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REVIEW

Benign prostatic hyperplasia surgical re-treatment after prostatic urethral lift

A narrative review

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ABSTRACT

INTRODUCTION: Prostatic urethral lift (PUL) accounts for approximately one-quarter of all surgical benign prostatic hyperplasia (BPH) procedures performed in the U.S.[1] Within five years of a patient's PUL procedure, approximately 1/7 patients will require surgical BPH retreatment.[2] We aimed to highlight the evidence of surgical BPH retreatment modalities after PUL, with a focus on safety, short-term efficacy, durability, and relative costs.

METHODS: A literature review was performed using PubMed, and an exhaustive review of miscellaneous online resources was completed. The search was limited to English, human studies. Citations of relevant studies were reviewed.

RESULTS: No study has examined the efficacy, safety, or durability of transurethral resection of the prostate (TURP) or repeat PUL in the post-PUL setting. Recently, groups have examined laser enucleation (n=81), water vapor thermal therapy (WVTT) (n=5), robotic simple prostatectomy (SP) (n=2), and prostatic artery embolization (PAE) (n=1) in the post-PUL setting. Holmium enucleation of the prostate (HoLEP) after PUL appears to be safe and has similar functional outcomes to HoLEP controls. Other treatment modalities examined appear safe but have limited efficacy evidence supporting their use. Photo-selective vaporization of the prostate (PVP) and robotic waterjet treatment (RWT) have no safety or efficacy studies to support their use in the post-PUL setting.

CONCLUSIONS: Despite increasing numbers of patients expected to require surgical retreatment after PUL in North America, there is currently limited evidence and a lack of recommendations guiding the evaluation and management of these patients. HoLEP is associated with the strongest evidence to support its use in the post-PUL setting.

INTRODUCTION

Minimally invasive surgical therapies (MISTs) are predominantly office-based treatments designed to lessen the morbidity of benign prostatic hyperplasia (BPH) surgical treatment, transition patients off medications, and preserve antegrade ejaculatory function.[2,3] Prostatic urethral lift (PUL) received Food and Drug Administration (FDA) approval for the surgical treatment of BPH in 2013, and in January 2020 received updated approval to treat prostate glands up to 100 cc in size.[4] A recent abstract presented by Cruz et al revealed that PUL accounted for 23.7% of all Medicare-billed BPH procedures in 2019, an absolute increase of 22.2% from 2015.[1]

The initial randomized, controlled L.I.F.T. trial examining PUL outcomes demonstrated surgical BPH retreatment at five years post-PUL to be 13.6%.[2] As highlighted in an editorial by Dr. Kaplan and Dr. McVary, this rate did not account for patients who required surgical removal of the implants that had encrusted in the bladder or were removed prophylactically (9.2%, 13/140).[5] Of the patients with available followup data (n=113) at five years, the rate of surgical BPH retreatment or surgical clip removal was 28.3% at five years.[2] Real-world, retrospective data examining 2942 PUL patients demonstrated rates of surgical intervention (BPH retreatment and clip removal) to be 5.2% at one-year and 11.9% at two years.[6] As the proportion of PUL procedures continues

KEY MESSAGES

- Despite an increasing number of patients expected to require surgical re-treatment after PUL, there is limited evidence and a lack of recommendations to guide the management of these patients.
- HoLEP is associated with the strongest evidence to support its use after PUL.
- PVP and RWT have no peer-reviewed evidence to support their use in the post-PUL setting.
- There is no peer-reviewed evidence examining the durability, cost, or sexual impact of PUL retreatment modalities.

to increase in the U.S., we can continue to expect an increasing number of patients to require surgical reintervention after their PUL procedure.

Anecdotally, we have experienced an increasing number of patients presenting to our center for holmium enucleation of the prostate (HoLEP) post-PUL. In our own retrospective experience, post-PUL HoLEP is associated with longer operative time, an increased number of morcellator blades used per case resulting in higher operative costs, and similar functional outcomes compared to controls.[7] When counselling patients seeking surgical retreatment options after PUL, we recognized our own knowledge gap regarding the safety and efficacy of available options. With this review, we aimed to highlight the evidence available for surgical BPH retreatment modalities after PUL, with a focus on safety, short-term efficacy, durability, and costs.

METHODS

A literature search using the PubMed database was performed on December 12, 2022, for English, full-text articles and abstracts. Studies published after November 2022 were not included in the search. The following keywords were used: "prostatic urethral lift" OR "urolift." Secondary searches were performed querying each alternative treatment modality with prostatic urethral lift and urolift. Duplicate abstracts were excluded. All 247 abstract results were reviewed by one author (ND) to determine appropriateness for inclusion in the narrative review. All relevant full-texts and their citations were reviewed, and overall, 29 were included and referenced. In the absence of any peer-reviewed published literature, surgical-center and surgical treatment manufacturer websites were reviewed, and information was also extracted from social media sources.

RESULTS

Retreatment/reintervention

BPH re-treatment after MISTs consists of medical therapy reinitiation (alpha-blockers and 5-alpha reductase inhibitors [5-ARIs]), or surgical reintervention if symptoms are more severe.[2,6,8] The definition of surgical retreatment after PUL has not been clearly defined.[5] The initial L.I.F.T. study defined surgical retreatment as the requirement for further surgical treatment of BPH with either the addition of PUL clips, a transurethral resection of the prostate (TURP), or a laser BPH treatment (unclear if laser enucleation or ablation).[2,5] The authors of the L.I.F.T. study did not include surgical interventions for encrusted/migrated PUL clips within this definition.[2] Dr. McVary and Dr. Kaplan have previously recommended that a standard definition of surgical retreatment is required when comparing MISTs to decrease the heterogeneity in outcome reporting between studies.[5]

For reasons mentioned previously, rates of surgical reintervention (BPH retreatment and clip removal) vary from 2–6%/year between controlled studies, real-world retrospective data, and meta-analysis.[2,6,9–11] Predictors of PUL failure requiring surgical intervention have not been clearly defined. Chin et al performed a multiregression analysis of L.I.F.T. study patients (n=140) and real-world data (n=3226) examining predictors of PUL failure requiring further BPH retreatment and found preoperative International Prostate Symptom Score (IPSS) and quality of life to be significantly predictive of retreatment.[12] Gland size >100 cc within this analysis was associated with an odds ratio (OR) of 2.38, but a p-value that did not reach a level of significance (p=0.144).[12]

Evaluation

Indications for BPH reintervention after PUL within randomized controlled trials is not clearly defined.[2,9] Das et al defined PUL failure as, "significant lower urinary tract symptoms [LUTS] not responding to medical treatments/too severe for medical therapy/desire to avoid oral medications, or urinary retention," within their study examining the role of PUL retreatment with HoLEP.[4] Other reported indications for interven-

tion after PUL include clip removal after misplacement within the bladder, implant encrustation, and pain.[2,13,14] Despite PUL insertion being recommended by the American Urological Association, European Association of Urology, Canadian Urological Association, and National Institute for Health and Care Excellence guidelines, there are currently no recommendations for the management of men with recurrent LUTS or urinary retention after PUL or any of the other MISTs.[15-18]

Surgical BPH retreatment options

Repeat PUL

A common BPH retreatment strategy, used in the initial PUL randomized controlled trials and retrospective cohort studies after PUL failure, is to reconfigure the prostatic urethra by placing more PUL clips.[2,9] Support for the use of repeat PUL in the retreatment of patients with prior failed PUL is based on limited evidence. Within the L.I.F.T. study, six patients (4.3%) underwent repeat PUL placement.[2] In retrospective, real-world cohort studies, repeat PUL procedures occurred in 1.5% of patients at one year and 3% of patients at two years of followup.[6] Despite PUL clips often being used for repeat treatments, there are no published indications for when PUL is or should be used instead of TURP or laser BPH treatments. No study to date has reported the patient characteristics, operative characteristics (operating room time, number of implants), perioperative complications, catheter duration, postoperative IPSS/postvoid residual/ejaculatory function, durability of outcomes, costs, or freedom from next BPH treatments of patients undergoing repeat PUL placement (Table 1).

TURP

TURP is a frequently performed BPH procedure after PUL failure.[2,6,9] Support for the use of TURP in the retreatment of patients with failed PUL is based on limited evidence. Within the L.I.F.T. study, 13 patients (9.2%) underwent retreatment with TURP or laser treatment.[2] Like repeat PUL, TURP has no published outcome data in the post-PUL setting[6,11] (Table 1). Interestingly, TURP has been reported to be more difficult after PUL due to fracture of the TUR cautery loop by the embedded clips. Despite anecdotal comments about this on social media, we were unable to identify reports of this in a peer-reviewed setting, nor increased operative times or costs associated with loop fracture.

Water vapor thermal therapy

Support for the use of water vapor thermal therapy (WVTT) in the management of failed PUL BPH retreatment is based on limited evidence. The most recent and only study examining the role of WVTT in a salvage post-PUL setting reported the results of 19 patients after failed BPH surgery (26.3%, 5/19 PUL).[19] Treatment failure was defined as recurrent LUTS or requirement for medical therapy. Preoperative workup for these patients prior to WVTT included a urologic history, magnetic resonance imaging or transrectal ultrasound, and perioperative cystourethroscopy.[19] Although the WVTT postoperative outcomes were reported as one heterogenous cohort after several previous different procedures, the authors report that the post-PUL patients had a median reintervention time of 20 months and prostate size of 64 mL (Table 1). Overall, the entire cohort had a low rate of postoperative complications after WVTT. Complications included the requirement for a catheter in 2/19 patients after the 7–14-day standard removal, however, it is not clear if urinary retention occurred in post-PUL patients. The authors report that the PUL clips were left in place after WVTT treatment and recommend that the surgeon must be attentive at the time of WVTT to avoid injury to the sphincter given altered anatomy after PUL and to be aware of the theoretical loosening of clips due to tissue apoptosis after WVTT.[19] At three months followup, no clip complications were noted by the authors. Preservation of ejaculatory function and durability of treatment were not examined.

Simple prostatectomy

Support for the use of robotic simple prostatectomy (SP) in the management of patients with prior PUL is based on limited evidence. One abstract was identified reporting the outcomes of "salvage" robotic SP compared to a non-salvage cohort.[20] Within the salvage cohort, 9% (2/22) of patients had undergone prior PUL. Details about the preoperative evaluation and timing from PUL to SP were not defined (Table 1). Mean length of stay was 1.91 days in the salvage cohort. Functional outcomes within the salvage group did not differ from the SP control cohort, however, specific post-PUL SP outcomes were not examined.

Robotic waterjet treatment

We were unable to identify any evidence to support the use of robotic waterjet treatment (RWT) in the failed PUL setting. On review of the Aquablation website and the websites of providers marketing RWT, we

Table 1. Post-PUL retreatment modalities

Author	Year	Country	Study type	n	Prostate size (cm^3)	Time from PUL (months)	LOS (days)	Complications (%)	EBL (mL)	ER visit (%)	PVR Δ (mL)	AUASS Δ	Peak flow Δ (mL/s)
Repeat PUL													
Roehrborn[2]	2017	USA	RCT	6	NR	NR	NR	NR	NR	NR	NR	NR	NR
Page[6]	2021	UK	Retrospective	57	NR	NR	NR	NR	NR	NR	NR	NR	NR
TURP													
Roehrborn[2]	2017	USA	RCT	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Gratzke[9]	2016	Germany	RCT	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
WVTT													
Gauhar[19]	2022	Singapore	Retrospective	5	64	20	NR	0	NR	NR	NR	NR	NR
SP													
Pathak[20]	2022	USA	Retrospective	2	NR	NR	NR	NR	NR	NR	NR	NR	NR
RWT													
None													
HoLEP													
McAdams[13]	2017	USA	Retrospective	7	80	8	NR	0	59	NR	NR	NR	NR
Das[4]	2022	USA	Retrospective	22	90	14.4	NR	18.2	NR	9.1	-124	-5	8.3
Durant[23]	2022	USA	Retrospective	24	NR	NR	NR	NR	NR	NR	NR	NR	NR
Assmus[7]	2022	USA	Retrospective	22	104.8	NR	NR	7.7	NR	13.3	NR	-4.3	NR
David[14]	2022	USA	Retrospective	1	84	NR	NR	0	NR	NR	NR	NR	NR
Parikh[21]	2019	USA	Retrospective	3	NR	NR	NR	NR	NR	NR	NR	NR	NR
Iqbal[22]	2018	UK	Retrospective	1	NR	0.25	NR	0	NR	NR	NR	NR	NR
TFL													
Smith[24]	2021	USA	Retrospective	1	198	24	1	NR	NR	NR	NR	-10	43.9
PVP													
None													
PAE													
Tapping[26]	2017	UK	Retrospective	1	99	1	NR	NR	NR	NR	NR	-6	10

AUASS: American Urological Association Symptom Score; EBL: estimated blood loss; ER: emergency room; HoLEP: holmium laser enucleation of the prostate; LOS: length of stay; PAE: prostatic artery embolization; PUL: prostatic urethral lift; PVP: photo-selective vaporization of the prostate; PVR: postvoid residual; RCT: randomized controlled trial; RWT: robotic waterjet treatment; SP: simple prostatectomy; TFL: thulium fiber laser enucleation; TURP: transurethral resection of prostate; WVTT: water vapor thermal therapy.

did not identify any recommendations for use of RWT in the post-PUL setting (Table 1).

Transurethral laser enucleation

Holmium laser enucleation of the prostate

Support for the use of HoLEP in the re-treatment of patients with failed PUL is based on a moderate amount and quality of evidence. Seven studies have investigated HoLEP after PUL treatment[4,7,13,14,21-23] (Table 1). McAdams presented a multi-institutional case series (n=7) of patients who underwent HoLEP after failed PUL.[13] The majority of these patients (6/7) were treated for persistent LUTS/urinary retention and one patient underwent HoLEP for chronic pain after

PUL. All patients underwent cystourethroscopy prior to HoLEP in this setting. The median time from PUL to HoLEP was 8.6 months. Mean prostate size was 80 cc. The group noted no Clavien-Dindo complications and disadvantaged morcellation due to PUL clips. Aberrant clip locations were noted in 6/22 clips.

Das et al compared patients undergoing HoLEP after PUL (n=22) to a control cohort of patients undergoing HoLEP (771) and demonstrated that post-PUL HoLEP was associated with decreased overall operative efficiency and morcellation efficiency.[4] The authors of this study did not find any difference in functional outcomes or complications between patients with and without prior PUL after HoLEP. Median time from PUL to HoLEP was 14.4 months and three (13.6%) of these patients had catheters preoperatively. Interestingly, one of the patients within this post-PUL HoLEP series required a second transurethral procedure to remove a calcified adenoma that would not morcellate, thus requiring a transurethral resection.

Another retrospective study examined "salvage" HoLEP procedures in patients who had undergone prior BPH surgery, of which 24 (11.1%) had a prior PUL.[23] "Salvage" HoLEP was associated with longer operative times and hospital stays, but there was no difference in functional outcomes in this heterogenous salvage cohort. The median time from PUL to HoLEP in this cohort was 15.9 months. Within these two large published post-PUL HoLEP series, 54.3% (25/46) prostates were >80 cc on pre-HoLEP imaging.[4,23] Rates of ejaculatory function were not reported prior to HoLEP in any of the post-PUL HoLEP studies.

In our local experience comparing 22 men who underwent HoLEP after PUL to 455 men undergoing HoLEP as a control, patients who underwent HoLEP after PUL had longer operative times, worse morcellation efficiency, and required an increased number of morcellator blades (1.3 vs. 1.0 blades/case).[7] We did not identify any difference in rate of same-day catheter removal, rate of same-day discharge, 90-day complication rates, or continence rates. Rates of ejaculatory function were not reported prior to HoLEP in any of the post-PUL HoLEP studies. Rates of ejaculatory function were not reported prior to HoLEP in any of the post-PUL HoLEP studies.

Thulium fiber laser enucleation

The use of thulium fiber laser enucleation (TFL) as an energy source for prostate enucleation in the surgical BPH retreatment after PUL is supported by limited evidence. We were able to identify a single case study examining an en-bloc technique used for TFL enucleation of a 198 cc gland[24] (Table 1). The authors of the study report that the PUL clips hampered morcellation efficiency and the surgeon required the use of three morcellator blades in total. The patient was discharged without a catheter on postoperative day 1, without complication and with an improvement in functional outcomes (IPSS and uro-flow).

Photo vaporization of the prostate

We were unable to identify any peer-reviewed evidence to support the use of photo vaporization of the prostate (PVP) in the post-PUL setting (Table 1) A review of the Boston Scientific website demonstrates anecdotal editorial statements from three urologists supporting the use of PVP in the failed PUL setting.[25] The urologists suggest that Greenlight "can remove Urolift (PUL) implants," "can…vaporize the majority of the obstructing tissue," and "remove the median lobe and the Urolift (PUL) implants and create a nice open channel for the patient to void through and have significant relief of their symptoms." The editorial provides step-by-step recommendations and trouble-shooting techniques for the urologist in the post-PUL setting.

Prostatic artery embolization

Support for prostatic artery embolization (PAE) use after failed PUL is based on limited evidence. We were able to identify a case report of one patient who underwent PAE after PUL[26] (Table 1). The time from PUL failure to PAE was one month and the patient's prostate size was 99 cc. The patient's symptomatic LUTS (IPSS=14) prompted PAE. The PAE procedure was technically unaffected by the patient's prior PUL procedure. The patient did not undergo preoperative cystourethroscopy. At 12 months postoperatively, prostate volume decreased to 53 cc and IPSS decreased by 10 points.

Surgical interventions for misfired/migrated clips or clip encrustation

Despite a 7.1% rate (10/140) of clip encrustation in the initial L.I.F.T. study, changes in technique and more distal clip placement have reportedly decreased the rates of implant encrustation to 1%.[2,10,27] In a 2022 study, the rate of post-market implant encrustation based on voluntary surgeon reporting was 43/779,844.[28] This reported rate of encrustation is much lower than the rates reported within post-PUL HoLEP retrospective studies (1.0–7.1%).[4,13,21,23] There are no studies comparing the efficiency or relative costs associated with different removal techniques for PUL clip encrustation.

DISCUSSION

It is likely that the proportion of MISTs, specifically PUL, will see continued growth. Based on our models, assuming a linear growth rate of 3.7%, evidenced from 2015–2019 in Medicare reimbursement data, and a surgical retreatment rate of 13.6% after five years, Medicare-reimbursed PUL cases performed from 2019–2024 will demand approximately 24 807 post-PUL retreatment BPH procedures (Figure 1).

Currently, there is a lack of guidance within national urologic guidelines for the evaluation of patients with persistent LUTS after failed PUL.[15-17] Consideration, based on expert opinion, should be made to add cystourethroscopy after PUL with persistent LUTS to the BPH surgical guidelines. Cystourethroscopy should be used to evaluate for misplaced or encrusted PUL clips and assess the prostatic urethra and bladder anatomy prior to repeat MISTs or surgical intervention. Cystourethroscopy may influence the surgeon's treatment selection and candidacy for repeat PUL clip insertions, removal of encrusted clips, or extirpative or ablative treatment options.

As emphasized within our review, the most efficient, efficacious, safe, and cost-effective BPH retreatment modality after failed-PUL has yet to be determined. The most used surgical treatments within the initial PUL studies were TURP and repeat PUL placement. Chin et al reports that "…each of these methods of retreatment was routine and unaffected by the presence of the implants."[29] Despite the use of TURP and repeat PUL placement, no group has reported perioperative outcomes, short or long-term postoperative outcomes, or examined the costs associated with post-PUL TURP or repeat PUL placement.

Among post-PUL retreatment modalities, HoLEP has the most robust clinical evidence supporting its use. Within our review, we identified 11 retrospective studies (including our local data, n=22) examining 89 total patients who underwent post-PUL BPH retreatment. Of these patients, 89.9% (80/89) examined HoLEP outcomes after PUL. HoLEP is the only post-PUL retreatment modality shown to have similar functional outcomes to HoLEP patients with no prior BPH surgery.[4,7,23] WVTT and robotic SP studies have examined functional outcomes compared to controls, however, post-PUL WVTT and SP patients made up a minority of the patients within the post-surgery/salvage cohorts (5/19, 26.3%, and 2/22, 9.1%, respectively).[19,20]

In our experience in evaluating patients after failed PUL, these patients are seeking a treatment option with more robust and durable long-term outcomes to avoid the annularity of BPH procedures and the costs and discomfort associated them. As HoLEP providers, we will continue to treat patients with HoLEP after PUL given evidence supporting its efficacy, safety, and hypothesized long-term durability.

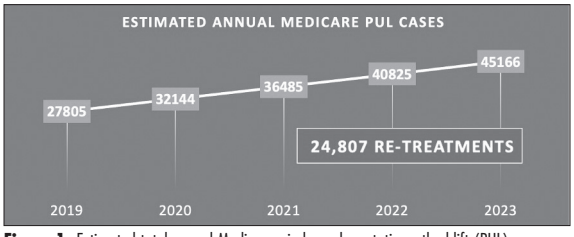

Figure 1. Estimated total annual Medicare-reimbursed prostatic urethral lift (PUL) cases and overall surgical benign prostatic hyperplasia (BPH) retreatment cases, 2019–2024 (assuming 3.7% growth in PUL Medicare cases annually).

CONCLUSIONS

Based on our review, the number of patients treated with PUL is increasing annually and thus, we find ourselves in a situation where many patients in North America will require retreatment for persistent or recurrent LUTS. HoLEP has the most robust clinical evidence supporting its use of any post-PUL retreatment modality. Some BPH modalities currently used for the treatment of BPH in the post-PUL setting have little to no clinical evidence supporting their use. We encourage urologists to continue to examine the outcomes of all BPH modalities after PUL to better understand the utility of these treatments in the post-PUL setting and subsequently better counsel our patients to offer cost-effective treatments in line with patient expectations.

COMPETING INTERESTS: Dr. Lee is a consultant for Boston Scientific. Dr. Krambeck is a consultant for Boston Scientific, Karl Storz, Wolf, and Virtuoso Surgical; and is the data safety monitoring board chair for Sonomotion. All other authors have no competing personal or financial interests to declare.

This paper has been peer-reviewed.

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