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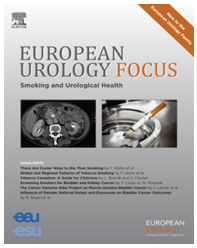

Review – Benign Prostatic Hyperplasia

Mini-Review: What Is New in Urolift?

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Abstract

Context: Lower urinary tract symptoms (LUTS) are one of the most common benign conditions affecting aging men. Among surgical procedures, minimally invasive treatment options have emerged with the main objective to be at least equally effective as current standard techniques, but with a more favourable safety profile.
Objective: To present the technical principle for prostatic urethral lift (PUL) and review clinical outcomes.
Evidence acquisition: Medline, PubMed, the Cochrane database, and Embase were screened for randomised controlled trials, clinical trials, and reviews on PUL.
Evidence synthesis: Data from the L.I.F.T study proved that PUL can provide rapid and durable relief of LUTS without compromising sexual function. The BPH6 trial compared PUL with transurethral resection of the prostate (TURP), and its outcomes indicated that improvement of LUTS was more pronounced after TURP, whereas PUL was superior in terms of quality of recovery, ejaculatory function, and quality of sleep.
Conclusions: PUL is an attractive option for selected patients who seek rapid and durable relief of LUTS with complete preservation of sexual function and fast recovery after intervention.
Patient summary: Prostatic urethral lift is an efficient and safe minimally invasive procedure that offers rapid and durable relief of lower urinary tract symptoms without compromising sexual function.

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1. Introduction

The renewed interest in minimally invasive treatment options for the management of male lower urinary tract symptoms (LUTS) due to benign prostatic enlargement (BPE) has led to a plethora of innovative techniques including intraprostatic injections, medical devices, new ablative procedures, and prostatic artery embolisation [1,2]. The common main objective is to be equally effective as standard techniques, but with a more favourable safety profile. Patients desire a procedure offering rapid and durable relief of LUTS with a fast and smooth return to normal activity. Ejaculatory function is compromised after current standard procedures, which is a great concern for sexually active men facing surgery. A true minimally invasive procedure is supposed to preserve sexual function including both erectile and ejaculatory function. Ideally, it can be performed in the ambulatory setting under local anaesthesia. Among the emerging minimally invasive treatment options, the prostatic urethral lift (PUL; Urolift,

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Neotract Inc., Pleasanton, CA, USA) has stood the test of critical clinical evaluation, which led to its approval by the US Food and Drug Administration and NICE within 4 yr after introduction. As part of international guideline recommendations, it is about to become the standard of care [3].

2. Evidence acquisition

Medline, PubMed, the Cochrane database, and Embase were screened for randomised controlled trials, clinical trials, and reviews on PUL.

3. Evidence synthesis

3.1. Technical principle

PUL relies on the creation of a continuous anterior channel through the prostatic urethra, extending from the bladder neck to the verumontanum (Fig. 1). Under cystoscopic visualisation, permanent tissue-retracting implants loaded on a dedicated delivery device are placed anterolaterally at the 2-o'clock and 10-o'clock positions. Preservation of the neurovascular bundles and the dorsal venous plexus is assured in this way. Patients ideally treated with PUL have a prostate volume between 20 and 70 cm^3 with typical lateral lobe obstruction ("kissing lobes"). The procedure can be performed in an ambulatory setting under local anaesthesia, and usually no catheterisation is necessary. Relative contraindications are a protruding middle lobe, a high bladder neck, and prostates larger than 100 cm^3. PUL was not primarily designed to address these anatomical features. With the expertise growing in the field, more advanced and refined techniques may be able to treat these particular configurations [4]. Of note, any surgical treatments are still possible without limitation after PUL [5]. A recent small series revealed that Urolift implants were useful not only for treatment of LUTS but also as markers for external beam radiation treatment for concomitant prostate cancer in the same patient [6].

3.2. Clinical evidence

The multicentre, prospective, randomised, controlled and blinded L.I.F.T study enrolled 206 patients who were randomised to PUL or sham to evaluate the safety and efficacy of the procedure [7]. The primary endpoint was met, with a 50% improvement in AUASI score from a baseline of 22.2 points to 11.1 points after PUL ($p < 0.0001$), which was 88% better than in the control group. The clinical impact on maximum flow rate (Q_{max}), quality of life, and secondary

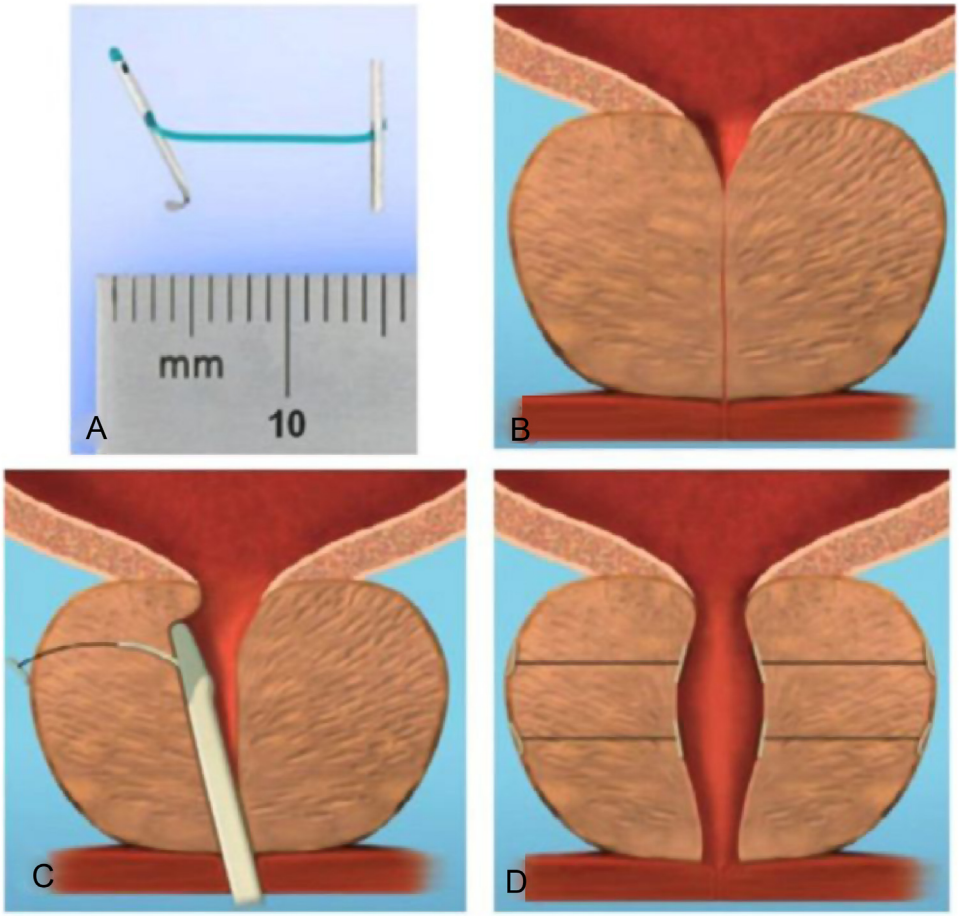

Fig. 1 – Prostatic urethral lift: Urolift. (A) Permanent tissue-retracting implant: capsular tab made of nitinol, polyethylene terephthalate monofilament, and stainless steel urethral end piece. (B) Bladder outlet obstruction due to encroaching lateral lobes. (C) Delivery of the Urolift implant. (D) Expansion of the prostatic urethra after treatment. Images courtesy of Neotract Inc.

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symptom scores such as the Benign Prostatic Hyperpalsia Impact Index (BPHII) was significantly better after PUL, and responses were maintained throughout 12 mo. The safety assessment was favourable, with only mild to moderate adverse events. Evaluation of sexual function revealed no case of erectile or ejaculatory impairment after PUL. Patients undergoing PUL returned to preoperative physical activity within 8.6 d. The long-term efficacy was confirmed by 5-yr results from the L.I.F.T study [8]. The significant improvements in LUTS, as determined using the International Prostate Symptom Score (IPSS) and quality-of-life assessment, were stable throughout the 5-yr follow-up, at 35% and 44% ($p < 0.0001$), respectively, in the intent-to-treat analysis. At 5 yr, Q_{max} was still increased by approximately 50% ($p < 0.0001$) and the positive change in BPHII was 47% ($p < 0.0001$). Over the 5-yr follow-up, no case of de novo sustained erectile or ejaculatory dysfunction was documented. The retreatment rate due to failure to cure was 13.6% after 5 yr.

The prospective, multinational and nonblinded BPH6 trial enrolling 80 LUTS patients was conducted to establish the noninferiority of PUL to the reference method, transurethral resection of the prostate (TURP) [9]. A novel assessment tool termed BPH6 was introduced, which captures the following six domains: symptom relief, recovery experience, sexual function, urinary continence, and safety. Meaningful relief of LUTS was achieved after both procedures, but clinical outcomes revealed a significantly stronger impact on IPSS, Q_{max}, and postvoid residual volume after TURP, whereas PUL was superior in terms of quality of recovery and preservation of ejaculatory function. PUL patients returned to preoperative activity after 11 d, compared to 17 d after TURP. Ejaculatory assessment determined using the Male Sexual Health Questionnaire-Ejaculation Disorder score revealed 100% for PUL, while significant impairment (60.6%) was detected for TURP ($p < 0.0001$). No differences were detected for incontinence, erectile function, and safety. Catheterisation longer than 24 h after procedure was found in 74% of patients after TURP, compared to 45% after PUL ($p = 0.01$). In the final analysis of the proportion of patients who met the BPH6 primary endpoint, PUL (34.9%) was favoured over TURP (8.6%; noninferiority $p = 0.0002$; superiority $p = 0.006$). These clinical outcomes were confirmed by the 2-yr results (Table 1) [10]. After 2 yr, the retreatment rate due to failure to cure was 13.6% in the PUL arm (6 patients) and 5.7% after

Table 1 – Clinical outcomes after PUL and TURP from the BPH6 study [10] (adapted with permission).

	2 wk		1 mo		3 mo		6 mo		12 mo		24 mo	
	PUL	TURP	PUL	TURP	PUL	TURP	PUL	TURP	PUL	TURP	PUL	TURP
IPSS												
Change	−7.3	−6.8	−11.6	−10.0	−11.7	−11.8	−13.0	−14.6	−10.9	−15.4	−9.2	−15.3
p value	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Comparison *p* value	0.827		0.417		0.978		0.421		0.013		0.004	
IPSS HRQoL												
Change	−1.7	−1.0	−2.5	−1.8	−2.6	−2.4	−2.8	−2.9	−2.8	−3.1	−2.5	−3.3
p value	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Comparison *p* value	0.143		0.138		0.55		0.791		0.436		0.066	
BPHII												
Change	−1.0	−0.2	−3.4	−2.0	−4.8	−3.4	−5.2	−5.0	−5.0	−5.2	−4.1	−5.4
p value	0.131	0.775	<0.001	0.003	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Comparison *p* value	0.39		0.138		0.101		0.795		0.836		0.131	
Q_{max}												
Change					4.2	12.7	3.9	9.6	4.0	13.7	5.0	15.8
p value					<0.001	0.003	<0.001	0.002	<0.001	0.003	<0.001	0.002
Comparison *p* value					<0.001		0.003		<0.001		0.002	
PVR												
Change					−10.3	−51.0	−4.8	−54.2	7.4	−70.0	−10.6	−42.5
p value					0.258	<0.001	0.67	0.001	0.684	<0.001	0.277	0.015
Comparison *p* value					0.014		0.009		0.002		0.091	
SHIM												
Change			0.6	−0.4	−0.7	−1.0	−0.5	−0.8	−0.1	−0.9	−0.2	−1.8
p value			0.132	0.751	0.386	0.328	0.484	0.367	0.940	0.29	0.832	0.067
Comparison *p* value			0.318		0.861		0.833		0.486		0.201	
MSHQ-EjD: function												
Change			1.7	−0.9	0.7	−3.0	1.1	−3.2	1.3	−3.7	0.3	−4.0
p value			0.023	0.435	0.251	<0.001	0.009	<0.001	0.03	<0.001	0.666	<0.001
Comparison *p* value			0.049		<0.001		<0.001		<0.001		<0.001	
MSHQ-EjD: bother												
Change			−0.8	−0.2	−0.7	0.2	−0.1	−0.1	−0.5	0.0	−0.1	−0.3
p value			0.015	0.682	0.062	0.470	0.861	0.825	0.214	0.896	0.734	0.415
Comparison *p* value			0.32		0.069		0.979		0.359		0.771	

BPHII = Benign Prostatic Hyperplasia Impact Index; HRQoL = health-related quality of life; IPSS = International Prostate Symptom Score; MHSQ-EjD = Male Sexual Health Questionnaire for Ejaculatory Dysfunction; PUL = prostatic urethral lift; PVR = postvoid residual urine volume; Q_{max} = maximum urinary flow rate; SHIM = Sexual Health Inventory for Men; TURP = transurethral resection of the prostate.

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TURP (2 patients). The quality of sleep as assessed by the Jenkins Sleep Questionnaire revealed positive responses in both arms, but a statistically significant stronger impact was confirmed for PUL. This was associated with a better outcome for health-related quality of life (odds ratio 1.12; $p < 0.001$).

4. Conclusions

In the attempt to provide tailored treatments adapted to the individual clinical profile and the demands of each patient, the emergence of minimally invasive treatment options represents enrichment of the current armamentarium for the management of male LUTS due to BPE. Urologists need to know the pros and cons for the novel technologies for proper decision-making. Urolift offers rapid and durable relief of LUTS with complete preservation of sexual function. In selected patients particularly interested in sexual activity and rapid recovery, it may be an attractive option.

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Study concept and design: Magistro, Stief, Woo.
Acquisition of data: Magistro, Woo.
Analysis and interpretation of data: Magistro, Woo.
Drafting of the manuscript: Magistro, Woo.
Critical revision of the manuscript for important intellectual content: Magistro, Stief, Woo.
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References

[1] Magistro G, Chapple CR, Elhilali M, et al. Emerging minimally invasive treatment options for male lower urinary tract symptoms. Eur Urol 2017;72:986–97.
[2] Magistro G, Stief CG, Gratzke C. New intraprostatic injectables and prostatic urethral lift for male LUTS. Nat Rev Urol 2015;12:461–71.
[3] Gravas S, Bachmann A, Descazeaud A, et al. EAU guidelines on the management of non-neurogenic male lower urinary tract symptoms (LUTS), incl. benign prostatic obstruction (BPO). European Association of Urology; 2017. https://uroweb.org/wp-content/uploads/Non-Neurogenic-Male-LUTS_2705.pdf
[4] Walsh LP. State of the art: advanced techniques for prostatic urethral lift for the relief of prostate obstruction under local anesthesia. Can J Urol 2017;24:8859–64.
[5] McAdams S, Funk JT, Navetta AF, El Tayeb MM, Humphreys MR. Holmium laser enucleation of the prostate after prostatic urethral lift surgery: feasibility and technical considerations from a multi-institutional case series. J Endourol 2017;31:774–9.
[6] Keehn A, Fram E, Garg M, Maria P. UroLift in place of fiducial markers for patients with benign prostatic hyperplasia undergoing external beam radiation therapy. Urology 2017;104:230–4.
[7] Roehrborn CG, Gange SN, Shore ND, et al. The prostatic urethral lift for the treatment of lower urinary tract symptoms associated with prostate enlargement due to benign prostatic hyperplasia: the L.I.F.T. study. J Urol 2013;190:2161–7.
[8] Roehrborn CG, Barkin J, Gange SN, et al. Five year results of the prospective randomized controlled prostatic urethral L.I.F.T. study. Can J Urol 2017;24:8802–13.
[9] Sonksen J, Barber NJ, Speakman MJ, et al. Prospective, randomized, multinational study of prostatic urethral lift versus transurethral resection of the prostate: 12-month results from the BPH6 study. Eur Urol 2015;68:643–52.
[10] Gratzke C, Barber N, Speakman MJ, et al. Prostatic urethral lift vs transurethral resection of the prostate: 2-year results of the BPH6 prospective, multicentre, randomized study. BJU Int 2017;119:767–75.