UroLift: a new minimally-invasive treatment for benign prostatic hyperplasia

Patrick Jones, Bhavan P. Rai, Omar Aboumarzouk and Bhaskar K. Somani

Ther Adv Urol
2016, Vol. 8(6) 372–376
DOI: 10.1177/1756287216671497

Abstract: 'UroLift' has emerged as a new minimally-invasive nonablative surgical technique for benign prostatic hyperplasia (BPH). We discuss the procedure, cost, evidence, advantages and disadvantages of this procedure. It is a novel technology suitable for a selected group of patients that allows for a bespoke treatment for men with BPH.

Keywords: BPH, prostate, PUL, UroLift

Correspondence to:
Bhaskar K. Somani, MRCS, FEBU, FRCS (Urol)
Department of Urology, University Hospital Southampton NHS Trust, Tremona Road, Southampton SO16 6YD, UK
bhaskarsomani@yahoo.com

Bhavan Prasad Rai, MRCS, FRCS (Urol)
James Cook University Hospital, South Tees Hospital NHS Foundation Trust, UK

Omar Aboumarzouk, MRCS, FRCS (Urol)
Department of Urology, Bristol Urological Institute, Bristol, UK

Patrick Jones, MRCS
Department of Urology, Blackpool Victoria Hospital, Blackpool, UK

Introduction

The prevalence of benign prostatic hyperplasia (BPH) in men and its association with age are well established in the urological literature [Loeb *et al.* 2009]. The symptomatic sequelae of this disease can lead to significant symptoms and treatment challenges, which are encountered by urology and primary care professionals alike. Surgery remains the therapeutic cornerstone when pharmacological options are exhausted. In an era fuelled by advancements in minimally-invasive technologies, the 'UroLift' device (NeoTract Inc., Pleasanton, CA, USA), formally known as the prostatic urethral lift (PUL), is the latest addition to the surgical toolkit available to urologists treating men with bothersome lower urinary tract symptoms (LUTS) secondary to BPH [Jones *et al.* 2016a]. This nonablative minimally-invasive option is postulated to deliver sustainable improvements in functional outcomes while maintaining a strong safety profile and causing minimal *de novo* sexual dysfunction [Garcia *et al.* 2015]. Key objectives for any new surgical intervention are to demonstrate clinical efficacy, safety, long-term durability and economic feasibility. Since the first original study on UroLift in 2011 with a case series of 19 patients, it has gone on to gain regulatory approval by the United States (US) Food and Drug Administration (FDA) in 2013 and the United Kingdom (UK) National Institute of Clinical Excellence (NICE) in 2015 with subsequent adoption and dissemination across a number of countries worldwide [Woo *et al.* 2011].

With increasing availability of the UroLift device, education and awareness is needed in order to update and guide treatment strategies accordingly as well as augment reproducibility. To this effect, the objective of this article is to provide an overview of this novel technique and discuss key considerations for management in patients with BPH.

The procedure

In contrast to other endoscopic, minimally-invasive treatments for BPH, the *modus operandum* of the UroLift technology is mechanical rather than ablative or cavitating [Garcia *et al.* 2015]. Carried out in the lithotomy position under cystoscopic guidance, deployment of adjustable implants serves to retract the obstructing lateral lobes and create an open, continuous voiding channel through the prosatic fossa, from the verumontanum up to the bladder neck. The device itself is a custom designed disposable cartridge consisting of a nitinol capsular tab and a urethral stainless steel tab (8 mm) bridged in between by a nonabsorbable polyethylene terephthalate (PET) monofilament suture. The initial deployment is 1.5 cm distal to the bladder neck with the needle path kept parallel to the bladder neck. The second deployment is just anterior to the verumontanum, with additional implants placed between these two, with the idea to open a continuous channel through the anterior aspect of prostate. The number of implants is dependent on the adenoma size and configuration (range 2–10 according to Garcia *et al.* 2015) and these are typically placed at the 2 o'clock and 10 o'clock positions (angled anterolaterally), at least 1.5 cm distal to the bladder neck in order to preserve its integrity. This tissue-sparing method allows for expansion of the urethral lumen and theoretically avoids damage to the dorsal venous complex and the primary neurovascular bundles. It can be performed under

Table 1. Inclusion and exclusion criteria in most studies.

Inclusion criteria	Exclusion criteria (in most studies)
• Age > 50 years • Prostate volume 20–70 ml (on ultrasound) • IPSS > 12 • Qmax < 15 ml/s • PVR < 350 ml	• Obstructive median lobe • Active urinary tract infection • PSA > 10 ng/ml (unless negative biopsy) • Prostatitis within past 1 year • History of urinary retention • Previous BPH surgery • Previous pelvic surgery/irradiation

BPH, benign prostatic hyperplasia; IPSS, international prostate symptom score; PSA, prostate specific antigen; PVR, postvoid residual; Qmax, maximum urinary flow rate; QoL, quality of life.

Table 2. Advantages and disadvantages of 'UroLift'.

Advantages	Disadvantages
• Can be performed under local, spinal and general anaesthesia • Day case procedure • Short learning curve • Patients preserve existing sexual function • Strong safety profile • Shorter procedure time • Can discontinue medical therapy afterwards • Fewer ancillary theatre staff required • Catheter-free post procedure • Implants do not prevent TURP at future date • Good improvement in IPSS and QoL	• Technical difficulty in patients with high bladder neck • Not suitable in patients with obstructing median lobe • Not suitable in patients with history of urinary retention • Contraindicated for larger prostates (>100 ml) • Limited long term data • Limited research on patients with multiple comorbidities • Potentially high re-retreatment rate in long term • High cost per implant • Mild improvement only in Qmax and PVR

IPSS, international prostate symptom score; PVR, postvoid residual; Qmax, maximum urinary flow rate; QoL, quality of life; TURP, transurethral resection of the prostate.

general, spinal or local anaesthetic and in the day-case setting [Jones *et al.* 2016b; Rassweiler *et al.* 2006; Marra *et al.* 2015].

Patient selection

Careful patient selection is paramount for surgical success and certainly it is not suitable for all patients with bladder outflow obstruction (see Table 1). Overall, there are three key factors, which potentially exclude a patient from receiving this surgical option. Firstly, men with obstructing median lobes are contraindicated and therefore should undergo preoperative cystoscopy to determine prostate anatomy and size. Secondly, it is not recommended for those patients with large prostate burdens (>100 ml). Finally, it is not suitable for patients with a history of urinary retention.

Advantages

The UroLift device holds a number of advantages (see Table 2). Maintaining distance from the bladder neck when implanting the device allows for preservation of antegrade ejaculation. Perhaps therefore its greatest asset is that there have been no *de novo* cases of sexual dysfunction reported in any of the studies published [Jones *et al.* 2016b]. Compare this with transurethral resection of the prostate (TURP), which a recent systematic review found to cause retrograde ejaculation in up to three quarters of men receiving it [Marra *et al.* 2015]. Given that it can be performed under local anaesthesia (LA) as an office-based setting or under general anaesthetic as a day-case procedure, an overnight hospital stay can be avoided in most patients. Furthermore, the patient is often catheter-free on discharge. UroLift is therefore expected to emerge as an attractive option for men wanting to avoid ablative or cavitating surgery, with a high priority of preservation of sexual function. Added to this, there is early return to work and rapid symptom resolution with no catheter on discharge; its popularity from a patient point of view is self-evident.

From a surgeon's perspective, the perceived learning curve is far more manageable than laser procedures such as Holmium laser enucleation of the prostate (HoLEP). Should the patient need to undergo future procedures, these transprostatic implants can be dealt with and TURP can be performed using the resectoscope without much difficulty. No deaths attributed to the UroLift surgery have been reported. Side effects of the procedure are usually mild and self-limiting.

Although the cost of the UroLift procedure might be slightly higher than other procedures, as a greater number of procedures can be carried out per operating session, treating a higher number of patients, there is clearly a financial incentive for the clinicians and hospitals regarding the overall remuneration.

Disadvantages

While the UroLift system has demonstrated clear strengths, it is not without limitations (see Table 2). The exclusion of patients with obstructive median lobes, larger prostate volumes and a history of urinary retention eliminates a large proportion of patients. In addition, experience has shown patients with a high bladder neck and long prostatic urethral length make this procedure extremely difficult to perform. Although there are a number of original studies published with medium-term (12 month) outcomes, to date there exists only one study with follow up data >2 years [Roehrborn *et al.* 2015], which shows a retreatment rate of 11%. Sufficient long term results that show sustained benefits of the procedure are therefore lacking.

In contrast to TURP, UroLift system does not collect tissue specimens and therefore cannot pick up incidental cases of prostate cancer. None of the studies published to date have reported a final maximum urinary flow rate (Qmax) >15 ml/s [Jones *et al.* 2016b]. Patients should therefore be counselled that they may not gain the same improvements in symptoms such as flow improvements, as they would do with more traditional surgeries and that further alternative surgeries might be necessary in the long term.

Complications

Over 95% of the adverse events reported in published studies have been Clavien grade 1 complications, which were therefore self-limiting and did not require any form of treatment or surgical intervention [Jones *et al.* 2016b].The most commonly recorded of these were pelvic pain (a burning sensation) and dysuria. At medium term follow up, there have been no major complications cited. This compares more favourably than TURP, which is associated with urinary tract infections (2.3–5%), stricture formation (2.2–9.8%), bladder neck contractures (0.3–9.2%) and retrograde ejaculation (53–75%) [Rassweiler *et al.* 2006].

Cost

To date there have been no original studies formally incorporating cost-effectiveness analyses. In 2016, Neotract were invited to submit 'economic evidence' to be critiqued by NICE and the Medical Technologies Evaluation Programme (MTEP) [Ray *et al.* 2016]. Estimated cost savings per patient for UroLift (if implemented as a day-case procedure) were £159 and £286 compared with inpatient bipolar TURP and monopolar TURP respectively. These values were calculated from pragmatic estimations made by an expert committee and lacked actual comparative data from primary research. The principal cost driver is the implant, which costs £330 each. The overall equipment cost per procedure can therefore easily rise to over £1000 for a typical case according to MTEP estimations [Ray *et al.* 2016].

Current evidence for UroLift

To date, there have been five cohort studies [Woo *et al.* 2011; Chin *et al.* 2012; McNicholas *et al.* 2013; Bozkurt *et al.* 2016; Shore *et al.* 2014], one crossover study [Cantwell *et al.* 2014] and two randomized studies [Roehrborn *et al.* 2015; Sønksen *et al.* 2015] (UroLift *versus* sham, UroLift *versus* TURP) published on the UroLift system (English language studies only). A recent systematic review found the technology to yield clear improvement in subjective outcomes [Jones *et al.* 2016b]. The mean international prostate symptom score (IPSS) improved from 24.1 to 14 and the mean quality of life (QoL) improved from 4.5 to 2.3. However, there were only marginal improvements seen in the objective parameters measured. For Qmax and postvoid residual (PVR), the mean preoperative *versus* postoperative values were, 8.4 ml/s *versus* 11.8 ml/s and 93 ml *versus* 84.7 ml respectively. After 12 months, 6.9% of patients required retreatment in the form of TURP.

Findings from the Luminal Improvement Following Prostatic Tissue Approximation for Treatment of LUTS Secondary to BPH (LIFT) study were presented (not fully published) earlier in 2016 with 48 of the original 206 patients followed up at 4 years [Kaplan, 2015]. Although overall improvement in IPSS in these patients was 46%, approximately half of the group had undergone repeat surgery during the follow up.

Further considerations and potential limitations

With the increasing attention and excitement surrounding the UroLift system it can be difficult for clinicians to gain a balanced understanding on how the evidence gathered will translate to everyday practice. Accordingly, there are important points for consideration.

Firstly, the published outcomes have been achieved by investigators within a clinical trial setting who are highly motivated, with an invested interest to actively develop the technique. Moreover, the majority of studies have been funded by the manufacturer Neotract. The learning curve and reported outcomes when carried out in new centres may not therefore be as impressive. The estimated learning curve appears to have been for performing the procedure in patients under general anaesthesia. It is likely the learning curve in the office setting under LA will be steeper. There is also concern regarding how well an awake, younger man will tolerate rigid cystoscopy under LA [Roehrborn *et al.* 2016]. In the UK, diagnostic or therapeutic rigid cystoscopy are almost always done under a general anaesthesia.

Secondly, while it is reported as a technical feasibility in prostate sizes up to 100 ml, no study has carried out the procedure with a mean prostate volume over 50 ml [Jones *et al.* 2016b]. While proponents put forward its suitability for patients with multiple comorbidities, certain studies including the landmark LIFT study made such patients ineligible for participation and performed the procedure in otherwise mostly healthy subjects. Sexual function is increasingly recognized and measured as an important primary outcome. Furthermore, research has shown erectile dysfunction to have a greater impact on quality of life than LUTS [Marra *et al.* 2015]. As such, the development of UroLift should be praised in identifying this therapeutic void and acting upon it.

Future research

The uroLift System TOlerability and ReCovery When Administering Local Anaesthesia (LOCAL) study is currently in progress in the US and the estimated study completion date is 2018. This multi-centre, non-randomized single-arm study is evaluating the surgical recovery for patients undergoing UroLift under LA and is measuring how well they tolerate this procedure awake. The investigators aim to follow up the patient cohort to 5 years. This high profile study should certainly add to the canon of evidence for this minimally-invasive and novel technology. More studies are needed however, which report data from hospitals, which have adopted the technique outside of the trial settings. Use of standardized performance metrics is needed to allow for better data collection and comparison between centres and to other surgical techniques.

Conclusion

The UroLift system is a novel technology that allows for a bespoke patient-centred approach to be delivered, which yields clinically meaningful symptom improvement. It is likely to attract younger patients (with suitable prostate anatomy) who wish to preserve sexual function as a high priority or want to avoid ablative or cavitating surgery. Further studies are needed with longer-term follow up to better understand this intervention's implications for practice.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Conflict of interest statement

The authors declare that there is no conflict of interest.

References

Bozkurt, A., Karabakan, M., Keskin, E., Hirik, E., Balci, M., Nuhoglu, B. *et al.* (2016) Prostatic urethral lift: a new minimally invasive treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia. *Urol Int* 96: 202–206.

Cantwell, A., Bogache, W., Richardson, S., Tutrone, R., Barkin, J., Fagelson, J. *et al.* (2014) Multicentre prospective crossover study of the 'prostatic urethral lift' for the treatment of lower urinary tract symptoms

secondary to benign prostatic hyperplasia. *BJU Int* 113: 615–622.

Chin, P., Bolton, D., Jack, G., Rashid, P., Thavaseelan, J., Yu, R. *et al.* (2012) Prostatic urethral lift: two-year results after treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia. *Urology* 79: 5–11.

Garcia, C., Rashin, P. and Woo, H. (2015) Prostatic urethral lift: a minimally invasive treatment for benign prostatic hyperplasia. *Prostate Int* 3: 1–5.

Jones, P., Rai, B., Aboumarzouk, O. and Somani, B. (2016a) Prostatic urethral lift vs prostate arterial embolization: novel nonablative strategies in the management of lower urinary tract symptoms secondary to benign prostate hyperplasia. *Urology* 87: 11–17.

Jones, P., Rajkumar, G., Rai, B., Aboumarzouk, O., Cleaveland, P., Srirangam, S. *et al.* (2016b) Medium term outcomes of UroLift (minimum 12 months follow-up): evidence from a systematic review. *Urology* S0090–S4295. DOI:10.1016/j.urology.2016.05.003.

Kaplan, S. (2015) The prostate urethral lift: will it be uplifting or downgraded as a treatment strategy for benign prostatic hyperplasia? *Eur Urol* 67: 714–715.

Loeb, S., Kettermann, A., Carter, H., Ferrucci, L., Metter, E., Walsh, P. *et al.* (2009) Prostate volume changes over time: results from the Baltimore longitudinal study of aging. *J. Urol* 182: 1458–1462.

Marra, G., Sturch, P., Oderda, M., Tabatabaei, S., Muir, G., Gontero, P. *et al.* (2015) Systematic review of lower urinary tract symptoms/benign prostatic hyperplasia surgical treatments on men's ejaculatory function: time for a bespoke approach? *Int J Urol* 23: 22–35.

McNicholas, T., Woo, H., Chin, P., Bolton, D., Fernández Arjona, M., Sievert, K. *et al.* (2013) Minimally invasive prostatic urethral lift: surgical technique and multinational experience. *Eur Urol* 64: 292–299.

Rassweiler, J., Teber, D., Kuntz, R. and Hofmann, R. (2006) Complications of transurethral resection of the prostate (TURP): incidence, management, and prevention. *Eur Urol* 50: 969–979.

Ray, A., Morgan, H., Wilkes, A., Carter, K. and Carolan-Rees, G. (2016) The UroLift system for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia: a NICE medical technology guidance. *Appl Health Econ Health Policy* 30: 1–12.

Roehrborn, C., Gange, S., Shore, N., Giddens, J., Bolton, D., Cowan, B. *et al.* (2016) Four year results from the largest, prospective, randomized study of prostatic urethral lift (PUL). *Eur Urol Suppl* 15(Suppl. 3): e1077. DOI:10.1016/S1569-9056(16)61078-3.

Roehrborn, C., Rukstalis, D., Barkin, J., Gange, S., Shore, N., Giddens, J. *et al.* (2015) Three year results of the prostatic urethral L.I.F.T. study. *Can J Urol* 22: 7772–7782.

Shore, N., Freedman, S. and Gange, S. (2014) Prospective multi-center study elucidating patient experience after prostatic urethral lift. *Can J Urol* 21: 7094–7101.

Sønksen, J., Barber, N., Speakman, M., Berges, R., Wetterauer, U., Greene, D. *et al.* (2015) Prospective, randomized, multinational study of prostatic urethral lift versus transurethral resection of the prostate: 12-month results from the BPH6 study. *Eur Urol* 68: 643–652.

Woo, H., Chin, P., McNicholas, T., Gill, H., Plante, M., Bruskewitz, R. *et al.* (2011) Safety and feasibility of the prostatic urethral lift: a novel, minimally invasive treatment for lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH). *BJU Int* 108: 82–88.