EFFICACY AND SAFETY OF TRANSVAGINAL MESH REPAIR OF SEVERE PELVIC ORGAN PROLAPSE WITH THE PERIGEE-APOGEE SYSTEM: MID TERM DATA

Hind A(1), Viola D(1), Pini G(2), Martino F(1), Rossi R(1), Martinelli A(1), Manoni L(1), Gualerzi C(3), Leoni S(1).

Abstract accettato al 39° Annual Meeting ICS 2009 (International Continence Society)
San Francisco, CA, USA - Ottobre 2009

Hypothesis / aims of study
To determine the efficacy and safety of transvaginal mesh repair of pelvic organ prolapse (POP) using the Perigeè-Apogeè system with at least 18 months mean followup analysis.

Study design, materials and methods
A prospective and observational evaluation of 65 women (pts) with symptomatic POP (grade III or IV according to the Halfway System Baden Walker classification), operated on between January 2006 and December 2008, was made: 19 (29.2%) had anterior POP, 13 (20%) had posterior POP, 15 (23%) anterior and posterior POP, 17 (26.1%) had total POP (9 with uterine prolapse and 8 with vault prolapse). POP repair has been performed with the use of the tension free transvaginal mesh kits Perigeè-Apogeè (American Medical System, AMS), made of a polypropylene macroporous monofilament mesh: Perigeè has been used to repair anterior POP, apogeè to repair posterior and/or superior POP, whereas total POP has been repaired using both. Preoperative evaluation included history, pelvic examination, urine culture, abdominal ultrasound with postvoid residual volume and urodynamic study.

30 (46.1%) out of the 65 pts studied had urodynamic evidence of latent stress urinary incontinence (SUI) and underwent a concomitant TOT sling procedure, either Monarcâ or the adjustable one, Safyre â , while 4 (44.4%) of the 9 pts with uterine prolapse underwent concomitant vaginal colpohysterectomy. Follow-up visits were scheduled at 1 and 4 weeks, 3, 6, 12 and 24 months. The primary outcomes of our study were to assess the rate of POP recurrence, defined as de novo POP ≥ grade 1, subjective failure rate, defined as patient’s complaint of palpable prolapse, vaginal pressure or heaviness, and the secondary one was to determine the rate of complications.

Results
Mean follow-up was 18 months (range 3-36), mean age was 68 (range 50-85).

No intraoperative complications were recorded. In 4 pts (6.1%) a vaginal erosion occurred: in 1 the erosion was such that the removal of the mesh was done (anterior erosion in a 84 years old lady operated on for cystorectocele); conservative therapy was enough in the remaining cases: topic estrogentic therapy in 2 pts and partial removal of the mesh in 1 pt (anterior erosion; at 20 months followup no recurrence). Transient dyspareunia and pelvic pain were seen in 6 pts (9.2%) and in 5 pts (7.7%) respectively: both resolved in 3 months.

No cases of infection were recorded. 37.1% (13/35) of the pts not treated with a TOT developed a stress urinary incontinence and were subsequently treated with a transobturator sling.
Adjustable bulbourethral sling ARGUS® is effective also in severe male incontinence: An alternative to artificial sphincter.

MP56
1Dept. of Urology, ASMN Reggio Emilia, ITALY, 2Dept. of Urology, University of Modena & Reggio Emilia, ITALY

Introduction & Objectives
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 complication rate.

We present our experience with an adjustable bulbourethral sling in 48 incontinent patient with 32 months follow up reporting results, complications and postoperative urodynamics evaluation.

Methods
Between 07/2006 and 03/2009 (32 months) 48 man, with urodynamic confirmed stress urinary incontinence (SUI), underwent to the male adjustable perineal sling ARGUS® (PROMEDON, Cordoba, Argentina).

Description of the sling:
- GLH: retropubic polypropylene barbed mesh, joined to two silicone columns formed by multiple courses that allow post surgery readjustment (Fig 1).
- Two retropubic silicon rings keep columns over the rectus fascia preventing moving downwards and to allow readjustment.
- 3.5 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 2 cm on both sides of the midline up to the approximation of the rectus muscles.
- 1 cm median perineal incision to expose the bulbospongiosus muscle, perineal aponeurosis and corpora cavernosa. Fig 5. The needle is introduced and moved horizontally with deep grasping the fascia, all the way to the more caudal urethra, moved vertically through the retro pubic space towards the pro-epipubic suprapubic incision.
- Endoscopy 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 approximatio. (Fig 6)
- The adjustment of the washers and pad tightening will be controlled by cystoscopy and water column with a 3-45 cm H2O, 250 cc adequate leak point pressure. (Fig 6-4)
- The catheter is removed 24-48 hours after surgery.

Clinical Evaluation

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<th>Clinical Evaluation</th>
<th>PRE-OBTERRATE</th>
<th>POST-OBTERRATE</th>
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<tr>
<td>Pad Test 24h (g)</td>
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<td>ICIQ-SF Questionnaire*</td>
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<td>Urodynamics</td>
<td>PGI-I score*</td>
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<td>Uroflowmetry</td>
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<td>PVR (1.7-5.6,12.2-24)</td>
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<td>Full Urodynamics Study</td>
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SUI Etiology
- TURP
- Prostatectomy Simple Open
- Radical Retropubic
- Radical Laspicroscopic
- Bladder Neck Incision
- Bn sclerosis post RP

Adjustment
- Mean time (days) 1,9 (1-3)
- Time elapsed (days) 15 (7-35)
- Thickening (mm) 7
- Loosening (mm) 4
- QoL
- ICIQ-SF -15,4 (-9,20)
- PGI-I score 1,75 (1-4)

Conclusions
Waiting for long term follow-up and randomized trials our data shows that the new adjustable sling Argus® offers:
- Ready results, as soon as catheter removal.
- Physiologic voiding and sparing of bulbocavernous muscles
- Low complication rate.
- Easy adjustment under local anesthesia.
- Heavy incontinence responds as well as moderate one.
- Effective also in patients complicated by other previous prosthesis failure and by radiation therapy.
- Stable results after 32 months.
- Best results, in term of QoL, are offered in case of severe incontinence.
Materials and methods: Between July 2006 and April 2010 65 pts, mean age 69 years (55-76), underwent to the *adjustable bulbourethral “Argus”®* (Promedon, Cordoba, Argentina) sling operation because of stress urinary incontinence, due to prostatic surgery: 4 TURP, 5 prostatic adenomectomies, 56 radical retropubic prostatectomies, 44 open and 12 laparoscopic. Of the 56 pts operated on for prostatic cancer, 20 underwent adjuvant radiotherapy and 15 tried other anti-incontinence procedures, unsuccessfully. Patients were evaluated pre-operatively with 24-hr pad test, urodynamics, cystoscopy and ICIQ-SF; post-operatively with 24-hr pad test, uroflowmetry and post voiding residual volume (at 1st, 3rd, 6th, 12th and 24th month), full urodynamic study (at 12th and 24th month), ICIQ-SF and Patient Global Impression of Improvement (PGI-I) score. Urinary incontinence was mild (pad test ≤150g) in 19 pts, moderate (pad test 150g≥400 g) in 25 pts and severe (pad test >400 g) in 21 pts. Mean follow-up was 30 months (1-43). Results: 57 pts (88%) were continent (0-1 pad die), 16 after sling modulation under local or locoregional anesthesia; 6 pts (9%) reported a ≥50% improvement and in 2 pts (3%) the prostheses had to be removed. Mean 24-hr pad test reductions was 320 g (95–500), without clinical or ultrasound signs of obstruction, with a mean post-residual volume of 25 ml (0-65 ml). Nonetheless, we had a mild urodynamic obstruction, with a mean free Q max of 14 ml/sec (10-18ml/sec), mean Q max (P/F study) of 11 ml/sec (9-14ml/sec) with a mean Pdet at Qmax of 48 cmH2O (36-67 cmH2O). We had not cases of de novo detrusor overactivity and/or filling LUTS, with a considerable improvement of the pts quality of life: ICIQ-SF -15.4(-9, -20), PGI-score 1.75(1-4).

Complications rate was low: 1 case of erosion of the sling; 6 cases of bladder perforation, promptly recognized intraoperatively and without any consequences, apart from a longer catheterization period. Early postoperative perineal discomfort was present in 20 pts (30%) and disappeared within one month. No infections were reported.

Concluding message: In our opinion bulbourethral “Argus”® sling is a reliable and effective therapeutic option to treat male iatrogenic urinary incontinence; keeping its good results over a 4 years period let us forecast its stability also on the long run.
L’Urologia ASMN rappresenta attualmente un Centro di riferimento Nazionale per l’impianto delle Sling Argus nell’incontinenza urinaria maschile

Workshop periodici per la formazione (ogni 45 gg circa) degli Specialisti
Studio internazionale multicentrico di fase IV, randomizzato open label

“Terapia combinata nella ipertrofia prostatica benigna verso terapia step-up con alfa-litico”

In via di presentazione al Comitato Etico ASMN di Reggio Emilia – Studio sponsorizzato GSK
Referente Dott. Sebastiano Spatafora
### Protocolli Oncologia ad interesse Urologico

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<th>Responsabile</th>
<th>pazienti</th>
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<td>49</td>
<td>Dr. Rondini</td>
<td>Sunitinib</td>
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**GIP**
Studi multicentrici e di fase II in cui pazienti affetti da carcinomma renale avanzato ricevono Torisel come trattamento di II linea dopo terapia con chechine, inibitori di tiroxina chimici e inibitori dell'angioossidasi.

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<th>Renal</th>
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<td>9</td>
<td>Dr. Rondini</td>
<td>Torisel</td>
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**QNC 7000.D01**
Studi multicentrici di fase III in cui pazienti affetti da carcinomma renale invasivo invasivo a distanza non chiuso ricevono sunitinib come trattamento di I linea.

**Prostata**

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**ALGAFTA**
A double-blind, randomised, multiple dose, Phase II, multicentre study of Alphaden™ in the treatment of patients with symptomatic hormone refractory prostate cancer with skeletal metastases.

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<td>21</td>
<td>Dr. Salvo</td>
<td>Alphaden</td>
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**PORPC62**
Sospendere dell'androgeno depravazione e mantenere e chque aero intermittente in continuo nel trattamento del paziente con carcinoma prostatico resistente alla castrazione chimica.

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<td>Dr. Rondini</td>
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ADJUSTABLE SLING FOR MALE URINARY INCONTINENCE – 3 YEARS FOLLOW UP - ARGUS®

vene 26 marzo – ore 15.00 – 3ª sessione: incontinenza

EFFETTI DELLA LEGGE 40/2004 SUI RISULTATI DELLE TECNICHE DI PROCREAZIONE MEDICAMENTOSA NELLE INFERTILITÀ DA GRAVE FATTORE MASCHILE: ESPERIENZA DI UN CENTRO DI RIFERIMENTO DI TERZO LIVELLO
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Sebastiano Spatafora, Matteo Spagni, Roberto Rossi, Ferdinando Martino, Sergio Leoni