How I Do It: The prostatic urethral lift for obstructive median lobes

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ASHLEY MS, PHILLIPS J, EURE G. How I Do It: The prostatic urethral lift for obstructive median lobes. *Can J Urol* 2023;30(2):11509-11515.

Millions of men in North America suffering from lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH) are managed on medical therapy. Most patients, however, report poor adherence, and yet relatively few pursue more definitive surgical solutions. The Prostatic Urethral Lift (PUL) was designed to address many of the patient-identified barriers to surgery, namely iatrogenic sexual dysfunction, incontinence, lengthy recovery and postoperative catheterization. Randomized studies and large real world multicenter and database studies have demonstrated safety and effectiveness of PUL when addressing lateral lobe disease. In recent years further technique and device development has led to the FDA approval for PUL addressing obstructive median lobes as well. At 12 months, PUL median lobe patients in a controlled trial and a large retrospective study experienced average IPSS improvement of 13.5 and 11.6 points, QoL improvement of 3.0 and 2.1 points, and Qmax improvement of 6.4 and 7.1 mL/sec, respectively. In the controlled setting, both ejaculatory and erectile function were preserved and postoperative catheterization rates, while higher than lateral lobe PUL rates, were similarly short lived with a mean duration of 1.2 days. We describe the current technique for performing PUL to address the obstructive median lobe and detail a new device, which can make it easier to alleviate obstruction due to trilobar anatomy.

Key Words: prostatic urethral lift, PUL, UroLift, benign prostatic hyperplasia, BPH, prostate, LUTS, middle lobe, median lobe

Introduction

Lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH) is a recurrent healthcare issue involving millions of men and costing billions of dollars each year in North America alone.[1] While the majority of men are managed on medical therapy, studies show 1-year adherence to be as low as 29%.[2] When asked, over 65% of men on BPH medication would be interested in a nonmedical option that has a low risk of permanent side effects, preserves their sexual function, and can return them to their normal lifestyle quickly.[3] BPH clinical guidelines recognize the need for a minimally invasive treatment option for the large population of men poorly served by medical therapy but reticent to accept the risks of traditional surgery.[4]

The Prostatic Urethral Lift (PUL) procedure using the UroLift System (Teleflex, Pleasanton, CA, USA) has become a standard of care for appropriate patients suffering from LUTS secondary to BPH.[4,5] Randomized studies have demonstrated rapid and significant improvement in LUTS with durability through 5 years.[6,7] Because PUL does not require heating, cutting, removal, or destruction of prostate tissue; recovery is rapid, most

Accepted for publication February 2023

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often requiring no postoperative catheter. Additionally, significant adverse effects associated with resective procedures, such as transfusion, stricture, sexual dysfunction, and sustained incontinence, are largely avoided. To date, it is the only leading BPH procedure shown to not cause new and lasting sexual dysfunction. Thermal ablation procedures, while similarly effective, appear to offer less reliable preservation of ejaculatory function and typically require extended postoperative catheterization.[8-11] The more extensive uptake of PUL as a minimally invasive BPH treatment may rely upon these key differences.[12]

Introduction of PUL to the urologic community focused on treatment of lateral lobe obstruction exclusively. Standard and advanced PUL technique for lateral lobes has been described with notable tolerability under local anesthesia.[13,14] Chin first described by video a PUL technique to additionally treat the obstructive median lobe (OML).[15] This technique was then studied in a multicenter trial of OML patients clinically controlled to LIFT study lateral lobe patients.[16] Results indicated that PUL for OML is at least as effective as it is for lateral lobes through 12 months, and the FDA now indicates PUL for the treatment of BPH, including lateral and median lobe hyperplasia, in men with prostates no larger than 100 cc.

Recent studies of PUL real-world clinical experience in thousands of patients further validate the conclusion that PUL is equally effective for median and lateral lobes.[17] We describe the current technique to treat prostates with both lateral and median lobe obstruction, including the utilization of a new UroLift Advanced Tissue Control device (UroLift ATC) designed to render this technique more straightforward.

Methods and technique

BPH shared decision-making: education and work up

Effective patient education is essential and includes emphasizing that a) BPH is a chronic condition associated with ongoing prostate growth that can cause increasing obstruction over time; and b) a primary treatment objective is protecting the bladder: to relieve obstruction so the bladder can recuperate and to avoid further decompensation, potentially leading to irreparable decline in function. By orienting BPH patients this way, they may be more motivated to seek additional care if the first treatment option, typically medication, is unsatisfactory.

We then talk about what information will guide our shared decision-making. First, without exception, each patient completes an IPSS/QoL questionnaire to help facilitate the discussion of symptoms and bother. Also typical are a uroflow assessment and PVR scan if IPSS is ≥ 8. As per the AUA BPH guidelines, we emphasize the need for imaging of the prostate which can be accomplished with several modalities. Even prior to alpha blocker trial, we underscore the benefit of evaluation of the prostate anatomy via ultrasound or previously performed MRI or CT to help with treatment choices. In addition to sizing, a cystoscopy is often very helpful to answer three questions: 1) prostate morphology particularly with regard to obstructive median lobe, 2) tolerance of transurethral access under local anesthesia, and 3) bladder trabeculation, which can be a powerful factor in the treatment discussion. Finally, in addition to these assessments of the lower urinary tract, we discuss key aspects to treatment choice decision-making: prior experience with BPH medication and general view of lifelong maintenance medications, the personal importance of maintaining sexual function and maintaining ejaculation specifically, sensitivity to recovery time, expectations of catheter duration, and lifestyle goals.

If starting a patient on an alpha blocker or increased dosage, we generally follow up within 6 weeks to determine if LUTS are now acceptable and if any adverse effects are present and tolerable. We find that waiting beyond this 6 to 8 week window for follow up risks losing the patient, as issues may lead to poor adherence and disappointment. Particularly important at this stage is to not focus entirely on LUTS but also interrogate for potential pharmaceutical adverse effects (congestion, sexual dysfunction, asthenia, dizziness, etc.). If the patient is not satisfied, alternative alpha blocker and/or addition of 5-ARI is common, but often the next choice may be PUL due to its tolerability under local anesthesia in an office setting, minimal catheterization, rapid relief and preservation of sexual function. Men less sensitive to these benefits typically contemplate a traditional surgical procedure, but it is known that a smaller fraction of them follow through with surgery, unless there are compelling comorbidities such as renal insufficiency, chronic retention, bladder stones or gross hematuria associated with BPH.

Ideal median lobe morphology for UroLift

The UroLift system is FDA indicated for prostates up to 100 cc with lateral and/or median lobe obstruction. The primary goal of the PUL procedure is to create a patent channel coursing through the anterior aspect of the prostatic fossa from bladder to veru montanum. This objective remains unchanged when also treating

an obstructive median lobe. Whether lateral or median lobe, the UroLift implant does not remove tissue but instead focally compresses the adenoma where the anterior channel is created. With lateral lobes, excessive adenoma often remains in the posterior aspect of the prostate, but the anterior channel decouples this anatomical feature from physiological obstruction. With the median lobe, the tissue is laterally fixed so as not to "ball valve" into the prostatic fossa. Excessive intravesical adenoma may remain but not such that it obstructs the anterior channel.

The ideal median lobe for PUL treatment has at least one defined sulcus and the lobe protrudes to some extent into the prostate or across the bladder neck. There is a small cohort of median lobe morphologies in which the median lobe protrudes into the bladder but very minimally affects the bladder neck area. This anatomical configuration is more difficult for the PUL technique since there is no sulcus to build upon and it is difficult to distract intravesical tissue into the prostatic fossa for lateral fixation.

PUL obstructive median lobe technique

To describe the motions required with a UroLift implant system, it is instructional to use the terminology of airplane piloting. The device can be moved in and out along the urethra, but also in three additional ways. "Roll" refers to how the device is rotated about its axis; "Pitch" refers to how the device can be tilted anteriorly or posteriorly; and "Yaw" refers to how the device can be angled laterally, Figure 1.

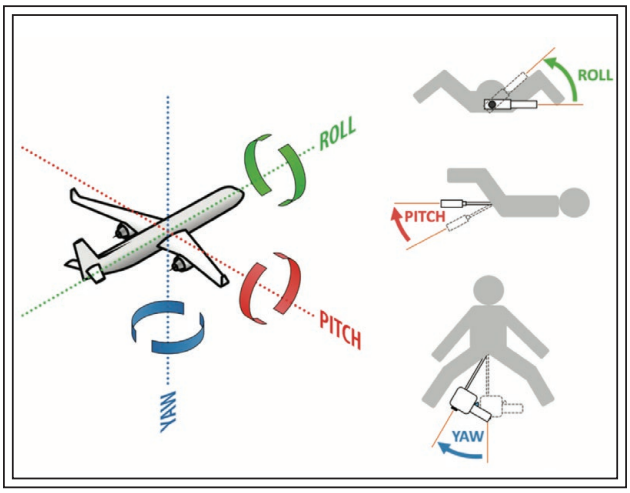

Figure 1. Terminology for UroLift device manipulation: **(a)** pilot terminology for aircraft; **(b)** "roll" is rotation of device; "pitch" is anterior/posterior angulation; and "yaw" is lateral angulation.

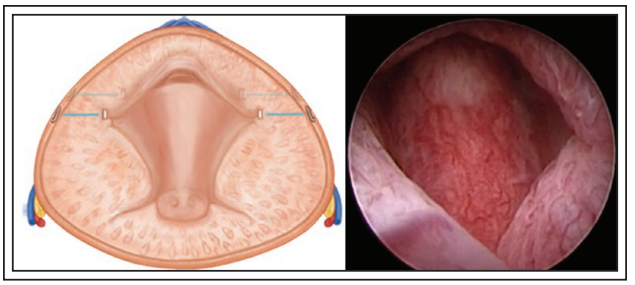

Figure 2. Lateral lobes are displaced by four implants creating an anterior channel through the prostatic fossa. The untreated median lobe continues to obstruct at the bladder neck.

Lateral lobe obstruction is treated first, with a premium on anterior lift with the most proximal implants. To deploy the proximal implant, with the device rolled to 3 or 9 o'clock, retract approximately 1.5 cm from the bladder neck keeping the device tip in the anterior aspect of the prostatic fossa. For the right lobe, as example, roll the device from 9 to 10 o'clock and tilt the device in this direction (anterolaterally), compressing the lobe until it is clear the tissue no longer compresses (tissue stops moving in the scope view), typically about 20 degrees angulation. There is no need to continue to angle the device once the tissue stops compressing, because that will simply move the entire prostate closer to bone. Before deploying the needle, it is important to keep the device tip in place while gently returning the roll to 9 o'clock and lower the pitch to near level (horizontal). This maneuver allows the needle to avoid striking the pubic symphysis or entering the detrusor. Once proximal implants are placed, distal implants should be deployed anterior to the veru montanum in the anterior 1/3 of the prostatic fossa, either in a similar anterior lifting fashion or more laterally compressed, Figure 2.

Once an anterior channel is achieved within the prostatic fossa, assess whether then median lobe remains obstructive. If so, the obstructive median lobe can be addressed. The goal is to widen a lateral sulcus of the median lobe by compressing and fixating that portion of the median lobe contralateral to the sulcus, Figure 3. This maneuver is achieved similarly to the anterior lift of the proximal implants but upside down, in the posterolateral direction. For example, to open the right sulcus of a median lobe, place the device in the sulcus with the needle port at the bladder neck pointing to 3 o'clock. It can be helpful to visualize the prior placed proximal implant on the right side as a fiducial marker for the prostate side of the bladder

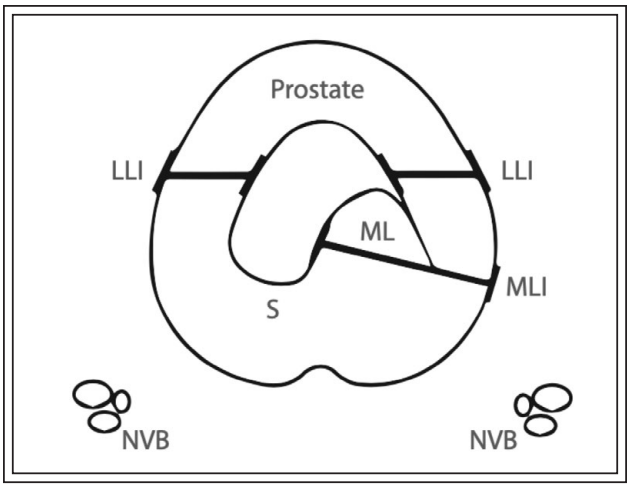

Figure 3. Schematic of median lobe lateral distraction and fixation. Lateral lobe implants **(LLI)** create anterior channel as median lobe implant **(MLI)** fixates median lobe **(ML)**, opening sulcus **(S)**. No implants are near the neurovascular bundles **(NVB)**.

neck, Figure 4. Slowly compress the lobe laterally while retracting the device; this also retracts part of the median lobe across the bladder neck into the prostatic fossa. Keeping compression on the distracted tissue, roll the device to 4 o'clock and compress in that direction, posterolaterally, further distracting tissue into the prostatic fossa and moving it downward. Very importantly, as with the anterior deployments, before the needle is deployed, roll the device back to

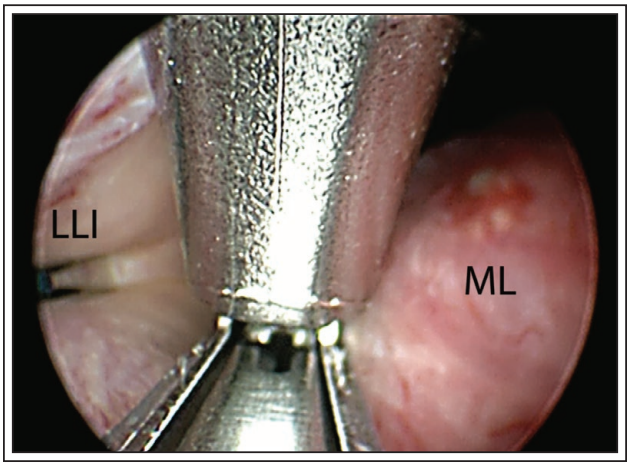

Figure 4. Proximal right lateral lobe implant **(LLI)** can be used as a visual fiducial marker to show device is distal to the bladder neck and adjacent to median lobe **(ML)**.

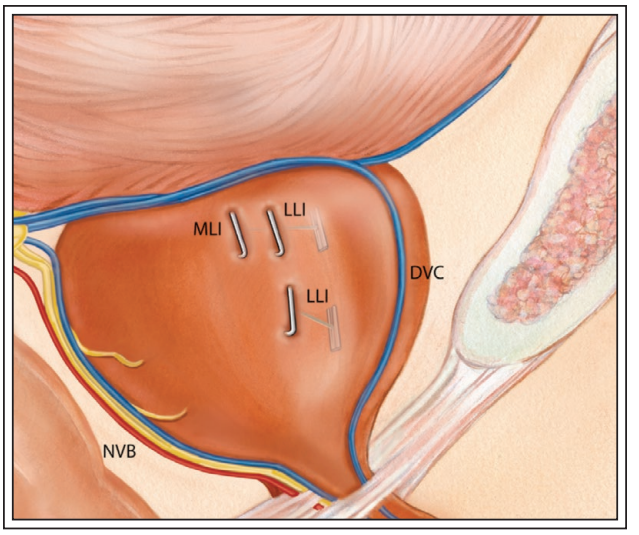

Figure 5. Cartoon of typical implant locations. Despite posterolateral distraction of median lobe, the final median lobe implant **(MLI)** remains close to the bladder neck in the anterior aspect of the prostate along with the lateral lobe implants **(LLI)**. No implants are near the dorsal venous complex **(DVC)** or neurovascular bundles **(NVB)**.

3 o'clock and level off the pitch to nearly horizontal. This final maneuver allows for the needle to avoid firing toward the neurovascular bundle or seminal vesicle. Despite this posterolateral distraction, the final position of the median lobe implant is actually quite anterior on the prostate, near the bladder neck, Figure 5. When properly deployed, typically only one implant is required for the median lobe. However, if the tip of the device has rolled off the distracted tissue during manipulation another implant may be required.

Tip: median lobe compression

The most challenging aspect of the median lobe technique is manipulating the lobe without sliding off the adenoma tissue, and simultaneously avoiding urothelium abrasion. A technique has been developed that leverages the fact that adenoma can often take a temporary compression with very slow shape recovery. After deploying the final lateral lobe implant, before removing the used device, advance it to the bladder neck and place it in the desired median lobe sulcus. Begin in the deepest sulcus and apply downward pressure for 30 seconds. Move one breadth of the scope toward midline and repeat with 30 second compression until you have moved all the way across the median lobe, then do the same on the way back. This can often take 5-10 minutes, which may seem

interminable during the process, but can save more time than that when deploying the median lobe implant, and increases probability of needing only one implant, rather than two.

UroLift ATC device

An instrument has become recently available that greatly facilitates treatment of the obstructive median lobe, the UroLift ATC device (Teleflex, Pleasanton, CA, USA). A pair or retractable steel wings have been added to the device tip that create an oblong footprint that is about 1.75 mm long axially and 0.7 mm wide laterally, Figure 6. The wings compress when the device is advanced or retracted into the sheath and automatically open once the tip is exposed in situ. Rather than obstructing the cystoscopic view, the wings tend to hold tissue at bay increasing the visual field. Etched markings on the wings also aid in estimating where the needle will penetrate the prostate tissue when deployed, a welcome guide when deploying implants near the bladder neck. Most importantly, however, is how the wing shape facilitates median lobe manipulation. With the standard UroLift device, the most challenging aspect of treating the median lobe is keeping the narrow device tip from rolling off the adenoma while manipulating it posterolaterally. The ATC wings provide a wider base that can capture the adenoma and keep the needle port centered on the target tissue, Figure 7, as the tissue is manipulated into position. This greatly improved control does require a gentler approach when manipulating the tissue so as to avoid urothelial abrasion, particularly as the inferior wing sweeps the tissue laterally. In our experience

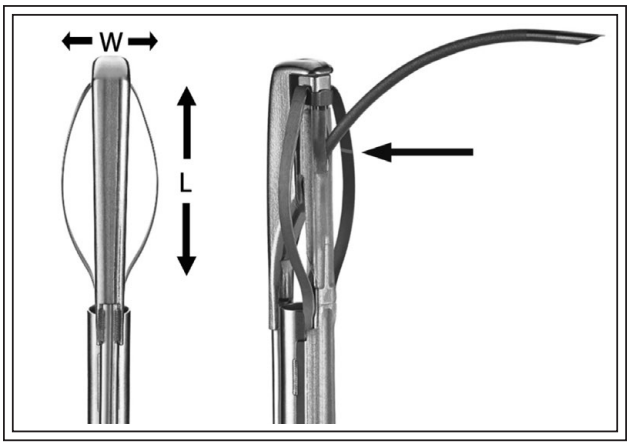

Figure 6. UroLift ATC device has compressible wings that facilitate tissue distraction. Width of wings **(W)** is 0.7 mm and length **(L)** is 1.75 mm. Etched marking **(arrow)** indicates where needle will enter tissue.

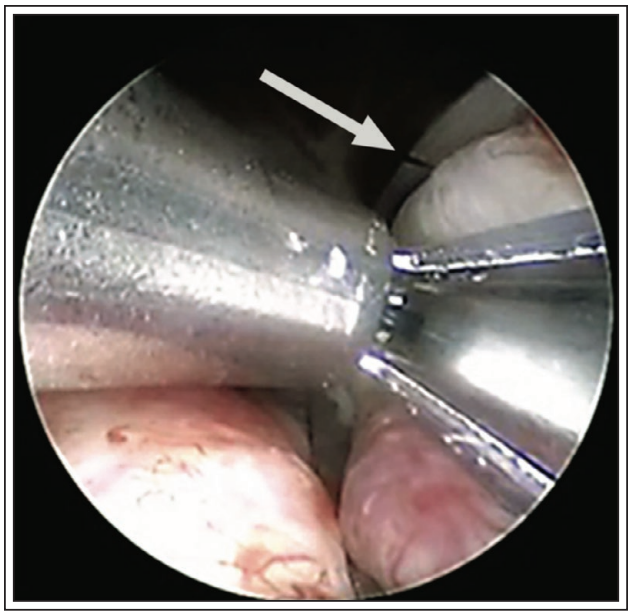

Figure 7. UroLift ATC compressing a median lobe. Needle has been deployed and retracted with placement aided by etched markings **(arrow)**. Suture is visible as capsular tab is tensioned onto prostatic capsule. Expanded device wings capture the median lobe tissue and stabilize the device on the adenoma.

this technique is easily learned so that median lobe treatment is less abrading, more straight forward to do, and more likely to result in needing only a single implant in the obstructive median lobe.

To treat the obstructive median lobe with the UroLift ATC, introduce the device into the sheath when the sheath tip is in the bladder, so that the wings can expand within the bladder lumen. As one retracts the device tip into a median lobe sulcus at the bladder neck, gently drop the ATC wings around the median lobe tissue. It can be helpful to visualize the proximal lateral implant as a fiducial for the bladder neck to assure that the needle exit lines on the ATC wings are indeed distal to the bladder neck. At this point, begin to apply pressure to the median lobe while angling posterolaterally (4 or 8 o'clock) and pulling this portion of the median lobe into the prostatic fossa while continuing to rotate toward 3 or 9 o'clock. This must be done gently with particular focus on the inferior wing, so as not to tear the urothelium. Next, flatten the pitch of the device to near horizontal. It is helpful apply a lateral yaw of at least 30 degrees to assure the needle exits the prostate capsule. When in this final position, deploy the needle and retract it. Because this deployment is near the bladder neck, we prefer to

advance very slowly and deploy the urethral end piece just as the white line appears on the suture to deploy as distally as possible. The final median lobe implant is indeed near the bladder neck and is typically deeply embedded in the tissue. In the MedLift trial and in our experience this does not result in encrustation.

Tip: what NOT to do

It is very important that PUL implants never be delivered into the tissue proximal to the bladder neck. The LIFT randomized study demonstrated that implants delivered into the prostate were free of encrustation, but implants exposed to the bladder lumen showed a high propensity for encrustation. Additionally, it is important not to deploy the implant into the detrusor muscle or of course near the ureteral orifices. Thus, once the base of the obstructive median lobe is appropriately distracted posterolaterally into the prostatic fossa and fixed with an implant, and a patent anterior channel is confirmed, residual intravesical adenoma must be left as is. By laterally fixating the base of the median lobe it is less likely to 'ball valve,' and intravesical tissue will likely not contribute to prostatic obstruction.

Results

The visual result of treating the obstructive median lobe can be quite dramatic. Figure 8 shows how the prostate can look after treating just the lateral lobes followed by the noticeable improvement when finishing with a median lobe implant. Because the procedure requires more manipulation at the bladder neck, and because there is by definition more proximal adenoma with obstructive median lobes, we typically place a catheter overnight to address any potential edema or hematuria. This is different from pure lateral lobe PUL cases that generally do not require catheterization.

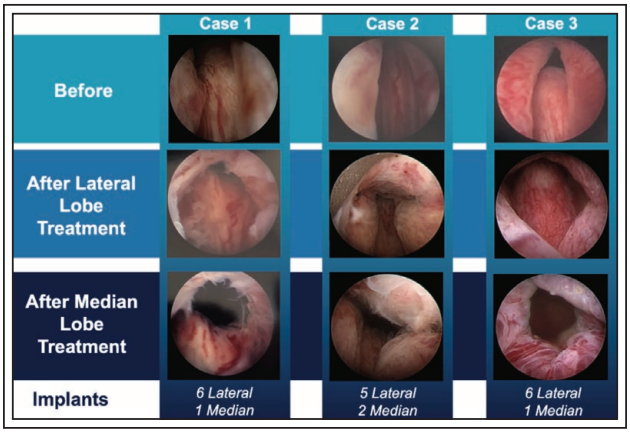

Figure 8. Representative cystoscopy results of the Prostatic Urethral Lift procedure before and after treatment in patients with median lobe obstruction. Obstructive median lobe noted at baseline; anterior channel established after lateral lobe treatment, but median lobe obstruction remains; after median lobe implant, anterior channel visible across bladder neck.

A recent publication analyzed safety and effectiveness of PUL for obstructive median lobe across controlled clinical trials and in a real world retrospective study.[17] PUL results for 225 men with obstructive median lobes were compared to those with lateral lobe treatment only and with those undergoing sham or TURP controls. The overarching conclusion of the analysis is that PUL is as safe and as effective when treating median lobes as it is treating lateral lobes. At 12 months, PUL median lobe patients in a controlled trial and a large retrospective study experienced average IPSS improvement of 13.5 ± 7.7 and 11.6 ± 9.2, QoL improvement of 3.0 ± 1.5 and 2.1 ± 2.0, and Qmax improvement of 6.4 and 7.1 mL/sec, respectively. In the controlled setting, both ejaculatory and erectile function were preserved and postoperative catheterization rates were higher than lateral lobe rates (80% vs. 32%), but similarly short lived with a mean duration of 1.2 days. These results further validate those of prior published single center studies.[18]

In addition to the large body of controlled and real world data supporting PUL treatment of obstructive median lobe, one of the authors tracked 12 consecutive patients to 6 months using the UroLift ATC for obstructive median lobe. The results align with those of the large studies cited. Two patients presented in urinary retention, and both remained catheter free after PUL. Nine non-retention patients showed a matched mean IPSS improvement of 10.7 (95%CI: 5.8-15.6) with QoL improving by 3.0 points (95%CI: 2.2-3.8). One patient was converted to TURP at 6 weeks; cystoscopy indicating his median lobe was insufficiently anchored. Six of eight patients on medication at baseline were free of medications at 6 months. One of these patients presented with an IPSS of 7 with finasteride but wanted to come off medication. His IPSS remained 7 after PUL, but he was free of BPH medication.

Discussion and Conclusions

The Prostatic Urethral Lift was first conducted exclusively on lateral lobes but has recently been developed and FDA approved for treatment of obstructive median lobes as well. Conducting PUL for obstructive median lobe has heretofore been one

of the more advanced PUL techniques, due to the necessity of implants delivered near the bladder neck and the potential difficulty encountered in distracting the median lobe tissue posterolaterally into the prostatic fossa. With the recent availability of the UroLift ATC device designed for intravesicular protrusion, the technique has been refined and is more straightforward to conduct. Care must still be given to device targeting and implant delivery, however proper technique generally results in one additional implant to address the median lobe tissue. In some instances, two implants into the median lobe may be required.

Considerable evidence has been published demonstrating that appropriate treatment of the obstructive median lobe with PUL is as safe and effective as treatment of lateral lobes. Real world retrospective studies have shown that PUL is increasingly being conducted for median lobe obstruction with results that mirror those of controlled clinical trials. This represents an advancement in BPH care, as we can now offer the benefits of PUL, namely preservation of sexual function, rapid recovery and minimal post operative catheterization, to men with median lobe obstruction. Furthermore, treating median lobes with the UroLift ATC device has made the procedure more accessible to a broad range of urologists.

Disclosure

Some of the data presented in the manuscript were obtained through clinical studies sponsored by Teleflex, Inc. At the time of development and submission of the manuscript, authors M.A., J.P. and G.E. were paid consultants of Teleflex. The authors would like to thank Ted Lamson, PhD for his collaboration during the preparation of the manuscript. □

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