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Sling for Post-prostatectomy
Urinary Incontinence**
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Abstract

Incontinence post-prostatectomy remains a problem, even when minor or moderate. In order to minimise surgical morbidity and costs, sling procedures have been proposed. The authors have developed a new transobturator male sling (TOMS) procedure and reported their results after one-year experience. **Materials and Methods:** A prospective multicentre study was conducted in 96 patients suffering from minor or moderate post-prostatectomy incontinence. Evaluation of the I-Stop™ two-arms bulbar TOMS was based on clinical form assessment using the Incontinence Questionnaire-Short Form 36 (ICIQ-SF 36) questionnaire pre- and post-operatively, and at three, six, nine and 12 months. **Results:** The surgical procedure was considered easy to perform and no post-surgery complications were reported except for one retention. The median number of pads per day decreased significantly from two pads before surgery to one during the follow-up period. The SF-36 continence and quality of life score improved from a median of 117 to 308, and the median ICIQ and quality of life score decreased from 15 to 5 one year after the intervention. **Conclusion:** The I-Stop TOMS is an attractive, simple sling technique for moderate or minor post-prostatectomy stress incontinence and offers an improvement in the quality of life.

Keywords

Urinary incontinence, sphincter deficiency, prostatectomy, surgery, sling

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The number of patients suffering from post-prostatectomy incontinence is increasing. Despite improvement in surgical techniques, the number of such patients has increased with the progression of early-detected localised prostate cancer in men. Depending on the study and definition of incontinence, the incidence of post-prostatectomy incontinence is estimated to be from 1 to 55% of men.¹ The wide range of reported rates of incontinence early after surgery decreases during the one-year post-surgery period and with physiotherapy sphincter exercise. Incontinence that persists after one year is estimated to affect fewer than 5% of patients.² Quality of life is strongly affected, and even a minor leakage requiring one pad a day may be highly bothersome.³ Transurethral prostatectomy or high-frequency ultrasounds are rarely causes of incontinence.

Clinical symptoms are stress urinary incontinence (SUI) that increases with physical effort during the day, but for some patients urine may be expressed mainly during the afternoon. Initial assessment includes a urinary diary, a questionnaire in order to gauge the precise type of incontinence and severity and number of pads used or, optimally, a pad test. The International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) questionnaire is a very simple and useful tool recommended by the European Urological Association. Urge incontinence may be associated with an overactive detrusor. The severity of incontinence affects quality of life. According to Stamey, the grading of SUI can be mild

(incontinence only with severe stress, such as coughing or sneezing), moderate (incontinence with minimal stress, including walking) or severe (major incontinence and incontinence during the night). Practically, severe incontinence is suspected when the number of totally wet pads used is more than four per day, or when there is over 200ml of urine during the 24-hour pad test.

After first-line treatment with pelvic floor exercises, the persistence of incontinence requires complementary examinations. Ultrasound evaluates residual urine, and a urethrocytostocopy evaluates the sphincter and anastomosis. Urodynamics is indicated before surgery to determine bladder capacity and activity. However, a sphincter deficiency is difficult to determine. Low maximal urethral closure pressure suggests a sphincter deficiency, but a normal value may be associated with a weak sphincter. An associated overactive bladder or anastomosis strictures must be ruled out and treated before incontinence surgery. The pathophysiology of male stress SUI is mainly a sphincter deficiency, but an excess of mobility of the bulbar and membranous urethra may be an associated factor.

A transobturator sling is the logical progression in minimally invasive treatment for mild or moderate male incontinence. For severe SUI, an artificial sphincter⁴ remains the gold standard technique for severe incontinence due to sphincter deficiency, with an 80% continence rate, despite a high cost and risk of erosion or infection.

These factors and the need for patients to press a pump for each micturition make many patients reluctant to have this type of surgery for moderate incontinence. In order to minimise surgical morbidity and cost, for mild or moderate incontinence minimally invasive options have been proposed, i.e. sling procedures and balloons, bulking agents and stem cell therapy.

As regards urethral bulking agents,⁵ many agents have been used but they are often disappointing. Short-term results are good, but long-term success is poor even with reinjections. Stem cell therapy is a research treatment that involves a complicated laboratory procedure. An adjustable balloon⁶ is an alternative to the sling procedure and is based on a mechanism of lateral compression of the proximal urethra. Patients who use up to one pad a day were reported in 60% of cases, but the high rate of complications during and post-surgery and several adjustments were of some concern. Slings are the more commonly proposed treatment for mild to moderate male SUI.

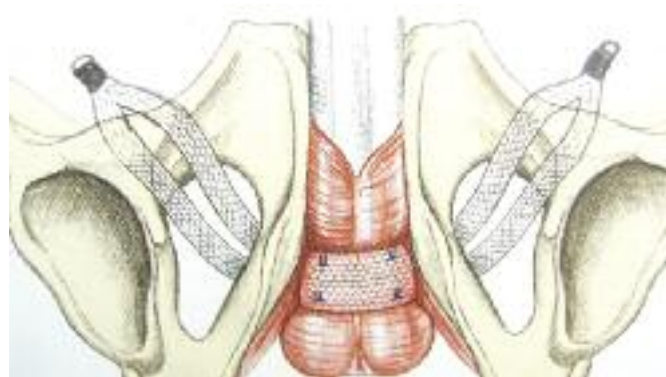
The concept of minimally invasive surgery with perineal bolsters acting as a sling on the bulbar urethra was described by Schaeffer et al.⁷ The initial success rate was excellent for continence with no significant outlet obstruction, but the outcome was complicated with bolster removal due to pain, infection or erosion. Efficacy was demonstrated in an average of four years⁸ with a 42% cure rate. In order to improve tolerance and by using a retropubic puncture, John⁹ used a bulbourethral composite suspension with porcine dermis and polypropylene sling, and Xu et al.¹⁰ used a sling made of polyester plus polypropylene. There is concern regarding the retropubic route due to a risk of a bladder puncture or erosion, and the adhesions from the prostatectomy may increase the risk of using this route.

A new concept of a large perineal sling on the bulbar urethra was introduced with the In Vance bone-anchored male sling, which is made of a large triangular silicone-coated biomaterial. Comiter et al.¹¹ reported 65% cured and pad-free patients at minimum two-year follow-up with a polypropylene or polyester mesh using bone anchor fixation. However, up to 16% of patients reported perineal pain or numbness that persisted for many weeks. These adverse effects might possibly be due to irritation in the area of the bone screws or a lesion to the perineal nerves¹² during ischiopubic rami dissection. In addition, infection of the biomaterial frequently occurred due to the use of a large silicone-coated membrane instead of macroporous mesh tape and biomaterial, characteristics that may explain morbidity, including osteomyelitis from bone screws. After radiation, patients had a significantly lower cure rate.

Different biomaterials were also used for the sling (allograft, porcine xenograft, synthetic and composite mesh), but a poor outcome resulted from the non-synthetic graft.¹³ The successful tolerance of polypropylene is widely accepted. A urodynamic study¹¹ revealed that the bulbar urethral sling had no significant effects on voiding function. Nevertheless, post-surgery retention may occur, possibly due to an excess in sling tension or an acontractility bladder reflex. A decision should be discussed with the patient about the possibility of immediate re-operation to release the tension on the tape or to wait a few days with self-catheterisation.

The transobturator route was usually used for female incontinence, but in males this route was initially reported by Bauer et al.¹⁴ in a cadaver study of three males using a helical puncture from inside to outside. We

Figure 1: The Four-arm Transobturator Male Sling



The sling is made of a central part on the bulbar urethra and two arms laterally on each side attached at the end to a clip in order to connect them to a specific needle.

conducted a cadaver study¹⁵ that confirmed this approach, and added the feasibility of outside-inside puncture in male patients. A prospective study¹⁵ with Ethical Committee approval then followed and was conducted using a polypropylene sling on the bulbar urethra and a transobturator puncture. Other bulbar slings have also been described recently. The Argus sling¹⁶ is adjustable and made of silicone that is exposed to erosion or infection. The De Leval sling¹⁷ is a polypropylene sling but with an additional subcutaneous lateral route to tie the two lateral arms to each other. The stronger attachment must be evaluated in respect of potential complications due to a larger amount of biomaterial and a wider dissection. The Ad Vance male sling system¹⁸ is located more proximally on the bulbar-membranous urethra in order to modify mobility and to act as a hammock-like support of the posterior sphincter complex, but tension is also applied on the sling. A proximal dissection close to the sphincter is a potential risk for a major deficiency. In addition, the membranous urethra is thin and fragile, which exposes it to urethral erosion.

There is concern regarding the retropubic route due to a risk of a bladder puncture or erosion, and the adhesions from the prostatectomy may increase the risk of using this route.

There have been encouraging results with the transobturator male sling (TOMS) on continence and good tolerance with minimal pain and no infection. The initial TOMS with two arms showed the following results on continence. After surgery, 30% of patients used no pads per day, and 32% used one pad per day. Sling failure was the result of the sling having slipped and not being close to the urethra. A new larger four-arm TOMS using the same biomaterial was studied using the same criteria in a prospective study conducted from May 2008.

The Transobturator Male Sling Procedure

The sling (developed by CL Medical) (see *Figure 1*) has four arms (two arms on each side) made with monofilament polypropylene, with macropores over 75 micrometres, is non-extensible, 45cm long and 1.4cm wide, and has a central part that is 2.8cm wide over the urethra. The sling is attached at each end to a clip in order to

connect it to a specific needle. A hemet or helical needle is used according to surgeon preference.

The surgical technique is performed under spinal or general anaesthesia, and a 16F Foley urethral catheter is inserted. The patient is placed in the lithotomy position and a 6cm median vertical perineal incision is made below the inferior border of the pubic symphysis to expose the bulbospongiosus muscle. The perineal aponeurosis at the top of the triangular space is then delimited laterally by each ischiocavernosus muscle and medial to the bulbospongiosus. A short 2mm incision through the pelvic fascia enables access to the obturator muscle just under the ischiopubic ramus bone. A stab incision is made at the top of the thigh, 4cm from the median line and 4cm below the major adductor longus muscle. The transobturator puncture is

The patient is placed in the lithotomy position and a 6cm median vertical perineal incision is made below the inferior border of the pubic symphysis to expose the bulbospongiosus muscle.

preferentially outside-inside with a Hemet needle. The end-point of the puncture is the opening in the pelvic fascia. After the sling is attached to the needle, pulling back the needle implants the two arms of the sling in the same passage. The same procedure is repeated on the other side. The sling is sutured to the bulbospongiosus muscle with non-absorbable sutures and then pulled firmly from each side in order to obtain a 2mm visible mark on the bulbospongiosus muscle. The perineal body is not dissected, but in case of rolling of the inferior edge of the sling on the bulb, the bulb is dissected just enough to apply it under the sling, then sutured to the sling. No retrograde urethral pressure adjustment is necessary. The incision is closed without drainage and the urethral catheter left for two days. Before hospital discharge, a post-void residual and pelvic pain evaluation on the visual analogue scale (VAS) should be obtained.

Clinical Results with the Four-arm Transobturator Male Sling

A prospective multicentre study was conducted on 96 male patients suffering from mild or moderate post-prostatectomy incontinence after a failure of physiotherapy and a minimum of one year after surgery without radiation. The study received Ethical Committee approval.

Pre- and post-surgery assessments included previous medical history, physical examination, a clinical study questionnaire about urological

symptoms and number of pads used per day, and urodynamics (uroflowmetry and post-void residual urine). The patients completed the ICIQ-SF and the SF36 questionnaire and a VAS before and after surgery. The number of patients studied at follow-up visits at one, three and six months, respectively, was 93, 80 and 54.

Changes in SF-36 and ICIQ were found not to follow an approximate normal distribution. Accordingly, changes in these end-points were analysed using Wilcoxon's sign-rank test. Changes in flowmetry more closely followed an approximate normal distribution and were analysed using Student's t-test. Both tests examined departures from the null hypothesis of no overall change from baseline. All analyses were performed using the univariate procedure in SAS v9.1. P-values of less than 0.05 were considered statistically significant, and those less than 0.001 were considered to be highly statistically significant.

Results

The surgery was considered by the surgeon to be easy to perform in all cases. The median operative time for the procedure was 30 minutes (25–45 minutes). No surgery complications were reported, no significant intra-operative bleeding (>200ml) occurred and there was no nerve, bowel or vascular injury. On the VAS, the median pain value the day after surgery was 2, then decreased significantly to 1.2 at one month and remained at 0.4 for all further visits. After urethral catheter removal, residual urine was less than 50ml for all patients. The maximal flow rate median value was 23ml/sec before surgery and 17.5ml/sec at one month, then 19ml/sec at three and six months. The change was significant one month post-surgery but not for the three- and six-month follow-up period. Overall, median pad use decreased significantly from two pads per day before surgery to one pad per day for all the visits thereafter. At one, three and six months the number of pad-free patients was, respectively, 60, 51 and 51%.

Continence rate of use of no or one pad per day was, respectively, 74, 82 and 83%. The SF-36 score of continence, measured on a scale ranging from 0 to 500, improved highly significantly ($p < 0.001$) from a median score of 117 before the TOMS was inserted to 350 at one-month, 338 at three-month and 308 at six-month follow-up. The ICIQ incontinence median score decreased highly significantly ($p < 0.001$) from 14 before the TOMS was inserted to 5 at one- and three-month follow-up and to 6 at six-month follow-up.

Conclusion

The new four-arm TOMS is an attractive, simple and safe sling for mild or moderate post-prostatectomy incontinence in non-radiated patients. Most of the patents are cured and have improved quality of life. ■

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