

## THE INSIDE-OUT TRANSOBTURATOR SLING FOR THE SURGICAL TREATMENT OF POST-RADICAL PROSTATECTOMY URINARY INCONTINENCE: INTERIM RESULTS OF A PROSPECTIVE, OBSERVATIONAL STUDY AFTER A 2-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 foramina, 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<sub>2</sub>O. 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 urethroscopy, and urethrocytography. 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  $\leq 2$  and reduced by at least 50%. Peri- and post-operative complications were recorded.

### Results

From April 2006 through March 2010, 130 consecutive patients who fulfilled inclusion and exclusion criteria underwent the sling procedure using the same operative protocol. As of March 2010, 58 patients who consecutively underwent the sling procedure were expected to have a minimum follow-up of 2 years.

Mean age of the patients was  $67.6 \pm 6.5$  years (range 52–79). Mean body mass index was  $27.0 \pm 3.6$  (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  $40 \pm 21$  cm H<sub>2</sub>O (range 5–101) and  $45 \pm 22$  cm H<sub>2</sub>O (range 10–100). After sling tensioning, mean MUP and ALPP were  $89 \pm 24$  cm H<sub>2</sub>O (range 44–141) and  $109 \pm 26$  cm H<sub>2</sub>O (range 60–165). Mean increase in MUP and ALPP between post- and pre-tensioning of the sling was  $49 \pm 29$  cm H<sub>2</sub>O (range 1–125) and  $64 \pm 32$  cm H<sub>2</sub>O (range 20–135), respectively.

Mean operative time was  $65 \pm 18$  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.

A minimum follow-up of 6, 12 and 24 months was available on 54 (93%), 56 (96%), and 53 (91%) of the 58 patients, respectively (Table 1). Among the 5 patients (8.6%) not seen at the 24-month follow-up visit, 3 were cured and 2 were improved at their last visit. Overall, at 24 months, 75.9% of the patients were cured or improved while 15.5% were failures (Table 1). Of note, among the 18 patients with preoperative severe SUI, 6 (33.3%) were cured and 7 (38.9%) others were improved. SUI cure/improvement rates appeared to be slightly lower at the 24 months than at the 6 or 12 months time points, with a drop of  $\pm 10\%$  (75% versus  $\pm 85\%$ ).

**Table 1. Postoperative pad usage**

Follow-up	6-month visit			12-month visit			24-month visit		
Preoperative SUI severity / Outcome	Mild to moderate SUI	Severe SUI	Entire cohort	Mild to moderate	Severe SUI	Entire cohort	Mild to moderate SUI	Severe SUI	Entire cohort
Cure	22 (55.0%)	9 (50.0%)	31 (53.5%)	23 (57.5%)	8 (44.5%)	31 (53.5%)	19 (47.5%)	6 (33.3%)	25 (43.1%)

<b>Improvement</b>	13 (32.5%)	5 (27.8%)	18 (31.0%)	14 (35.0%)	6 (33.3%)	20 (34.4%)	12 (30.0%)	7 (38.9%)	19 (32.8%)
<b>Failure</b>	1 (2.5%)	4 (22.2%)	5 (8.6%)	1 (2.5%)	4 (22.2%)	5 (8.6%)	4 (10.0%)	5 (27.8%)	9 (15.5%)
<b>Data not available</b>	4 (10.0%)	0 (0.0%)	4 (6.9%)	2 (5.0%)	0 (0.0%)	2 (3.5%)	5 (12.5%)	0 (0.0%)	5 (8.6%)

Mild to moderate SUI:  $\leq 5$  pads/day. Severe SUI:  $> 5$  pads/day.

The 9 failures included 3 patients who had undergone post-RP radiation therapy and 4 patients who had a vesico-urethral anastomotic (n=3) or bulbar urethra (n=1) stricture before sling implantation. Three and 5 patients were subsequently implanted with or offered the placement of an AUS, respectively.

Preoperative and postoperative max flow rate and postvoid residual values were not different (Table 2). Overall, QoL was substantially enhanced and 75% of the patients were satisfied with the procedure.

**Table 2. Postoperative evolution of QoL scores and voiding parameters**

QoL and voiding parameters	Baseline (mean $\pm$ SD [range])	6-month visit (mean $\pm$ SD [range])	12-month visit (mean $\pm$ SD [range])	24-month visit (mean $\pm$ SD [range])
Ditrovie QoL scores (scale from 10 [best] to 50 [worst])	32 $\pm$ 7 (17-50)	16 $\pm$ 8 (10-40)	17 $\pm$ 8 (10-42)	18 $\pm$ 9 (10-40)
Max flow rate (mL/sec)	20 $\pm$ 9 (6-46)	18 $\pm$ 9 (6-44)	17 $\pm$ 10 (4-51)	18 $\pm$ 13 (7-76)
Post void residual (mL)	17 $\pm$ 32 (0-160)	21 $\pm$ 51 (0-243)	6 $\pm$ 21 (0-87)	2 $\pm$ 9 (0-50)

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 and appeared to be efficient at short term. The sling procedure does not compromise concomitant penile prostheses or subsequent AUS implantation. Analysis of a larger population of patients with longer follow-up is required to determine the long-term efficacy of this sling procedure.

#### Concluding message

The 2-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.

<b>Specify source of funding or grant</b>	<b>None</b>
<b>Is this a clinical trial?</b>	<b>Yes</b>
<b>Is this study registered in a public clinical trials registry?</b>	<b>No</b>
<b>Is this a Randomised Controlled Trial (RCT)?</b>	<b>No</b>
<b>What were the subjects in the study?</b>	<b>HUMAN</b>
<b>Was this study approved by an ethics committee?</b>	<b>Yes</b>
<b>Specify Name of Ethics Committee</b>	<b>Comité d'Ethique Hospitalo-Facultaire Universitaire de Liège</b>
<b>Was the Declaration of Helsinki followed?</b>	<b>Yes</b>
<b>Was informed consent obtained from the patients?</b>	<b>Yes</b>