Italian experience with Prostatic Urethral Lift using pure local anaesthesia

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Abstract

Prostatic urethral lift (PUL) is a minimally invasive surgical treatment for obstructive lower urinary tract symptoms. We report the experience of two centres in Italy where PUL was performed under pure local anaesthetic. The procedure was well tolerated with no serious adverse events. Clinical outcomes at 1, 6 and 12 months were comparable with those reported in the literature.

Key words: Prostatic Urethral Lift, local anesthesia, minimally invasive treatment MIST, Benign prostatic hypertension BPH.

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Introduction

Benign prostatic hyperplasia affects over 500 million men worldwide. The resulting lower urinary tract symptoms (LUTS) are common in men and can impact significantly on quality of life and are associated with considerable economic burden. BPH affects over 40% of men in their 50s and over 80% of men in their 70s (1).

Treatment options for LUTS from BPH range from medication to surgery. Minimally-invasive surgical treatments (MISTS) are now available, which offer the patient greater choice in the management of their symptoms. MISTS have been shown to provide effective and durable symptom relief, quick recovery and low risk of complications or risk to sexual function (2-8).

MISTS also provide the opportunity to treat the patient in an ambulatory setting as a day case procedure. Across many surgical specialties, day surgery has been increasing. This increase has been largely driven by enhanced recovery programmes that encourage early mobilisation, advances in both anaesthesia and surgical techniques and a drive to reduce healthcare costs (9). Added to this, globally, the Covid-19 pandemic has put unprecedented strain on healthcare services. Recovery of these services has meant hospitals are seeking to redesign pathways and find new, more efficient ways of working to address the waiting list of patients, while also reducing the time patients are in hospital to as little as safely possible.

Developing effective local anaesthesia (LA) protocols for treating BPH with MISTs has a number of benefits (10). Surgical lists can be put together that comprise just procedures that are being performed under LA, thereby avoiding the need for an anaesthetist or recovery staff. Patients undergoing procedures under LA can transit directly to a secondary recovery area, enabling more efficient use of space and faster progression through the day surgery pathway.

Among the new MISTs for BPH, prostatic urethral lift (PUL) is one of the most widespread and well-studied procedures in the world (2-6). The reasons for its success are various: preservation of sexual function (3), rapid post-operative recovery (5), durable symptom relief in the long term (3), low complication rate (2, 3), low risk of catheterization compared to other MISTs (2, 7, 8).

Prostatic urethral lift (PUL) is performed using the UroLift® System. This system comprises the delivery device, which is inserted transurethrally through a rigid sheath under cystoscopic visualisation to reach the targeted area of obstruction. Each delivery device contains one UroLift implant, which are deployed by the delivery device to hold apart the obstructing prostatic lobes. Each implant is made with common implantable materials: nitinol, stainless steel, and PET suture.

The ability to perform PUL under pure LA without sedation is an important element in our surgical management of BPH, which reinforces the minimally invasive aspect of the procedure and helps to improve the speed of recovery for our patients. Here we report the results of the first Italian experience performing PUL under local anesthesia (LA). Our primary objective was to evaluate the tolerability of this procedure under LA, using the validated Visual Analogue Scale measurement instrument (VAS). We also collected clinical outcomes to compare with other clinical studies with PUL in the literature.

Methods

A prospective study was conducted with patients treated with PUL (Urolift® System) under LA, between November 2017 and September 2021 in two Italian centers. The only exclusion criteria was the presence of an obstructive median lobe seen during the initial cystoscopy or a prostate size greater than 90 ml.

Prior to the procedure, baseline measurements for maximum urinary flow rate (Qmax), post-void residual volume (PVR), and International Prostate Symptom Score (IPSS) were collected. Patients were also questioned about their sexual health using recognized questionnaires – MSHQ (Male Sexual Health Questionnaire) and IIEF-15 (International Index of Erectile Function).

In both centres, the procedure was performed in an endoscopy suite, using a set-up that would be typical of an outpatient setting. We followed a similar local anaesthesia protocol used by other units in Europe where prostatic urethral lift is being performed under LA. The LA protocol in this study was as follows:

1. 20 mins before the procedure: Intraurethral syringe injection of 20mg (2 vials) of cold lidocaine 2% (4oC; taken from the fridge), followed by an intraurethral injection of 2 tubes (15 g) of cold lubricant with lidocaine (Luan 2.5% Gel; 4oC taken from the fridge).
2. Penis clamp holds the anaesthetic and lubricant in place.

3. Patient is moved to the procedure room, placed into the lithotomy position and draped.
4. 2 further tubes (15 g) of cold lidocaine lubricant was added just before starting the procedure.

Medication administered during or following the procedure was:

- Midazolam/pethidine was available for use if required.
- Before starting the procedure, intravenous ciprofloxacin or ceftriaxone was administered intravenously.
- Ketorolac tromethamine/tramadol (Lixidol) 30 mg/ml was given to the patient during the procedure.
- If the pain score on the visual analogue scale (VAS) was >4, intravenous paracetamol was administered prior to discharge.

Pain scores were collected at the end of the procedure to assess the level of pain felt by the patient during the procedure under LA. Pain scores were assessed using the visual analogue scale (VAS); a validated, subjective measure for acute and chronic pain. To record the VAS score, the patient is asked to make a mark on a 10-cm line that represents a continuum between "no pain" and "worst pain." The patient marked the line in a place that best represents the level of pain felt during the PUL procedure.

Depending on which unit the patient was treated in, and in accordance with local pathways, the patient was either discharged the same day in one of the two centres or the following day in the other centre.

Follow-up visits were scheduled for 1, 6, 12, and 24, 36, 48 months postoperatively. Maximum urinary flow (Qmax), PVR, and IPSS were assessed at each follow-up visit to evaluate the effectiveness of PUL in reducing symptoms of BPH. During these visits, patients who did not have erectile dysfunction prior to PUL were questioned on changes in sexual function from their baseline reports. MSHQ and IIEF-15 questionnaires were also used to assess the impact of PUL on sexual function.

Results

A total of 55 patients were treated with PUL under pure LA. The procedures were performed by two surgeons. Baseline patient and procedural characteristics are provided in Table 1. Patients had a mean age of 67 years (range 50-87) and a mean prostate size of 45 mL (range 17-90). Twenty patients (36%) had severe BPH obstruction and had a previous episode of acute urinary retention (AUR) and/or urinary tract infection (UTI). None of the patients were in acute urinary retention at the time of the PUL procedure and all the PUL cases were scheduled elective procedures, with none performed as emergency procedures. Sixteen patients (29%) had a catheter at the time of procedure.

A mean of 3.6 (2–13) UroLift implants were implanted in procedures of an average of 16 minutes duration (range 8-60). Median length of hospital stay was 1 day (range 1-3), including the procedural day.

The average pain score recorded using the VAS was 3.7 ± 1.9. When asked whether the pain sensations had been higher, lower or the same during the PUL procedure compared with the preoperative cystoscopy, only 15% of the patients responded it was higher. In all cases there was a good tolerance to the procedure. One patient (1.8%) required intravenous midazolam (2 mg) due to agitation.

Following PUL, catheterization rate was 31.3%. Of those patients who were catheterized following the procedure, 86.6% were catheterized for 1 day (reason for catheterization: haematuria). The catheter was removed on the same day as the procedure in 4.4% of patients (reason for catheterization: mild haematuria). In 6.6 % of patients, the catheter was removed after 2 days (reason for

Table 1 Baseline Patient and Procedural Characteristics.
Qmax: maximum urinary flow rate (Qmax). PVR: post-void residual volume. IPSS: International Prostate Symptom Score. VAS: Visual Analogue Score. AUR: acute urinary retention. UTI: Urinary tract infection.

N (total)	**55**
Age (years)	67 (range 50-87)
Prostate size (ml)	45 (range 17-90)
Patients catheterised at time of intervention	16 (29%)
Prior episode of AUR and/or UTI	20 (36%)
Baseline IPSS	23.8 ± 4.3
Baseline Qmax (mL/sec)	6.8 ± 2.3
Baseline PVR (mL)	133 ± 59
Anaesthesia	100% LA*
*1 patients was given midazolam for agitation	
No. of implants per patient	Mean 3.6 (range 2-13)
Procedure duration (minutes)	16 (range 8-60)
VAS	3.7 ± 1.9
Post-op catheterisation	14%
Length of stay (days)	1 (range 1-3)

catheterization: acute urinary retention). One patient had a catheter for 5 days post-procedure (reason for catheterization: fever). All patients were catheter free at last follow-up.

Median follow up was 24 months (range 1-47). IPSS and Qmax improved over time, with durable improvement seen at 1 year (Table 2). At the latest follow-up, 52% of patients were satisfied and described experiencing complete symptoms relief. MSQH and IIEF-15 scores were available for 28 patients at the 1-year follow-up. Changes in the MSQH scores showed subjective improvement in ejaculation volume at suspension of alpha-blockers; minimal subjective improvement of erection quality. Changes in IIEF-15 scores increased from an average baseline of 12 (range 7-13) to 17 (range 7-20) at 1 month, 15 (range 9-18) at 6 months, and 14 (range 7-20) at 12 months.

No adverse events of Clavien–Dindo Grade > 2 was reported postoperatively. Sixteen patients had Grade 1 adverse events following the procedure, which were treated with analgesic medication. Grade 2 adverse events (urinary infection and fever following the procedure) were recorded in one patient.

Discussion

Prostatic urethral lift is a minimally invasive treatment option for men with LUTS from BPH, which can be performed under a local or general anaesthetic. We have reported our early experience in Italy of treating patients under pure LA. We found that performing PUL under pure LA was straightforward and was generally well tolerated by patients. VAS scores (average 3.8) were comparable with those reported from other units performing PUL under LA (4, 11) and comparable with VAS scores reported for cystoscopy (4).

Clinical outcomes were also comparable with those reported in the literature for PUL performed under both local and general anaesthetic (2-6), suggesting that performing PUL under LA does not adversely affect the expected improvements in symptoms. PUL was shown to have a good safety profile, with no worsening of sexual function observed.

Despite a high catheterization rate at baseline due to urinary retention, it was encouraging that all patients were catheter free by their last follow-up and most were catheter free by day 2 post procedure.

Conclusion

This early experience confirms that PUL when performed under LA is a well-tolerated, safe and effective approach for the treatment of LUTS due to bladder outlet obstruction. Clinical outcomes (IPSS and Qmax) from this real-world experience of treating patients with PUL reflects the peer-reviewed evidence from the early randomized controlled studies with PUL (2-4, 6). PUL is an attractive option for selected patients who seek rapid relief of LUTS with preservation of sexual function.

Table 2 IPSS, Qmax and PVR outcomes.
Qmax: maximum urinary flow rate (Qmax). PVR: post-void residual volume. IPSS: International Prostate Symptom Score.

Outcomes - IPSS	1 Month	6 Months	1 Year
N (total) - Paired subjects	48	35	26
IPSS Baseline	23.8 ± 4.5	23.7 ± 4.6	24.0 ± 4.5
IPSS Follow-up	14.6 ± 5.2	13.8 ± 5.7	13.5 ± 6.2
IPSS Change	-9.1 ± 5.8	-9.8 ± 6.6	-10.5 ± 6.7
p-value	p < 0.0001	p < 0.0001	p < 0.0001
Outcomes - Qmax	1 Month	6 Months	1 Year
N (total) - Paired subjects	31	22	17
Qmax (mL/sec) Baseline	6.6 ± 2.2	6.2 ± 2.3	6.5 ± 2.1
Qmax (mL/sec) Follow-up	14.8 ± 2.7	13.2 ± 2.2	12.3 ± 1.7
Qmax (mL/sec) Change	8.2 ± 2.4	6.9 ± 2.6	6.0 ± 2.2
p-value	p < 0.0001	p < 0.0001	p < 0.0001
Outcomes - PVR	1 Month	6 Months	1 Year
N (total) - Paired subjects	46	32	26
PVR (mL) Baseline	132.1 ± 61.7	139.8 ± 62.1	134.0 ± 60.3
PVR (mL) Follow-up	54.4 ± 31.7	57.3 ± 32.0	66.3 ± 32.1
PVR (mL) Change	-77.7 ± 53.4	-82.5 ± 55.1	-67.6 ± 56.5
p-value	p < 0.0001	p < 0.0001	p < 0.0001

Qmax: maximum urinary flow rate (Qmax). PVR: post-void residual volume. IPSS: International Prostate Symptom Score.

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