94

Hind A[1], Pini G[2], Viola D[1], Martino F[1], Rossi R[1], Leoni S[1]
1. *Arcispedale Santa Maria Nuova Reggio Emilia,* ***2.*** *University of Modena and Reggio Emilia*

URODYNAMIC AND CLINICAL RESULTS OF AN ADJUSTABLE SLING FOR MALE URINARY INCONTINENCE - 32 MONTHS FOLLOW UP - ARGUS® IS EFFECTIVE ALSO IN SEVERE CASES.

Hypothesis / aims of study
Recently there have been developed some new bulbourethral slings that lack adjustability, which any way, seem to result superior to the periurethral bulking agents and limiting the indication of the artificial urinary sphincter with lower complization rate. We present our experience with an adjustable bulbourethral sling in 48 incontinent patients, reporting results, complications and postoperative urodynamic evaluation.
Study design, materials and methods
Between 07/2006 and 03/2009 (32 months) 48 men, with urodynamically confirmed stress incontinence, underwent to the male adjustable perineal sling ARGUS®. Mean age 68.4 years (55-76 years).

Patients were evaluated pre-operatively: 24-hr pad test, ICIQ-SF, cystoscopy, and urodynamics; post-operatively: 24-hr pad test, ICIQ-SF and the post-operative Patient Global Impression of Improvement (PGI-I) score, uroflowmetry and post voiding residual volume (at 1st, 3rd ,6th ,12th and 24th) and full urodynamic study (12th and 24th month).

Urinary incontinence derived from: TURP (2), simple open prostatectomy (3), retropubic (31) and laparoscopic (8) radical prostatectomy, bladder neck incision for sclerosis post radical prostatectomy (4). 15 (31.2%) received adjuvant external beam radiotherapy. 14 (29.2%) underwent to precedent others anti-incontinence procedures and 22 (45.8%) to perineal rehabilitation with poor results. 13 patients had “mild” incontinence (24-hr pad weight ≤150 g); 21 patients “moderate” incontinence (from 150 up to 400 g) and 14 “totally” incontinent (continuous leakage; >400 g). 3 patients with bladder neck stricture and 2 with bulbar urethral stenosis underwent endoscopic treatment 6 months before implants. Minimal time elapsed from original surgery was 12 months.

Description of the sling: The sling consists of a radiopaque pad made of silicon foam, joined to two silicone columns formed by multiple cones that allow for the possibility of post surgery readjustment. The sling has two radiopaque silicon rings, which are placed over the rectus fascia in the sling columns to prevent them from moving downwards and to allow readjustment. The kit contains 35 mm diameter TVT like needles that pass through the perineum to the suprapubic region.

Note of Technique: Spinal anesthesia, Foley catheter and lithotomy position. Two 3-cm suprapubic incisions are performed 2-cm on both sides of the midline up to the aponeurosis of rectus muscle. A 5-cm median perineal incision is made to expose the bulbospongiosus muscle; blunt dissection is used to identify the spaces between the corpora cavernosa laterally and the corpus spongiosum medially. Sparing bulbocavernous muscle, the perineal aponeurosis must be reached. Where the needles are introduced on both sides, they should be moved horizontally until deeply perforating perineal aponeurosis; afterwards moved vertically through the retropubic space towards the pre opened suprapubic incisions. Endoscopic control is performed in order to check the integrity of bladder and urethra. Transference of the sling columns into the abdomen, the “washers” will then be used to hold the end of the columns up to the aponeurosis. The adjustment of the washers and pad tightening will be controlled by cystoscopy and water column with a 35-45 cm H20 retrograde leak point pressure. The catheter is removed 24-48 hours after surgery.

Results
Mean follow up 18 months (range 1-32). Mean 24-hr pad test reductions –320 g (from –95 to –500). Mean free Q max is 14 ml/sec (10-18ml/sec); mean Q max (P/F study) is 11 ml/sec (9-14ml/sec); mean Pdet at open was 48 CmH2O (36-67 CmH20), mean Pdet Max Flow was: 67 CmH2O (43-83 CmH2O); mean post-residual volume was 25 ml (0-65 ml).

Nor ex novo detrusor hyperactivity on urodynamic charts neither ex novo storage symptoms was complaint. 11 (22.9%) needed sling adjustment in local anesthesia (7 tightening, 4 loosening), mean time adjustment 1,9 (1-3); mean days elapsed from Argus® insertion to modulation 15 (7-65 days). Mean ICIQ-SF score improvement was -15,4 (from -9 to -20); median postoperative PGI-I score was 1,3 (1-4).

There were neither infection nor erosion nor rejection. Early postoperative perineal discomfort was presented in 18 patients (37.5%) and disappeared within two months. One patients (2.1%) complained severe pain in the left lower art lasted for 2 months. We removed sling in 1 patients (2.1%): in suspicion of rectal wall perforation, not confirmed by rectoscopy and cystography (seminal vesical direction). There was an indication to remove another sling because of persistent obstruction but preoperative cystoscopy revealed the obstruction was due to a recurrence of bladder neck stenosis.

Some flexible cystoscopy and TURB performed respectivelly in 2 and 1 patient (follow up and resection of non muscle invasive bladder cancer) have not been altered the complete continence they achieved before.

Interpretation of results
Dry patients (not using any more pads) are 44 (91.6%); 28 of them (58,3%) loose some drops of urine (occasionally at sudden increase of abdominal pressure). 2 patient (4.2%) have been partially improved (24 hr pad test: 50% improvement).
Urodinamyc parameters at 12th and 24th month are overlapped.

Concluding message
Waiting for long term follow-up and randomized trials our data shows that the new adjustable sling Argus® is a promising minimal invasive procedure for the treatment of male stress incontinence. Our results clearly demonstrate that heavy incontinence responds as well as moderate one. It's effective also in patients complicated by other previous prosthesis failure and by radiation therapy. It

offers ready results, as soon as catheter removal, low complication rate, easy adjustment under local anesthesia, stable results after 32 months, physiologic voiding and sparing of bulbocavernous muscles. The best results, in term of QoL, seem to be offered in case of severe incontinence.

Specify source of funding or grant	**We have not had any source of funding or grants.**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require eithics committee approval because	**Because is not an experimantal study**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**