

TRANS-OBTURATOR MALE SLING TOMS FOR THE TREATMENT OF URINARY STRESS INCONTINENCE IN MEN.

Aims of study

Despite improvement in the surgical technique of radical prostatectomy, stress urinary incontinence (SUI) remains a problem that affects the quality of life of many patients. The prevalence of post-prostatectomy depends on the definition of incontinence. In order to minimize surgical morbidity and cost of the artificial sphincter, sling procedures were described with or without bone anchor. With the experience of the female trans-obturator polypropylene sling, a new trans-obturator male sling (TOMS) was developed, the first results with minimal one year experience are reported.

Material and methods

A prospective multicenter clinical study was conducted on male patients suffering from post prostatectomy incontinence and failure of physiotherapy. Patients with minor or moderate SUI were included with minimal 12 month follow-up. Exclusion criteria were pre or post-operative radiation, less than one year interval from surgery, bladder outlet obstruction, bladder overactivity or hypocompliance. Pre operative assessments included clinical study questionnaire, urodynamics (uretrocystometry, uroflowmetry, bladder residual), a pad test short form, ICIQ and SF36 questionnaire, Visual analogic pain scale (VAS). Post-operative evaluations were at 1, 6, 12, 18 and 24 months using the same evaluation except uretrocystomanometry. Per and post-operative hazards were recorded on a case report form. The sling was made of polypropylene macroporous non extensible, 1 cm large, connected at each end to a needle attachment device. Hemet or helicoidal needle was used according to surgeon preference. The surgical technique was done under spinal or general anaesthesia, a 16 F Foley urethral catheter was inserted then a median perineal incision exposed the angle between each corpus cavernosum and corpus spongiosum. The trans-obturator puncture was outside-inside similar to the female procedure. The sling was applied to the urethra then pulled firmly from each side until to have a visible mark on the corpus spongiosum. No retrograde pressure adjustment was realized. The urethral catheter was left for 1day. Before hospital discharge, a uroflowmetry, a residual, and a pelvic pain evaluation on VAS were obtained.

Results

A total of 14 patients, age 70.8 (57-87) years old underwent surgery. Mean follow-up was 18 (12-23) months. The surgery was easy to perform in all the cases. No per-operative complications were reported, no significant intra-operative bleeding (>200ml) occurred or nerve, bowel or vascular injury. One patient experienced temporary urinary retention, one a low stream, and residual was always less than 100 ml. Mean pad use modified from 2.4 to 0.9, and 50% of them used no pad. Pad test mean weigh decreased from 62g to 8 g. The SF36 score improved from a median of 126 (57-325) to 317 (92-500), the Mann-Whitney test was significant with $p < 0.001$. The ICI-Q score improved from 13 (6-16) to 7 (0-15). The pain mean value was 2.5 post-operatively, 0.9 at one month and 0.1 at one year.

Interpretation of results

Patients with minimal and moderate incontinence are demanding of improvement and even only one pad a day affects their quality of life. Many new minimal invasive techniques (injectable biomaterials, balloons, sling with bone screw attachment or with retropubic puncture) have been proposed for managing SUI in males but they had adverse side effects or poor results. The artificial sphincter remains the gold standard technique, but the cost and the erosion or infection rate limit the indication for severe incontinence. The transobturator sling has no screw fixation and minimal well tolerated polypropylene biomaterial, this may explain the good tolerance and minimal pain. This route is an alternative to retropubic puncture that limit the risk of bladder perforation. This short series demonstrate the feasibility, the good tolerance, and marked improvement in continence.

Concluding message

The trans-obturator male sling (TOMS) is a new attractive surgical procedure for moderate or minor post-prostatectomy SUI. The implanted biomaterial is non mechanical, easy to insert and well tolerated. Most of the patients are improved or continent with one year follow-up. In properly informed patients, this sling may afford an improvement in their quality of life.

Specify source of funding or grant	no funding or grant
Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	Yes
Specify Name of Public Registry, Registration Number	Haute autorité de Santé
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	CCPPRB Rouen France
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes