Recent advances in UroLift: A comprehensive overview

Andrew Denisenko[1], Bhaskar Somani[2], Vineet Agrawal[3]

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ABSTRACT

Objective: Recent years have seen a steep rise in minimally invasive surgical therapy (MIST) for benign prostate hyperplasia (BPH). Prostatic urethral lift (UroLift) is a mechanical intervention aimed at reducing lower urinary tract symptoms, which affect patients with BPH.

Material and methods: A narrative synthesis of all studies regarding UroLift is performed over the last decade, evaluating its impact on International Prostate Symptom Score (IPSS), quality of life (QoL), Q_{max}, Benign Prostate Hypertrophy Impact Index, and sexual health metrics.

Results: The studies included have demonstrated significant improvements in the objective parameters measured. UroLift has a low side-effect profile and is comparable to transurethral resection of the prostate in QoL changes and is superior with respect to recovery time and ejaculatory function.

Conclusion: Our findings suggest that UroLift may be an appropriate treatment for individuals undergoing treatment for BPH who are concerned with sexual and ejaculatory functions. More studies are needed to determine who is eligible for UroLift, as well as the long-term impact of UroLift on individuals with BPH.

Keywords: BPH; ejaculatory function; LUTS; minimally invasive surgical therapy; sexual health; UroLift.

[1]Geisinger Commonwealth School of Medicine, Pennsylvania, United States
[2]University Hospital Southampton NHS Trust, Southampton, United Kingdom
[3]The Guthrie Clinic, Pennsylvania, United States

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Corresponding Author: Andrew Denisenko
E-mail: adenisenko@som.geisinger.edu

Introduction

Benign prostatic hyperplasia (BPH) is a common condition in the aging male population, being prevalent in about 8% of men in their 40s and 50% of men between their 50s and 60s.[1] BPH is most often associated with lower urinary tract symptoms (LUTSs), including frequency, urgency, nocturia, urinary incontinence, and sexual dysfunction.[1,2]

The current gold standard surgical treatment for BPH is transurethral resection of the prostate (TURP). TURP has a morbidity rate of 11.1%, and complications of this procedure include transurethral resection (TUR) syndrome, retrograde ejaculation, and urinary stress incontinence.[3,4] In light of this, alternate therapeutic approaches have been investigated recently in an effort to reduce adverse events and sexual side effects.

As an emerging therapy for BPH, approved in 2013, prostatic urethral lift (UroLift) has been increasingly gaining popularity due to its minimally invasive nature and decreased side effect profile.[3] UroLift is a mechanical intervention that allows for a widening of the anterior prostatic urethra at by retracting the lateral lobes of the prostate with nitinol and stainless-steel implants. UroLift can be performed in the office under local anesthesia and facilitates a faster recovery time and minimal adverse effects with preservation of sexual function.[5] Within the scope of this review, we aim to discuss literature within the past decade in the field of UroLift with respect to the procedure, outcomes, comparison with TURP, and adverse effects.

Material and Methods

A scientific literature review was conducted, which utilized the databases Medline, Scopus,

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Embase, and Science Direct. Search terms included Boolean operator "OR" with queries "UroLift," "Prostatic Urethral lift," "Urethral Lift," "Benign Prostatic Hyperplasia," and "BPH." Filters such as clinical trial, meta-analysis, randomized controlled trial, review, and systematic review were applied. Special consideration was given to studies published within the past 5 years, studies that compare UroLift to TURP, and recent reports that describe unusual adverse events. The impact of COVID-19 pandemic on the field of urology and the UroLift procedure was assessed as well, given the potential for procedure delays.

Prostatic Urethral Lift Procedure

UroLift is undertaken by implanting permanent monofilament implants under transurethral endoscopy to displace the lateral prostatic lobes in order to reduce urethral obstruction. The implants can be adjusted based on the individual anatomy of the patient by adjusting the monofilament tension and width. The procedure can be done under minimal anesthesia and in the outpatient setting.[6]

UroLift has a very specific inclusion criteria, with careful patient selection being a requirement for sustained success of the procedure. Inclusion criteria are restricted to men >50 years old, prostate volume of 20-70 mL on ultrasound, IPSS >12, $Q_{max} < 15\ mL\ s^{-1}$, and postvoid residual volume of <350 mL.[7] Contraindications to the procedure in trials include men with prostate burden of >100 mL and history of urinary retention.[7]

Early Studies and Recent Successes

One of the initial UroLift studies was conducted by Woo et al[11] in 2011 in an investigation of the procedure in 64 Australian men, with an inclusion criterion score of IPSS score of >13.[8] This study demonstrated improvements in LUTS and IPSS, with no decrease in sexual or ejaculatory function. Documented adverse effects included dysuria, hematuria, and irritation, which resolved within 1 month.[8]

Main Points

- UroLift has a low side effect profile.
- UroLift is comparable to TURP in QoL changes.
- UroLift is superior to TURP in regard to recovery time and ejaculatory function.
- UroLift may be an appropriate treatment for individuals being treated for BPH who are concerned with sexual and ejaculatory functions.

The largest and longest term multicenter randomized blinded trial of UroLift that has yet been conducted was the L.I.F.T study. This study had 206 subjects with age >50 years, IPPS ≥13, peak flow rate ($Q_{max} \leq 12\ mL\ s^{-1}$), prostate length 30-80 mm, and prostate volume from 30 to 80 cc. The project evaluated parameters such as IPSS, quality of life (QoL), maximum urine flow rate (Q_{max}), and Benign Prostate Hypertrophy Impact Index (BPHII). This study demonstrated improvement in LUTS and urine flow and preserved sexual function.[6] This study had 1, 3, and 5 year follow-ups, which showed significant reduction in LUTS and a marked improvement in QoL, with no reported sexual dysfunction in study participants.[9,10] At 1 year, IPSS, Q_{max}, QoL, Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD), and MSHQ-Bother were all significantly improved. Follow-ups at 3 and 5 years mirrored these results, with showing sustained significant improvements in LUTS symptoms and QoL.[9,10] Over this 5-year period, 10 subjects had implants removed, which had been placed too proximally, with an additional three subjects undergoing prophylactic removal of implants.[10]

McNicholas et al[11] conducted a 2013 multicenter study of 102 men, which also demonstrated minimal adverse effects, with improvements in IPSS, QoL, BPHII, and Q_{max} at 1 year. This study also demonstrated an absence of sexual adverse effects, with symptom relief typically experienced by 2 weeks.[11]

A multicenter prospective crossover study by Cantwell et al[12] corroborated these previous findings in the 53 patients initially enrolled in the study.[12] By 1 year, there were improvements in IPSS, QoL, BPHII, and Q_{max} compared to baseline. Only 2% of patients required further intervention with TURP, and no patients recorded deficiencies in sexual function. At 12 months, there were no significant improvements in MSHQ-EjD or sexual health inventory for men (SHIM).

Shore et al[13] evaluated patient experience following UroLift in a multicenter study of 51 participants.[13] Subjects were ≥50 years old, with an IPSS score of ≥12, a peak flow rate of ≤12 mL, and a prostate volume between 30 and 80 cc. This study explored 1-month post-procedure QoL recovery, work productivity, activity impairment, symptom response, flow rate, and sexual function. Following 1 month, 86% of patients reported high quality of recovery (score of ≥80 on the Quality of Recovery Visual Analog Scale). Ninety percent of patients reported condition improvement with symptom response. One month follow-up showed significant improvements in IPSS, QoL, and Q_{max}. MSHQ-EjD function and EjD-Bother showed significant improvements, consistent with previous studies.[11]

The effect of UroLift on sexual function was further evaluated in a randomized control study of 64 patients published by McVary et al[14] which utilized the SHIM and MSHQ-EjD.[14] This study found no evidence of any erectile or ejaculatory function decrease. As observed in previous studies, there was an improvement in sexual function as observed by improved ejaculatory bother score and SHIM significantly improved from baseline at 1 year. IPSS and Q_{max} were also significantly improved.[14]

A crossover study was carried out by Rukstalis et al[15] to determine the 24-month effectiveness of the procedure in 53 patients.[15] These patients initially underwent a sham procedure and were followed for 3 months before being administered the UroLift system implants and followed for 24 months. Urinary symptom relief, QoL, urinary flow rate, sexual function, and adverse effects were evaluated. Following 24 months after crossover, the IPSS, QoL, BPHII, and maximum urinary flow rate had significantly improved from baseline. Eight percent of patients required TURP, and a patient was given additional UroLift implants during the follow-up time. This study did not find any reported erectile or ejaculatory dysfunction.[15]

A small 2017 study on a sample of 11 patients conducted by Bardoli et al[16] in a single hospital setting corroborated many of these previous results.[16] The patients had an age range of 56-90, with an average age of 71. Following the procedure, post-void residuals were 306.8 mL on average (120-499 mL, SD 120.6), and Q_{max} was 7 mL s^{-1} (4-14 SD, 2.8 mL s^{-1}). Following UroLift, post-void residual was significantly decreased. Q_{max} was not significantly improved. There were no reported sexual dysfunctions. This study measured average hospital stay (10.6 hours) and operating theater time (18.7 minutes), which were significantly reduced compared to other surgical treatments.[16]

A recent study by Sievert et al[17] evaluated UroLift in 84 patients who were initially candidates for TURP. The only exclusion criteria in this study were obstructing median lobe, and patients were accepted for UroLift regardless of prostate size, high post-void residual, or history of retention.[17] Patient follow-up occurred up to 24 months. At 12 and 24 month, mean IPSS, QoL, and Q_{max} significantly improved. As in previous studies, sexual function and ejaculation either remained at baseline or improved.[17]

UroLift vs TURP, the BPH6 Study

In 2015, a prospective, randomized, controlled trial involving 80 men was undertaken to compare UroLift against TURP, specifically in order to evaluate LUTS improvement, recovery, worsening of erectile and ejaculatory functions, continence, and safety (BPH6).[18] The 1-year results of this study showed that preservation of ejaculation and the quality of recovery were significantly improved compared to TURP ($P < .01$), while symptom relief was significantly improved with both TURP and UroLift. Taken together, UroLift was superior to TURP with respect to the BPH6 criteria of the study.

Two-year results of the BPH6 studies showed that improvements in IPSS, QoL, BPHII, and maximum urinary flow rate were recorded in both treatments.[19] IPSS and Q_{max} were superior in the TURP group, while improvements in IPSS QoL and BPHII were not statistically different between either treatment. Erectile function was not significantly different. As shown in the 1-year study, UroLift was associated with superior quality of recovery ($P = .008$), ejaculatory function preservation ($P < .001$), and performance on composite BPH6. The study also found that UroLift resulted in improved quality of sleep at 24 months ($P = .05$).[19]

UroLift in Patients with Obstructing Median Lobe

At the time of the initial L.I.F.T study, obstructing median lobes (OMLs) of the prostate were a contraindication to the procedure, which was done only on patients with obstructing lateral lobes (LL). However, a 2018 study by Rukstalis et al[20] demonstrated that the procedure could be performed despite this condition.[20] This approach was accomplished by a modified technique, which involved pulling the intravesically protruding prostatic tissue into the prostatic fossa by fixing the tissue to either side of the urethra. Inclusion criteria for a nonrandomized cohort of 45 men were identical to the L.I.F.T study, without the requirement for OML: $\geq$50 years of age, IPSS $\geq$ 13, and $Q_{max} \leq 12$ mL s^{-1}. The study used a primary endpoint analysis to measure IPSS improvements over baseline and rate of post-procedure complications. The outcomes of this study were compared against the original L.I.F.T results and combined.

Measurements at 1, 3, 6, and 12 months showed significant improvements in combined mean IPSS by 30.5% ($P < .00001$). At 3, 6, and 12 months, combined QoL and BPHII improved by 53.4% and 60.8%, respectively ($P < .00001$). Combined Q_{max} improvement was 71.7% ($P < .00001$). The symptoms of patients with obstructive median lobe improved by at least the same amount at every measurement interval (OML 13.5-15.9, LL 0.0-11.1 points, $P \leq .0$). This study demonstrated that patients with OML can gain a similar benefit to patients with LL obstruction.[20]

These data have been acknowledged by recent European Association of Urology (EAU) guidelines. However, because of the

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scarcity of studies that explore the impact of UroLift on patients with OML, the EAU recommends more investigation into the procedure on patients with OML before it can be broadly recommended.[21]

UroLift Adverse Events and Limitations

Early studies have shown that adverse effects associated with UroLift are typically mild and transient. This is complemented by a favorable sexual side effect profile. Serious adverse effects in the literature are sparse. In the initial L.I.F.T study, two such adverse events were noted: clot retention with reintroduction of warfarin and bladder stone formation at 12 months that was not linked to the implants.[6] This same study has 127 follow-up cystoscopy recordings available, which demonstrated no strictures or encrustation of the implanted materials.

Shore et al[13] recorded mild to moderate Clavien-Dindo Grade 1 events reported, which had resolved by 1 month. Transient hematuria, dysuria, incontinence, and pelvic pain were recorded.[13] Cantwell et al[12] recorded dysuria, hematuria, and pelvic pain that occurred in patients who underwent UroLift, and these events were also observed in patients who underwent a sham procedure.[12]

While rare, other serious adverse events have been documented in case studies. In 2019, Pollock et al[22] described the development of pelvic hematoma 4 days following UroLift, the first such event to have been described.[22] In this case, the hematoma was self-limiting and required no further intervention. A similar event featuring bilateral pelvic hematoma that needed to be operatively managed was reported.[23] In another 2020 case report, a patient developed a pelvic hematoma resulting in renal failure, which required temporary dialysis and resulted in a progression of Chronic Kidney Disease (CKD) from stage III to IV. This case highlighted the need for UroLift studies in patients with CKD.[24] A July 2020 study described another previously unreported complication, in which a patient who presented with postoperative groin pain was found to have ureteric obstruction, hydronephrosis, and calyceal rupture as a result of an erroneously placed clip cross the vesico-ureteric junction.[25] Another noteworthy concern regarding UroLift is a relatively high retreatment rate. The L.I.F.T trial reported that 13.6% of participants required repeated Prostatic Urethral Lift (PUL) or TURP, removal of encrusted clips, or continued medical therapy.[9] Similarly, 13.6% of participants in the BPH6 study required additional procedures by 2 years.[19]

With respect to the long-term adverse effects of UroLift, the 5-year follow-up of the initial LIFT study showed no significant adverse events.[10] Surgical retreatment due to failure to cure was 13.6%, and 4.3% of these events received additional UroLift implants. Implants that were inserted too proximally were susceptible to encrustation and could intrude into the bladder vesicle. There were no significant adverse events over the 5-year period, which related to sexual dysfunction.[10]

A noteworthy limitation of the UroLift procedure is its cost effectiveness when compared to similar types of minimally invasive surgery. An economic analysis conducted by Ulchaker et al[26] compared UroLift to Prostiva and Rezūm and concluded that while similar in effectiveness, UroLift costs twice as much as the alternative treatments.[26] This is an important consideration in the process of implementing value-based care and warrants careful consideration of the advantages of UroLift compared to other modalities in selecting treatment.

Impact of COVID-19

The COVID-19 pandemic has significantly disrupted the medical establishment and has had a pronounced impact on the ability to carry out elective procedures. In a study by Amparore et al[27] recommendations by international and European national urological associations/societies were examined considering the pandemic.[27] They found that in the outpatient setting, prostate biopsies and elective procedures for BPH were most likely to be impacted. In the inpatient setting, procedures for lower risk prostate/renal cancers, nonobstructive stones, and BPH were impacted. Certain risk-reducing strategies for minimally invasive procedures have been recommended, such as specific smoke evacuation systems, appropriate filtering of aerosolized particles, and use of lowest allowed intra-abdominal pressure during laparoscopic procedures.[27]

A study by Katz et al[28] that evaluated the triaging of office-based urology procedures placed UroLift into a category of procedures "targeting symptomatology of conditions," namely, LUTS.[28] Katz et al stated that such procedures can be safely delayed by at least 3-6 months based on individual factors, resources, and shared decision-making.[28] A similar strategy was recommended by López-Fando et al[29] which aimed at reorganizing management in female and functional urological activity. The recommendations in this study suggested delaying procedures such as UroLift until the end of the COVID-19 crisis, and when the procedure is necessary, to prioritize patients who use indwelling catheters.[29,30]

Discussion

There is a significant body of evidence that supports UroLift as a viable treatment for BPH due to a favorable outcome for

LUTS, preserved or improved sexual function, and quick recovery period. UroLift is a safe procedure with a mild adverse effect profile and exceedingly rare occurrence of severe or life-threatening adverse effects. L.I.F.T trial 3- and 5-year follow-ups have shown sustained improvements in IPSS, QoL, BPHII, and Q_{max}, as well as improved sexual health parameters.[9,10]

UroLift outcomes are comparable to TURP based on the BMP6 study and can be preferable based on what is most important to the patient, demonstrating the need for shared decision-making and an evaluation of each patient's priorities. The BMP6 study is the only study to our knowledge, which compares UroLift against a common BPH treatment approach. This highlights the need for more studies, which compare UroLift against TURP, as well as other therapies such as transurethral vaporization of the prostate or holmium laser enucleation of the prostate. There are also drawbacks to consider in the form of a higher rate of retreatment and relatively higher price, which will need to be discussed with prospective patients.

The contraindications to the procedure are also subject to re-evaluation based on new findings, as is demonstrated by studies that included patients with median lobe obstruction,[20] expanding the inclusion criteria to include a greater assortment of patients.[17] More studies are needed to determine whether patients with median lobe obstruction are good candidates for UroLift. Further investigation in this field may expand the inclusion criteria or identify individuals who are at high risk for complications from UroLift.

As a newer minimally invasive therapy, UroLift stands to benefit from continued study and long-term (>5 year) follow-up of patients. To the best of our knowledge, only two of the studies examined had 2 year or greater follow-up.[10,15] Additionally, it may be prudent to explore the application of UroLift in patients with chronic diseases such as CKD, prostate cancer, and other urologic conditions.

Conclusion

Our findings suggest that UroLift may be an appropriate treatment for individuals undergoing treatment for BPH who are concerned with sexual and ejaculatory functions. More studies are needed to determine who is eligible for UroLift, as well as the long-term impact of UroLift on individuals with BPH.

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