Incontinence after Prostatectomy – The Transobturator I-STOP™ Male Sling as a New Treatment Option

a report by
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A new minimally invasive sling technique has been developed for the management of post-prostatectomy incontinence as a simple and well-tolerated alternative to artificial sphincter, using the latest improvements in female transobturator sling with specific adaptation for males. Early results are encouraging and this technique seems to be a valuable alternative to the artificial sphincter in moderate incontinence and could also be proposed to patients with minor, but annoying, incontinence.

Stress urinary incontinence (SUI) following prostatectomy is a very distressing complication. The rate of persistent post-radical prostatectomy incontinence, despite active conservative measurements, varies widely at 2–65% depending on continence definition, method of assessment and surgical procedure. Prostatectomy is the curative surgery of a localised prostate cancer, particularly for men with a long life expectancy. The prevalence of prostatectomy has increased due to early detection by prostate-specific antigen of adenocarcinoma, which is the most common cancer in men. After prostatectomy for benign prostatic hyperplasia, incontinence is less common but still has devastating effects on the patient's quality of life.

The gold standard in severe cases is still the implantation of an artificial hydraulic urinary sphincter; however, the materials are expensive and may expose the patient to urethral erosion or infection, leading to explantation. In moderate incontinence, a variety of alternative minimally invasive techniques have been proposed, such as injection or sling. Endo-urethral bulking-agent injection may initially improve minimal incontinence, but the injections must be repeated in the majority of cases and the results often dramatically decrease with time.

These considerations have more recently led to developments in the field of sub-urethral male sling. Initial reports were compressive bulbo-urethral slings with silicone material and retropubic suspensions. These showed efficacy, but retropubic puncture may expose the patient to bladder perforation. Moreover, the tension of the sling was intentionally compressively adjusted using retrograde urethral pressure. An alternative procedure has been proposed using the bone-anchored male sling attached to the pubic bone, with the sling biomaterial being a large-surface silicone mesh. Although efficacy was reported in approximately 70% of cases, prolonged perineal pain was frequent and some patients experienced biomaterial infection leading to explantation.

The transobturator I-STOP™ male sling was developed to provide moderate compressive support to the bulbo-urethra via a well-tolerated biomaterial using a simple technique. Clinical experience of female transobturator I-STOP sling in routine practice has been the cornerstone to extending this material for male incontinence specificity and adapted to the male pelvic anatomy. The prosthetic implant is placed under the bulbo-urethra and passes through the obturator foramen as the sole lateral fixation.

Initial Experience

An anatomical cadaveric study was conducted to validate the transobturator route in males and to validate the point and direction of the puncture. A preliminary human implantation was then carried out in four cases with the same material as that used for women, but with a specific male transobturator puncture and a perineal incision. The results were encouraging, with three patients totally dry and one improved for incontinence. A pilot, prospective multicentre study of 50 patients with moderate post-prostatectomy incontinence has been in progress since June 2006.

Technique

Material

The I-STOP sling, developed by CL Médical, has the following characteristics:

- exclusively monofilament polypropylene mesh;
- macropores over 75 micrometres;
- no-string effect as the width (15mm) is

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maintained despite sustained traction;
- no shape memory;
- non-aggressive edges;
- low weight per area obtained by fine thread; and
- specific knit weave.

Delivery System

The sling is attached at each end to a clip. Two long, curved needles with special handles are supplied with the implantation kit.

Surgical Technique

Implantation was performed under general anaesthesia with patients placed in the dorsal lithotomy position. A 16-French urethral catheter was inserted at the beginning of the procedure and removed on day two.

A perineal sagital incision was made and the bulbocavernosus muscle exposed but left *in situ*. The dissection was then conducted laterally in the space between the urethra and each corpus cavernosa covered by ischicavernosal muscle. A short incision of the perineal fascia (i.e. perineal aponeurosis) affords access more deeply towards the obturator muscle just above the ischio-pubic ramus bone. This allows palpation of the inside landmark using the tip of the finger.

Outcome

Prospective multicentre studies have confirmed that this new technique is easy to perform. Results have been evaluated on validated questionnaires and pad tests. While the one-year outcome is still awaited, the preliminary results at three months in the operated-on patients have demonstrated either cure or incontinence improvement. Moreover, the patients did not suffer any perineal pain and no biomaterial infection or urinary retention was observed.

Lessons from clinical experience underline the fact that the male pelvic anatomy is different from the female and the transobturator technique must take into account male specificity. The direction of the puncture needle is deeper and in a narrow area to reach the right place close to the inferior pubic ramus through the obturator foramen. The perineal dissection beyond the fascia is also deeper than that for the female, but this step is quickly performed and with little or no bleeding. The biomaterial implanted has no silicone, with a surface close to the urethra large enough to support it with no string effect. The amount of biomaterial is limited in order to minimise the risk of prosthetic infection. The transobturator route is also a major step in avoiding the risk of retropubic bladder perforation or the risk of osteitis or pain from bone-anchor fixation.

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A puncture of the root of the thigh, 4cm from the median line and 4cm below the major adductor muscle, is performed. The specific needle is inserted to puncture the obturator foramen in order to reach the tip of the finger on the inside landmark. The tape is clipped to the needle tip and exteriorised inside-outwards to the thigh. After puncturing the opposite side, the sling is adjusted with a pressure on the bulbocavernosus muscle and a four-corner non-resorbable suture is carried out to avoid any sliding of the tape and to prevent any string effect. No retrograde pressure is performed in order to adjust the sling pressure, however, a visible curved depression is obtained on the muscle in order to afford only a slight compression. The wound is closed in two layers with an absorbable suture.

Pressure of the male sling is adjusted using only visual control, with no retrograde pressure. This approach is advocated as many anatomical and functional structures providing continence must be considered as well as standing position and SUI factors.

Another consideration is that of cost-effectiveness – the I-STOP male sling is far less expensive than an artificial sphincter or bone-anchor sling.

Conclusion

The preliminary results of the transobturator I-STOP male sling are sufficiently encouraging to consider it as a new treatment option of choice for moderate post-prostatectomy incontinence and also in patients with minor, but troubling, incontinence. ■