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THE INSIDE-OUT TRANSOBTURATOR SLING FOR THE SURGICAL TREATMENT OF POST-RADICAL PROSTATECTOMY URINARY INCONTINENCE: INTERIM RESULTS OF A PROSPECTIVE, OBSERVATIONAL STUDY AFTER A 1-YEAR MINIMUM FOLLOW-UP

Hypothesis / aims of study

The aim of this study was to prospectively evaluate the short-term safety and efficacy of the inside-out transobturator sling procedure for treating post-radical prostatectomy (RP) stress urinary incontinence (SUI).

Study design, materials and methods

The sling technique uses specific instruments and a polypropylene mesh with 2 arms that are passed inside to outside through the obturator foramens, pulled for compressing the bulbar urethra upward, and tied to each other across the midline. Intra-operative urodynamic evaluation is performed to record the urethral pressure profile (UPP) and to measure the abdominal leak point pressure (ALPP) and maximal urethral pressure (MUP) before and after sling tensioning. Urodynamic measurements are repeated until tension on both arms of the mesh increases ALPP to approximately 100 cm H_2O. In case of associated urethral stenosis, classic endoscopic urethrotomy is performed first.

Inclusion criteria were clinically and urodynamically demonstrated SUI, positive bulbar compression test, and signed informed consent. Patients with detrusor overactivity or active urinary infection were excluded.

Baseline evaluation included detailed history, physical examination with a bulbar urethra compression test, urine analysis, multichannel urodynamics, administration of self-questionnaires assessing urinary continence (questions 1 through 3 of the urinary section of the UCLA-PCI-SF questionnaire (1)) and quality of life (QoL) (Ditrovie questionnaire (2)), flexible urethrocystoscopy, and urethrocystography. The degree of incontinence was arbitrarily categorized as mild (1–2 pads/day), moderate (3–5 pads/day) or severe (>5 pads/day), as previously described (3).

Follow-up evaluation at 1, 6, 12 months, and yearly thereafter included physical examination, uroflowmetry with PVR measurement, and administration of the self-questionnaires assessing urinary continence and QoL. All patients were also asked to self-evaluate their satisfaction with the treatment.

Cure was defined by no pad use and improvement by a number of pads/day ≤ 2 and reduced by at least 50%. Peri- and post-operative complications were recorded.

Results

From April 2006 through March 2009, 95 consecutive patients who fulfilled inclusion and exclusion criteria underwent the sling procedure using the same operative protocol. As of March 2009, 58 patients who consecutively underwent the sling procedure were expected to have a minimum follow-up of 1 year.

Mean age of the patients was 67.6 ± 6.5 years (range 52-79). Mean body mass index was 27.0 ± 3.6 (range 21.3 – 39.0). Of the 58 patients, 9 (16%) patients had undergone prior surgery for SUI: bulking agent injection in 5 patients, prior sling implantation in 1 patient and artificial urinary sphincter (AUS) implantation in 4 patients. A previous urethrotomy or urethral dilatation for urethral stenosis had been performed in 8 (14%) patients and 8 (14%) patients had had pelvic irradiation. Preoperatively, 14 (24%), 26 (45%), and 18 (31%) patients were using 2 (mild SUI), 3 to 5 (moderate SUI), and >5 pads/day (severe SUI), respectively.

The sling procedure was performed under general and spinal anesthesia in 22 (38%) and 36 (62%) patients, respectively, and was preceded by an endoscopic urethrotomy in 5 (9%) patients. Penile prostheses were implanted concomitantly to the sling in 2 patients.

Before sling tensioning, mean MUP and ALPP were 40 ± 21 cm H_2O (range 5-101) and 45 ± 22 cm H_2O (range 10-100). After sling tensioning, mean MUP and ALPP were 89 ± 24 cm H_2O (range 44-141) and 109 ± 26 cm H_2O (range 60-165). Mean increase in MUP and ALPP between post- and pre-tensioning of the sling was 49 ± 29 cm H_2O (range 1-125) and 64 ± 32 cm H_2O (range 20-135), respectively.

Mean operative time was 65 ± 18 minutes. No intra-operative complication was noted. Seven (12%) patients required suprapubic catheterization; normal voiding resumed in all 7 patients except 1 who underwent urinary diversion for complete radiation-induced anastomotic stenosis. Mild perineal hematoma not requiring therapy was observed in 6 patients.

Six-month and 1-year minimum follow-up was available on 54 (93%) and 56 (96%) of the 58 patients, respectively (Table 1). Two patients were completely lost to follow-up after the 1-month visit. At this 1-month visit, one patient was cured while the other was improved.

Table 1. Postoperative pad usage

Follow-up	6-month visit			1-year visit		
Preoperative SUI severity / Outcome	Mild to moderate SUI (≤5 pads/d)	Severe SUI (> 5 pads/d)	Entire cohort (≥ 2 pads/d)	Mild to moderate SUI (≤ 5 pads/d)	Severe SUI (> 5 pads/d)	Entire cohort (≥ 2 pads/d)
Cure	22 (55.0%)	9 (50.0%)	31 (53.5%)	23 (57.5%)	8 (44.5%)	31 (53.5%)
Improvement	13 (32.5%)	5 (27.8%)	18 (31.0%)	14 (35.0%)	6 (33.3%)	20 (34.4%)
Failure	1 (2.5%)	4 (22.2%)	5 (8.6%)	1 (2.5%)	4 (22.2%)	5 (8.6%)
Data not available	4 (10.0%)	0 (0.0%)	4 (6.9%)	2 (5.0%)	0 (0.0%)	2 (3.5%)

Of note, at 12 months, among the 18 patients with preoperative severe incontinence, 8 (44.5%) were cured and 6 (35%) others were improved. In addition, SUI cure/improvement rates appeared to be similar at the 6 and 12 months time points.
The 3 failures included one patient who had undergone post-RP radiation therapy. This man later developed a complete urethral anastomotic closure and underwent cystectomy with transileal ureterostomy 9 months after the sling procedure. The two other failed patients had a vesico-urethral anastomotic stricture before sling implantation. Both patients were implanted with an AUS after the sling procedure. After cutting the mesh arms laterally to the bulb, the AUS cuff was placed without difficulty around the bulbar urethra.
Preoperative and postoperative max flow rate and postvoid residual values were not different (Table 2). Overall, QoL was substantially enhanced and 85% patients were satisfied with the procedure.

Table 2. Postoperative evolution of QoL scores and voiding parameters

QoL and voiding parameters	Baseline (mean ± SD [range])	6-month visit (mean ± SD [range])	1-year visit (mean ± SD [range])
Ditrovie QoL scores (scale from 10 [best] to 50 [worst])	32 ± 7 (17-50)	16 ± 8 (10-40)	17 ± 8 (10-42)
Max flow rate (mL/sec)	20 ± 9 (6-46)	18 ± 9 (6-44)	17 ± 10 (4-51)
Post void residual (mL)	17 ± 32 (0-160)	21 ± 51 (0-243)	6 ± 21 (0-87)

No sling infection, urethra erosion, persistent pain or neurological complication was observed. No sling was withdrawn or cut.

Interpretation of results

The inside-out transobturator sling was associated with a minimal risk of intra- and post-operative complications. Postoperative SUI cure/improvement rates were found to remain stable over a 1-year period. The sling procedure appeared to be efficient at short term even in the group of patients with severe SUI before surgery. The sling procedure does not compromise concomitant penile prostheses or subsequent AUS implantation. Longer follow-up times are required to determine the long-term efficacy of this sling procedure.

Concluding message

The one-year results of this prospective study suggest that the inside-out transobturator sling is a safe and efficient surgical procedure at short term for the treatment of post-RP SUI.

References

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Specify source of funding or grant	**None**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**B7072006345**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Ethics Committee of the University of Liège, Belgium**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**