

Persistent need for ongoing medical or surgical therapy despite UroLift

Data from an academic center

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ABSTRACT

INTRODUCTION: Prostatic urethral lift (PUL) is a popular surgical option for benign prostatic hyperplasia (BPH) with lower urinary tract symptoms (LUTS). Prior five-year data from the multicenter L.I.F.T. trial suggested durability and a surgical retreatment rate of 13.6% at five years. We assessed the proportion of patients who had ongoing medical or surgical BPH management following PUL.

METHODS: With institutional review board approval, cases of PUL performed from 2015–2020 at our academic institution were retrospectively reviewed for management of BPH following PUL.

RESULTS: A total of 209 men were identified, with followup available for 198 (95%). Mean age was 68.9 years and mean followup was 18.5 months. Mean prostate size was 43 g. Patients were discharged from recovery in 97% of cases, with 29% discharged with indwelling or intermittent catheterization. The rate of 30-day complications was 18%, with 89% graded Clavien I–II. Postoperatively, mean improvements in International Prostate Symptom Score (IPSS) and quality of life (QoL) subscore were 5.3 and 1.1 points, respectively. Unplanned emergency room or clinic visits within 30 days of the procedure occurred in 14% and 17% of men, respectively, with 4% requiring hospital readmission. In followup, α -blockers and/or 5 α -reductase inhibitors were continued or initiated postoperatively for 44% of men; 20% of men required repeat surgical intervention at a mean of 19.2 months (1.4–56.4), consisting of repeat PUL (30%), transurethral resection of prostate (28%), or thulium laser enucleation (18%). Overall, 53% of men needed medication and/or repeat surgery for BPH following PUL, and this was independent of age, race, prostate volume, intravesical prostate protrusion, baseline IPSS and QoL, stricture, number of implants used, or a history of urinary retention ($p > 0.05$).

CONCLUSIONS: Most men undergoing PUL require ongoing medical and/or surgical management for BPH. Patients should be counselled as to the likelihood of failure as a unimodal therapy long-term.

INTRODUCTION

Prostatic urethral lift (PUL), branded UroLift®, is one of the numerous minimally invasive surgical options for the management of bladder outlet obstruction (BOO) secondary to benign prostatic hyperplasia (BPH). It involves mechanical compression of the urethral lumen against the prostatic capsule via the deployment of multiple nitinol and stainless steel implants. According to American Urological Association (AUA) guidelines, this treatment modality is an option for patients with prostate volume from 30–80 g and without any midline prostatic tissue (median lobe).¹ Reported preservation of antegrade ejaculation, relatively short learning curve, and short procedural time have factored into swift adoption among urologists worldwide.²

Our academic center has participated in clinical trials involving PUL, most notably the MedLift trial.³ Five-year data from the L.I.F.T. study suggested durable improvement in multiple measures of lower urinary tract symptoms (LUTS) attributable to BOO as measured by the International Prostate Symptoms Score (IPSS), quality of life (QoL), BPH Impact Index, and max flow during uroflometry (Q_{max}). In that analysis, surgical retreatment was 13.6% at five years.⁴ The growing body of literature on PUL outcomes demonstrates a wide range of surgical retreatment rates. Simply looking at such rates, however, does not account for patients either maintained or newly initiated on medical

KEY MESSAGES

- Most men undergoing PUL have symptomatic improvement at the time of followup.
- A significant proportion of men will require continued medical treatment for LUTS attributable to BPH following PUL.
- Up to 20% of men will require surgical retreatment for their LUTS following PUL.
- Patients should be counselled as to the potential need for continued medical and/or surgical therapy following PUL as a unimodal treatment for BPH.

management of obstructive LUTS with α -adrenergic blockers (e.g., tamsulosin) or 5α -reductase inhibitors (e.g., finasteride).

The objective of the present study was to review the rates of PUL failure as indicated by persistent use of medical therapy or surgical re-intervention at a single high-volume center.

METHODS

Following institutional review board approval, we retrospectively reviewed all cases of PUL performed at our academic institution from 2015–2020. Any man who received a PUL in this timeframe was included in the study. We did not exclude any patients on the basis of particular medication usage or for having prior surgical or procedural BPH treatment. We excluded patients with aberrant lower urinary tract anatomy (urinary diversion, buried penis, etc.) and certain types of neurogenic lower urinary tract dysfunction (spinal cord injury, spina bifida, traumatic brain injury). We collected demographics, data regarding medication usage, symptomatology (IPSS and QoL subscores), operative details, complications, and reinterventions. When available, we recorded data on imaging and/or cystoscopic findings of prostate anatomy. Both α -blockers and 5α -reductase inhibitors were considered medical therapy for symptomatic relief of LUTS attributable to BOO. Surgical reinterventions considered included all procedures specifically used to relieve LUTS attributable to BOO. Statistical analyses were performed using the JMP Statistical Discovery® software (Cary, NC, U.S.).

RESULTS

A total of 209 men who underwent PUL from 2015–2020 by five different urologists at a tertiary care center were included for analysis. Mean age at the time of surgery was 69 ± 9 years old and mean followup was 18.5 ± 16.7 months. Most men were White (88%) and 23% had a history of diabetes mellitus.

The predominant symptom for most men prior to surgery was urinary retention requiring indwelling or intermittent catheterization (28%), followed by nocturia (15%) and weak urinary stream (15%). Preoperative prostate measurement was performed in 63% of patients with a mean size of 43 (8–138) g. Preoperative cystoscopy was performed in 36% of men. Cystoscopic findings included significant intravesical prostatic protrusion in 22%, bladder trabeculation in 95%, and urethral stricture in 8%. Five percent of men had another surgical treatment for LUTS attributable to BOO prior to PUL. This included unspecified laser therapy (2), transurethral microwave therapy (1), transurethral needle ablation (1), transurethral resection (TURP; 4), PUL (1), and transurethral prosthetic stent placement (1). Data regarding pre- and postoperative symptom questionnaires are included in Figure 1. The mean reduction in IPSS and QoL subscores following PUL were 5.3 and 1.1 points, respectively ($p<0.0001$).

Mean operating room time was 19 ± 9 minutes and intraoperative complications occurred in 3%. Of those six complications, five involved product misfiring resulting in bleeding requiring cauterization with or without removal of a PUL implant. The other complication was the unintentional creation of a small false passage in the urethra upon manipulation. Most (97%) men were

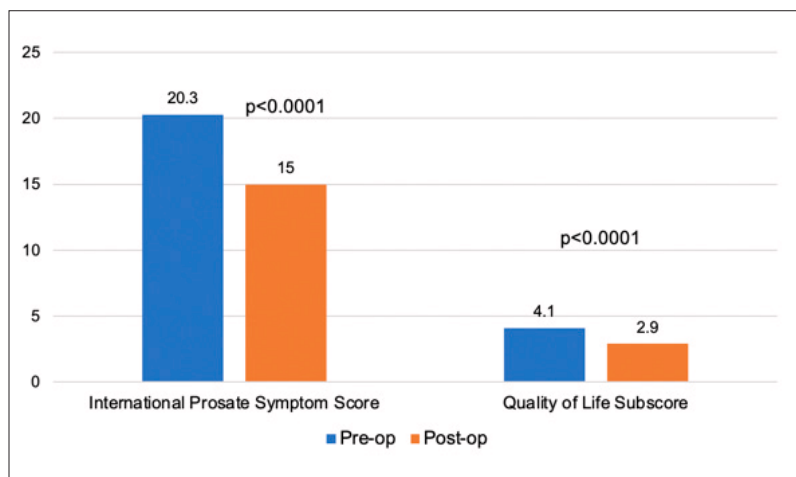


Figure 1. Pre- and postoperative voiding dysfunction metrics.

discharged immediately after the procedure, with 29% requiring an indwelling Foley catheter or initiation of intermittent catheterization based upon concern for clinically significant postvoid residuals. Concomitant urethral stricture dilation was performed in 5% of cases. A postoperative complication within 30 days of surgery was noted in 18% of patients, with only 2% being major (Clavien III–V). The 30-day readmission rate was 4%. An unanticipated emergency room or clinic visit within 30 days occurred in 14% and 17% of men, respectively.

Outcomes data are included in Table 1 for the 95% of patients for which followup data was available. Forty-four percent of men required either continuation or initiation of medication for LUTS during followup. Of those 44% of men, 88% had prescriptions that were continued postoperatively, while the remainder required a new prescription of a α -blocker and 5 α -reductase inhibitor following PUL. Repeat surgery was performed in 20% of men at mean of 19.2 \pm 13.2

months following PUL. The most common reinterventions included repeat PUL (30%), TURP (28%), and thulium enucleation of the prostate (18%). Overall, 53% of men required medication and/or repeat surgery for BOO/BPH following PUL, and this was independent of age, race, prostate volume, intravesical prostate protrusion, baseline IPSS and QoL, stricture, number of implants used, or a history of urinary retention ($p>0.05$).

DISCUSSION

The present study demonstrates that despite a high likelihood for short-term symptomatic relief, most men who undergo PUL will require continued medical and/or surgical management of obstructive LUTS at intermediate-term followup. The surgical retreatment and medical retreatment rates were high, at 20% and 44%, respectively. This was independent of multiple risk factors, including prostate size, retention history, and baseline symptomatology. Immediate complications were common at 18% but the vast majority were minor. Patients also required an emergency room or unanticipated urology clinic visit 14% and 17% of the time, respectively.

A review of the literature demonstrates a wide range of treatment failure rates for PUL. For the 74% of patients retained at five years ($n=104$), results from the L.I.F.T. multicenter study demonstrated a surgical retreatment rate with additional PUL or other transurethral surgery of 13.6%.⁴ Interestingly, this number is an underestimation, as a proportion of the unretained patients at five years dropped out of the study because they elected to undergo TURP (and were therefore not included in the 13.6%). A retrospective cohort analysis ($n=2942$; similar patient demographics to the present study) out of the U.K. between 2017 and 2020 demonstrated an endoscopic reintervention rate of 11.9% at two years and 30-day emergency room visit rate of 12%.⁵ In a recent systematic review by Miller et al of over 2000 patients, the annual reintervention rate was, on average, 6% per year overall and 10.7% in studies with 1–3 years of mean followup.⁶ In a large analysis of TURP, prostate photovaporization, and PUL, just under 3% of patients were retreated after TURP within two years, while 5.2% were retreated following PUL; on multivariate analysis, PUL was independently associated with a nearly two-fold increased likelihood of retreatment within two years relative to TURP.⁷

A primary motivation of the present study was that the current literature does not consider continued medical therapy as treatment failure. This is an important data point, as a significant proportion of men elect

Table 1. Complications and continued interventions following prostatic urethral lift

Metric	n	%
30-day complications	37	18%
None	167	82%
Minor	33	16%
Major	4	2%
Postop retention	59	29%
30-day readmission	9	4%
New/continued medication use	90	44%
New	11	12%
Continued	79	88%
Unanticipated ER visit	29	14%
Unanticipated clinic visit	36	17%
Repeat surgery	40	20%
Green light prostatectomy	1	3%
Robotic simple prostatectomy	3	8%
Suprapubic tube placement	2	5%
Thulium enucleation of the prostate	7	18%
Transurethral incision of prostate	1	3%
Transurethral resection of prostate	11	28%
Urethral dilation	1	3%
Repeat prostatic urethral lift	12	30%
Other	2	5%

to undergo surgery for BPH with the intention of avoiding long-term medical management.^{8,9} Long-term treatment adherence to medical therapy for BPH secondary to BOO is low, given the significant side effect profile.¹⁰ For example, post-finasteride syndrome is characterized by sexual, psychological, and physical symptoms that persist in certain men following discontinuation of their 5 α -reductase inhibitor.¹¹ Approximately one-quarter of patients using tamsulosin long-term will experience side effects, with the most common being dizziness (6%) and abnormal ejaculation (4%).¹² In the present study, a near majority of the patients required ongoing or newly prescribed administration of α -blockers or 5 α -reductase inhibitors for the symptomatic relief of BOO attributable to BPH following PUL. Given that PUL is an option often selected by patients specifically for preservation of their sexual/ejaculatory function, a frank discussion about the likelihood of ongoing or future need for medication that may compromise sexual/ejaculatory function seems warranted.

Limitations

Our study is not without limitations, including those inherent to a single-center, retrospective review, such as lack of generalizability and risk of bias. All consecutive patients who received PUL were included in the study without explicit exclusion criteria, which lead to significant heterogeneity within the patient population in terms of diagnostic workup, prostate size, and symptomatology. Continued medical therapy for LUTS secondary to BPH was inferred based on the status of an active prescription at followup appointments; continued usage may reflect failure of the provider to discontinue medication and does not directly attest to adherence. Finally, rates of repeat surgical and/or medical treatment may underestimate reality, as patients receiving care outside of our health system would not have been captured in our review.

Despite these limitations, we believe our study provides valuable insight into rates of treatment failure for PUL for symptomatic BOO. As a popular treatment in the era of minimally invasive surgical therapy for BPH, urologists must have a candid discussion with patients about the likelihood of requiring subsequent treatment, whether it be medical and/or surgical. Although PUL does not necessarily preclude further treatment for BPH, it may render future surgery more challenging¹³ and possibly impact efficacy of medical therapy.

CONCLUSIONS

Most men undergoing PUL require ongoing medical and/or surgical management for BPH. Patients should be counselled as to the likelihood of failure as a unimodal therapy long-term. As this does not appear related to patient selection, the overall value of PUL to men with LUTS attributed to BPH should be carefully assessed, especially in those who intend to avoid long-term medical management.

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This paper has been peer-reviewed.

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