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ADJUSTABLE MALE SLING SUCCESSFULLY CAN BE **IMPLANTED** TRANSOBTURATOR APPROACH FOR TREATING POST-PROSTATECTOMY URINARY INCONTINENCE. SURGICAL TECHNIQUE AND EARLY RESULTS OF A MULTICENTER **TRIAL**

Synopsis of video

Male incontinence

<u>Aim</u>

To show the detailed technique used for implantation, the transobturator approach of the adjustable male Sling (ARGUS T™ -PROMEDON SA) and its early results.

Patients and Methods

37 patients with Urinary Incontinence (UI): 30 patients with post-radical prostatectomy urinary incontinence (PRP-UI), and 7 postadenomectomy, from 5 centers were included between November 2007 and August 2008. 2 of them also received radiotherapy for the treatment of prostate cancer. 6 of the 37 had undergone previous unsuccessful anti-incontinence treatment: Suprapubic Argus:1, Pro Act: 3, bulking agent: 2.

The mean age was 69 years (58-81). Till March 2009 the mean follow-up was 10 months (7-19) the patients underwent a complete urologic evaluation including a validated International Consultation on Incontinence Questionnaire (ICIQ - SF), (0-21). The 24-hour pad test classified the incontinence as severe: > 400gr or gravitational, moderate: 100-400g or mild: < 100gr; the Visual Analogue Scale (VAS): (0= not bothered - 10= severely bothered), Urethrocistoscopy, and Urodynamic test: filling, emptying, including the valsalve abdominal leak point pressure (ALPP) without urethral catheter, and the retrograde urethral pressure (RUP).

The results will be expressed globally as dry patients: without any pads (or one for daily protection). Improvement: 1 pad a day, and Failure: 2 or more pads daily or sling removal. The Surgical technique are exposed in detail in this video.

Results

The degree of incontinence of the 37 patients was: severe in 29, moderate in 7, and mild in 1. The ICIQ-SF changed from 18.81 (12-21) to 3 (0-21), the Pad test and the preoperative ALPP were 1182gr (100-2880) and 46.2 cm of water (4-92).

The VAS and RUP changed pre- to post-operatively from 8.9 to 2 and from 16.9 to 35.2 cm of water, respectively. Overall, the results the Dry, Improved and Failed were: 28 (75.7%), 5 (13.5%) and 4 (10.8%), respectively. 4 patients failed: 1 due to infection and removal of the Sling, 1 case with the sling "in situ" use 2 or more pads/day, and 2 because during the readjustment they did not reach a pressure higher than 20 cm of water.

5 patients needed to be readjusted: 1 deadjusment resulted improved and of the 4 adjusted 2 resulted dry and the other 2 failed.

Complications

- 2 patients infected in the immediate post-operative period (7 to 15 days)
- 1 patient with perineal pain, improved before 30 days with common analgesics.
- 2 patients had acute urinary retention, 1 patient improved after sling loosening,
- 1 (dry) patient continues with clean Intermittent Self-Catheterization 4 months before restarting with spontaneous voiding without residual urine and maintaining its dry condition.

In this short term follow up, the transobturator approach for ARGUS T have demonstrated that this adjustable male sling can be used with efficacy and safety (89% Dry + Improved) with an acceptable rate of complications.

Concluding message

The obvious advantages of harmlessness, easy to perform, and short learning curve makes the transobturator approach very provocative. Long term follow- up is necessary to confirm these encouraging early results.

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Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
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Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes