Treatment of cystocele by trans-obturator tension free preconfigured polypropilene mesh (Prolift A®)

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INTRODUCTION AND AIM OF THE STUDY

Aim of the work is to evaluate the effectiveness and safety of the correction of cystocele by anterior vaginal wall tension free suspension with polypropylene mesh.

MATERIALS AND METHODS

From November 2005 to November 2007 18 selected women affected by symptomatic anterior vaginal prolapse underwent correction of the defect by suspension of bladder with a four arm preconfigured tension free hammock suspended by a transobturator approach (Prolift A ®).

The clinical evaluation included anatomical examination, urodynamic study and Valsalva **LPP** with manual reduction of cystocele, Qtip test, HWS graduation of prolapse. The control was made 2 and 6 months after surgery. Patients' mean age was 68 years (59-71), all in menopause, none with hysterectomy, and none with rectocele or hysterocele. Six patients were affected by obstructive dysuria confirmed by urodynamics.

RESULTS

The operative mean time was 42 min and the mean postoperative hospital stay 2,3 days. No intraoperative complications were reported.

After surgery complete resolution of prolapse has been reported at 2 and 6 months. No *de novo* bladder overactivity or *de novo* obstruction occurred. The bladder obstruction was removed in the 6 obstructed patients.

- Mean operating time 42 min (range 30-75)
- Mean post operative hospital stay 2,3 days (range 1-5)
- No OAB *de novo*
- Obstruction removed in 6 obstructed patients
- 1 patient with *de novo* stress incontinence
- 1 patient with hysterocele

We observed 1 occurrence of hysterocele and 1 *de novo* stress urinary incontinence (SUI) subsequently corrected with suburethral tension free polypropylene mesh. One retrovesical haematoma was reabsorbed spontaneously within 30 days. No erosion of the vaginal wall or the bladder has been observed.

	Preop	Postop	
Qtip	42°	38°	
Qmax	14,6 ml/sec (8-22)	22,6 ml/sec (18-29)	P: 0.0001

DISCUSSION

Despite our small series, the Prolift A technique seems to be reliable and safe. Furthermore, it allows a solution of anterior prolapse with a short hospital stay.We did not treat urethral mobility in the same session delaying it till the stabilization of results and if SUI were present. In this case, the approach with TVT secure® seemed the most appropriate choice since this method does not involve the obturator foramen already "occupied" by the mesh.

CONCLUSION

Prolift A repair seems to be a safe technique to correct pelvic organ prolapse. Anatomical and functional results must be assessed with a long-term follow-up to confirm the effectiveness and safety of the procedure.

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Composite Tension-free sling (Uromesh 2): long term results of minimally invasive treatment in moderate and severe anterior vaginal wall prolapse.

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INTRODUCTION AND AIM OF THE STUDY

Current minimally invasive surgical strategies for the therapy of anterior vaginal wall prolapse with cystocele associated with urethral hypermobility suggest that concomitant mid urethral and bladder neck support is needed after having performed the anterior bladder plication. While the placement of a synthetic tension-free sling posteriorly to the bladder appears to be an excellent procedure to effectively treat moderate to severe anterior vaginal wall prolapses, the clinical long-term tolerability of the slings has yet to be assessed. Thus, a retrospective review was performed on the clinical tolerability and efficacy of a composite tension-free sling, comprised of two non-reabsorbable polypropylene lateral sections joined by a central suture which reabsorbs after 90 days or after completion of tissue fibroblastic reaction, thus securing the non-reabsorbable portions to the connective tissue.

MATERIALS AND METHODS

Diagnosis, methods, definitions and measure units are in conformity with the standards established by the International Continence Society. Thanks to its dorsally ellipsoid shape, the polypropylene tension-free sling used (Uromesh 2) is easily lodged in the vescical-vaginal space after bladder plication, with the reabsorbable central portion resting in the midline, in the mid-urethral region anteriorly and behind the vescical neck and the bladder, posteriorly. All patients received locoregional spinal anesthesia. A total of 66 patients presenting with anterior vaginal wall prolapse as per Baden Walker were treated via vaginal approach by anterior bladder plication followed by bilateral transobturator placement of the sling via bilateral transobturator access, secured by inside-outside suture and viceversa. Fifty-four patients pre-operatively presented with a grade 2 anterior vaginal wall prolapse associated with type II urinary incontinence (81.8%) documented by Qtip test showing an angle > 40 degrees and by McGuire's test. Twelve patients with grade 3

anterior vaginal wall prolapse suffered from irritative symptomatology of the lower urinary tract with clinical presentation of recurrent urinary infections in absence of stress urinary incontinence (18.2%). During the procedure, cystocele repair made evident a previously latent urinary incontinence ascribable to urethral hypermobility (occult incontinence) in 3 patients. Optimal sling tension was established during the procedure by performing Valsalva's maneuver with a full bladder, taking care to obtain urethra-vescical support which was minimal albeit appropriate to obtain an almost complete urinary continence. The patients were assessed both pre- and post-operatively by means of quality of life questionnaires and by introital ultrasound imaging.

RESULTS

Sixty-three patients enjoyed a fully successful outcome (95.5%) whereas an improvement was observed for the three remaining patients (4.5%). The maximum pre-operative urinary flow was 22 ml/sec (± 8ml/sec), while post-surgery flow decreased to 12 ml/sec (± 2 ml/sec) ($p<0.05$). The average post-operative hospital stay was 4 days. Complications were classified as peri-operative, and early or late post-operative events. No major complications were observed. Four patients developed post-operative urinary retention, which was resolved maintaining an in-dwelling catheter for 7 days in one case (1.5%) or by giving Mestinon in three cases (4.5%) until the central portion of the sling was reabsorbed and spontaneous clinical resolution of urinary retention was achieved. Cutaneous infection to the labial region was observed in 3 patients (4.5%) although all cases resolved after 6 days of parenteral broad spectrum antibiotics. One patient suffering from thrombocytopenia developed a bilateral bruise in the thigh (1.5%) which however was asymptomatic and resolved spontaneously after 15 days. No patient experienced recurrence either of cystocele or urinary incontinence. The average follow-up was 42 months. No urethral or vaginal erosions, *de novo* detrusor instability and late urinary obstructions were observed. Questionnaires rating quality of life showed that 63 patients (95.4%) enjoyed a completely satisfactory return to their social relation activities.

DISCUSSION

This case series showed that efficacy of the composite polypropylene, reabsorbable central portion sling is similar to that achieved by conventional surgery in the surgical treatment of cystoceles associated with urethral hypermobility. Subjective and objective urinary incontinence were resolved attaining **success** rates comparable to those described for retropubic surgery. The Uromesh 2 sling placed via bilateral transobturator approach was not associated with any major complications. All cases of early post-

operative complications were treated conservatively until they resolved spontaneously or until complete reabsorption of the central portion of the sling. No late complications occurred, and in particular there was no evidence of the *de novo* detrusor instability which in literature is associated with Burch colposuspension.

CONCLUSION

This 4-year follow-up did not show any case of recurrence either of cystoceles or of stress urinary incontinence, whereas clinical recurrences of urinary incontinence are described in literature to affect 30% of patients undergoing Burch colposuspension within 2 years from surgery. The Uromesh 2 sling, successfully placed via transobturator approach, has proven to be effective both clinically and in terms of health care costs. Finally, the transobturator technique was shown to be easily reproducible and to be truly minimally invasive, in terms of average length of hospital stay and post-operative morbidity.

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MANAGEMENT OF PERIURETHRAL GRANULOMA FOLLOWING INJECTION WITH DEXTRANOMER/HYALURONIC ACID COPOLYMER FOR STRESS URINARY INCONTINENCE

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INTRODUCTION AND AIM OF THE STUDY

The evidence-based, peer-reviewed literature provides support for several well-established surgical interventions for the management of female SUI (FSUI). However, the popularity of minimally invasive means of treating FSUI has increased over the last 50 years, especially with the development of new materials for urethral injection, aiming at augmenting tissue bulk around the sphincter, thus increasing bladder outlet resistance. This procedure provides a simpler therapeutic approach for FSUI, particularly for women in whom surgery has failed and who are unsuitable for major operations. Among the investigated materials, dextranomer/hyaluronic acid (Dx/HA) copolymer is nonimmunogenic, nonmigratory, nonmutagenic, and nonallergenic. It is currently being used for the treatment of either VUR or SUI. Although rarely, its use may expose to a risk of granuloma developing locally. We report the management of 4 cases of periurethral granuloma secondary to Dx/HA copolymer injection for the treatment of FSUI.

MATERIALS AND METHODS

The clinical files of patients complaining of periurethral granuloma secondary to Dx/HA copolymer injection have been revised.

RESULTS

Case 1. On December 2002 a 71-year old woman attended our Department complaining of mixed UI (MUI). Her surgical history was positive for isteroannessectomy and Burch

colposuspension. Urodynamics showed an idiopathic detrusor overactivity (IDO) and an urethral sphincter deficiency (USD) with urodynamic SUI (USI). On March 2003 she underwent a periurethral injection of Dx/HA copolymer. She presented with a right periurethral mass, confirmed by perineal ultrasound. Surgical debridement of the granuloma using a cold scalpel was performed. SUI were resolved with a transobturator sling (TVT-O) implant.

Case 2. On May 2003 a 54-year old lady underwent a periurethral injection of Dx/HA copolymer for FSUI. She presented with MUI and perineal pain. Urodynamics showed IDO, USD, USI, and incomplete voiding. Physical examination documented a left periurethral palpable mass. Surgical debridement of the granuloma using a cold scalpel was performed. She's going to a tension-free vaginal tape (TVT) implant.

Case 3. On August 2006 a 71-year old lady underwent a periurethral injection of Dx/HA copolymer for FSUI. After surgery continent status worsened and the patients started to complained of dyspareunia. Perineal ultrasound detected a small hyperechoic mass at the bladder neck level. Urodynamics showed IDO, USD and USI. The patient underwent TVT-O implant with the resolution of FSUI and the disappearance of dyspareunia.

Case 4. On 2003 a 69-year old lady underwent two consecutive sets of periurethral injections of Dx/HA copolymer for FSUI without any success. Moreover she complained of urgency, frequency and dyspareunia. Urodynamics showed USD with USI. On December 2004 she underwent TVT implant, with an improvement of the continence status. Perineal ultrasound showed a tape positioned at a 22 mm distance from the bladder neck, entrapping Dx/HA copolymer residuals and creating a thick sheath around the mid urethra. The patient refused any invasive treatment and started a pelvic floor muscle training.

DISCUSSION

The outcome of urethral injection for the management of SUI is highly dependent on the substance that is injected rather than the route of injection. Only a case of

granulomatous inflammatory reaction at the implantation site appearing macroscopically as a perineal protruding mass after periurethral injection of Dx/HA copolymer for the treatment of FSUI has been reported in the Literature

CONCLUSION

The biocompatible material Dx/HA copolymer represents an improvement over existing injectable materials in terms of improved durability, lack of need for pre-treatment testing, and no reported autoimmune or migratory complications. However, there is a risk of granuloma developing locally after the use of this material.

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Abstract 32

MANAGEMENT OF HEALING ABNORMALITIES AFTER ABDOMINAL PELVIC ORGAN PROLAPSE REPAIR

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INTRODUCTION AND AIM OF THE STUDY

Although no specific operation is the “Gold Standard” for pelvic organ prolapse (POP), abdominal sacropexy, using synthetic mesh, is now well accepted for POP repair. Aim of this study is to report the management of healing abnormalities (HAs), as defined by the International UroGynecological Association (IUGA), in a series of 150 patients who underwent abdominal POP repair. Finally, we investigated the anatomical and functional outcome of HAs treatment.

MATERIALS AND METHODS

From January 2000 to December 2006, 150 consecutive patients underwent POP repair using synthetic mesh. All the patients underwent an accurate preoperative evaluation including history, recording of medical co-morbidities, physical examination, bladder diary, urine culture, 1-h pad test, pelvic ultrasound, Urogenital Distress Inventory (UDI-6) and Impact Incontinence Quality of Life (IIQ-7) questionnaires. Vaginal inspection was performed in the gynaecological and standing positions, at rest and under maximum straining with a full bladder. POP was graded according to Baden & Walker Halfway system (B&W) and with POP quantification (POP-Q) system for quantitative description of

POP. All the patients underwent urodynamic assessment, complying with ICS standards. Follow-up visits were scheduled at 3, 6, and 9 months and then annually. HAs were classified and recognized according to IUGA guidelines.

RESULTS

Out of 150 patients, 47 underwent colposacropexy (CSP), 64 CSP plus hysterectomy (HY) and 39 hysterosacropexy (HSP). The overall rate of HAs was 6.6% (10 patients), 6 were considered simple and 4 complex. The HAs were uniformly distributed throughout the three groups: 3 patients after CSP (6.3%), 3 after CSP + HY (5%) and 2 after HSP (5.1%). The site of the healing abnormalities was: vaginal apex in 7 patients and the posterior vaginal wall in 3. Three patients were completely asymptomatic and the HA was detected during clinical check-ups at 3, 31 and 66 months; 3 patients reported occasional vaginal bleeding, 2 persistent vaginal discharge and 2 dyspaurenia. The mean time of presentation, after surgery, was 16.5 months with a range between 2 and 5 months. One patient with erosion and infection required a complete abdominal removal of the mesh and developed a recurrent cystocele after six months. One patient, with recurrent vaginal erosion after partial mesh removal, developed a vesico-vaginal fistula and required an abdominal surgery to remove completely the mesh and correct the fistula. All the other 8 patients, after failed conservative medical therapy, were treated by the vaginal route. Two patients needed a second revision; at a mean follow-up of 35 months, all these 8 patients are completely asymptomatic and the anatomical result has been maintained.

DISCUSSION

Mesh erosion is one of the most frequent complications and it can be managed according to a conservative or non-conservative strategy, depending on the site and the extension of the erosion, the mesh material and the patient's clinical status. Some authors have suggested to use oestrogen therapy in small vaginal erosion to favour the

spontaneous healing or to prepare the vagina in case of surgical repair. However, in women on oestrogen therapy, there was an increase of mesh erosion when HY was associated to sacral colpopexy. Some authors suggested that polypropylene tape erosion should be treated with complete removal of the mesh itself without regarding the site, the erosion width and the tissue local condition. Generally, when the erosion involves the lower urinary tract (bladder or urethra) independently of any sling materials, the mesh should be removed by explantation. However, when the erosion is limited to the vagina, conservative management with observation could be considered a viable option. The conservative treatment is usually advocated for autologous, allograft and new, loosely woven polypropylene slings, but for other synthetic materials, such as polyester and silicone slings the advice is to remove entirely the mesh even in cases of vaginal erosion because it is unlikely that epithelialization over these materials would occur. When a conservative approach is scheduled, a question remains to be answered: what is a reasonable time to wait for epithelialization and what is the maximal area of sling exposure to consider for conservative management? Kobashi et al suggested that in case of exposure of up to approximately 1 cm. the mesh should become epithelialized within 6 weeks, and even larger areas of exposure could become epithelialized after a longer observation period [1].

CONCLUSION

The treatment of HA after POP repair using synthetic mesh is a challenging situation and surgeons should possess comprehensive understanding of pelvic floor anatomy, surgical adeptness and expertise in graft explantation. A long term follow-up is mandatory as HAs may be asymptomatic.

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ENDOSCOPIC TREATMENT OF VESICAL PERFORATION AFTER TENSION-FREE VAGINAL-TAPE (TVT).

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INTRODUCTION AND AIM OF THE STUDY

Vesical perforation for TVT malposition for stress urinary incontinence in women has to be considered. An endoscopic control of bladder is necessary after the procedure. Groutz (1) reports that in 3.9% of cases an injury of the urinary tract occurs during the procedure, probably due to the surgeon's inexperience, and that the endoscopic management of vesical perforation is considered a good alternative to laparotomy (2).

Aim of the study is to verify that the endoscopic management of vesical perforation is an efficacious procedure.

MATERIALS AND METHODS

In the last four years, six women (mean age 42.3, range 37-61), with the polypropylene tape inside the bladder, underwent an emergency endoscopic resection, because of hematuria and dysuria that persisted after 3-6 months post tension-free vaginal tape for stress urinary incontinence.

The diagnosis was made by ultrasound, x-ray and cystourethroscopy. Use of endoscopic forceps couldn't solve the problem in the majority of cases, but termic effect of resection damaged the tape in all cases, touching the vesical wall to close the electric loop. The complete resection of bladder mucosa allows the healing of it as shown by a cystoscopic post-operative control 3 months after the operation.

The video shows the mesh that perfored bilaterally the bladder neck. The postoperative cystoscopic control demonstrated the complete healing of the bladder neck with the exception of one point with a little residual polypropylene, subsequently removed endoscopically.

RESULTS

All the patients had a regular postoperative follow up without UTI 3 months after surgery. Only one patient complained again of the stress urinary incontinence. Two women had overactive bladder *de novo* (ICIq and OAB-screener). Only one presented a bladder stone in the wall 8 months after the endoscopic management.

DISCUSSION AND CONCLUSION

In our experience, the endoscopic management of the vesical perforation after TVT is a simple procedure without complications. After the resection of the mesh, post-surgery fibrosis caused urethral fixation and permitted maintenance of continence in 5/6 patients. The persistence of polypropylene inside the bladder wall, perhaps, is the cause of the overactive bladder *de novo*. Finally, clinical suspicion of bladder complications should arouse when evaluating patients presenting with urinary symptoms after TVT procedure.

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Abstract 34

TENSION READJUSTABLE TAPE IN I.S.D. ASSOCIATED WITH SEVERE UROGENITAL PROLAPSE. VIDEO PROCEDURE VIA THE TRANSVAGINAL APPROACH**.**

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INTRODUCTION AND AIM OF THE STUDY:

The video shows the different stages of surgery and, in particular, the prosthetic treatment in the retrotrigonal region of the bladder, without additional colpotomy, which was performed after a Tension Readjustable Tape (TRT) procedure for I.S.D. treatment, in order to obtain complete correction of the severe anterior descensus and limit the risks of erosion[1].

MATERIALS AND METHODS

Video procedure. The patient is positioned in the lithotomy position, a Scott retractor is used and a 18-French bladder catheter is inserted. The preliminary stage of vaginal hysterectomy is then performed. The pedicles of the cardinal, uterosacral and utero-ovarian ligaments are peritonized and accurately exteriorized. After the hydrodissection, an anterior sagittal incision of the vagina is performed approximately at 1.5 to 1 cm from the urethral meatus up to the bladder neck localized through the palpation of a Foley balloon stretched upwards. Pubo-vesical cervical fascia (PVCF) is detached laterally and on the inferior border of the colpotomy using scissors. An abdominal skin incision of 6 cm is then performed until the rectus abdominis muscle fascia is visualized 1.5 cm from the pubic symphysis. A short bilateral paraurethral enlargement is then made via a transvaginal access, without digitoclasia, for the easy passage of the 2 metallic needles. The needles protrude from the abdominal incision retropubically through the paraurethral space, the inner surface of the ischiopubic branch and the paravesical space up to the Retzius space and are then identified. After performing a cystoscopic control, the two pairs

of wires connected to the mesh are inserted through the eyes of the needles, which are transferred and recovered retropubically. The four wires having the same length are inserted, fastened with a screw and cut at their extremities, which protrude from the central hole of the ogive (a permanent element of the titanium system). A prosthetic patch is then placed below the urethrovesical junction. Through a clockwise rotation of a movable manipulator, which is inserted into the ogive, the wires connected to the mesh are progressively rewound and their tension is adjusted. The ogive is positioned loosely in a median suprafascial position. After closing the abdominal incision, through the exteriorization of the manipulator, the vagina is closed with absorbable stitches. The anterior margins of the vaginal opening are clamped by an Allis forceps. After infiltration, a retro-dissection of the retrotrigonal region of the bladder is made, starting 1 cm below the previous colpotomy, thus penetrating the paravesical fossae with a finger up to the tendinous arch of the pelvic fascia. A preformed Type I polypropylene prosthetic patch with 2 fins is positioned. The fins are inserted "tension free" into the devascularized space between the bladder and FPVC. After the medialization of the pedicles of the cardinal and uterosacral ligaments, the vaginal epithelium is closed with absorbable stitches transversally and the wires of the exteriorized utero-ovarian pedicles are cut at the sides of the vaginal incision. The treatment of posterior descensus concludes the surgical TRT procedure associated with severe urogenital prolapse.

The negative stress test with 300 mL filled in the orthostatic position and the urodynamic V.L.P.P. evaluation >60 cmH_2O, performed 7 to 10 days after surgery will evidence "the correct" modulation of the mesh tension, allowing the disconnection of the manipulator and the closing of its inlet hole[2]. An abdominopelvic CT scan without contrast agent will be performed at 12 months in order to verify the median retropubic suprafascial positioning of the ogive.

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