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ORIGINAL ARTICLE

The UroLift® System for lower urinary tract obstruction: patient selection for optimum clinical outcome

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ABSTRACT

Introduction: The minimally invasive UroLift® System procedure in moderate-to-severe benign prostate hyperplasia (BPH) refractory to medical treatment may be superior over other prostate procedures regarding its preserved sexual function post-operatively. We aimed to optimise patient selection criteria for the UroLift® System.

Material and methods: Fifty-one men that underwent UroLift® System surgery were retrospectively reviewed over >24 months. We evaluated the efficacy and safety of UroLift® System, pre-operatively and at three, six, 12, and 24 months post-operatively, assessing the International Prostate Symptom Score (IPPS), urinary flow rates (Qmax), post void residual (PVR) bladder scan volumes and the International Index of Erectile Function (IIEF). Adverse events were assessed by Clavien-Dindo Classification.

Results: The 51 men undergoing UroLift® System had a success rate of 92.2% over 2 years, with improvements in Qmax, IPSS and PVR. IIEF was preserved in all cases. Adverse events were Clavien-Dindo grade 1, most commonly mild-to-severe dysuria (19.6%), and resolved spontaneously. Four patients failed to improve.

Conclusion: Patient-related selection criteria to optimise the UroLift® System clinical outcomes include age, Qmax, PVR urine, median lobe, PSA levels, prostate volume, IPSS and IIEF scores. The UroLift® System is safe and effective in moderate-to-severe BPH refractory to pharmacological treatments and avoids retrograde ejaculation.

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BPH; UroLift; LUTS; IPSS

Introduction

Benign prostatic hyperplasia (BPH) is a common, age-related condition affecting as many as 40% to 80% of men in their fifties to seventies [1]. An individual's quality of life (QoL) can be negatively impacted by the presence of chronic lower urinary tract symptoms (LUTS) as a result of BPH, often causing disturbance in sleep and sexual function, with reduced concentration and clinical depression [2].

Pharmacological agents, such as alpha-blockers and 5 alpha-reductase inhibitors, provide limited symptomatic relief in moderate-to-severe urinary obstruction. Of those who are medically managed, 30–50% will discontinue treatment after the first year due to insufficient relief of their symptoms or significant side effects [3,4], predominately associated with erectile dysfunction (3–10%), ejaculatory dysfunction (1–10%), dizziness (2–21%), headaches (5–12%) and chronic fatigue [5]. Symptomatic untreated BPH may lead to irreversible detrusor damage, potentially reducing the efficacy of subsequent surgery [6]. It is therefore important to treat symptomatic BPH early to minimise the progression of bothersome LUTS and reduce treatment-associated complications.

Surgery is reserved for patients with moderate-to-severe obstruction refractory to medical treatments or for those who have developed complications associated with LUTS and bladder outflow obstruction (BOO), such as renal insufficiency, recurrent infections or urinary retention. The commonest surgical intervention, the transurethral resection of the prostate (TURP), has been demonstrated to be highly effective in relieving LUTS, with an International Prostate Symptom Score (IPSS) improvement of 14.9 [5]. However, long-term complications include retrograde ejaculation (53–75%), erectile dysfunction (3.2–34%), urethral stricture (2–9%), stress urinary incontinence (3%) and transurethral resection

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syndrome (1.4–3%) [7–10]. Other surgical treatments, including transurethral microwave therapy (TUMT) and transurethral needle ablation (TUNA), are also associated with urinary incontinence (<3%), erectile dysfunction (3.1–7.5%) and retrograde ejaculation (0–22%) [5,9]. The tissue injury from surgery leads to worsening of LUTS within four to sis weeks after the procedure, acute urinary retention, and unplanned post-operative catheterisation [5,7,8].

The UroLift® System (NeoTract Inc., Pleasanton, CA, USA) was developed to provide a more minimally invasive outpatient solution to men refractory to medical treatment who did not wish to undergo higher risk associated surgery. It was approved by the US Food and Drug Administration (FDA) in 2013 and the UK National Institute for Clinical and Health Excellence (NICE) in 2015. The consensus was that the technique led to rapid recovery with early symptom relief. As there have been no reports of de-novo sexual or ejaculatory dysfunction associated with the UroLift® System procedure [11], it may be ideal for younger, sexually active men who request management of bothersome LUTS.

Thus, our study aimed to assess the overall efficacy and safety of the UroLift® System in a group of patients following failed medical treatment of BPH, with the main focus being on patient selection criteria for optimal efficacy of the UroLift® System.

Material and methods

Study design

A cohort of 51 men aged > 40 years with moderate-to-severe symptomatic BPH refractory to conservative and medical therapies were carefully selected for the UroLift® System. All men were assessed between 2016 and 2018. Men selected for the UroLift® System (Table 1) included men with symptomatic BPH, IPSS ≥15, a peak urinary flow rate (Qmax) of ≤15 ml/s with a voided volume of ≥150 ml and a 30–70 cc prostatic volume measured by trans-rectal ultrasound (TRUS).

Men not selected for the UroLift® System included those with symptomatic BPH suffering with either a serum prostate specific antigen (PSA) level > 6 ng/ml, or acute urinary retention (AUR), or an estimated prostatic volume > 70 cc or a history of previous prostate surgery. Men with a significant obstructive median lobe of the prostate >1cm protruding into the bladder base as identified by abdominal ultrasound were also ineligible. For this reason, there was no indication for a pre-operative flexible cystoscopy on any of our patients.

Table 1. Patient selection criteria.

Inclusion criteria
Males ≥40 years of age
IPSS of ≥15
Peak urinary flow rate (Q_{max}) of ≤15 ml/s for a voided volume of ≥150 ml
Prostate gland size within 30–70 cc estimated volume by TRUS
Exclusion criteria
Post-void residual (RV) of >500 mL
Protruding median lobe of the prostate on abdominal ultrasound >1cm
Acute urinary retention (AUR)
Prostate specific antigen (PSA) measure of >6 ng/mL
Previous prostate surgery (TURP or Laser)

We evaluated the efficacy and safety outcomes of the UroLift® System, pre-operatively and at three, six, 12, and 24 months post-operatively assessing the International Prostate Symptom Score (IPPS), urinary flow rates (Qmax), post void residual (PVR) bladder scan volumes and the International Index of Erectile Function (IIEF). Post-operative complications were assessed by the Clavien-Dindo Classification. For those who failed to improve after the UroLift® System, subsequent treatment modalities were recorded.

The UroLift® System procedure

The procedure aims to deploy small permanent implants transurethrally in order to create a continuous anterolateral channel between the bladder neck and the verumontanum, so as to pull the two lateral lobes of the prostate towards the outer fibrous capsule. The implant is constructed of a nitinol capsular tab at one end and a urethral stainless-steel end-piece at the other end, connected by a non-absorbable polyethylene terephthalate (PET) monofilament suture.

As previously described, patients are placed in the lithotomy position and a cystoscope is introduced with a 0° lens to visualise the anatomical configuration of the prostate lobes and to assess for any bladder neck hypertrophy (Figure 1(a)). Using a 19 F or 20 F cystoscope sheath, the implant delivery device (UroLift System®, NeoTract, Pleasanton, CA) with a 2.9 mm telescope lens is advanced and angled laterally (20–30°) between the 3 and 9 o'clock position (Figure 2(a)) [12]. Once the anterior third of the obstructing lateral lobe has been compressed, a spring-actuated 19-gauge needle is released and traverses the compressed prostate gland from the urethra to the outer capsule. The first implant deployed should be placed at least 1.5 cm distal to the bladder neck and 1 cm proximal to the verumontanum. As the needle is

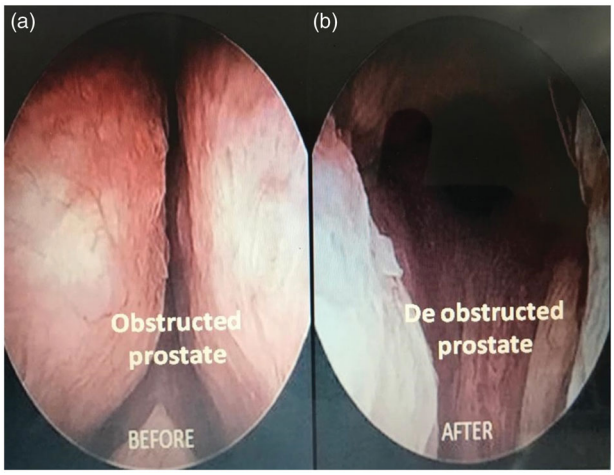

Figure 1. (a) Endoscopic view of the prostate lobes obstructing the urethral lumen. (b) Post-UroLift endoscopic view showing an unobstructed prostatic urethra.

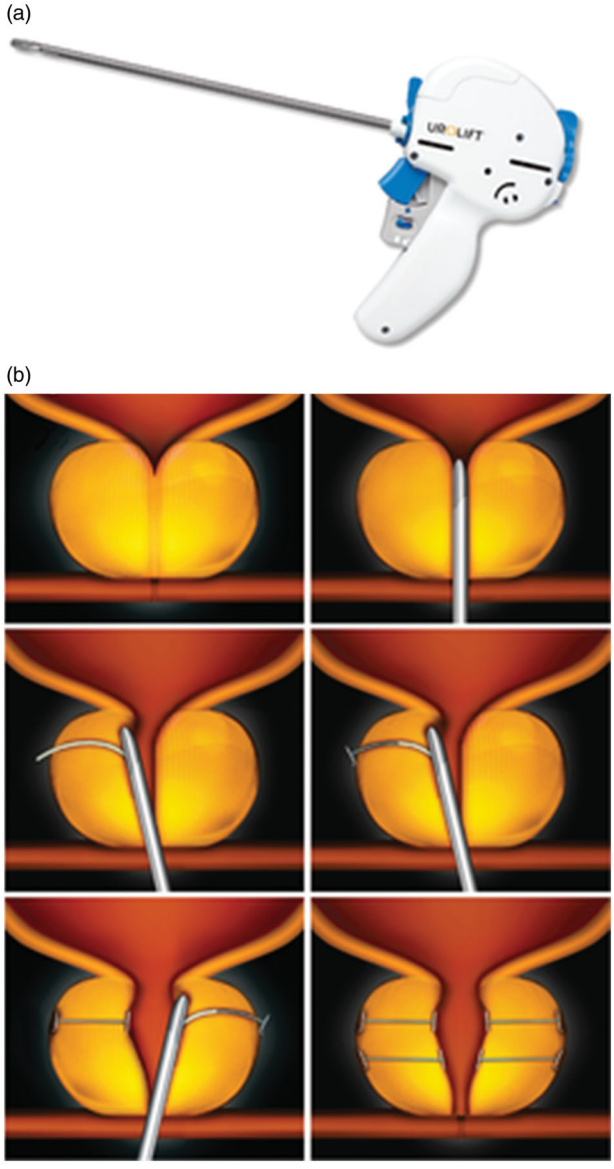

Figure 2. (a) The UroLift® System delivery device. (b) Stepwise method of the UroLift® System.

retracted, the implant's capsular tab engages the prostatic capsule and tensions the suture [13]. The PET monofilament is cut to the customised width of the compressed lobe, and the urethral end-piece is secured to promote epithelialisation of the implant. After each implant is deployed, a cystoscope is used to confirm its correct placement with a good unobstruction effect (Figure 1(b)). The end result after deployment ensures that the two lateral lobes are retracted more laterally with a wider prostatic urethral lumen (Figure 2(b)). Multiple implants can be delivered to secure the prostatic urethra in place, with the number of implants needed depending on the size and anatomical configuration of the prostate gland. For example, a large prostate may require four implants, two on each lobe. Therefore, each implant's length and site are tailored to the individual's prostate anatomy.

There is no need for a routine post-operative catheter, which is generally indicated if there had been significant bleeding during surgery or the patient failed to void spontaneously in the immediate post-operative period, which might have been related to prostatic swelling induced by the procedure. Furthermore, if the implants had been inappropriately placed, they could be extracted using endoscopic graspers or biopsy forceps by removing the urethral end piece; the capsular tab could remain behind without causing future complications. If the patient's obstructive symptoms did not improve following the UroLift® System treatment, the implants would not prohibit other subsequent surgical interventions, including transurethral resection of the prostate (TURP) or laser treatments.

Ethics

We undertook a retrospective, anonymized audit of our work to assess clinical effectiveness of an internationally approved treatment. Therefore ethical approval was not required.

Results

A total of 51 patients were reviewed with an average age of 66 years (44–82), significant LUTS with IPSS of 25 (18–32), poor urinary maximum flow rate (Qmax) of 9.7 ml/s (4–14 ml/s) and high post void residual (PVR) volumes of 203 mls (44–488 mls). The average operative time was 14.5 min (8–30 min). The average number of implants used for each patient was 2.7 (2–4).

Table 2. Post-operative complications.

Event Clavien-Dindo Grade 1	UroLift® System group, *n* (%)
Dysuria	10 (19.6%)
Haematuria	5 (9.8%)
Pelvic pain	2 (3.9%)
Urge incontinence	1 (2.0%)
Urinary tract infection	2 (3.9%)
Acute urinary retention	1 (2.0%)

In 47 of 51 patients, the Qmax increased by 6.6 ml/s (68%), IPSS decreased by 12 (48%), and the PVR volume reduced by 139.7 ml (67.8%), showing an overall success rate of the UroLift® System procedure of 92.2% at the end of 24-months follow up. These patients' symptoms improved significantly from baseline and these outcomes were maintained over the 2-year follow-up period. Sexual function, in particular antegrade ejaculation and orgasmic sensation, were preserved in all cases.

The post-operative adverse effects associated with the UroLift® System were all Clavien-Dindo grade 1 and typically transient, resolving within three weeks of the procedure (Table 2). The more common adverse events in this series were mild-to-severe dysuria with complete resolution within three to four weeks (19.6%) and transient visible haematuria (9.8%). One patient reported left-sided pelvic pain, which subsequently improved within three months. Additionally, one patient with a prostatic volume of 70 cc who received four implants failed to void after the UroLift® System procedure but had a successful trial without catheter two weeks later.

Only 4 (7.8%) patients' symptoms failed to improve over the 2-year follow-up period with the UroLift® System alone. At the three-month follow-up appointments, these patients with poor symptom resolution were first identified and multi-channel urodynamic studies were arranged. Two of these patients had high voiding pressures (>70 cm H_2O) with poor flow and underwent uncomplicated TURP. For the other two patients with low voiding pressures (<35 cm H_2O) with high residual volumes (300–500 ml), they were advised to practise clean intermittent self-catheterisation (CISC).

Discussion

In the present study, patient-related selection criteria to optimise the UroLift® System clinical outcomes included age, flow rate (Qmax), post void residual (PVR) urine, median lobe, PSA levels, prostate volume, IPSS and IIEF scores. In our study, the overall success rate of the 51 men undergoing the UroLift® System was 92.2% over the 2-year follow-up, with improvements in Qmax, IPSS and PVR. IIEF was preserved in all cases. Adverse events were Clavien-Dindo grade 1, most commonly mild-to-severe dysuria (19.6%) and transient visible haematuria (9.8%), spontaneously resolving within the period of early follow-up. Only four of 51 patients failed to improve after the UroLift® System, requiring alternative treatments.

Optimising the safety and efficacy of minimally invasive procedures for men refractory to medical treatment whilst ensuring rapid recovery and early symptomatic relief is essential, as seen with the use of transurethral enucleation of the prostate (TUEP) combined with laparoscopic bladder diverticulectomy in patients with bladder diverticula combined with BPH [14]. Although we retrospectively assessed our cohort of patients, various studies have reported similar success outcomes to the present study [15–18]. In these studies, outcomes remained stable over 2- to 5-year follow-up periods. The UroLift® System has shown to deliver similar durable responses from the procedure, with average improvements for total IPSS (41.1%), quality of life (48.8%), Qmax (53.1%) and individual IPSS symptoms after 3 years [15]. The same cohort of patients demonstrated sustained improvements in IPPS (36%), quality of life (50%), BPHII (52%), and Qmax (44%) after 5 years [19].

Antegrade ejaculation is maintained as the bladder neck anatomical configuration remains uninterrupted [20]. Currently, there have been no reports of de-novo sustained ejaculatory or erectile dysfunction following the UroLift® System procedure, in keeping with our data [11]. In fact, this study reported an improvement of 14% in the Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD) function scores by 12 months, as well as improvements in the ability to ejaculate (4%), intensity of ejaculation (23%) and amount of ejaculate (22%) in their cohort [11]. The UroLift® System's tissue-sparing nature makes this procedure superior in preserving sexual function, when compared to the rates of retrograde ejaculation (53–75%) and erectile dysfunction (3.2–34%) seen in TURP, as well as erectile dysfunction (3–10%) and ejaculatory dysfunction (1–10%) seen with pharmacological agents [5,7–10].

The UroLift® System procedure can be performed under local, spinal or general anaesthesia, with the addition of further sedation if required, which is particularly advantageous for high-risk patients with multiple co-morbidities. The choice of anaesthesia does not change the overall outcome of the procedure,

with no anaesthetic complications recorded in our series.

In our study, only four out of 51 patients (7.8%) required re-treatment for failure to cure obstructive symptoms with CISC and TURP respectively, with clinical improvement at follow-up. Urodynamics were performed before these re-treatments. The L.I.F.T. study trial data showed re-treatment rates of 5% at 1 year, 10.7% at 3 years, and 13.6% at 5 years for the original 140 participants randomised to the procedure [16,17,19], with another study reporting a failure rate of 6.5% after 1 year [12]. This contrasts with other prostate surgeries, such as TURP, TUMT and TUNA, which have reported 3–14.5%, 9–21% and 14–51% re-treatment rates at 5 years respectively [21–25]. The UroLift® System offers successful clinical outcomes, with low failure rates in relation to other prostate procedures; however overall, it is our opinion that urodynamics would be helpful in risk stratifying those patients who may fail the UroLift® System.

In our series, few post-operative complications were reported: dysuria (19.6%), haematuria (9.8%), pelvic pain (3.9%), urinary tract infection (3.9%), urge incontinence (2.0%) and acute urinary retention (2.0%). McNicholas et al. published that the most common adverse events were transient dysuria (25%), haematuria (16%), and urgency (10%) in a study of 102 patients treated using the UroLift® System [12]. Similar symptoms of transient haematuria (80%) with a median duration of four days, dysuria (74%), incontinence (25%) and pelvic pain (20%) were also recorded in a multi-centre study of patients treated with the UroLift® System [26]. Similar to our study, these Clavien-Dindo grade 1 adverse events resolved spontaneously within one month and no serious adverse events were recorded. This demonstrates the favourable safety profile of the UroLift® System device. However, there have been some reports of serious adverse events associated with the UroLift® System: clot retention associated with re-initiation of warfarin and bladder stone removal at 12 months not associated with the implant [15].

Conclusion

The UroLift® System is a safe and effective treatment modality for patients with moderate-to-severe BPH-associated LUTS refractory to conservative and pharmacological treatment. In our series, the UroLift® System had an overall success rate of 92.2% at the end of the 24-month follow-up in a carefully selected cohort of patients. Our study demonstrated significant improvements in urinary flow rates, IPSS scores and residual volumes, with the complete preservation of sexual function. Post-operative complications were mild and spontaneously resolved within three weeks. Careful patient selection for the UroLift® System is essential to optimise clinical outcomes, considering factors such as age, urinary flow rate, post-residual volume, median lobe anatomy, PSA levels, prostate volume, IPSS and IEF scores. Further validation of our outcomes using a large cohort and multi-centre approach is required and the role of urodynamic assessment of patients earlier in the selection period to identify those unsuitable for the procedure is needed. However, the UroLift® System is ideal for younger, sexually active men, unresponsive to conservative and medical treatments, who request management of bothersome LUTS.

Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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Data availability statement

Due to the nature of this research, participants of this study did not agree for their data to be shared publicly, so supporting data is not available.

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