinence and sexual dysfunction related adverse effects, such as erectile dysfunction and retrograde ejaculation. Moreover, some of these newer therapies have the potential to be performed in an outpatient office setting, avoiding the need for general anesthesia, has reduced recovery time and improved control of post-procedural pain. Over the years, various treatment modalities with distinct efficacy and safety profiles have emerged in experimental and clinical use. However, only a handful have gained in popularity and stood the test of time.[1] Herein, we aim to provide an update to the readership regarding the minimally invasive treatment modalities for BPH, specifically focused on office-based procedures namely the prostatic urethral lift and the convective water vapor ablation therapy.

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Prostatic urethral lift (PUL)

The PUL, performed with the UroLift system (NeoTract/Teleflex Inc., Pleasanton, CA, USA), is a minimally invasive technique that utilizes permanent nitinol and stainless steel implants to retract the obstructing lateral lobes of the prostate to allow expansion of the urethral lumen via a tissue-sparing approach.[2] These implants

are placed under cystoscopic guidance in an ambulatory setting and are sized in situ to the prostatic lobe after deployment with a UroLift delivery device. This procedure is indicated for patients who do not desire surgery or have failed medical management. Although the use in patients with median lobes or intravesical protrusion has been studied in one prospective cohort study, it is not recommended for this indication by current AUA guidelines.[3] According to the FDA, this treatment is restricted to prostate glands under 80 grams in size by ultrasound or other cross sectional imaging.

The mode of action for the UroLift procedure is primarily mechanical which allows for an opening of the anterior prostatic urethra from the bladder neck up to the verumontanum. Further pre-clinical research on canine and cadaveric models suggests that the long term effects of the UroLift includes inciting acute ischemia which leads to tissue remodeling and focal atrophy to the compression zones of the PUL implants.[4] If a continuous open channel is observed cystopically after UroLift implants are deployed, the procedure is deemed complete. The ideal PUL candidate is one with lateral lobe hyperplasia and a prostate volume under 80 grams.

This procedure can be performed under local anesthesia, including the use of topical anesthetics (lidocaine), oral sedations (benzodiazepines) or analgesics (acetaminophen, opioids).[5] If performed in an office setting, chilled topical lidocaine gel should be applied intraurethrally for sufficient anesthetic coverage. Moreover, adequate time should be given for the preoperative anesthetics to take effect.[6] If necessary, additional anesthetic via a prostatic block can be provided using 1% lidocaine injections. This is similar to that performed during a transrectal ultrasound prostate biopsy. When performing the procedure, it is recommended to start working from the bladder neck towards the verumontanum distally. UroLift implants should also be deployed in the anterior chamber to avoid injury and disruption to the neurovascular bundle.

As PUL is gaining in popularity among clinicians, there is increasing evidence in the literature demonstrating the efficacy and durability of PUL for the treatment of BPH. In 2011, both Chin and Woo demonstrated the initial safety and feasibility of the PUL procedure. Both authors found significant improvement in patient's International Prostate Symptom Score (IPSS), Quality of Life (QoL), Benign Prostatic Hyperplasia Impact Index (BPHII) and maximum urinary flow rate (Qmax) parameters as early as 2 weeks with durable effect of up to 2 years.[4,7] Postoperative adverse events were also rare and transient but expected with any minimally invasive transurethral procedures, with the most common being hematuria, followed by dysuria and other irritative symptoms. Using standardized questionnaires, Chin et al also demonstrated the preservation of sexual function after the PUL procedure. In fact, they reported significant improvements in the Male Sexual Health Questionnaire – Ejaculatory (MSHQ-EjD) bother parameters even up to 2 years after PUL as well as improvements in the International Index of Erectile Function (IIEF-5) and MSHQ-EjD function scores.[7]

To date, the largest, multinational, randomized control trial investigating the utility of PUL is the L.I.F.T. study. This study, led by Roehrborn et al, also reports the longest post-procedural follow up outcomes of up to 5 years. In fact, it was the encouraging results from this trial that supported the decision for FDA approval of the UroLift in 2013.[8] According to this prospective study, IPSS, QoL, Qmax and BPHII scores all showed rapid, significant and durable responses after PUL in both intention to treat and per protocol analysis. The authors also report preservation of sexual function with maintenance of IIEF-5 scores and significant improvement of MSHQ-EjD scores of up to 4 years. Moreover, there were no reported cases of de novo development of ejaculatory or erectile dysfunction.[9-13]

Another randomized controlled trial conducted in Europe comparing the efficacy between PUL to the gold standard TURP with regards to symptomatic relief, quality of recovery, erectile and ejaculatory function, continence preservation and safety is the BPH6 study. This study found that while significant LUTS relief was achieved with both procedures, preservation of ejaculatory function and speed of recovery was superior with PUL when compared to TURP. Health-related quality of life and rates of urge incontinence also did not significantly differ between treatment option while erectile function was appropriately maintained for both modalities. In addition, retreatment rates secondary to return of LUTS or dissatisfaction of surgical outcomes were not significantly different between the two cohorts with 3 (7%) and 2 (6%) patients occurring within 1 year after PUL and TURP, respectively, and an additional 2 patients undergoing retreatment for PUL after 1 year (total 11%). Overall composite endpoint analysis revealed that the PUL procedure was superior to TURP in achieving the primary endpoint of the BPH6 study.[14,15]

While current evidence for PUL are based on subjects with lateral lobe enlargements only, a recent MedLift study in 2018 sought to examine the efficacy and safety of PUL in the treatment of obstructing median lobes. Conventionally, UroLift implants are deployed at the 2 and 10 o'clock positions when viewing the transverse plane of the urethra in order

to compress the obstructing lateral lobes. For median lobes however, the implants are intended to affix the obstructing portion laterally to the prostatic urethra and should be deployed anterior to the 4 or 8 o'clock positions to avoid damage to the neurovascular bundles. This method achieves resolution of LUTS by opening of the bladder neck and reducing the "ball-valve" effect caused by an enlarged median lobe. Results of this study demonstrated promising results with significant improvements of IPSS, QoL, BPHII and Qmax of up to 1 year. Eighty-six percent of patients also reported > 70 on the Quality of Recovery Visual Analog Scale 1 month post-procedure. Aside from effectiveness, the primary safety endpoint for using PUL to treat median lobes were also met, with a 0% observed rate of postoperative device related adverse effect. There were also no reported cases of de novo development of ejaculatory and erectile dysfunction. An effort was made to compare and combine the results from the MedLift data to that of the LIFT study to demonstrate the full effectiveness of the PUL procedure and similar improvement of LUTS relief were found. The combined data also reported an improvement in ejaculatory function and maintenance of erectile function among sexually active men.[16] Due to its tissue-sparing approach, antegrade ejaculation is likely maintained after PUL as the prostatic tissue, bladder neck and urethral tissues are all preserved. As sexual function is known to have a major impact on quality of life, this procedure may be well suited for patients who wish to preserve their sexual function.[17]

Water vapor thermal therapy

The Rezūm system (Boston Scientific, Marlborough, MA, USA) is a novel, minimally invasive therapy that uses convective water vapor thermal energy to treat LUTS secondary to BPH. Following FDA clearance in 2015, this technology utilizes a platform technology that convectively delivers stored thermal energy created by radiofrequency currents in the form of steam to targeted tissue. As the water vapor comes in contact with prostatic tissue, it condenses back into water, releasing large amounts of thermal energy (540 cal/mL H_2O), disrupting the prostatic cell membranes, and finally leads to immediate cell death and necrosis. Subsequently, the body takes about 3 months to resorb the dead tissue, decreasing prostate volume and relieving LUTS in the process.[18,19] A study by Mynderse et al characterizing the effects of Rezūm on prostate tissue using magnetic resonance imaging showed that thermal energy delivered to the prostate is predominantly confined to the targeted treatment zones and does not compromise integrity of surrounding structures.[20] This is consistent with thermodynamic principles of convective heating and allows reduced risk of injury to the bladder, rectum or urinary sphincter, minimizing postoperative complication rates.[21] One of the major advantages that makes the Rezūm such a desirable treatment option is its ability to be performed safely as an outpatient procedure with only local anesthesia.[22]

The mechanism of action for the Rezūm procedure is achieving symptomatic relief through the reduction of prostatic volume via thermal energy ablation. At 6 months, prostate volumes and targeted transitional zone volumes are reported to be reduced by a mean of 29% and 38%, respectively. Furthermore, convective thermal lesion sizes are generally reduced by > 95% 6 months' post-procedure.[20] The Rezūm procedure is suitable for men over the ages of 50, prostate volumes between 30 to 80 grams and can also be done in patients with enlarged median lobes. However, it is contraindicated in patients with concurrent artificial urinary sphincter or penile prosthesis implants in place.

Four-year results from a randomized controlled study assessing the efficacy of Rezūm by McVary and Roehrborn reported objective improvement of LUTS observed as early as 2 weeks' post-procedure which remained consistently durable throughout all 4 years.[23-26] Specifically, IPSS, QoL, Qmax and BPHII all had significant improvements of 47%, 43%, 50% and 52% at 4 years' post-procedure, respectively. In addition, clinically meaningful improvements of Qmax and IPSS scores were observed for patients who underwent treatment of enlarged median lobes when compared to those who had untreated median lobes. Moreover, urinary incontinence scores decreased by 15% and there were no reported cases of sexual dysfunction with this procedure. Both IIEF and MSHQ-EjD scores were stable and maintained throughout entire lengths of follow up.[27] To negate the potential placebo effects for this treatment procedure, paired analysis of outcomes was performed as part of the crossover study. When comparing the control arm and crossover subjects, the authors observed a significantly greater improvement of IPSS, QoL and Qmax after the crossover treatments when compared to that of the control period.[24]

Darson et al also conducted a retrospective analysis among patients in community urology practice groups in an attempt to provide a broader and more realistic view of the Rezūm procedure in a real-world setting. Patient age and prostate sizes varied from 47-96 years and 13-183 grams, respectively, and the

study also reported significantly improved IPSS, QoL and PVR scores in patients with varying severity of LUTS.[28] Based on the criteria used to define clinically meaningful IPSS responses, 72.6% patients reported IPSS decrease of ≥ 50% at 3 months with 60.5% reporting similar sustained improvements after 2 years. Furthermore, responses relative to a ≥ 3 or ≥ 5 point IPSS decrease were observed in 93.0% and 79.1% of patients at 2 years, respectively. Overall, majority of patients achieved evident responses as early as 1 month post-procedure and these responses remained sustainable at the 24 month follow up period.[29,30] These studies corroborate previously published literature indicating the safety and reproducibility of responses to convective water vapor thermal therapy.

With regards to safety of the Rezūm, procedure-related adverse effects were transient and of mild-to-moderate severity. Majority of these procedure-related adverse effects resolved spontaneously within 3 weeks. The most common events were dysuria (16.9%), hematuria (11.8%), hematospermia (7.4%) and other irritative symptoms.[23] Serious procedure-related adverse events were rare at < 2% and included one case of extended urinary retention, bladder neck

TABLE 1. **Comparison between UroLift and Rezūm**

	Prostatic urethral lift (UroLift)	**Water vapor thermal therapy (Rezūm)**
Mechanism of action	• Mechanical • Obstructing prostatic lobes held apart by small implants • Long term: tissue atrophy	• Heat • Necrosis of prostatic lobes using water vapor/steam injections • Long term: volume reduction
Procedure type*	Novel, minimally invasive surgical procedure for the treatment of BPH via a transurethral approach	
Indications*	• Moderate, to severe LUTS secondary to benign prostatic enlargement/ obstruction with underlying BPH • Failed medical management / Non-surgical candidates • Desires preservation of sexual function	
Anesthesia requirements*	Local anesthesia (sufficient), transrectal prostatic block (if required)	
Treatment setting/location*	Office, ambulatory surgical center, operating room (if required)	
Treated lobes*	Lateral or median	
Procedure time*	Less than 1 hour	
Onset of action*	< 1 month	
Prostate size	• Minimum: none • Maximum: 80 grams	• Minimum: 30 grams • Maximum: 80 grams
Post-procedural catheterization	~20% for an average of 1 day	~100% for an average of 3.4 days
Longest reported trial data	5 years	4 years
Randomized data	• 3 months against sham control • 24 months against TURP	• 3 months against sham control
Improvement of symptoms	• IPSS: 8-12 point decrease • Qmax: 2-5 mL/sec increase	• IPSS: 8-12 point decrease • Qmax: 3-6 mL/sec increase
Impact on sexual function	• No impact on erectile function • No impact on ejaculatory function	• No impact on erectile function • 3%-6% risk of developing ejaculatory dysfunction
Safety and adverse events*	• Transient, self-resolving within weeks • Mild to moderate symptoms, most commonly hematuria, dysuria, irritative symptoms	
Cost/reimbursements	Covered by all of Medicare and most commercial plans	Covered by some of Medicare and most commercial plans

*refers to both Urolift and Rezūm

contracture and urosepsis each.[24] No de novo erectile dysfunction or late-occurring adverse events were reported after 2 years.[25,26] Additionally, all procedures were successfully performed in an office or ambulatory surgical center under local anesthesia. Catheterization after the procedure was performed in > 90% of patients with a mean of 3.4 days. Of these, only 32% truly necessitated catheterization due to unsuccessful void trial before discharge while the remaining 68% were entirely at the surgeon's discretion.[23] As such, these catheterization rates may not actually reflect the true need or required duration for post-procedural catheterization.

Retreatment rates remain an important consideration when assessing durability of a procedure. The 4 year retreatment rates were reported to be 4.4% after Rezūm water vapor thermal therapy.[26] This contrasts with other conductive thermal ablative devices such as the transurethral needle ablation (TUNA) and transurethral microwave thermotherapy (TUMT) that reported a 14%-51% and 9%-21% of retreatment rates at 5 years, respectively.[31-36] Retreatment rates for the PUL has also been reported at 10.6% at 3 years and 13.6% at 5 years, while that of TURP ranges between 3% and 14.5% after 5 years.[13,37,38] These comparisons indicate that the water vapor thermal therapy has the potential to provide significant LUTS relief that deliver durable and impactful clinical improvements. See Table 1 for comparison between Urolift and Rezūm.

Conclusions

Both the UroLift and Rezūm systems are minimally invasive treatment options capable of providing rapid, significant and durable relief of LUTS secondary to BPH and both are included in the current American Urological Association (AUA) guidelines for the surgical management of BPH. These procedures can be offered to patients desiring treatment of LUTS associated with BPH, wanting preservation of ejaculatory function, and have prostate volumes less than 80 grams. In the case PUL, patients with obstructing median lobes should be informed that the success rate for patients with median lobes are lower when compared to patients with isolated lateral lobe hyperplasia. While the UroLift procedure has the benefit of offering a catheter-free procedure, the Rezūm system may offer some inherent benefits in treating patients with urinary symptoms associated with obstructing median lobes. Both these emerging technologies have demonstrated comparable efficacy to current standard therapies and can be performed as an outpatient procedure without the use of general anesthesia and with minimal associated perioperative adverse events. It also has no discernable effects on sexual function, making these procedures a more desirable option for many patients. Ultimately, an individualized, shared decision-making approach based on patient preference and clinical parameters is essential in selecting the optimal treatment for each patient.

Disclosures

Dr. Akhil K. Das is a consultant for Lumenis and Richard Wolf.
Joon Yau Leong has no disclosures.
Dr. Claus Roehrborn is an investigator and consultant for Boston Scientific, NeoTract/Teleflex and PROCEPT BioRobotics. □

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