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INTRODUCTION

Techniques and innovative technologies for the treatment of BPH

The surgical management of benign prostatic hyperplasia (BPH) has changed in the past 5 years and the recently updated American Urological Association (AUA) guidelines reflect these changes. Historically, transurethral resection of the prostate (TURP) was the endoscopic treatment of choice for under 80 grams. Open prostatectomy was considered the procedure of choice for larger prostate glands (> 80 grams).

Newer techniques and innovative technologies have changed the strategies utilized by physicians for the procedure-oriented management of BPH. The updated AUA guidelines for BPH state laser enucleation procedures of the prostate, either with holmium or thulium, is the endoscopic treatment of choice for BPH, independent of prostate size. Holmium laser enucleation of the prostate (HoLEP) was the first described technique for endoscopic enucleation of the prostate. HoLEP has been extensively studied in randomized prospective trials comparing HoLEP to TURP or open prostatectomy. HoLEP has proven to be superior to TURP and open prostatectomy and this technique is utilized by many physicians throughout the world and is considered by many the "gold standard" for the surgical management of BPH. The photoselective vaporization of the prostate or PVP can be used for patients with prostates between 30-80 grams and shows significant benefit in patients who are on anticoagulation therapy. New technologies such as urethral lift procedures (Urolift) or steam therapy procedures (Rezūm) have been incorporated into the AUA BPH guidelines for patients desiring office based technology with preservation of antegrade ejaculation and with minimal sexual side effects with these procedures. Lastly, the newest technology, robot assisted water jet system called Aquablation of the prostate, may prove to be an important technique to treat patients with symptomatic BPH. Aquablation has also been recently incorporated to the updated AUA guidelines BPH for patients in patients with prostate sizes between 30 g to 80 g.

These newer technologies and innovative techniques was the impetus for the topic selection for the 2nd annual Jefferson urology symposium, **Emerging Technologies for the Treatment of BPH**. These five technologies/techniques have been summarized with the data presented at this meeting. We hope that you find this information helpful and useful as a quick reference guide to incorporate these new technologies and techniques into your practice.

I want to thank the symposium faculty and the Jefferson Urology Scholar students who assisted in preparing this supplement. The publisher of The Canadian Journal of Urology International is also acknowledged for allowing us to share our symposium educational program to a wider audience.

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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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Photoselective vaporization of the prostate: application, outcomes and safety

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SANDHU JS, LEONG JY, DAS AK. Photoselective vaporization of the prostate: application, outcomes and safety. *Can J Urol* 2019;26(Suppl 1):8-12.

Introduction: *Open prostatectomy and transurethral resection of the prostate (TURP) has been the gold standard therapy for moderate to severe lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH). In recent years, laser vaporization technologies have now been recognized by international guidelines as an effective treatment alternative to TURP for treating BPH.*

Materials and methods: *In this contemporary review, we aim to discuss the application, outcomes and safety of photoselective vaporization of the prostate (PVP), specifically with the GreenLight laser. We also discuss the properties and evolution of the GreenLight laser as understanding the basic principles of this laser system.*

Results: *GreenLight PVP is a durable and effective alternative to TURP, especially in high-risk patients on systemic anticoagulation. Aside from providing similar efficacy and safety, the GreenLight PVP also allows for decreased hospitalization times, catheterization times and subsequently decreased healthcare costs. The latest generation laser, 180W XPS system, is found to be more cost-effective and efficacious in tissue vaporization when compared to previous laser generations.*

Conclusions: *Laser vaporization is a safe and effective option to treating LUTS secondary to BPH. A patient-centered approach considering patient preference and preoperative parameters should be employed to determine the ideal treatment option for each individual patient.*

Key Words: GreenLight, PVP, BPH, LUTS, photoselective vaporization of prostate

Introduction

Benign prostatic hyperplasia (BPH) is one of the most common diseases affecting the aging man and its prevalence rises markedly with increasing age. An estimated 90% of men is thought to be affected by BPH by the age of 85, of which, 25%-30% eventually require treatment.[1,2] For many decades, open prostatectomy and transurethral resection of the prostate (TURP) have been the gold standard therapy for moderate to severe lower urinary tract symptoms (LUTS) secondary to BPH.[3,4] In recent years, however, an effort has been made to further improve the clinical outcomes and efficacy of treatment options offered to patients suffering from this highly prevalent disease. The primary goal is to develop an alternative therapy that can not only effectively relieve symptomatic LUTS, but also be a tolerable and feasible option in high-risk patients, all while reducing patient morbidity, length of hospital stay and medical costs.[5]

With strong evidence from longitudinal cohort studies and meta-analyses, laser vaporization technologies have now been recognized by the American Urological Association (AUA) and European Association of Urology (EAU) as an effective treatment alternative to TURP for treating BPH.[3,4] There are currently four approved and commonly utilized laser systems among the urology community, namely the GreenLight, holmium, thulium and diode laser. Each individual system possesses distinct characteristics suitable for a large gamut of applications. Ultimately, the goal of these laser therapies is to relieve bladder outlet obstruction by means of reducing the prostate size via vaporization, resection or enucleation techniques.[5] In this contemporary review, we discuss the application, outcomes and safety of photoselective vaporization of the prostate (PVP), specifically with the GreenLight laser (Boston Scientific, Marlborough, MA, USA).

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Evolution of the GreenLight laser: from 60W to 180W in 10 years

The GreenLight laser is a non-contact, side-firing laser system that operates in a near continuous mode.[6] Since its introduction in the late 1990s by Kuntzman as the 60W potassium-titanyl-phosphate (KTP) laser, the GreenLight laser has undergone extensive studies and advancements over the decades to continuously improve its efficacy and safety for the treatment of BPH.[7] Following their initial experience, they subsequently described the utility of the first generation 80W KTP laser PVP in 1998 together with its 5 year postoperative outcomes.[8] In 2006, the first 2090 laser fiber and the 120W HPS GreenLight laser was developed by combining the neodymium:YAG laser resonator with a lithium triborate (LBO) crystal in place of the KTP. The next upgrade was the introduction of the side-firing, 600µm silica Mojo fiber which allowed for increased power output from 275kJ to 400kJ when compared to the 2090 fiber.[9] Next came the 180W XPS (LBO) laser system and the MoXy liquid-cooled, steel-capped laser fiber in 2010 which allowed for increased power, speed and efficiency to vaporize tissue.[10] With the latest XPS/MoXy system, both the power output and area of laser beam were increased by 50% while the depth of optical penetration remained the same at 1-2 mm. This improvement in technology allowed for increase in speeds and efficiency of tissue vaporization while minimizing complications such as thermal tissue injury or capsular perforation.[11] Moreover, the MoXy fiber optic also offers improved hemostatic properties, reduction of tissue debris devitrification and has increased fiber longevity compared to previous fibers, allowing for additional cost savings. Its Active Cooling Cap technology increases fiber protection by preventing overheating of the laser via a temperature feedback mechanism, such that when used correctly, only a single MoXy fiber is required for an entire case, regardless of prostate size.[12,13] Overall, comprehensive research comparing the outcomes of lasers with different power outputs have demonstrated each generation of laser being more efficacious and advantageous than the next. As such, with its comparable postoperative outcomes and superior intraoperative safety profile, international guidelines have approved the GreenLight PVP as an alternative to TURP for the treatment of LUTS secondary to BPH.[3,4]

Photoselective vaporization: principles and properties of the GreenLight

The two primary mechanisms of laser therapy in BPH surgery is to induce thermal injury via laser coagulation and laser vaporization. When the laser beam is concentrated on targeted prostatic tissue, the optical energy is converted to thermal energy, which gradually heats the tissue. During laser coagulation, prostatic tissue is heated with temperatures below 100°C to induce tissue coagulation necrosis, causing sloughing of the prostatic urothelium which ultimately leads to delayed anatomical debulking. Conversely, tissue vaporization occurs when temperatures exceeds 100°C and is usually evidenced by the formation of bubbles during the procedure. Additionally, varying extents of coagulation necrosis is observed beneath the vaporized area as the temperature gradually decreases with increasing distance from the laser source.[14]

Utilizing a 532-nm wavelength emission, the GreenLight laser is preferentially absorbed by oxyhemoglobin and has a lower affinity towards water, allowing vaporization of the highly vascularized transitional zone of the prostate, permitting differentiation with the more avascular prostatic capsule.[15] It has a penetration depth of approximately 0.8 mm and majority of the laser energy is concentrated to the superficial tissues, preventing it from penetrating deep into targeted prostatic tissue. It also has a coagulation depth of 1-2 mm around the areas of vaporization, which is ideal such that it is not too shallow, giving rise to its beneficial and adequate hemostatic properties, but also not too deep allowing for excellent efficacy and decreased postoperative complications. Deep coagulation has been associated with an increased risk of dysuria, irritative symptoms, and bladder neck contractures secondary to tissue sloughing, edema and scarring.[7,16]

Outcomes of the GreenLight PVP

The first 80W KTP prototype showed significant and durable improvements in voiding parameters in BPH patients durable up to 5 years post-procedure.[17] Although retreatment rates were observed at 6.8%-8.9%, initial experience by Ruszat et al further reported that PVP can be safely performed in patients who are on systemic anticoagulation.[18,19] Subsequent upgrading to the 120W HPS and 180W XPS also showed consistent improvements in the International Prostate Symptom Score (IPSS), Quality of Life (QoL), maximum urinary flow rate (Qmax) and post-void residual volume (PVR) parameters regardless of prostate sizes. Furthermore, as described by Spaliviero, PVP was successfully performed as an outpatient procedure in all patients in their series with 70% of patients being discharged home catheter-free.[16,20,21]

When comparing amongst the different GreenLight laser systems, the most recent 180W system has shown to provide more efficient tissue vaporization when compared to earlier generation lasers. While there were no significant differences among postoperative parameters between the 180W XPS and 120W HPS laser, operative and catheterization times appeared shorter among the XPS group.[22,23] Mean quantity of fiber and 3 L saline bags used were also significantly lower in the 180W XPS group.[15] These results suggest that while both GreenLight systems were able to provide safe and effective tissue vaporization with clinical relief of BPH obstruction, the 180W XPS system allows for increased cost savings with regards to both intraoperative materials utilized as well as reduced operative, hospitalization and catheterization times. Indeed, a systematic review by Brunken et al also revealed that among all GreenLight generations, the 180W XPS offered the greatest efficiency of energy and resource utilization, decreased operative times and increased tissue removal, all while minimizing complication rates.[24]

Subsequently, randomized controlled trials comparing the outcomes and safety of the GreenLight to current BPH treatment options have also been extensively conducted. Accruing over 290 patients among 29 sites in nine European countries, the GOLIATH study remains the largest, prospective, randomized controlled trial to date, comparing the 180W XPS PVP to the gold standard TURP. Their study reported comparable and durable outcomes between the GreenLight XPS to TURP with regards to IPSS, Qmax, complication-free rates and storage symptoms even after 2 years. Reintervention rates between the two treatment modalities were also similar at 9.0% for the GreenLight XPS and 7.6% for TURP. Furthermore, patients treated with PVP were found to have a significantly shorter median length of catheterization, hospitalization times and time until stable health while patients undergoing TURP resulted in 5 times more surgical interventions to resolve postoperative bleeding.[25,26]

Other randomized trials comparing the older generation PVP lasers to TURP have also demonstrated similar improvements in Qmax, IPSS, QoL and PVR parameters with maintenance of sexual function.[27] However, when compared to TURP, PVP was found to be cheaper, had shorter catheterization and hospital stays and had fewer perioperative adverse events. In a study by Al-Ansari et al, there were no major intraoperative complications reported or blood transfusions required with the PVP procedure, but among the TURP cohort, 20% required transfusions, 17% suffered capsular perforations and 5% developed TUR syndrome.[28] Ultimately, a meta-analysis conducted by Cornu et al assessing the outcomes and complication rates of transurethral procedures for BPH found that the functional outcomes, namely IPSS, Qmax and PVR, after the 120W PVP procedure were similar to that of the monopolar TURP. However, the PVP has a lower transfusion rate and shorter hospitalization and catheterization time compared to TURP.[29] Table 1 summarizes the available clinical data to date for the GreenLight PVP.

TABLE 1. **Summary table of clinical data to date for GreenLight photoselective vaporization of the prostate**

Endpoint	Time point	Clinical outcomes
IPSS	Baseline	21.2 ± 5.9
	24 mo	6.9 ± 6.0
IPSS-QoL	Baseline	4.6 ± 1.1
	24 mo	1.3 ± 1.2
Qmax (mL/s)	Baseline	9.5 ± 3.0
	24 mo	21.6 ± 10.7
PVR (mL)	Baseline	110.1 ± 88.5
	24 mo	45.6 ± 65.5
Prostate volume (mL)	Baseline	48.6 ± 19.2
	24 mo	23.9 ± 13.0
PSA (ng/mL)	Baseline	2.7 ± 2.1
	24 mo	1.4 ± 1.7
OABq-SF symptoms	Baseline	44.2 ± 20.5
	24 mo	15.3 ± 16.7
OABq-SF health	Baseline	59.0 ± 21.9
	24 mo	88.5 ± 15.8
ICIQ-UI SF	Baseline	3.9 ± 4.7
	24 mo	2.8 ± 4.1
IIEF-5	Baseline	13.2 ± 7.6
	24 mo	12.9 ± 7.5
Complication-free	24 mo	83.6%
Retrograde ejaculation	6 mo	30%-67.1%
Urinary incontinence	12 mo	1%

IPSS = International Prostate Symptom Score
Qmax = maximum urinary flow rate
PVR = post-void residual urine
PSA = prostate-specific antigen
OABq-SF = overactive bladder questionnaire-short form
ICIQ-US SF = International Consultation on Incontinence Questionnaire-Urinary Incontinence short form
IIEF-5 = International Index of Erectile Function-5

Safety profile, durability and adverse events

The main advantage of the GreenLight laser is its effective hemostatic properties and low bleeding rates. This allows it to be a viable treatment option for high-risk patients who are on anticoagulation. While ongoing oral anticoagulation portends a much higher risk of bleeding and is relatively contraindicated in electrocautery TURP or open prostatectomy, GreenLight PVP does not concur that risk.

A study by Ruszat et al reported no occurrence of bleeding complications necessitating blood transfusions in 116 men who underwent PVP on anticoagulation. Postoperative hemoglobin was also not significantly decreased in men on anticoagulation when compared to those who were not.[30] A comparable study by Sandhu et al also demonstrated the safety of PVP among men on systemic anticoagulation with no cases of blood transfusions, hematuria or clot retentions being reported. In their study, serum hematocrit was also not significantly decreased after the procedure (40.0% to 38.3%, $p > 0.05$).[31]

While similar studies have also proven the safety of PVP in men on anticoagulation, Yuan et al performed the PVP among 128 high-risk men and found no major complications or mortalities in men who had high cardiovascular risk, high pulmonary risk, were receiving anticoagulant medication or had a coexisting bleeding disorder.[32-34] Thus, the evidence suggests that the GreenLight PVP procedure can be a suitable and effective treatment option in men on systemic anticoagulation who are at high-risk of significant bleeding.

With regards to durability, functional outcomes after GreenLight PVP has shown to be stable even up to a mean follow up of 5 years with reoperation rates being reported to be as low as 4.8% with the XPS system.[35] Retreatment rates for the 80W KTP and 120W HPS laser, however, were slightly higher (8.9%-14.8%) further suggesting the inefficiency of earlier generation lasers to provide immediate tissue removal.[18,19,28] It is also important to note that addressing larger prostates with the GreenLight PVP requires a certain level of expertise as a high TURP conversion rate has been reported in these patients.[20]

One of the disadvantages to the PVP procedure is that tissue analysis for pathology evaluation is often unavailable due to its vaporization techniques. Conceptually, the risk of missing undiagnosed prostate cancer does exist. However, a recent analysis of the SEER database by Meeks et al found that when patients are screened appropriately with serum prostate-specific antigen (PSA) levels, the risk of missing clinically significant prostate cancer is as low as 0.26%.[36] As such, digital rectal exams, serum PSA screening and prostate biopsies should be performed prior to PVP in patients who at risk for prostate cancer.

Conclusions

Overall, the GreenLight PVP has been shown to be a durable and effective treatment option in treating LUTS secondary to BPH and is especially safe in men on anticoagulation who are at higher risk of bleeding. As such, current consensus guidelines have recommended this procedure in patients on anticoagulants or in high-risk surgical candidates.[3,4] The PVP also has the added advantage of cost savings with decreased catheterization time, hospital stay and can also be performed as an outpatient procedure.

Nevertheless, surgeons should note that being familiar with one laser system may not necessarily translate to expertise with another laser and that techniques and surgical approaches vary widely among different laser systems. However, with the new and improved training curriculum for the GreenLight simulator, trainees can potentially acquire the necessary skills and knowledge to a predetermined level of proficiency.

While ongoing trials and research continue to develop better and improved technologies for the treatment of this highly prevalent disease, the ultimate goal as physicians is to acquire an individualized, shared decision-making process with each patient to determine the ideal treatment option based on patient preference and preoperative parameters.

Disclosures

Dr. Jaspreet S. Sandhu and Joon Yau Leong have no disclosures.
Dr. Akhil K. Das is a consultant for Lumenis and Richard Wolf. □

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Holmium laser enucleation of the prostate (HoLEP): a review and update

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DAS AK, TEPLITSKY S, HUMPHREYS MR. Holmium laser enucleation of the prostate (HoLEP): a review and update. *Can J Urol* 2019;26(Suppl 1):13-19.

Introduction: *Lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH) is one of the most common diseases affecting the aging man, with almost 80% of men greater than 70 affected. Historically, transurethral resection of the prostate (TURP) has been considered the historical gold standard in the treatment of LUTS due to BPH for many years, contemporary literature indicates that holmium laser enucleation of the prostate (HoLEP) has replaced TURP and open simple prostatectomy as the size independent surgical gold standard for BPH treatment.*

Materials and methods: *In this review, we discuss the current techniques utilized, outcomes and safety, as well as the long term durability of results. Adverse events associated with the HoLEP procedure, both enucleation and morcellation, are covered as well.*

Results: *HoLEP has a robust body of literature supporting the technique, which demonstrates its ability to surpass other surgical BPH procedures, including TURP and open simple prostatectomy. Additionally, there is long term durability of both subjective and objective outcomes greater than 10 years associated with this procedure. One randomized trial showed specific postoperative outcome measures that were superior to TURP at 7 years of follow up, including Qmax (4.36 mL/s improvement), erectile function (2.39 points improvement on the IIEF erectile function section), and weight of prostate removed (15.7 grams greater), while other studies have shown greater reduction in postoperative PSA, lower detrusor pressure at Qmax, and more.*

Conclusions: *Overall, HoLEP has proven to be an extremely durable and effective treatment for patients suffering from LUTS due to BPH. Both the Europeans and AUA guidelines on the surgical treatment of BPH recommend HoLEP as a size-independent treatment option for those men with moderate to severe symptoms. HoLEP is an excellent option for many patients who may not be good candidates for other procedures based on prostate size, age, or bleeding risk.*

Key Words: HoLEP, BPH, LUTS

Introduction

Benign prostatic hyperplasia (BPH) is a common condition affecting many men over the age of 50, with almost 80% of men greater than 70 affected.[1] BPH is caused by unregulated proliferation within the prostate, which can cause physical obstruction of the prostatic urethra and result in anatomic bladder outlet obstruction (BOO).[2] Historically, transurethral resection of the prostate (TURP) has been the gold standard to which all endoscopic procedures for BPH are compared.[3] This technique, although efficacious, has typically been reserved for smaller prostates and is associated with poor hemostasis and increased morbidity compared to newer methods.[4] This morbidity is associated with many complications which can arise from this procedure, such as transurethral resection syndrome which can lead to significant electrolyte abnormalities, prolonged postoperative catheterization, high retreatment rates, and prolonged hospital stay. These shortcomings of TURP have prompted the rise of newer modalities to treat BPH, such as holmium laser enucleation of the prostate (HoLEP).[5] In addition to TURP, open simple prostatectomy (OP) has historically been used to treat BPH, particularly for the treatment of patients with prostate size greater than 100 g. Contemporary literature comparing OP to HoLEP shows significantly less blood loss, shorter hospital stays, and less catheterization time in the HoLEP patients.[6]

The Holmium:Yttrium Aluminum Garnet laser (Holmium), with a wavelength of 2140 nm, was one of

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the earliest lasers to be successfully adopted for soft-tissue use within the lower urinary tract, specifically for BPH.[5] During HoLEP the complete adenoma is enucleated from the surgical capsule and displaced into the bladder before removal with an endoscopic device (transurethral soft-tissue morcellator). The HoLEP technique takes advantage of the distinct anatomical planes to remove the entire prostatic transition zone, thus removing more tissue than TURP and leading to a lower retreatment rate.[7] By removing the entire transition zone of the prostate, HoLEP is the endoscopic equivalent of an OP. HoLEP has proven to be more efficacious than TURP with improved outcomes such as; improved hemostasis, better short term urinary parameter improvements, fewer immediate complications, shorter catheter times and shorter hospital stays.[4,8] The American Urological Association (AUA) guidelines on the surgical treatment of BPH states that laser enucleation, with either holmium or thulium, is the only minimally invasive treatment options for BPH that is size independent.[9] This review will discuss the technique, outcomes, and safety of the HoLEP procedure.

Technique

The classical HoLEP technique has been described previously.[10] It is performed using a high-power holmium laser (100 or 120Watt platform, Lumenis, Yokneam, Israel) and an end-firing 550-micron laser fiber with energy settings of 2.0 J and frequency settings of 40-50 Hz. Many of the newer systems now offer two separate foot pedals, one for the enucleation settings and the other for hemostasis settings. Usually, hemostasis settings are set to 1.5 J and 30 Hz with a wide pulse but can vary depending on the surgeon's preference. Power requirements also differ amongst different platforms, with the 100W laser requiring 30 amp service, while the 120W laser requires 50 amp service.

HoLEP, in brief, is accomplished using a 26 French continuous flow endoscope with a laser bridge while morcellation requires an off-set nephroscope. The laser fiber is delivered through a laser catheter to help stabilize the laser fiber while at the end of the catheter there is a locking mechanism to keep the laser fiber at a fixed length during the procedure. The outflow port is placed to gravity, and the inflow port is wide open connected to 3 L of normal saline due to the large fluid requirements needed during the procedure. This set up may differ depending on which equipment is used, with Storz and Wolf having the three most commonly used products, and each having a slightly different variation for setup.

Classic laser enucleation technique involves the release of the three lobes (one median and 2 lateral) into the bladder. First step in enucleation is incising the urethral mucosa from bladder neck to the verumontanum and identifying the surgical capsule at the 5 and 7 o'clock positions. These incisions are carried distally to the level of the verumontanum, and widened while staying on the surgical capsule, thus isolating the median lobe. Next, the 5 o'clock and 7 o'clock incisions are joined proximal to the verumontanum. The median lobe is then dissected off the capsule in a retrograde fashion. The beak of the endoscope is used to mechanically push the tissue off the capsule, as the laser is used to develop the plane. The median lobe is separated from the capsule in a distal to proximal direction proceeding toward the bladder neck. The median lobe is then pushed up into the bladder, and the final prostatic attachments are released from the bladder neck allowing the median lobe to float into the bladder. The same approach is utilized for the lateral lobes, which are enucleated one at a time. Lateral lobe enucleation is accomplished with an additional incision of the urethral mucosa at the 12 o'clock position from bladder neck to verumontanum. This 12 o'clock incision is carried down to the surgical capsule and the adenoma is separated off the capsule using both the beak of the endoscope and the pulsed holmium laser. The 12 o'clock incision is widened, and thus separating the two lateral lobes anteriorly. The left lateral lobe is enucleated by connecting incisions from the 12 o'clock to 5 o'clock position and pushing the lobe in a retrograde fashion and placing it in the bladder. The right lateral lobe is enucleated by connecting incisions from the 12 o'clock to the 7 o'clock position and pushing the lobe in a retrograde fashion and placing the enucleated lobe into the bladder. Just prior to retrograde enucleation of the lateral lobes, a small bridge of urethral mucosa remains anteriorly and is taken down precisely with the laser to prevent damage to the external sphincter. This step is important in separating the urethral sphincter anteriorly from prostatic adenoma. Prior to tissue removal, hemostasis must be completed to optimize visibility during morcellation. The three lobes removed off the capsule, free floating in bladder, are retrieved using an endoscopic soft tissue morcellator. The morcellator has rigid hollow blades and requires an off-set nephroscope that has a straight working channel for placement of the morcellator blades. The blades of the morcellator can either oscillate or reciprocate depending on the type of morcellator. The morcellator sucks the morcellated tissue through the hollow blades into a retrieval device. During

morcellation, it is important to have the bladder full to ensure there is optimal visibility and to limit damage to the bladder mucosa.

To optimize visibility during enucleation and eventually morcellation, hemostasis is fully accomplished by defocusing the laser fiber tip away from the bleeding tissue, blanching of tissue is observed, during the incision and enucleation process. It is important to note that hemostasis is occurring during the enucleation portion of the procedure due to the unique properties of the holmium laser that coagulates as it cuts tissue. The relatively short wavelength of the holmium laser allows for significant absorption by water within the tissue that leads to rapid vaporization of the tissue and thus minimizes the depth of penetration to tissue at 0.4 mm, while still allowing for effective coagulation up to 3 mm. There is also an added benefit of only cutting across vessels once with pulsed laser energy of the holmium laser, rather than multiple cuts required with other more ablative lasers. With this excellent hemostasis seen with the endoscopic use of the holmium laser, this procedure is able to be utilized on anticoagulated patients, due to the low risk of bleeding secondary to the effective hemostasis the laser provides as shown by multiple studies.[11,12] In one large retrospective study of 1,124 HoLEP patients, Sun and colleagues compared the complication rates in patients not on anticoagulation versus single antiplatelet therapy versus dual antiplatelet therapy.[13] Results in this study showed that overall complications rate within 30 days did not differ (dual antiplatelet: 23.2%, single antiplatelet: 24.8%, no antiplatelet: 27.8%), though there is a significantly longer enucleation time in patients who were anticoagulated, likely due to visibility (dual antiplatelet: 56.9 min, single antiplatelet: 44.4 min, no antiplatelet: 38.5 min). In this study, no patients on dual or single antiplatelet therapy require postoperative transfusions, while one patient (0.1%) not on anticoagulation did.

Laser settings have also been studied, with one group performing HoLEP with a low-power system at 39.6W.[14] While this study did show the feasibility of using the holmium laser at these settings, they also reported increased total complication rate at 24.1%, many of which were postoperative bleeding. These results suggest that the higher energy laser is more effective for coagulation, and is beneficial for anticoagulated patients, but that a low-powered HoLEP is safe and feasible as we await directly comparative trials.

There have been some recent updates to the both the HoLEP technique and equipment utilized. Newer techniques include complete en-bloc enucleation and the more commonly used two lobe enucleation techniques. The two-lobe enucleation technique, the median lobe is undermined at the capsular level and is enucleated with the lateral lobe as one unit.[15] Initial reports on these newer techniques suggest a decrease in both enucleation and total operative time, and easier identification of the surgical capsule.[16,17] Another big change in operative efficiency has come from the improvements in the type of morcellators available. Currently, there are two commercially available morcellators in the USA. VersaCut, by Lumenis, was the first morcellator used for HoLEP. Piranha, by Wolf, is the newer perhaps more advanced morcellator is also available. The VersaCut has reciprocating blades which are controlled by a foot pedal, while the Piranha has oscillating blades which rotate at a selected rate. The suction mechanism is different for each as well, with the Lumenis allowing for continuous suction with or without morcellation, while the Wolf only provides microbursts of suction. Studies have compared the two morcellators.[18,19] Comparisons revealed similar results between the two, though the Piranha had a lower cost of use and higher rates of morcellation with a negligible learning curve. Most HoLEP surgeons' prefer the Piranha to the VersaCut due to the improved ergonomic design, efficient tissue removal properties and its safety profile. Lastly, recent advancement in laser technology in the form of a larger vapor bubble per pulse has initially shown to be useful in dissecting the adenoma off the capsule quicker with better hemostasis. This technology is currently being evaluated at several centers to see if there is a reduction in enucleation time.

Outcomes and safety of HoLEP

HoLEP has been highly scrutinized, with multiple large studies outlining results and complications. To our knowledge, the first randomized control trial comparing HoLEP to bipolar TURP with the inclusion of urodynamic findings was by Tan and colleagues.[20] This study highlighted significant improvements in the HoLEP group, especially that the detrusor pressure at Qmax to void was significantly less than in those who underwent TURP. This is important for patients undergoing the procedure who have compromised bladders. This patient population was followed out for 7 years, which showed that HoLEP is at least equivalent to TURP when comparing long term results, with a lower reoperation rate.[21] The study reported average ± standard deviations for the following results (HoLEP versus TURP): Qmax of 22.09 ± 15.47 versus 17.83 ± 8.61 (TURP) mL/s; AUA symptom score (AUASS) of 8.0 ± 5.2 versus 10.3 ± 7.42; quality of life (QOL) scores of 1.47

± 1.31 versus 1.31 ± 0.85; IIEF-EF (erectile function) of 11.6 ± 7.46 versus 9.21 ± 7.17; ICS male voiding score of 4.2 ± 3.76 versus 3.0 ± 2.41; ICSmale Incontinence Score of 3.07 ± 3.3 versus 1.17 ± 1.4. Although none of these results were significantly different, the paper did show significantly better results for HoLEP in terms of weight of resected prostate tissue in grams (40.4 ± 5.7, 24.7 ± 3.4), postoperative catheter time in hours (17.7 ± 0.7, 44.9 ± 10.1), and overall hospital time in hours (27.6 ± 2.7, 49.9 ± 5.6). Many additional large studies have looked at HoLEP. Krambeck et al analyzed 1,065 patients undergoing HoLEP, which reported both subjective and objective findings.[22] They found that HoLEP effectively reduced AUASS by an average of 15 points at the 12 month postoperative time point, as well as improving Qmax by a mean of 14.3 cc/s at the 12 month time point. Interoperative and postoperative complications were rare, with a report rate of 2.3%. Complications included 3 (0.28%) patients who suffered from postoperative retention, transient stress incontinence in 12.5% of patients at 6 weeks postoperation, permanent incontinence in 15 (1.4%) patients, and urethral strictures in 24 (2.25%) patients. Incidental prostate cancer was identified in 106 patients (10.1%).

These results are independent of age as well.[23] Mmeje et al retrospectively compared HoLEP results across age groups in 311 patients. Patients were stratified into groups 1-4 based on decade of life at time of surgery (50-59, 60-69, 70-79, and 80+). Overall complication rates (20%, 24.4%, 21.6% and 22.1%, in groups 1-4 respectively), severe complications defined as Clavien-Dindo grade 3 or higher (0%, 5.6%, 3.9%, 4.4%), average hospital length of stay (1.18, 1.28, 1.26, 1.68 days) and change in serum hemoglobin levels (1.22, 1.42, 1.57, 1.78 g/dL) were similar across the four groups. At 1 year of follow up, there were no reported differences in continence (100%, 95%, 93%, 88%), average AUA symptom score (6.4, 4.6, 5.2, 7.5), Qmax (24.0, 24.4, 22.4, 16.2 mL/s), or average PVR (16.3, 47.1, 65.5, 46.4 mL) across the groupings. This study shows that both the quality of life and functional improvements seen following the HoLEP procedure are not age limited, and that age does not appear to increase the risk of HoLEP or be a predictor of poor outcome. Considering these data, this procedure has no age limit and is useful for all BPH patients. This is in contrast to TURP, which has been previously shown to have an increasing incidence of blood transfusions and other morbidity associated with increasing age.[24] Another study looking at TURP in elderly patients, above the age of 80, found that significant complications occurred in 13.2% of the cohort studied, which is much higher than the 4.4% of severe complications seen in the same age group of this study.

In addition to objective subjective significant improvements associated with this procedure, it is also important to note that HoLEP is size independent. The AUA updated their latest guidelines for the surgical management of LUTS attributed to BPH in 2018. These guidelines indicate laser enucleation procedures, such as HoLEP, can be considered as a prostate size-independent treatment option based on surgeon experience. This recommendation is based on literature showing size does not alter outcomes.[25,26] Humphreys et al performed a retrospective study that compared results across three groups, one with prostate size below 75 grams, another between 75 to 125 grams, and the last greater than 125 grams. Results showed that postoperative hospitalization, catheterization, AUA symptom score, average maximum flow rate, and average PSA all showed no statistical difference across the three groupings. Other complications, such as transient stress incontinence, transient dysuria, blood transfusion requirement, and stricture rates were also similar between the groups, highlighting multifunctionality of the technique independent of the clinical situation. Building on this, Krambeck et al preformed a retrospective study looking at patients with prostate volumes greater than 175 grams. They examined 57 patients with an average prostate size of 217.8 cc (range: 175-391 cc). Their findings showed similar results across objective and subjective outcomes, as well as reporting no patients with persistent incontinence or need for catheterization. When taken together, these two studies indicate that this procedure can be effectively utilized for glands of all sizes, with no increase in complications.

When assessing patient preference across the different procedures, the literature favors HoLEP.[27] Abdu-Mushin and colleagues used an independent third-party to administer a survey to all patients who underwent any surgical treatment for BPH over a six year time period. The third party received 479 responses (55.6% response rate), including patients receiving HoLEP (n = 214), TURP (n = 210), holmium laser ablation of the prostate (n = 21), photoselective vaporization (n = 18), transurethral incision of the prostate (n = 9), and open simple prostatectomy (n = 7). Validated questionnaires examined many domains, but HoLEP had the most favorable outcomes in terms of urinary intermittency, weak stream, straining, and overall quality of life. Notably, patients undergoing the HoLEP procedure had the lowest level of regret across all procedures. This highlights real life experience and patient satisfaction with HoLEP compared to all other BPH surgical procedures.

Durability and adverse events

As HoLEP is a newer technique than TURP, which has been around since 1926, the long term durability of this procedure has been in question, with EAU guidelines suggesting the retreatment rate of this procedure is 1%-2% per year,[28] which is much higher than the 0% retreatment rate in HoLEP at 7 years of follow up reported by Gilling et al.[21] Multiple studies have assessed durability, often by comparing long term HoLEP results to TURP for comparison. Gu et al did this, looking at data 3 years after the operations.[29] These results showed no difference in durability but did highlight that HoLEP had improved outcomes in terms of average Qmax (17.71 versus 15.92 mL/s), average International Index of Erectile Function-5 (IIEF-5) score (14.48 versus 13.40), average TRUS prostate volume (35.44 versus 37.80 mL), and average postoperative PSA (1.53 versus 1.96 ng/mL) when compared to TURP patients. Another group conducted a similar study, comparing HoLEP and TURP patients 3 years after their inclusion in a randomized control trial.[30] The study found that at 3 years after their operation, both HoLEP and TURP had similar, stable results which were significantly improved from baseline. The study noted that there was no difference in late complication rates and that reoperation rates were not statistically different. Gilling and colleagues published their experience comparing results at 7 years.[21] These results confirmed previous studies, showing high resected prostate volume, shorter catheter time, and shorter hospital time. At 7 years, results indicated that HoLEP is at least equivalent to TURP at 7 years when assessing AUA symptoms score, quality of life questioning, and Qmax. HoLEP did have lower reoperation rates than TURP, though both were rare. The longest follow up study currently found, to our knowledge, is a 10 year follow up looking at durability and complications, with no comparison to TURP.[31] With 949 patients, and a mean follow up of 62 months, this study showed that results lasted throughout the duration of follow up, and that complications rates were very low, with persistent incontinence in 1.5% of patients, stricture in 1.6%, contracture in 0.8%, and reoperation in 0.7% of patients.

Additional studies have compared HoLEP to other, more invasive techniques as well, such as open prostatectomy (OP) and robotic simple prostatectomy (RSP). Data here shows that OP and HoLEP are equally good 5 years after the operations, with similar improvements in average urinary function (Qmax: 24.4 mL/s for HoLEP and OP; PVR: 11 mL in HoLEP, 5 mL in OP) , and similarly low reoperation rates (5% in HoLEP, 6.7% in OP).[32] To date, no long term data are available comparing HoLEP to RSP. However, short term results show both as efficacious, with HoLEP showing many notable advantages compared to RSR.[33] HoLEP had lower average operative times (103 versus 274 min), less average postoperative hemoglobin drop (1.8 versus 2.5 g/dL), lower transfusion rates (1.8% versus 9.4%), shorter average hospital stay (1.3 versus 2.3 days), and decrease average catheterization time (0.7 versus 8 days). Though these studies do not include long term results, this shows short term results highlighting HoLEP's advantages in blood loss, hospital stay, and catheterization times when compared to RSP.

One major concern many patients have regarding prostate surgery is the risk of sexual side effects. Several studies have examined the impact of HoLEP on erectile function.[34] One retrospective analysis of 393 patients compared their preoperative and postoperative IIEF-5 scores. Though there was a small decrease in average IIEF-5 score after the procedure, there was no statistical difference from preoperative scores to postoperative score taken 3 months, 6 months, 12 months, and 36 months. Interestingly, 8.9% of the patients surveyed reported improved erectile function after undergoing HoLEP. However, retrograde ejaculation is a common complication with this procedure, with multiple studies reporting an incidence of over 65%, and up to 90% of patients.[35-37] Placer et al showed that 70.3% of men undergoing HoLEP reported a loss of antegrade ejaculation, while 21% report a reduction in semen quality. These results highlight a significant concern with HoLEP, and patients must be appropriately counseled about this complication and their subsequent fertility potential.

One concern for many surgeons is the well-documented steep learning curve associated with learning HoLEP. The learning curve has been estimated at anywhere from 20-50 cases.[38-40] It appears that such a steep learning curve has limited the widespread adoption of this technique amongst US surgeons, with very few receiving HoLEP training, and seemingly even less interested in acquiring such training after completing residency. The recent systematic review by Kampantais et al showed that this procedure has an acceptable learning curve at around 50 cases with careful selection, which can fall to 25 or fewer when in a structured mentorship program or with the use of simulation. We feel that despite this learning curve, the benefits of the operative outcomes justify this surgery being utilized. There are additional concerns based on insurance reimbursement for the surgeon, which is an area of debate.

Conclusions

Overall, HoLEP is an extremely durable and effective treatment for patients suffering from LUTS due to BPH. The AUA guidelines highlight this by recommending HoLEP as a size-independent treatment option for those with moderate to severe symptoms from BPH. The literature shows HoLEP to be a superior surgical solution to TURP and OP in many respects and a growing body of research comparing HoLEP favorably to other techniques such as RSP. Specific objective postoperative outcome measures that were superior to TURP include Qmax, erectile function, and prostate volume after resection when compared to TURP. Subjective results favor HoLEP as well, with patient surveys showing increased happiness for those undergoing HoLEP compared to other procedures. Critically, HoLEP has proven to be more durable than TURP, with studies showing similarly stable results to OP over time, with studies out to greater than 10 years. While there are some limitations to this technique, such as the steep learning curve and high rate of retrograde ejaculation, this procedure has a large body of literature showing its efficacy, durability, and favorable risk profile. The research shows HoLEP is an option with many patients who may not be good candidates for other procedures based on prostate size, age, or bleeding risk. HoLEP is the endoscopic procedure of choice and is considered the gold standard for the surgical treatment of BPH.

Disclosures

Dr. Akhil K. Das is a consultant for Lumenis and Richard Wolf.
Seth Teplitsky has no disclosures.
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Aquablation of the prostate: a review and update

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ROEHRBORN CG, TEPLITSKY S, DAS AK. Aquablation of the prostate: a review and update. *Can J Urol* 2019;26(Suppl 1):20-24.

Introduction: *Invasive procedures, such as transurethral resection of the prostate (TURP), have long been the gold standard therapy for the treatment of lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH). In recent years, newer treatment modalities have arisen, such as Aquablation, with similar efficacy and improved adverse event profiles, with particular emphasis on postoperative sexual function.*

Materials and methods: *Aquablation is a new technology that utilizes machine-controlled water jets to ablate the soft tissue of the prostate as determined by the doctor. In this review, we will discuss the techniques currently being used to complete this procedure, the outcomes and safety, and finally, the long term data as well as the adverse events associated with Aquablation.*

Results: *Aquablation is rapidly effective in treating patients with LUTS due to BPH. Critically, in head to head comparison with TURP, Aquablation has equivalent objective results with much shorter resections times, and significantly less sexual side effects. Currently, the literature only reports results extending to 12 months post-procedure, and therefore long term durability of results beyond this time point remains unknown.*

Conclusions: *Aquablation is a safe and effective option for treating LUTS secondary to BPH. Aquablation is a new surgical option that shows very promising short term results, in particular, due to its short resection time regardless of gland size and low rate of sexual side effects. This technology still requires further investigation to confirm durability and efficacy over time.*

Key Words: Aquablation, BPH, LUTS

Introduction

Benign prostatic hyperplasia (BPH) is a common condition affecting approximately 25% of men at the age of 50, with almost 80% of men greater than 70 affected.[1] BPH is caused by the unregulated proliferation of the transitional zone of the prostate, which leads to compression of the urethra. Physical compression of the urethra is what causes an anatomic bladder outlet obstruction (BOO), and leads to the symptoms of BPH, known as lower urinary tract symptoms (LUTS).[2] The gold standard for endoscopic surgical treatment of this condition has been the transurethral resection of the prostate (TURP), which was first developed during the early 1920s.[3] The TURP technique, although effective, has well-established morbidities, such as infection, poor hemostasis, sexual side effects, and others.[4] This review examines the use of the new robot-assisted waterjet ablation of the prostate for treatment of BPH in a therapy termed Aquablation.

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Newer techniques have been developed with the goal of decreasing surgical morbidity for patients while remaining successful in alleviating BPH symptoms. One of the newest technologies is an ultrasound-guided, robot-assisted waterjet that can precisely ablate prostatic tissue, known as Aquablation. This technique is performed using the Aquabeam system (PROCEPT BioRobotics, Redwood Shores, CA, USA). This surgical intervention was developed with the hope of limiting bleeding, much like laser enucleation or ablation, but requiring significantly less time to complete. Additionally, this technique also shows promise in preserving sexual function, both erectile and ejaculatory, much like the UroLift (Neotract/Teleflex, Pleasanton, CA, USA) and Rezūm (Boston Scientific, Marlborough, MA, USA) procedures.

Technique

The technique for this procedure was first described by Faber et al, in 2015, using the Aquablation system from Aquabeam and has since been updated by multiple others describing their techniques.[5-7] In short, the AquaBeam Aquablation system has three main components: the conformal planning unit (CPU); robotic 24F hand-piece; and a console. The procedure can be performed under general anesthesia or spinal anesthesia. From here, the patient is placed in the dorsal lithotomy position, and the bi-planar transrectal ultrasound (TRUS) device is mounted into position. Next, the handpiece is utilized to gain bladder access, and allow visualization using a scope. The handpiece is positioned with the tip just inside the bladder before the scope is retracted to visualize the bladder neck and placed proximal to the external sphincter to protect it. Once proper positioning is confirmed, the handpiece can be stabilized using an articulating attachment mounted to the bed. With the handpiece in the appropriate position, the TRUS probe must be positioned. The TRUS probe is inserted to the center of the prostate. At this point, the surgeon can utilize the TRUS probe to compress the prostate and improve visualization for the Aquabeam handpiece.

Once the proper positioning of both the handpiece and the TRUS probe has been achieved, the software must be adjusted to confirm appropriate planning for the tissue ablation, which is performed using the mapping software. The software allows for changes in depth up to 25 millimeters, and the angle of resection up to 225 degrees. The complete ablation of the transition zone of the prostate is performed by outlining the prostate with the Aquabeam software. The high-velocity physiological saline is then initiated under the control of a foot pedal. The computer system automatically adjusts the flow rate in each direction to alter the depth of penetration and remove the tissue as outlined in the mapping stage. There are safety mechanisms in place to ensure only the outlined tissue is ablated, and the external sphincter remains protected. Once resection is complete, hemostasis can be completed either through electrocautery or balloon catheter tamponade, though the expert opinion currently favors balloon tamponade.[8] The balloon remains in place for 2 hours to ensure hemostasis. Post-procedure, a three-way catheter is inserted, and bladder irrigation is commenced. The patient can be discharged the next day following successful voiding after removal of the catheter.

Outcomes and safety of Aquablation

As this is a very new technology, much of the literature is very recent. Some of the earliest outcomes were reported by Gilling et al, who published their findings in a prospective, multicenter trial at three separate Australian centers which included 21 men.[9] All patients were between the ages 50-80 years and had prostates ranging from 25 mL to 100 mL. The results from this study showed an average procedural duration of 38 minutes and a mean resection time of 5 minutes, with an average hemoglobin drop of 5.7% after the operation. Subjective and objective findings were also reported, with data from 1, 3, 6, and 12 months. Average International Prostate Symptom Scores (IPSS) were significantly decreased down to an average of 6.8 from pre-treatment. Maximum flow rate (Qmax) increased to 18.3 mL/s at 12 months follow up. Post-void residual (PVR) volumes decreased down to an average of 31 mL, and the quality of life subjective scores improved significantly as well. The study was able to obtain urodynamic studies after the operation for comparison to baseline and found that detrusor pressure at maximum flow was decreased by 40% on average. Prostate volume reduced by 39% on average. Finally, no adverse events were reported, there was no incontinence seen, and sexual function was preserved in all patients.

Another important study was the WATER trial, which directly compared Aquablation to TURP results across 17 different centers.[10] This double-blind, randomized control trial included 181 patients. There was no significant difference seen in overall mean operative time, but resection time was significantly less with Aquablation. The trial was planned to assess Aquablation and TURP in a non-inferiority trial using composite endpoints for safety and efficacy. The group looked at 3 month postoperative safety data, as well as

6 month postoperative IPSS scores from patients. The primary safety end-point was defined as a persistent Clavien-Dindo grade 1 event, or a Clavien-Dindo grade 2 or higher event. At the 3 month time-point, safety data showed Aquablation to be non-inferior to TURP, with additional analysis showing Aquablation to be superior, with 26% of the Aquablation cohort meeting this safety end-point, while 42% from the TURP group met the criteria. Significantly, all the persistent Clavien-Dindo grade 1 events seen were due to retrograde ejaculation, which was seen in 6.9% of Aquablation patients and 24.6% of TURP patients. To further assess ejaculatory function, MSHQ-EjD self-reported data was collected, showing that 90 days after the procedure, on average the Aquablation patients had a slight improvement overall in ejaculatory scores, while TURP group had a significant decrease in scores, highlighting the superior nature of Aquablation compared to TURP with regard to preservation of ejaculatory dysfunction.

A similar analysis was done to assess incontinence, using the incontinence severity index, which is also self-reported. Result for this showed more significant improvement in the Aquablation group. At 6 months post operation, IPSS scores were compared to baseline scores. The IPSS change over time was utilized to determine the efficacy endpoint. Aquablation had an average IPSS of 6.0 at 6 months, compared to an average of 6.7 for TURP, which satisfied the non-inferior hypothesis. Lastly, Qmax and PVR volumes were assessed at 30-day postoperative intervals up to 180 days. These data show very similar results for PVR, with slightly improved Qmax at 180 days for the Aquablation compared to TURP. See Table 1 for Aquablation summary.

After the WATER trial, a WATER II trial was completed to assess the safety and feasibility of Aquablation in larger prostates, between 80-150 mL.[11] This trial was again prospective, with 16 different centers. In total, 101 men were included in the study. Despite the larger prostate size, average operating time was 37 minutes, with an average resection time of 8 minutes. A total of 66.3% of patients included required additional passes with the machine to complete the resection, but all were completed in a single operation. Again, composite endpoints were used for both safety and efficacy. At 3 months, safety was assessed using the same safety endpoints as described in the WATER trial. For efficacy, the change in IPSS scores at 3 months post operation from baseline was utilized. Both the safety and efficacy endpoints were then compared to an objective performance criterion (OPC) which allowed for assessment of non-inferiority. Intraoperative reports show that 82% of these procedures were done under spinal anesthesia. Safety endpoints at 3 months were met in 45.5% of patients, well below the OPC of 65%. These results were statistically significant and showed the safety endpoint was reached, and the procedure was non-inferior when compared to the OPC. When assessing efficacy, Aquablation greatly exceeded the OPC set for the change in IPSS score, showing the procedure as non-inferior for efficacy as well. Further, prostate volume reduction was measured, showing a 44% reduction in size at

TABLE 1. **Aquablation summary**

Study	Measure (time point)	Change observed
Aquablation 1 year results	IPSS (1 y)	16.2 points improvement
	Qmax (1 y)	9.7 mL/s increase
	PVR (1y)	89 mL decrease
	Pdet at Qmax (6 mo)	25.1 cm of H_2O decrease
	Bladder outlet obstruction index (6 mo)	35.2 points improvement
	Prostate volume (6 mo)	18 mL decrease
	Serum PSA (6 mo)	0.59 ng/mL decrease
WATER trial	IPSS (6 mo)	16.9 points improvement
	IPSS QoL score (6 mo)	3.5 point decrease
	Qmax (6 mo)	10.9 mL/s increase
	PVR (6 mo)	55 mL decrease
	Prostate size reduction (3 mo)	31% average decrease
	Serum PSA (6 mo)	1.2 ng/mL decrease

IPSS = International Prostate Symptom Score; Qmax = maximum flow rate; PVR = post-void residual; Pdet = detrusor pressure; PSA = prostate-specific antigen

3 month post operation. Hemostasis was achieved for most patients using a Foley catheter placed in the bladder under traction overnight using a device from PROCEPT BioRobotics. The other option, utilized in only three patients, was a balloon catheter inflated in the prostatic fossa. The average length of catheter duration was 94 hours, with an average of 18 hours under traction for those utilizing this method of hemostasis management. There was an average hemoglobin drop of 2.9 when comparing baseline to discharge lab values while using this method for hemostasis. Of the 101 patients, there were a total of 10 transfusions required between the completion of the operation and 1 month, with one patient requiring a return to the operating room. No patients needed transfusions beyond 1 month post-treatment.

Durability and adverse events

The same cohort used in the WATER I trial was further studied out to 12 months post-procedure to continue to investigate the safety and efficacy of this procedure when compared to TURP.[12] The notable findings of this study were that TURP and Aquablation operations had similar improvements in Qmax at 1 year, both had a similar decrease in serum PSA measurements at 1 year, and both had low rates of retreatment. The Aquablation group had 2.6% who underwent re-operation within 1 year, compared to 1.5% in TURP, which was not a statistically significant difference. The study also analyzed results in patients who had larger than 50 gram prostates before treatment.[13] The results in this sub-group heavily favored Aquablation, with both primary safety endpoint and primary efficacy endpoint determining Aquablation was superior to TURP for these patients. This subgroup had no difference in average procedure times, at 33 minutes for Aquablation and 36 minutes for TURP, but did have a significant difference in resection time at 4 minutes compared to 27 minutes for TURP. Additional analysis of this larger prostate size subgroup showed that on average, there was a greater drop in postoperative hemoglobin in the Aquablation than in TURP. When compared, this hemoglobin change postoperatively was significantly greater in the Aquablation group than the TURP group. Aquablation group had one patient requiring a transfusion while none in the TURP group needed it. Overall, this study helps to highlight that Aquablation and TURP have similar outcomes at 1 year, despite the newness and therefore unfamiliarity with the Aquablation procedure.

The same patients that made up the WATER II trial were studied out to 6 months.[14] When analyzing adverse events at 6 months, 22% of the subjects had experienced a Clavien-Dindo grade II event, 14% a grade III event, and 5% a grade IV event. Looking at efficacy, Qmax increased from 8.7 cc/s at baseline to 18.8 cc/sec at 6 months. PVR volume was lowered from 131 mL to 47 at 6 months. QoL decreased from 4.6 at baseline to 1.4 at 6 months. PSA showed a 44% reduction on average, while TRUS showed a 42% reduction in prostate volume compared to baseline. Looking at the patient's postoperative sexual function, MSHQ-EjD scores at 6 months still showed a slight improvement compared to baseline, though not as much as at 3 months. IIEF-5 scores improved by an average of 0.1 at 3 months, and an average of 0.7 at 6 months. These results depict the best long term data we currently have for Aquablation in patients with larger prostates and portray this procedure as a reasonable alternative.

Conclusions

Aquablation is a novel technique employing robotic and waterjet technology to patients suffering from LUTS associated with BPH. The initial results suggest to be as effective as TURP in treating BPH. This new technique is intriguing due to the extremely short treatment time regardless of gland size, lack of sexual side effects, and possible same day hospital discharge. These factors make this a desirable option for both patients and surgeon. The procedure has had a large randomized clinical trial directly comparing Aquablation to the gold standard of BPH treatment, TURP, and shown superior short term results. While there are many positives of this procedure, it is still very new, and large gaps in the literature remain. Before strong recommendations can be made, long term results from this procedure are required as current data only extends to 12 months after operation for smaller prostates, and 6 months after operation for larger prostates. Further, prostates greater than 150 mL have yet to be reported in the literature, which currently limits Aquablation to below 150 mL. Overall, this is a new surgical option that shows very promising short term results but requires further investigation to confirm durability and efficacy over time.

Disclosures

Dr. Claus Roehrborn is an investigator and consultant for Boston Scientific, NeoTract/Teleflex and PROCEPT BioRobotics.
Seth Teplitsky has no disclosure.
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Notes