Attività di Ricerca Urologia 2009-2010

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

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Abstract accettato al 39° Annual Meeting ICS 2009 (Int ernational 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 Perigeeâ -Apogeeâ 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 Perigeeâ-Apogeeâ (American Medical System, AMS), made of a polypropylene macroporous monofilament mesh: Perigee has been used to repair anterior POP, apogee 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).
Objective failure rate was 1.6% (1/65) , subjective failure rate was 3.1% (2/65).
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 estrogenic 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

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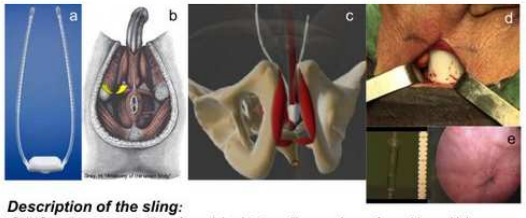
Introduction & Objectives

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 urodynamic evaluation.

Methods

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



Description of the sling:

•SLING: radiopaque pad silicon foam, joined to two silicone columns formed by multiple cones that allow post surgery readjustment **(Fig a)**

•Two radiopaque silicon rings keep columns over the rectus fascia preventing moving downwards and to allow readjustment.

•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 2-cm on both sides of the midline up to the aponeurosis of rectus muscle.

•5-cm median perineal incision to expose the bulbospongiosus muscle, perineal aponeurosis and corpora cavernosa. **(Fig b)** The needle is intruduced and 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. **(Fig c)**

•The adjustment of the washers and pad tightening will be controlled by cystoscope and water column with a 35-45 cmH_20 retrograde leak point pressure. **(Fig d-e)**

•The catheter is removed 24-48 hours after surgery.

Clinical Evaluation

PRE-OPERATIVE	POST-OPERATIVE
Pad Test 24h (g)	Pad Test 24h (g)
ICIQ-SF Questionaire*	ICIQ-SF Questionaire*
Urethrocystoscopy	PGI-I score#
Urodynamics	Uroflowmetry
	PVR (1°,3°,6°,12°,24°)
	Full Urodynamic Study

*ICIQ-SF: International Consultation on Incontinence - Short Form (score 0-21)
#PGI-I score: Patient Global Impression of Improvement (Score 1-7)

SUI Etiology

TURP		2
Prostatectomy	Simple Open	3
	Radical Retropubic	31
	Radical Laparoscopic	8
Bladder Neck Incision (BN sclerosis post RP)		4
Adjuvant EBRT		14 (29.2%)
Other prosthesis		14 (29.2%)
Kegel Exercises		22 (45.8%)

SUI Classification

≤150g	MILD	13pz
150≥ >400g	MODERATE	21pz
≥400g	SEVERE	14pz

Results

Outcomes

Follow up (months)	18 (1-32)
Success	**44 (91.6%)**
	16 (33.3%) **Totally Dry**
	28 (58.3%) **Some drops @ increase of Abd Press**
	11 (22.9%) **After Adjustment**
Partially Improved	**2 (4.2%)** up to 50% @ Pad Test24h
Failed	**2 (4.2%)** Removed

Adjustment

Mean time (#)	1,9 (1-3)
Time elapsed (day)	15 (7-65)
Thightening (pt)	7
Loosening (pt)	4

Complication

Infection	0
Erosion	0
Rejection	0
Perineal disconfort	18 (37,5%)

QoL

ICIQ-SF	-15,4 (-9,-20)
PGI-I score	1,75 (1-4)

UDS Changes

Pad test 24h (g)	-320 (-95;-500)
Free Qmax (ml/sec)	14 (10-18)
Qmax P/F Study (ml/sec)	11 (9-14)
PDet at Open (cmH_2O)	48 (36-67)
PDet Max Flow (cmH_2O)	67 (43-83)
PVR (ml)	25 (0-64)
Ex novo OAB	0
Ex novo Storage sympt	0

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.

AUA Annual Meeting 25-30 april 2009 chicago, illinois usa

C81 Adjustable bulbourethral "argus" sling withstands the proof of time and numbers: results at 43 months from the Italian reference centre

D. Viola, A. Hind, R. Rossi Cesolari, F. Martino, L. Manoni, G. Pini, S. Spatafora, A. Mora, M. Spagni, E. Casolari, A. Magnanini, S. Leoni (Reggio Emilia)

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 lable

“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

RENE			Responsabile		pazienti
18	**GIR1** Sunitinib precedente e successivo o solo successivo a Nefrectomia Citoriduttiva, Studio di fase II che coinvolge pazienti affetti da carcinoma renale metastatico.	**I linea**	Dr. Rondini	Sunitinib	1
19	**GIR2** Studio multicentrico di fase II in cui pazienti affetti da carcinoma renale avanzato ricevono Torisel come trattamento di II linea dopo terapia con citochine, inibitori di tirosino chinasi e inibitori dell'angiogenesi.	**II linea**	Dr. Rondini	Tensirolimus	3
20	**ONC 2008-004** Studio multicentrico di fase II in aperto, in cui i pazienti affetti da carcinoma renale avanzato/metastatico a cellule non chiare ricevono sunitinib come trattamento di I linea.	**I linea**	Dr. Rondini	Sunitinib	nuovo
PROSTATA					
21	**ALGETA - ALPHARADIN** A double blind, randomised, multiple dose, Phase III, multicentre study of Alpharadin™ in the treatment of patients with symptomatic hormone refractory prostate cancer with skeletal metastases	**II linea**	Gestito dalla medicina nucleare Dr.ssa Salvo	Alpharadin per il trattamento di metastasi ossee	3
22	**PON-PC-02** Sospensione dell'androgeno deprivazione vs mantenimento e chemioterapia intermittente vs continua nel trattamento del paziente con carcinoma prostatico resistente alla castrazione chimica.	**I linea**	Dr. Rondini	Farmaci a carico dell'ASMN	0

PRESENTAZIONI

59° CONVEGNO SUNI

Presidenti del Convegno
Giorgio Carmignani
Alchiede Simonato

ADJUSTABLE SLING FOR MALE URINARY INCONTINENCE – 3 YEARS FOLLOW UP - ARGUS®

A. Hind, G. Pini, D. Viola, M. Spagni, F. Martino, L. Manoni, R. Rossi, S. Leoni

venerdì 26 marzo - ore 15.00 3ª sessione: incontinenza

GENOVA 25-27 MARZO 2010

83° CONGRESSO NAZIONALE Società Italiana di Urologia

PRESIDENTE FRANCESCO ROCCO

MILANO 17 - 20 ottobre 2010 MILANOFIORI

P16 EFFETTI DELLA LEGGE 40/2004 SUI RISULTATI DELLE TECNICHE DI PROCREAZIONE MEDICALMENTE ASSISTITA NELLE INFERTILITÀ DA GRAVE FATTORE MASCHILE: ESPERIENZA DI UN CENTRO DI RIFERIMENTO DI TERZO LIVELLO

D. Viola, F. Martino, A. Hind, R. Rossi Cesolari, L. Manoni, A. Magnanini, S. Spatafora, M. Spagni, E. Casolari, A. Mora, S. Leoni, G. B. La Sala (Reggio Emilia)

82° Congresso Nazionale
Società Italiana di Urologia

V21 SLING BULBOURETRALE MODIFICABILE ARGUS NELL'INCONTINENZA URINARIA MASCHILE: DESCRIZIONE DELLA TECNICA CHIRURGICA IN 32 MESI DI ESPERIENZA
G. Pini, A. Hind, D. Viola, F. Martino, R. Rossi, L. Manoni, A. Martinelli, S. Leoni (Reggio Emilia)

P174 ILEOCISTOPLASTICA DI AMPLIAMENTO BIVALVE: TECNICA A CIMIERO TROIANO
S. Leoni, G. Pini, R. Rossi, A. Hind, A. Mora, F. Martino, M. Spagni, L. Manoni (Reggio Emilia)

P158 EFFICACIA E TOLLERABILITÀ A MEDIO TERMINE DELLA CORREZIONE TRANSVAGINALE DEL PROLASSO DEGLI ORGANI PELVICI CON PROTESI DI POLIPROPILENE TENSION-FREE: NOSTRA ESPERIENZA
A. Hind, D. Viola, G. Pini, A. Martinelli, F. Martino, R. Rossi, S. Leoni, C. Gualerzi (Reggio Emilia)

P161 SACRAL HITCH - PESSIA VESCICALE AL PROMONTORIO SACRALE - NUOVA ED EFFICACE TECNICA NEL REIMPIANTO URETERALE
S. Leoni, G. Pini, A. Hind, R. Rossi, D. Viola, F. Martino, L. Manoni, A. Martinelli (Reggio Emilia)

C153 EFFETTI DELLA LEGGE 40/2004 SULLE TECNICHE DI INSEMINAZIONE ARTIFICIALE NELLE COPPIE CON FATTORE MASCHILE DI STERILITÀ
F. Martino, D. Viola, G. Pini, A. Hind, S. Leoni, I. Rondini, A. Nicoli, F. Capodanno, G.B. La Sala (Reggio Emilia)

P107 SLING BULBOURETRALE MODIFICABILE NELL'INCONTINENZA URINARIA MASCHILE - ARGUS SYSTEM - RISULTATI CLINICI ED URODINAMICI CON FOLLOW-UP A 32 MESI
A. Hind, G. Pini, R. Rossi, D. Viola, F. Martino, A. Martinelli, S. Leoni (Reggio Emilia)

VIDEO

XVII CONGRESSO NAZIONALE

AURO.IT
ASSOCIAZIONE UROLOGI ITALIANI

22-25 SETTEMBRE 2010

03 INCISIONE DI URETEROCELE IN PAZIENTE ADULTO PER VIA COMBINATA, PERCUTANEA E TRANSURETRALE: TECNICA E RISULTATI ANATOMICI
Sebastiano Spatafora , S. Leoni, M. Spagni, D. Viola, A. Mora
(U.o. Urologia, Azienda Ospedaliera S. Maria Nuova)

POSTER

C.L.U. Club della Litiasi Urinaria

3° CONGRESSO NAZIONALE
Club Litiasi Urinaria

NAPOLI, 2-4 aprile 2009
Hotel Excelsior

TRATTAMENTO PERCUTANEO IN POSIZIONE SUPINA DI STENOSI DI ANASTOMOSI URETEROPIELICA SINISTRO-DESTRA
Sebastiano Spatafora, Matteo Spagni, Roberto Rossi, Ferdinando Martino, Sergio Leoni