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A multidisciplinary pelvic floor journal

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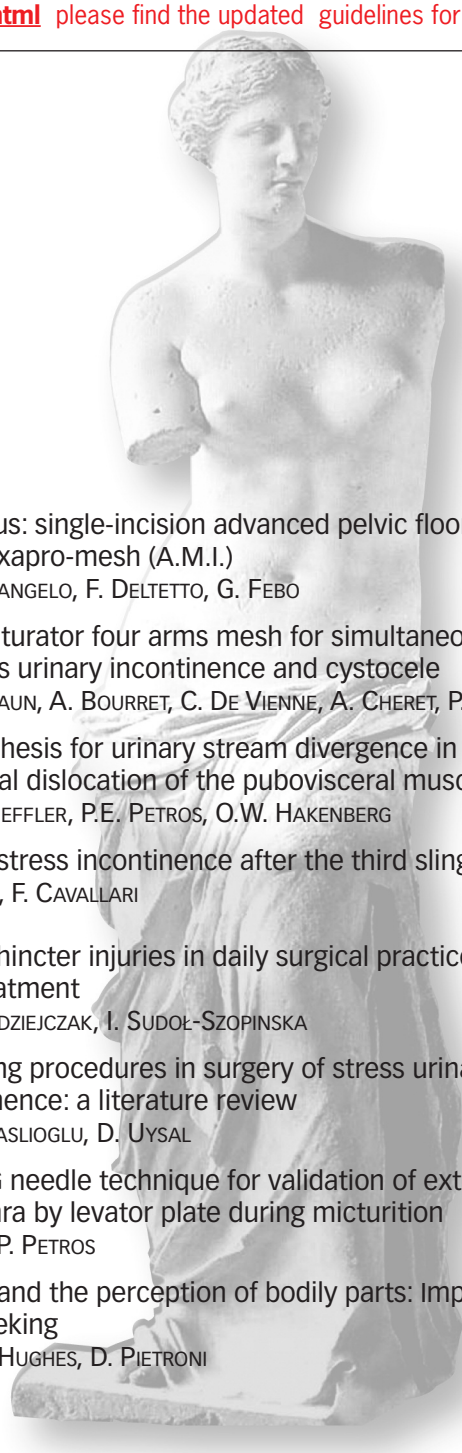

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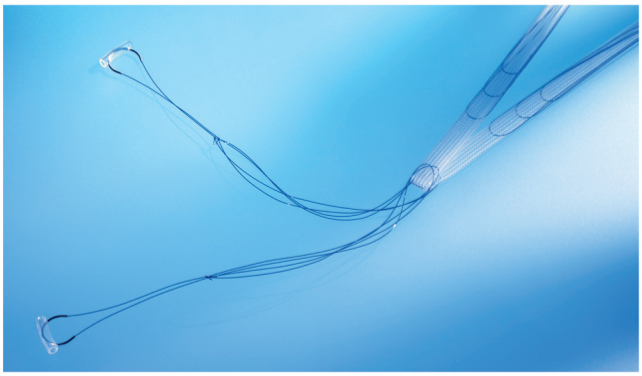
A.M.I. TOA / TVA System
for Female Stress Urinary Incontinence

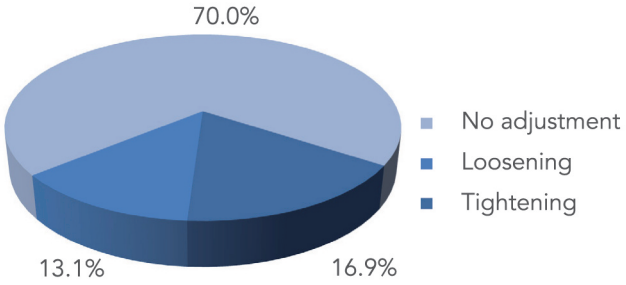
Q.: Who needs an adjustable sling?



If you think adjustability for slings is just a marketing ploy, it might be time to reconsider. The data below is taken from an analysis of **six, peer-reviewed studies** published, comprising a total of **392 patients** treated with either the A.M.I. TVA or TOA System for female stress urinary incontinence.
The results speak for themselves.

A.: About 30% of patients.

% of patients requiring adjustment



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6.4% considerably/substantially improved

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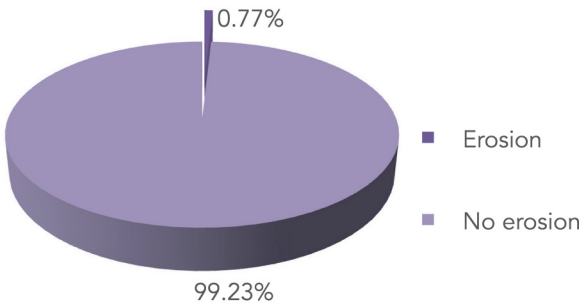

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Original article

Ingynious: single-incision advanced pelvic floor repair with hexapro-mesh (A.M.I.)

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Abstract: With the release of the FDA statement, it has become increasingly important to reduce mesh-related complications. The aim of this abstract is to describe a new generation single-incision pelvic reconstructive technique using an isoelastic ultra-light mesh (21 g/m). Between 1st March 2011 and 31st July 2012, women with pelvic organs prolapse ≥ stage II underwent repair through the InGYNious technique (AMI Agency for Medical Innovations, Austria). The surgical technique ensures the fixation of the anterior and of the posterior compartments to the sacro-spinous ligament and the recreation of lateral support to the arcus tendineus fascia pelvis (anterior) and to the iliococcygeus muscle (posterior). One-hundred-twenty-two InGYNious procedures were performed, 98 conserving the uterus and 24 in patients with vaginal vault prolapse. The only intraoperative complication was a single case of bladder lesion. At one-year follow-up 98 patients were reviewed. The objective cure rate was 93.9% (92/98) with only 2 (2.0%) cases of vaginal mesh exposure. In conclusion, the InGYNious procedure is a minimally invasive technique to treat pelvic prolapse through a single vaginal incision. Initial results show the procedure to be safe and early efficacy is promising. Longer-term follow-up is ongoing.

Key words: Pelvic prolapse surgery; Vaginal Mesh; Light mesh for prolapse; Single incision vaginal mesh; Prolapse conservative treatment.

INTRODUCTION

The high recurrence rate of pelvic organ prolapse after traditional pelvic reconstructive surgery has been estimated to be up to 30%.[1] On the other hand, with the release of the FDA statement,[2] it has become fashionable to criticize the use of mesh.[3] Thus, it has become increasingly important to improve surgical strategies to decrease the incidence of surgical failure and at the same time to reduce mesh-related complications.

The aim of this manuscript is to describe a new generation single-incision pelvic reconstructive procedure using an isoelastic ultra-light mesh, which could meet the criteria described above.

MATERIALS AND METHODS

Between 1st March 2011 and 31st July 2012, 122 InGYNious (A.M.I., Austria) procedures were performed. InGYNious is a new mini-invasive trocar-less procedural kit for pelvic floor repair, which allows to obtain a strong upper support and a complete reconstruction, combining these factors with the characteristics of one of the lightest mesh on the market (21 g/m^2) (Figure 1).

We reviewed the clinical records of patients who had been treated for stage II-IV pelvic organ prolapse with the InGYNious technique between March 1, 2011 and July 31, 2012.

Surgical technique

The surgical technique varied according the site of the pelvic organ prolapse. These step by step instructions describe the reconstruction of the anterior compartment (using the InGYNious Anterior mesh – Fifure 2 – if conserving the uterus or the InGYNious Vault mesh – Figure 3 – in the case of vault prolapse or concomitant hysterectomy).

STEP 1: **anterior infiltration** using normal saline 40-60 ml +/- adrenalin.

STEP 2: **anterior incision,** this is a full thickness vertical incision, deep enough to reach the layer under the fascia.

STEP 3: **open the paravesical space bilaterally**, reaching the spine and identifying the sacrospinous ligament and arcus tendineus fasciae pelvis.

STEP 4: **create the anterior apical attachments**, using a non-absorbable polyester suture, which is attached bilaterally to the sacrospinous ligament, > 2 cm from the spine, using i-Stitch (A.M.I.) (Figure 5), a narrow suture instrument which can easily access the sacrospinous ligament.

STEP 5: **create the anterior lateral attachments**, placed on each side in the arcus tendineus fascia pelvis, > 2 cm from the spine, using i-Stitch (A.M.I.).

STEP 6: **create the anterior superficial attachments**, to the anterior part of arcus tendineus fasciae pelvis, using i-Stitch (A.M.I.).

STEP 7: **placement of the mesh**, using feeders to pass the sutures in their correct position.

STEP 8: **fix all sutures**, following the levels order.

STEP 9: **vaginal skin closure.**

For reconstruction of the posterior compartment (using the InGYNious Posterior mesh – Figure 4), we opened the pararectal space bilaterally after infiltrating and making an incision in the posterior vagina wall. Once the spine was reached, we identified the sacrospinous ligament and iliococcygeus muscles. We create the posterior apical attachments placed on each side in the sacrospinous ligament, and the posterior lateral attachments placed on each side in

Figure 1. – HexaProMesh (A.M.I.), one of the lightest mesh on the market (21 g/m^2).

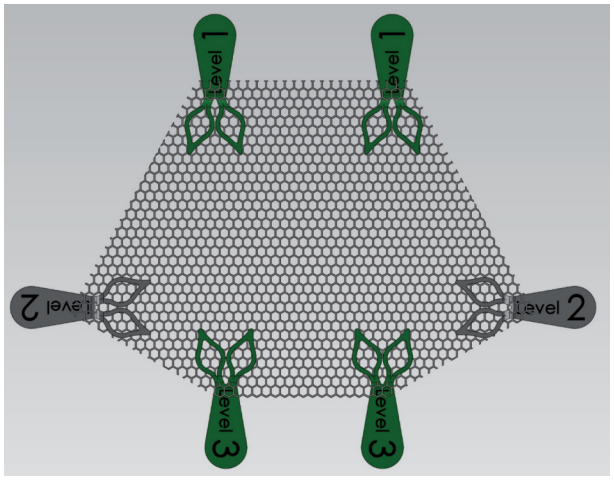

Figure 2. – InGYNious Anterior mesh (A.M.I.).

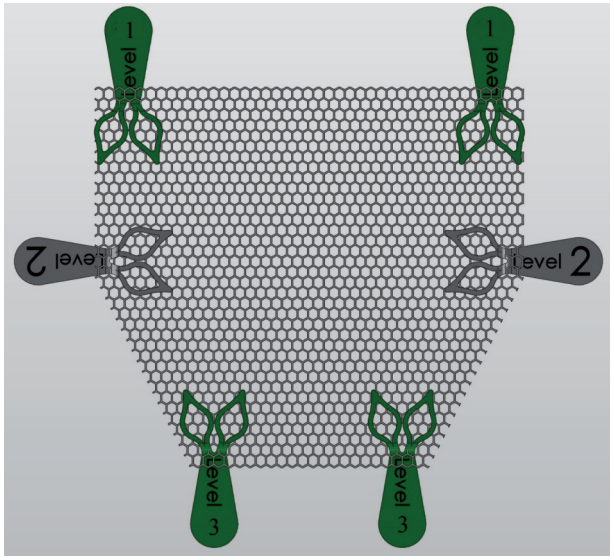

Figure 3. – InGYNious Vault mesh (A.M.I.).

the iliococcygeus muscle, 2 cm from the spine. The posterior superficial attachments are simply fixed in the perineal body.

For a complete reconstruction of both the anterior and the posterior compartment, separate incisions were performed and separate meshes were placed.

Post-operative care

The urinary catheter was removed 24 hours after the operation, or 48 hours post-operatively in the case of total repair. In all cases, patients were evaluated after urinary catheter removal for post-void residual volumes. If patient did not pass the voiding trial, she was sent home with an indwelling catheter and a second voiding trial was carried out on the seventh postoperative day.

All women received intravenous prophylactic antibiotic therapy for 48 hours following surgery, followed by five days of oral antibiotic therapy. All women received thromboprophylaxis with low molecular weight heparin for ten days after surgery. Post-operatively analgesics (intramuscular ketorolac) were given when requested by the patient. Post-operative reviews were performed at one month and again at one year.

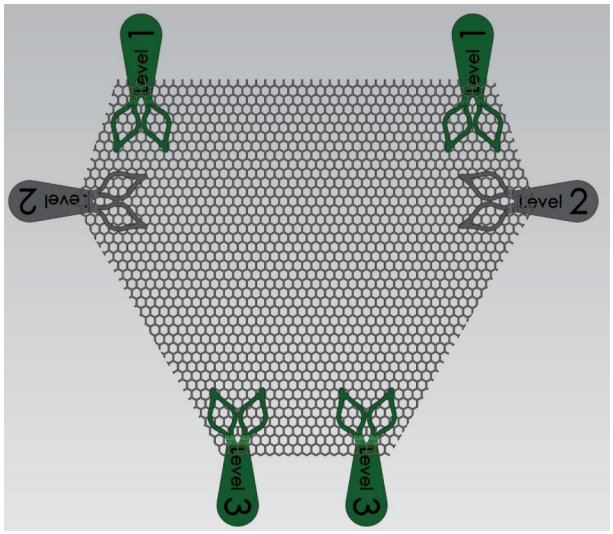

Figure 4. – InGYNious Posterior mesh (A.M.I.).

Figure 5. – i-Stitch (A.M.I.), the narrow suture instrument which can easily access the sacrospinous ligament.

RESULTS

Of the 122 InGYNious procedures performed, in 98 patients we conserved the uterus, while 24 patients had vaginal vault prolapse. Bladder perforation occurred in one case, resolved maintaining catheter for 10 days. Thirty-one (25.4%) patients had post-operative levator myalgia, temporarily resolved with analgesic therapy. At one-year follow-up, 98 of the 122 patients were reviewed and the objective cure rate was 93.9% (92 patients completely recovered). Two (2.0%) cases of vaginal mesh exposure was observed, due to incomplete wound healing, one required partial excision of mesh with approximation of vaginal flaps, and other was treated conservatively

CONCLUSIONS

According to the peri-operative and short-term follow up results, InGYNious seems to be a safe technique to correct pelvic organ prolapse with very good anatomical results. Moreover, the mesh of which is made Ingynious, called HexaPro-Mesh (AMI - Austria), is specifically designed to minimize fibrosis and retraction after surgery. In fact, it is a particularly soft isoelastic mesh, which has a weight of 21 g/m^2, less than other meshes used for the utero-vaginal prolapse, with a porosity of 93% and characteristic hexagonal pores that provide elasticity in all directions. At 1-year fol-

low-up we had only one case of mesh exposure, that was not a real erosion but it was due to incomplete wound healing.

Of course, anatomical and functional results, quality of life and sexual function questionnaires must be assessed with a long-term follow-up to evaluate the impact of the InGYNious procedure on the quality of life, but the results obtained so far are promising.

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Multidisciplinary Uro-Gyne-Procto Editorial Comment

To improve the integration among the three segments of the pelvic floor, some of the articles published in **Pelviperineology** are commented on by **Urologists**, **Gynecologists**, **Proctologists/Colo Rectal Surgeons** or **other Specialists** with their critical opinion and a teaching purpose. Differences, similarities and possible relationships between the data presented and what is known in the three or more fields of competence are stressed, or the absence of any analogy is indicated. The discussion is not a peer review, it concerns concepts, ideas, theories, not the methodology of the presentation.

Urol... The authors report their experience in the correction of vaginal prolapse by proposing a new technique that represents the evolution of the procedure proposed by Farnsworth. The possibility of correction of the prolapse with the method InGYNious which is a minimally invasive one, is certainly quite attractive. In this setting however from the surgical point of view, in terms of treating the prolapse, the opinion of the urologist is different. In fact the urologists usually prefers the vaginal approach to treat the anterior and posterior defects, independently of the use or not of meshes, but choose the abdominal approach by laparoscopy or more recently by robot-assisted laparoscopic technique for the correction of the central defect.

In this way, when the quality of the tissues allows it, the fascial repair of the anterior or posterior defects is in any case be preferable also because of the possibility of vaginal mesh exposure and painful contraction. These are not uncommon complications ranging between 4% and 35% and between 4% and 11% respectively.

Instead concerning the correction of the central defect by laparoscopic or robotic assisted colposacropexy, it is possible, also in this case, to restore the three levels of De Lancey with a reduced rate of intraoperative bleeding, shorter hospitalization and less wound complications. For the robotic approach there is currently not enough evidence of an impact on complication rates.

The choice of a surgical approach over another does not constitute a particular difference, provided that the surgeon observes the principle of a functional reconstructive surgery not interfering with the quality of life of the patient.

SALVATORE SIRACUSANO
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Gyneco... Dr Mistrangelo reports her technique which is an evolution of the more well known mesh techniques utilized for pelvic floor repair and currently the subject of much controversy and discussion due to the FDA directives of recent years. Dr Mistrangelo addresses this controversy directly and describes her technique where a low density iso-elastic mesh specifically designed to address and minimise complications due to the prosthesis is implanted in the patient. This technique preserves the three level attachment of the original CR Mesh procedure from which this technique has evolved but utilizes a single incision and a new minimally invasive method for suspensory suture application. The results of this retrospective observational study show great promise. We look forward with anticipation to the results of a prospective study where the technique is evaluated in a controlled trial and directly compared for safety and efficacy with the other techniques that are available.

BRUCE FARNSWORTH
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Procto... The procedure described in Mistrangelo's article involves all the pelvic floor compartments. In the posterior one which colorectal surgeons commonly deal with, the following anatomo-pathological entities are commonly addressed: low rectocele, which develops within the perineal body, rectal intussusception arising from the invagination either of the proximal rectum or of the medial-distal rectum, respectively as a recto-rectal or a recto-anal intussusception, and complete rectal prolapse. A rectocele must be differentiated from a posterior colpocele, which occurs in the central compartment, as a prolapse of the rectum or of the Douglas Pouch or both, into the posterior wall of the vagina. Colorectal surgeons treat these conditions with open or laparoscopic abdominal or transanal surgical procedures. During the last decade pelvic surgeons have evolved and refined the transvaginal techniques using a variety of prostheses, but despite this, the safety of these procedures is still under discussion, as delineated by the FDA 2011 advice. Nevertheless, data on transvaginal procedures have shown their efficacy in the POP repair. Farnsworth has been a pioneer in this field and when compared to laparoscopic or open surgery, data related to his technique have also highlighted an improvement of coexisting symptoms as obstructed defecation and fecal incontinence. Farnsworth described the use of prostheses (*A.M.I. CR mesh - GmbH Feldkirch-Austria*) to restore the three levels of De Lancey, thus achieving a support to the rectum and a more anatomical correction of the prolapsed pelvic organs. In more detail, Farnsworth improves posterior colpocele by recreating the 2° level of De Lancey with two trans-elevatory slings, and rectocele by recreating the 3° level of De Lancey through two posterior trans-perineal slings. Of the outmost importance from the proctologic point of view, the prosthesis placed between rectum and vagina has showed to improve also complete rectal prolapse and medial-distal rectal intussusception. InGYNious is an evolution of the Farnsworth's technique, using a smaller prostheses without the arms for the 2° and 3° level of De Lancey. Hence, though InGYNious corrects the posterior colpocele, it must be verified if the shape, dimension and lack of slings of this new device will also anatomically improve rectocele, rectal prolapse and rectal intussusception as in the CR mesh technique. Furthermore, as, the improvements of the coexisting functional symptoms that ensue with Farnsworth's procedure should be verified with a longer follow up, and randomized controlled trials could provide an interesting comparison between this promising procedure and the others available on the market of the POP treatments.

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Original article

Transobturator four arms mesh for simultaneous treatment of stress urinary incontinence and cystocele

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[4]*Ziv Medical center, Faculty of medicine, Safed - Ob/Gyn*

Abstract: Objective: Stress urinary incontinence associated with pelvic organ prolapse is a frequent condition. The aim was to evaluate whether insertion of the anterior arms of transobturator four arms mesh under the mid-urethra can treat simultaneously the cystocele and incontinence without causing de novo urgency symptoms or voiding dysfunction. *Methods:* A comparative prospective study was conducted. The study group included patients treated for stress urinary incontinence and cystocele with the same mesh. The control group included all patients treated with a seperated suburethral sling for stress urinary incontinence. Evaluation included POP-Q for prolapse documentation and cough stress test with full bladder for stress urinary incontinence. All patients completed the PFDI-20 and PFIQ-7 forms for prolapse symptoms and the PISQ-12 form for sexual function before and after the operation. *Results:* Fifteen patients in the study group were compared with 25 in the control group. The success rate of stress urinary incontinence treatment at the six-month follow-up was 93% for the study group and 84% for the control group. No signs of de novo urgency symptoms or persistent voiding dysfunction were detected. Significant improvement in mean total score and urinary score was detected in both groups on both pelvic floor questionnaires, and there was no difference between the groups before and after the operation. Sexual function improved in both groups. *Conclusions:* Stress urinary incontinence accompanied by cystocele can be treated in one operation with the same transobturator mesh, achieving both anatomical and functional cure and improvement in the patient's quality of life.

Key words: Cystocele; Life Quality Questionnaires; Stress Urinary Incontinence; Transobturator Four Arms Mesh.

INTRODUCTION

Stress urinary incontinence (SUI) associated with pelvic organ prolapse (POP) is a frequent condition. When considering surgical correction, it is important to assess not only the surgical strategies but also the definition and the diagnosis of SUI in the presence of POP (occult SUI). Postoperative SUI is significantly more likely to occur in patients with a positive pre-operative test, which means that these patients have an anatomical defect that requires a treatment.[1-3] When performing both repairs at the same time, two options are available: inserting a sub-urethral sling through a second incision on the anterior vaginal wall or inserting the anterior arms of the cystocele mesh as a sub-urethral sling through a single incision.[4,5] This latter approach is debatable, mainly concerning the position of mesh under the trigon, which theoretically can cause de novo urgency symptoms (unstable bladder). We have previously described cystocele repair with a transobturator four arms mesh in 57 patients treated for cystocele and SUI with the same mesh and demonstrated SUI cure rate of 87.7% without causing de novo urgency symptoms.[6]

At the CHU of Caen we have been treating cystocele and SUI in the same procedure and with the same mesh since 2004. The special surgical technique is further described. Starting in 2009, all patients with POP and SUI complete life quality questionnaires (LQQ). Our aim was to determine whether insertion of the anterior arms of the transobturator four arms mesh under the mid-urethra can treat simultaneously the cystocele and the SUI without causing de novo urgency symptoms and to compare this solution with treatment of SUI with a separate sling with respect to SUI cure rates, functional results, and quality of life.

MATERIALS AND METHODS

A comparative prospective study was conducted at the CHU of Caen, including all patients treated for SUI between January 2009 and January 2010 and completed LQQ forms. The study was approved by the local ethical committee. The study group included all patients who had cystocele and SUI, and who were treated with the IVS Tunneler™ 04 with quadra mesh (Polypropylene Monofilament Mesh, Covidien) in order to repair the SUI and cystocele with the same mesh. The control group included all patients who were treated with a suburethral sling for SUI alone or with correction of prolapse with a separate mesh.

Patients were evaluated before the operation, and postoperatively after six weeks and six months. Evaluation included Pelvic Organ Prolapse Quantification (POP-Q) for prolapse documentation and cough stress test with full bladder for evaluation of SUI. Occult SUI was determined by cough stress test after reduction of the prolapse. Urodynamic tests were conducted as needed, but not routinely. Furthermore, all patients were interviewed for urgency symptoms and voiding dysfunction before and after the operation. All patients completed the following LQQ forms: Pelvic Floor Distress Inventory (PFDI-20), Pelvic Floor Impact Questionnaire (PFIQ-7), and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) before the operation and six months after it.

The main outcome measures were: post-operative SUI, post-operative de novo urgency symptoms, post-operative voiding dysfunction, and differences in life quality assessed by LQQ.

Surgical technique

A midline incision of full thickness is performed on the anterior vagina, extending up to 1 centimeter from the urethral meatus. The bladder is dissected away from the vaginal wall, leaving Halban's fascia on the epithelium. The paravesical fossas are opened until the ischial spine and the arcus tendineus of the levator ani are reached. The paraurethral spaces are opened up to the ischiopubic rami. Between the paravesical fossas and the paraurethral spaces,

the internal part of the levator ani plate, the pubo coccygeous muscle, is visible and adhesive to the proximal urethra and the vaginal wall. Its thickness varies from one patient to another but it is usually about 1 centimeter at midline. The pubococcygeous muscle will serve as a barrier between the levels and support the suburethral part of the mesh, preventing any shifting toward the bladder neck (Figure 1A). The two anterior arms of the mesh (Polypropylene Monofilament Mesh, Covidien) are inserted with the IVS Tunneler™ 04 through the paraurethral dissection space, as in the case of a transobturator suburethral sling, exercising special care to ensure the absence of tension to treat the SUI (Figure 1B). The same tunneller is used for the insertion of the posterior arms, one centimeter lateral to the ischial spine on the arcus tendineus levator ani. The posterior part of the mesh is sutured to the uterine cervix or the vaginal vault with one or two absorbable sutures. The posterior arms are then pulled to create a subvesical hammock to treat the cystocoele. The pubococcygeous muscle prevents direct contact with the vesical trigone. Finally, the vaginal epithelium is sutured without colpectomy. The differences in the position of the four arms mesh for cystocele repair alone and for cystocele and SUI are illustrated in figure 2.

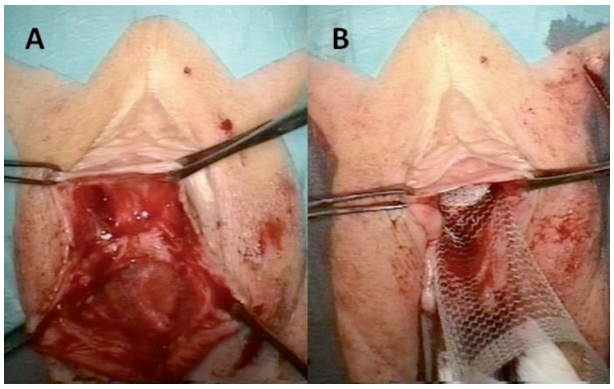

Figure 1. – Paraurethral and paravesical spaces separated by the pubococcygeous muscle (A). The anterior arms of the mesh are inserted through the paraurethral spaces as in the case of suburethral slings (B).

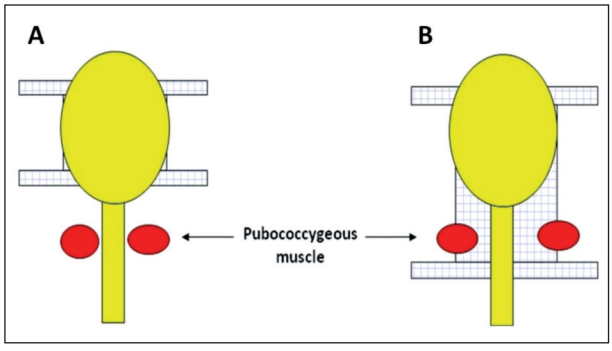

Figure 2. – Four armed transobturator mesh for cystocoele (A) and four armed mesh for cystocoele with concomitant SUI (B).

RESULTS

In the study group, 15 patients underwent simultaneous correction of SUI and cystocele using the IVS Tunneler™ 04 and quadra mesh (Covidien). The patients completed LQQ forms before the operation and six months after it. Grade III cystocele was found in 13 patients, with Ba from +1 to +4, and Grade II in 2 patients, with Ba at 0. In the control group, 25 patients had a separate suburethral sling inserted for SUI: 9 transobturator tape (TOT) (Covidien) and 16 MiniArc (AMS). Seventeen had correction of SUI alone, one had laparoscopic sacrocolpopexy with TOT, two had additional posterior vaginal repair with mesh, and four had anterior and posterior vaginal repair with meshes (Endofast, IBI) and separate TOT. Mean age for the study group was 61.5 (range 38-82) and for the control group 55.4 (range 31-84). In the study group, at the 6-month follow-up anatomical correction was excellent for all 15 patients, with Ba at -3 for 12 patients, at -2 for two patients, and at -1, non-symptomatic, for one patient. The functional results at 6 months are presented in Figure 3. The success rate of the SUI treatment at the 6-month follow-up was 93% for the study group and 84% for the control group. Postoperative success rate was determined by a negative cough stress test with full bladder. In the study group, 5 of 15 patients had mixed urinary incontinence associated with urgency before the operation. All 5 were cured by the operation. There was one patient with de novo urgency after the operation, which was resolved after treatment with antimuscarinic medication. Nine patients had voiding dysfunction (VD) associated to the cystocele before the operation. They were all cured after the operation. One patient had de novo VD after the operation, which was resolved spontaneously after ten days. No signs of unstable bladder or persistent VD were detected. All patients completed the PDFI-20 and PFIQ-7 forms for prolapse, urinary, and colorecto-anal symptoms. Significant improvement in mean total score and urinary score was detected in both groups on both questionnaires (Table 1). There was no difference between the groups when comparing the total or the urinary score before and after the operation (p values range between 0.12-0.8, CI 95%). PFIQ-7 scores were found to correlate more with the clinical interview than did PDFI-20

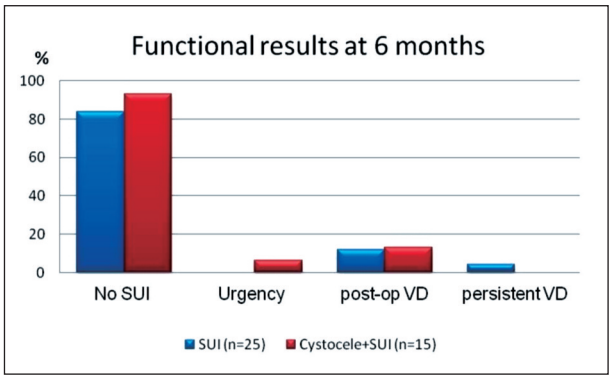

Figure 3. – Functional results 6 months after the operation for study and control groups.

TABLE 1. – Mean urinary symptoms score on PDFI-20 and PFIQ-7 and sexual score on PISQ-12 before and after operation for study (Cystocele + SUI) and control (SUI) groups. * non-significant.

	PDFI-20 urinary symptoms			PFIQ-7 urinary symptoms			PISQ-12		
	Pre-op	**Post-op**	***p***	**Pre-op**	**Post-op**	***p***	**Pre-op**	**Post-op**	***p***
SUI	38.37	12.915	***0.0003***	33.6	10.68	***0.005***	37.5	40.2	***0.44****
Cystocele +SUI	50.67	18.91	***0.01***	41.36	12.09	***0.009***	26.58	37.56	***0.012***

scores. The sexual function questionnaire, PISQ-12, was relevant for 10 of the 15 participants in the study group and for 11 of 25 participants in the control group. Sexual function improved in both groups but was significant only in the study group.

DISCUSSION

SUI (obvious or occult) and cystocele are often present together and can exist simultaneously, but SUI can also appear de novo after correction of cystocele. In the CARE study, a prophylactic Burch colposuspension at the time of abdominosacrocolpopexy (ASC) reduced significantly the rate of de novo SUI.[7] However, in the CARE study patients were not checked for occult SUI pre-operatively, which can explain the high rate of de novo SUI in the control group. When the two conditions coexist, involving either obvious or occult SUI, some surgeons prefer to correct only the cystocele, without additional correction for SUI. This approach is based on several observations showing that correction of cystocele alone, mainly using a transobturator mesh, can cure the SUI in up to 75% of cases.[8-11] In the presence of pre-operative SUI, there is a good chance that following this approach the patient will still require a second operation for SUI.

Correction of cystocele and SUI in the same operation can be performed in two ways: addition of a suburethral sling to the cystocele repair (with or without mesh) or correction of the cystocele with the four arms transobturator mesh and insertion of the upper arms as in the case of the insertion of the midurethral sling described here. Our earlier results with that latter technique have shown an almost 88% cure rate for SUI, although the results were obtained with a retrospective series.[6] When correcting both conditions in the same operation, the SUI cure rate is not the only parameter of interest; voiding dysfunction (VD) and de novo urgency symptoms are of major concern. VD is a common complication after incontinence and anterior prolapse repair. The rate of postoperative VD varies in different series and depends on the procedures used and on the definition of VD.[12,13] The addition of a suburethral sling in prolapse surgery has not been found to increase the risk of VD.[14] De novo urgency symptoms can occur after suburethral sling procedures or prolapse repair[15,16] and greatly affect women's quality of life.[17] Our special technique for performing both corrections, grading the pubococcygeous muscle and preventing direct contact with the bladder trigon, can theoretically prevent the appearance of de novo urgency symptoms caused by unstable bladder. Our results from the current study have confirmed what we had observed during routine follow-up: a high cure rate for both cystocele and SUI, without causing unstable bladder or VD. Indeed, the SUI cure rate in the study group was higher than in the control group, implying that correction of both conditions with one mesh may provide better anatomical correction and better results.

Improvement in the quality of life is difficult to assess after prolapse and incontinence surgery mainly because of the complexity of the symptoms. Improvement in anatomical results does not necessarily indicate improvement in functional results. Occasionally, even sub-optimal anatomical results can result in great relief for the patient. The symptoms that are frequently associated with POP can affect the quality of life of women in different ways. In assessing women's pelvic floor, it is of great important to use LQQs addition to interrogation and clinical examination. Asking patients repeatedly about their symptoms may result in a bias, whereas LQQs are designed to circumvent such biases. Moreover, the quality of life reflected in the LQQ may be quite different from that which transpires from the clinical interview. In 2001, two condition-specific LQQs were developed for women with various forms of pelvic floor disorders, the Pelvic Floor Distress Inventory (PFDI) and the Pelvic Floor Impact Questionnaire (PFIQ). Clinicians and researchers use PFDI and PFIQ together to measure the extent to which lower urinary tract, lower gastrointestinal tract, and pelvic organ prolapse symptoms affect the quality of life of women who suffer from disorders of the pelvic floor. Each LQQ has been shown to be psychometrically valid and reliable.[18,19] In 2003 PISQ-12was published. The questionnaire is used to evaluate sexual function in women with pelvic organ prolapse and/or urinary incontinence.[20]

The results of the present study demonstrate improvement in quality of life assessed by specific LQQs for POP and incontinence. The mean general score and the urinary symptoms score improved in both groups after the operation, without difference between the groups. We have found that PFIQ-7 correlated more with the clinical interview at follow-up than did PDFI-20. The difference can be explained by the nature of the questions in the two questionnaires.

One of the limitations of the current study has to do with the fact that the control group was heterogenic, with few patients treated also for prolapse and not only for SUI. Four patients underwent correction of cystocele using another system (Endofast, IBI) in which it is not possible to correct both the cystocele and the SUI with the same mesh. These patients were treated with a separate suburethral sling and were enrolled in the control group. In the control group we used TOT and MiniArc for the treatment of SUI. Several randomized studies have demonstrated the equivalence of MiniArc to transobturator types.[21-23] Therefore we enrolled the patients treated with various types of suburethral slings in one group. In the present study we used the IVS Tunneler™ 04 with quadra mesh (Polypropylene Monofilament Mesh, Covidien), which was out of the market at the end of 2010. Although this particular kit no longer exists, the concept of a transobturator mesh with 4 arms, the upper arms of which can be placed under the midurethra as a suburethral sling, remains.

This prospective study was designed to determine whether the simultaneous repair of cystocele and SUI with a cystocele mesh is equivalent to treatment of SUI alone as far as the results of the SUI treatment are concerned, and whether it can cause more bladder instability or voiding difficulties. Our results have demonstrated that in the combined procedure the success rates were even higher than in the case of treatment of SUI alone, without causing more bladder instability or voiding dysfunction. LQQ scores improved in all areas, including sexual function.

We conclude that SUI accompanied by cystocele can be treated in one operation with the same transobturator mesh, ensuring both anatomical and functional cure as well as improvement in the patient's quality of life.

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Hypothesis

A hypothesis for urinary stream divergence in the female: unilateral dislocation of the pubovisceral muscle

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Abstract: Objective: Cure of diverted urinary stream with TFS tensioned minisling pubovisceral muscle re-attachment Aim and hypothesis: To surgically correct a urinary stream divergent to the left side hypothesized to be caused by right pubovisceral muscle (PVM) avulsion. *Patient and Methods*: The patient presented with a divergent urinary stream to the left side with deficient right PVM attachment to the symphysis. Micturating cystography confirmed diversion of bladder neck and proximal urethra to the right side during micturition. A TFS U-Sling was used to re-attach the dislocated PCM to the tissues behind the pubic symphysis. *Results:* The direction of the stream returned to normal , the USI was cured and both conditions remained cured at 12 months review. *Conclusion:* We hypothesize that the TFS U-Sling works by penetrating the PVM fascia to "reglue" it to the tissues near ATFP origin, restoring the insertion point of the right backward urethral opening vectors and therefore, urinary stream direction.

Key words: Diverted Urinary Stream; Pubovisceral Muscle Dislocation; TFS U-Sling; Minisling.

INTRODUCTION

Pelvic floor trauma during delivery followed by age-related alterations of collagen /elastin distribution can lead to dysfunctional symptoms in women such as incontinence, abnormal emptying, urge and chronic pain.[1] More recently, avulsion of the pubococcygeus/puborectalis complex, now known as the "pubovisceral muscle" (PVM), at childbirth has been reported as an association of anterior vaginal wall prolapse.[2]

A complex case is reported in which a right-sided tear of the PVM was symptomatic with a urinary stream diverging to the left. Ethics approval was not required as this patient was treated according to standard hospital care. Informed consent for the surgery was obtained as was the patient's permission for publication of her case.

MATERIALS AND METHODS

A 69 year old woman reported with a poor urinary stream which diverted to the left side. On average, she had 3 incontinence episodes per day, especially when coughing but no urgency.

There was moderate laxity of the suburethral vaginal hammock but no urine loss with coughing. Palpation of the pubovisceral muscle attachments to the pubic bone showed a gap in the muscle layer on the right side which was located just next to the bladder neck. This spot was also very tender on palpation.

Video-urodynamic study: Normal bladder capacity (610 ml), early bladder filling sensation (80 ml), no detrusor hyperactivity, normal compliance. On micturition, the bladder neck and proximal urethra moved towards the right pelvic wall (Figure 1), the maximum flow rate was 8 ml/sec, the residual volume 40 ml. The urine stream diverted to the left.

SURGERY

We hypothesized that the left-sided stream deviation was caused by dislocation of the PVM. The aim of surgery was therefore to re-attach the collagenous insertion point of the PVM to the posterior aspect of pubic symphysis. We accomplished this by using the Tissue Fixation System (TFS) "U-sling" procedure (Figure 2). A full thickness incision was made in the anterior vaginal wall between bladder neck and the hysterectomy scar. The bladder was dissected off the vagina. A channel was dissected below the descending pubic ramus to the insertion point of the ATFP. The anchor was inserted and the tape was tightened to restore the laterally displaced tissues to their correct position more medially.

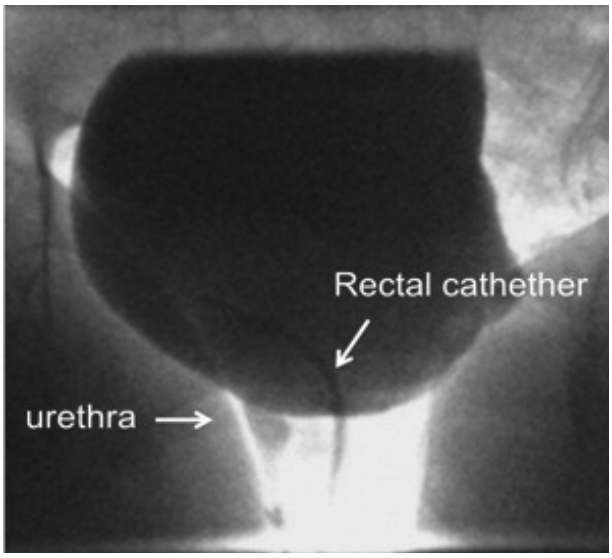

Figure 1. – Fluoroscopy at the start of micturition shows a rapid and marked movement of the proximal urethra towards the right pelvic wall.

Video TFS minisling surgery for 4th degree prolapse log onto www.integraltheory.org

RESULTS

First Follow up: This was done at four weeks after surgery. The urinary stream was now straight (normal) and the stress urinary incontinence was cured (no pad use). The anterior vaginal wall prolapse was entirely cured.

Post-operative Voiding Cystography showed a slight rotation of the bladder base, much less than before, with a straight urinary stream.

One year later pelvic re-evaluation was repeated, with identical results. The urinary stream remained straight.

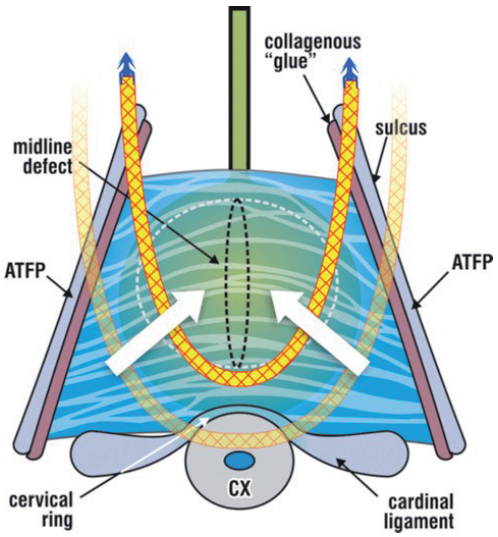

Figure 2. – U-sling procedure using the TFS, which re-attaches connective tissue structures, in this case, the aponeurotic fascia covering of the pubovisceral muscle (PVM) to the origin of the ATFP. As the tape is tightened, the tissues are restored to their more medial position (white arrows), closing the herniation, and reinforcing the anterior vaginal wall.

DISCUSSION

To the best of our knowledge this is the first case report of successful surgical cure of a divergent urine stream. It is also the first application of the TFS tensioned minisling for re-attachment of an avulsed pubococcygeus/puborectalis ("PVM") to its attachment point to the symphysis pubis. We used the "regluing" principle reported in the animal experiments which preceded the prototype midurethral sling operation : the tape created an artificial pubourethral neoligament and glued the tape to everything it came into contact with. In this case, the TFS applicator penetrated the connective tissues adjacent to the avulsed muscle and advanced it towards the posterior surface of the pubic symphysis where it penetrated tissues in the general area of the origin of the ATFP.

Other than a description of "splitting",[3] we could find no reference to incidence, causation or management in the female.

Pubovisceral muscle re-attachment operations Dietz et al[4] described 15 patients where they attempted to re-attach the displaced PVM using sutured mesh, with, however, a 74 % prolapse recurrence rate. Rostamina et al.[5] recently reported re-attachment of a dislocated PVM using ultrasound guided microsurgery, successful at 6 months. Our methodology does not rely on sutures to maintain the integrity of the anatomical restoration. The TFS anchor has a 2.5Kg pull out force which we consider sufficient to maintain PVM re-attachment during the healing period. We see a technical problem with the Rostamina method: any muscle tissue deficiency will make it impossible to re-attach the ruptured PVM with sutures. The TFS tape overcomes the "gap" problem as it creates a collagenous neoligament around the tape, using the same principle as the original TVT operation.

As regards the divergent urinary stream, we attribute this to the unbalanced action of the pubococcygeus/levator plate complex. In 1993, video xray studies demonstrated posteriorly acting directional muscle forces acting during micturition.[1] These were attributed to the levator plate muscle, which is the fused product of the lateral pubococcygeus muscle as they sweep behind the rectum to form the levator plate. We attribute restoration of the urinary stream direction to re-attachment of the right muscle to its retropubic attachment point.

We believe that rupture of the right PVM and right pubourethral ligament (PUL) resulted in the right PVM remnant pulling the urethra and bladder base to the right against an intact left PUL at the commencement of micturition. At micturition, the urethra is shortened and opened out (funneled) by bilateral backward/downward acting muscle vectors acting against PUL (see appendix). If the right muscle is ruptured, only the left side of the urethra can be tensioned, shortened and pulled open. The urinary stream diverges to the left.

Strengths of our paper. Description of a reproducible single incision minimally invasive operation for re-attachment of dislocated PVM muscles.

Weakness of our paper. The dislocation, though clinically obvious, was not confirmed by MRI.

CONCLUSION

We have described cure of a diverted urinary stream using a minimal technique which re-attaches the pubovisceral muscles and an anatomical rationale for causation of a diverted stream. Hopefully this will open the door to further research on a problem about which very little is known.

SUPPLEMENTARY MATERIAL

1. The Appendix details the anatomical basis for the hypothesis of urinary diversion.
2. The video demonstrates the TFS U-Sling operation. The video is of 2005 vintage. Nevertheless, the principles of the technique remain unchanged.

CONFLICT OF INTEREST

Scheffler, Hakenberg nil. Petros invented the TFS sling, infracoccygeal sacropexy operation and co-invented the TVT.

CONTRIBUTIONS OF EACH AUTHOR

Scheffler performed the assessment, diagnosis and postoperative followup. All authors participated in the decisions for surgery, the surgery and the writing of the manuscript.

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APPENDIX

The anatomical basis for the hypothesis

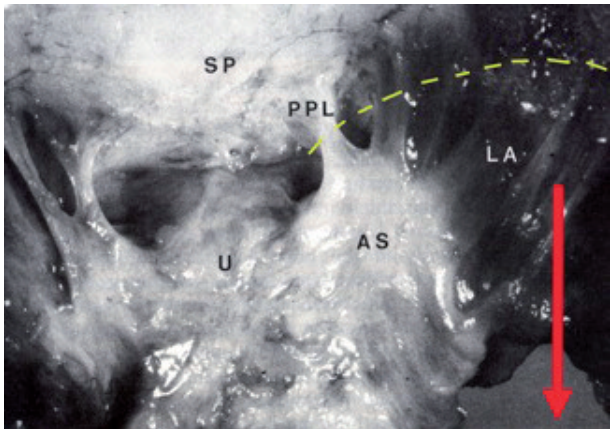

Figure 3. – The divergent insertions of the pubourethral ligament (PUL) into symphysis pubis (SP) and levator ani muscle (LA) and its aponeurotic sheet (AS). LA is equivalent to pubococcygeus muscle (PCM), but not necessarily pubovisceral muscle (PVM), as PUL does not insert into puborectalis which with PCM forms part of PVM. The PCM muscles sweep around the rectum to join and form part of levator plate, which contracts during micturition (red arrow).
The yellow line represents dislocation of LA from SP. During micturition, LA muscle still contracts (large red arrow), but against the left PUL, so the urethra and bladder base are pulled to the right. Photo from Zacharin RF, by permission.

In this next section, we provide the flow mechanics background for our hypothesis. In essence, it involves active opening out of the urethral outflow tract by an external musculoelastic mechanism driven by two striated muscle vectors, backward, levator plate and downward, conjoint longitudinal muscle of the anus. This has been validated by EMG and video X-ray studies.[1,2]

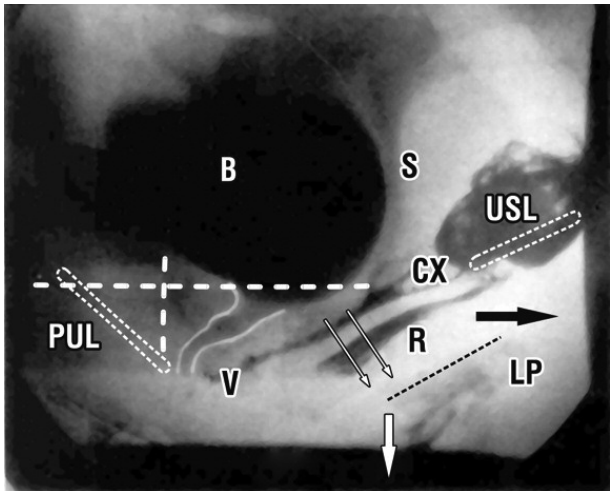

Figure 4. – Micturition X-ray. Levator plate (LP) vector pulls the bladder base and urethra backwards; the downward vector (white arrow) pulls downward on the posterior wall of the urethra opening it out "funneling". This action effectively shortens the urethra. This action also relies on LP being tensioned from pubic symphysis to sacrum. If the right side of LP is ruptured, only the left side can be tensioned, so only the left side is shortened. This scenario explains urinary stream divergence to the left and "spraying", as there will be a smoother flow of urine on the left side and much more turbulent flow on the right side. The important factor here is that the frictional resistance between the urine flow and the urethral wall is exponential, inversely to the 5th power of the radius.

$$\Delta P = P_{ves} - P_0 = \frac{8\rho Q^2 Lf}{\pi^2 d^5} + \frac{1}{2}\rho V^2 - \rho g \Delta h$$

This explains descriptions of a good stream on one side, with "splitting", a dribble on the other side

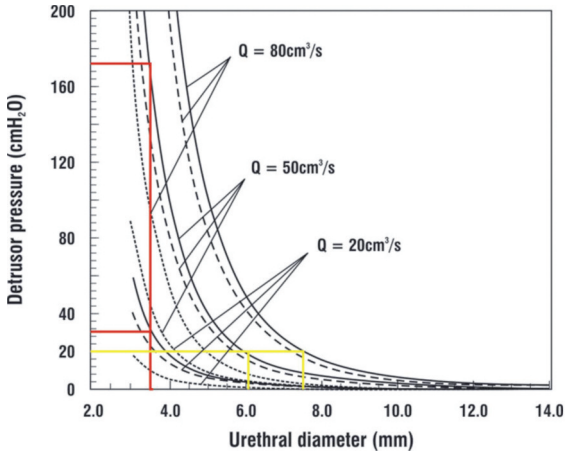

Figure 5. – Figure 5. The pressure flow curve is exponentially determined. Detrusor pressure as a function of the urethral diameter. For a tube length of 4 cm . . . . . , frictional component; - - - - - , dynamic component; _____ , total. A detrusor pressure of 30cm H2O is required to drive the urine out of a smooth tube 3.5cm in diameter at a flow rate of 20ml/sec . 170 cm pressure is required to achieve a flow rate of 50ml/sec.

"Splitting" and a diverted urinary stream are different.

The frictional and dynamic components of urethral resistance are exponentially determined and they apply to the right and left walls of the urethra. Inability to stretch one wall explains a good stream on one side and dribble on the other. Diversion is different. It requires rupture of the pubourethral ligament also.

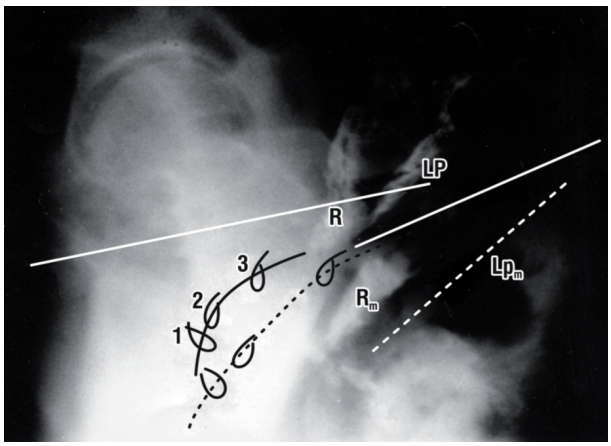

Figure 6. – Upper figure X-ray proof of an external musculoelastic mechanism pulling open the posterior urethral wall. Micturition (broken lines) X-ray superimposed on resting X-ray (unbroken lines). Clips have been applied to the anterior vaginal wall, '1', midurethra, '2' bladder neck, '3' bladder base. Note downward/backward displacement of clips '1,2&3'. The levator plate (LP) and rectum (R) are angulated downwards. Downward movement of clip '1' may indicate active contraction of the lower level muscles of the pelvic floor, such as bulbocavernosus and ischiocavernosus, opening out the posterior wall of the distal urethra. Clips 1 & 2 also indicate the movement of the distal half of urethra which is closely attached to the vagina. The broken lines and the subscript 'm' indicates the position of the LP and R during micturition. Vascular clips on anterior vaginal wall were stretched apart backwards and downwards. Intraabdominal forces are said to cause downward movement, but they could never initiate the backward stretching seen in figure 2. Only a muscle contraction can achieve this.

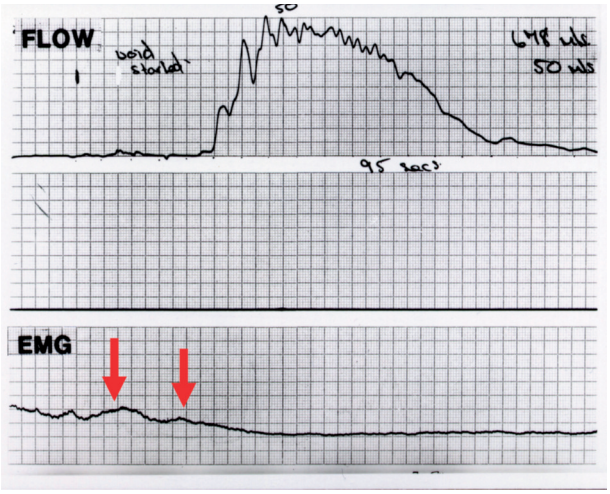

Figure 7. – Lower figure EMG in the posterior fornix of the vagina demonstrates commencement of muscle contraction (arrows) prior to commencement of voiding. This observation is consistent with active opening out of the outflow tract so as to decrease resistance to flow.

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A difficult case

Edited by Nissrine Nakib and Federico Cavallari

A series of difficult cases in pelvic floor diseases are presented with an educational purpose. The proposer describes symptoms, clinical findings and management plans. Opinions and suggestions of a number of Colleagues are reported. In the next issues of Pelviperineology, together with new difficult cases, results and further comments on each case will be published at three and six months follow up.

Severe stress incontinence after the third sling

Clinical Data: This is a 52 year old female with a history of urinary incontinence. She has mainly stress incontinence. In the past she had a transobturator midurethral sling in October of 2010, then periurethral bulking in May of 2011, and most recently a TFS midurethral sling in December of 2013. After her last sling she was dry for about a week and a half then developed severe stress incontinence again.
On exam she has no urethral hypermobility but florid stress incontinence. I performed a simulated procedure supporting the periurethral ligament. When I supported it on the right firmly it did seem to keep her from leaking to some degree but not entirely. When I did it on the left it helped to a much lesser degree.
Urodynamic Testing showed: 1) Large bladder capacity, 900 mL; 2) Excellent bladder compliance; 3) Stress urinary incontinence; moderate volume stress leak at Pabd 156 cm H2O at a volume of 319 mL; 4) Weak voiding detrusor contraction of Pdet ~9 cm H2O heavily augmented with abdominal straining with peak voiding Pabd >130 cm H2O. Flow was intermittent associated with intermittent abdominal straining and Valsalva; PVR ~120 mL.
On cystoscopic evaluation the urethra was normal, except for open bladder neck. The bladder was with 1+ trabeculation. No tumors, diverticulae, or stones. Bilateral u/o's were effluxing clear urine. The cystoscope was then withdrawn. The patient tolerated the procedure well.

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Comments / Discussion

I'd probably recommend a transvaginal urethrolysis and an autologous fascial sling at the bladder neck. There is a reasonable chance she will need to perform ISC to empty after, so she should agree to that. It is possible that the urethrolysis will restore enough mobility to allow for improved emptying even after the fascial sling.

Steven Siegel
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Actions
1. Exclude tethered vagina. If the TOT penetrates the lateral part of pubo-cocygeus, the urethra is pulled open when the patient gets out of bed. If this is so, you need to remove at least 2cm of tape either side of urethra to prevent re-attachment with a new sling. If she does not leak immediately getting out of bed or off a chair, look for the 2nd cause, fibrosis of the old scar.
2. A loosely applied sling fibroses and keeps the urethra in a partly open state. Therefore, the 1st rule after a failed sling is to remove the old sling. If this is not done, the 2nd sling has to compress the fibrosis before it can work. This explains the reduced cure rate with a 2nd sling. This fits with fibrosis holding the urethra open. The musculoelastic closure me-chanism acting around the PUL cannot work if a fibrosed tape is forcibly keeping the urethra open.
3. Obstructed micturition symptoms. If these appeared after bulking or after TFS, then the sling may be too tight or maybe the bulking is preventing the funneling required to open out the urethra during micturition. If after TFS, the problem will disappear after the urethrolysis. If symptoms appeared after the bulking, you may need to extend the dissection to bladder neck as part of the "urethrolysis". Management is the same for both conditions.
I agree with Steve about "transvaginal urethrolysis" as a critical 1st step.
I take this to mean dissecting the old tapes 1-2 cm clear of the urethra midline to lateral and freeing the bladder neck also. I do not agree about fascial bladder neck slings, as these offer no advantage to a well-placed midurethral sling and do not address the geometry of closure.
I would do the operation under LA if possible, or LA augmented by light spinal. After the dissection, I would do another "simulated operation": unilateral pressure immediately behind Pubic Symphysis. I always use this LA methodology for difficult failed cases.
The "simulated operation" should control the urine loss on coughing. If so, depending on the state of the urethra, you can proceed to a 2nd midurethral retropubic sling. TOTs usually work, but they are not physiological and do not address ISD as well.
If the urethra is very thin, it would be prudent to insert a layer of SIS or strip of vagina denuded of epithelium to protect the urethra prior to inserting the sling around such a graft. I see no benefit with a bladder neck sling as this can only prevent the funnelling so necessary to decrease the resistance, a prerequisite for normal micturition.

Peter Petros
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Did you do an ultrasound exam on the position of the tapes? In my experience it is important to know whether the tapes are positioned correctly or not.

Burghard Abendstein
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I'd recommend a Burch colposuspension procedure with 2 stitches on each side. No need to perform an urethrolysis. From now on every intervention that will be done transvaginally would increase the risk of pipeline urethra which is more devastating than her present condition.

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Doing the perineal ultrasound, you could also look permanent opening of the urethra, which could reflect tethered vagina, a finding frequently seen in preoperated patients especially with bulking agents.

Florian Wagenlehner
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I fear obstruction with the colposuspension. Get out the TOT, bulking agent, polypropylene and fibrotic tissue as much as possible - maybe there is some spare vaginal tissue of a little cystocele to cover the defect - wait at least three months and then put in a TVT or another TFS.

Alfons Gunnemann
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If the primary transobturatoric tape is positioned too caudally it can fix the urethra open with the effect of continuing stress urinary incontinence. Then the second tape (in this case TFS) can fail. So I agree with Peter and Steve to do a careful urethrolysis to free the urethra from the transobturatory tape. Intraoperatively do simulated operations (fill up the bladder and press from the abdomen against the bladder) and look, if unilateral elevation at midurethra will prevent leakage. I also would insert then a retropubic sling at midurethra.
We did some cases like that with good results. Always remember that the pubourethral ligament is very much important for stress continence and that it inserts retropubic.

Bernhard Liedl
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1- Despite all we think, we still don't know the full picture of pathophysiology of urinary incontinence and especially recurrent/persistent incontinence
2- I agree that the first task is to do a urethrolysis. I am of the opinion that you would need to let her heal from urethrolysis for about 3 months and then re-evaluate her. If you have video-urodynamics, I would highly recommend it- as it will give you 'visual' information about the open bladder neck, urethral kinking (from previous mid-urethral slings), etc.
3- Also, pay attention to ventral surface of the urethra- as this is where the PUL exist. As such, and pending on your re-evaluation results, an anterior approach (modified Burch) where you could bring urethra closer to dorsal surface of symphysis pubic could also be entertained.

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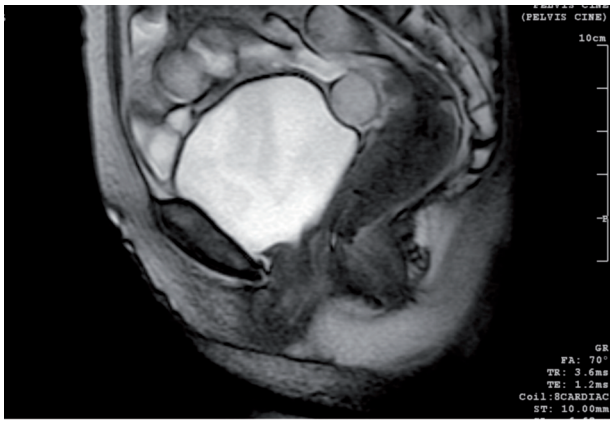

Figure 1. – Pre-TVT.

Let me show you, the example of "if the primary transobturatoric tape is positioned too caudally it can fix the urethra open with the effect of continuing stress urinary incontinence."
The preoperative cine MRI shows SUI with mild hypermobile urethra (Figure 1). The second cine MRI was performed 3 months later after failed TVT procedure. It is assumed that TVT tape was positioned on or dislocated to proximal urethra (Figure 2). You can see changed urethral axis and opened proximal urethra.
"Midurethra" is critical, isn't it?

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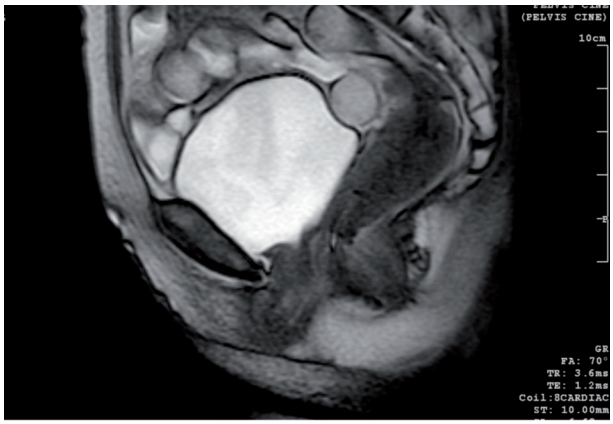

Figure 2 – Post-TVT.

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- New and old surgical techniques for pelvic floor reconstruction
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- Cure of pelvic floor dysfunction by pelvic floor surgery: updated evidence
- Neuromodulation in pelvic floor dysfunctions
- Drugs including Botox to treat vesical and anorectal dysfunctions
- Current results of clinical studies using alloplastic materials at the pelvic floor
- Slings and artificial sphincter in male and female
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Submission

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State of the art

Anal sphincter injuries in daily surgical practice - diagnosis and treatment

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Abstract: According to statistical data, the most common anal sphincter injuries have obstetric aetiology (obstetric anal sphincter defect) or are of iatrogenic nature (fissurectomy, fistulectomy). Apart from perineal repair, including third- or fourth-degree injuries, performed directly after childbirth, the majority of such defects are treated in the course of scheduled procedures. Acute anal injuries resulting from sexual abuse and anal rape, foreign bodies and accidental injuries (e.g. by explosions, impalements, car accidents, etc.) constitute a separate diagnostic and therapeutic problem. Contrary to scheduled procedures, acute anal sphincter injuries are frequently treated in clinics that do not possess appropriate diagnostic base and experience in anal sphincter repair. The article presents the principles of diagnosis and management of acute anal sphincter injuries. The patient is always hospitalised and in the majority of cases, undergoes a surgery. The diagnostic process encompasses: interview, general physical and anorectal examinations, which frequently have to be conducted under anaesthesia, as well as basic laboratory tests: blood group, complete blood count, electrolytes, coagulation parameters and urinalysis. Additional diagnostic examinations include: abdominal x-ray, abdominal ultrasound and, if possible, transrectal ultrasound. The best functional effects are obtained if the muscles are sutured directly after the injury. If the sphincter defect is extensive, or the patient's condition is severe, or if the injury concerns multiple organs, a stoma should be performed. Similarly, if the surgeon has no experience in anorectal procedures, a stoma should be performed and the patient should be referred to a clinic with greater experience in coloproctology. The management in the case of scheduled sphincteroplasty is different. It should be preceded by functional and imaging diagnostic examinations.

Key words: Anorectal trauma; Diagnostics; Management; Overlapping sphincteroplasty.

INTRODUCTION

The most common causes for anal sphincter damage are obstetric[1-3] (Figures 1A, 1B) and iatrogenic injuries (fissurectomy, fistulectomy) (Figures 2A, 2B). In daily surgical practice, anorectal trauma is a rare pathology that usually results from sexual abuse and anal rape, foreign bodies and accidental injuries (e.g. by explosions, impalements, car accidents, etc.)[4] (Figure 3). The last two are also associated with injuries to other organs, such as: urethra, urinary bladder, vagina or pubic bone. Rarely, anal sphincter defects may result from swallowed foreign bodies, such as bone pieces or glass. Isolated anal damage results from a fall on sharp objects or are caused by various machines used e.g. on agricultural farms. Acute sphincter traumas are usually managed in surgical wards that do not have experience in coloproctology. Scheduled sphincter repair procedures, on the other hand, are performed in coloproctological centres. The article presents the principles of diagnostic and therapeutic management in acute anal sphincter trauma, presence of a foreign body in the rectum and planned repair of sphincter muscles.

DIAGNOSTIC AND TREATMENT

The general condition of a patient with anal defect may be different: good in the case of mild, isolated injury, or severe, including shock, in the case of extensive anal injury concomitant with damage to other pelvic structures and abdominal organs. Due to its rich innervation, the perineal region is a "shock-prone" area. Therefore, initially, it is difficult to assess whether the patient is in shock due to pain or haemorrhage. Analgesic medicines should be administered instantly. Moreover, examination by palpation should be conducted (see below) and vital signs should be monitored.

Diagnostics

The diagnostic process in a patient with acute anal injury encompasses: interview, general physical and anorectal examinations which frequently have to be conducted under anaesthesia. Additional diagnostic examinations should also be performed.

Interview

In order to reduce the level of psychological stress, privacy is essential during the interview, particularly when it is suspected that the damage was caused in the course of sexual activities or sexual abuse. Furthermore, embarrassed patients may conceal the circumstances in which the injury was sustained, which hinders diagnosis and treatment. Medical documentation should include: time of damage

Figure 1A. – High-grade obstetric damage to the sphincters.

Figure 1B. – High-grade obstetric damage to the sphincters.

Figure 2A. – Anal sphincter damage following fistula surgery.

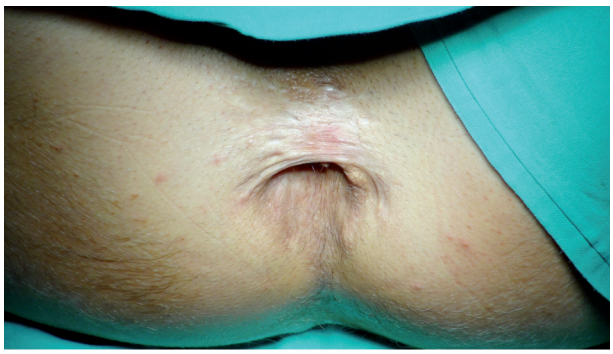

Figure 3. – Deformed anal canal in a patient after traffic accident (damage to multiple organs including sphincters).

(hour), time after which the patient reported to hospital and description of the circumstances in which the injury was sustained. The patient usually complains about pain in the anus and perineum as well as bleeding. The patients should be asked whether they passed stool or urine after the injury and whether there were traces of blood.

Physical examination

The level of consciousness as well as verbal and logical contact is assessed. The blood pressure and heart rate should be taken. If there is a suspicion that the patient may be intoxicated, this should be confirmed (if possible) with the blood alcohol test and the result should be included in the documentation. The abdomen should be examined by palpation. Additionally, a catheter should be inserted into the urinary bladder and urine should be checked for the presence of blood.

Anorectal examination

Anorectal examination consists of visual inspection of the anus and digital rectal examination. During visual inspection, one should assess the perianal region in terms of possible wounds, presence of blood or stool. So-called "anal sealing" are assessed (gaping anus usually attests to a severe damage to the sphincter muscles) (Figures 4). Subsequently, if possible, digital rectal examination should be conducted in Sims' position (sometimes pain prevents rectal examination). This examination enables the assessment of passive tone of the sphincters (which indirectly indicates the function of the internal anal sphincter) and subsequently, active tone during sphincter contraction (which indicates the function of the external anal sphincter and puborectalis muscle). The rectal contents (stool, blood, foreign body) should also be assessed. If possible, an endoscope should be inserted to the rectum (anoscope, rectoscope). Sometimes, it is necessary to examine the patient under anaesthesia.

Additional examinations

The fundamental examinations include: blood group, CBC, electrolytes, coagulation parameters and abdominal x-ray in a standing position or, if the patient's condition is severe, in a supine position as well as abdominal ultrasound. If a foreign body in the rectum is suspected, radiological examinations should be performed prior to the digital rectal examination. This particularly refers to the cases in which it is suspected that a sharp object was inserted into the rectum which might injure the physician performing the examination. If the hospital has such a possibility, performing anorectal endosonography – a transrectal ultrasound examination performed with a dedicated rectal transducer – may be very helpful.

Treatment

The best results of sphincter injury treatment are obtained when the repair procedure is performed directly after sustaining damage, i.e. not later than 24 hours after the injury, in a centre that has experience in anal reconstruction surgeries. The functional effects of delayed, scheduled repairs are considerably worse. Nevertheless, they seem to be a better alternative if the centre lacks experience.

Emergency sphincter repair

In the case of an isolated sphincter injury and good overall condition of the patient, emergency sphincteroplasty

Figure 2B. – Anal sphincter damage following fistula surgery.

Figure 4. – "Gaping anus" resulting from a considerable iatrogenic injury of the sphincters.

should be attempted. If the muscle is partially damaged, it is sutured by "end-to-end" technique and all crushed tissues are removed. In the case of doubts whether or not a given tissue is a muscle, one may apply electric stimulus that causes muscle contraction. A partial injury may be managed by single mattress stitches without mobilising the ends. If the entire thickness of the sphincters is damaged, it may be attempted to mobilise the muscle stumps and apply "overlapping" stitches (Figures 5A, 5B, 5C). Subsequently, anoderma and skin are sutured. Approximately 0.5 cm of the skin in the wound circumference should be left unsutured since this enables its drainage. If the wound crosses the ischiorectal fossa, an exceptionally thorough haemostasis should be performed (frequently, there is heavy bleeding from the ischiorectal fossa). A practical way to visualise the bleeding vessel in the ischiorectal fossa is to insert an endoscope which is superior to retractors in visualising deep wounds. The ischiorectal fossa heals by secondary intention with placed setons. Perineal wounds should always be thoroughly rinsed with hydrogen peroxide and should never be tightly stitched.

Indications for stoma

There is no consensus about indications for colostomy.[4] The decision to perform it is conditioned by several factors, such as: patient's overall condition, time that lapsed since the injury, the degree to which the rectum is filled with faeces and range of damage. If the condition of the patient is severe, the duration of the surgery should be reduced as much as possible – only essential, life-saving procedures should be performed, i.e. managing damaged organs and introducing a stoma. Optimal time for performing sphincteroplasty is 6 hours from the moment of sustaining injury. If over a dozen hours lapsed since the injury and perineal infection is suspected, it is always safer to perform a stoma. Experience of a surgeon in managing such injuries is also significant. If the surgeon on duty has no experience in anorectal procedures, stoma should be performed and the patient should be referred to a clinic with greater experience in coloproctology.

If damage to other organs is suspected, exploratory laparotomy should be conducted nearly always. A stoma should be performed in almost each case of extensive sphincter damage as well as in situations when repair is impossible due to technical reasons and when anal sphincter injury is accompanied by damage to other organs. An antibiotic therapy is always implemented.

Abandoning sphincteroplasty

– if the condition of the patient is grave: the duration of the surgery should be maximally reduced to include only essential, life-saving procedures, i.e. managing damaged organs and introducing a stoma;

– in extensive sphincter damage when repair is impossible due to technical reasons. The wound should be debrided and drained extensively. A stoma should be performed;

– when the surgeon lacks experience in managing such injuries.

Scheduled sphincteroplasty

A scheduled sphincteroplasty should be conducted in a coloproctological centre after the wound has completely healed, which usually occurs after min. 4-6 months following the injury. Theoretically, only injuries that do not exceed 1/3 of the muscle circumference are qualified to the repair procedure. However, in the authors' individual practice, repair attempts are sometimes undertaken when the damage is more extensive. In these cases, the patients always need a previously performed stoma.

Whereas emergency sphincter suturing is performed without prior functional diagnostics, the initial sphincter function should always be examined prior to qualifying the patient to a planned sphincteroplasty. This is essential since delayed reconstruction surgeries are not always effective and by properly documenting the extensiveness of damage, subsequent disappointment or even possible legal claims may be avoided. Therefore, the following should be conducted:

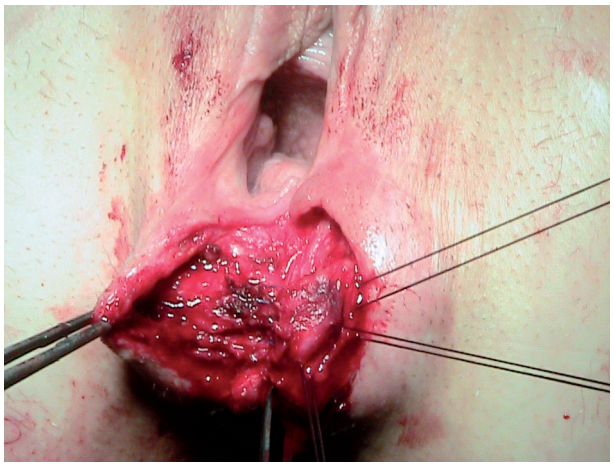

Figure 5A. – Mattress stitches.

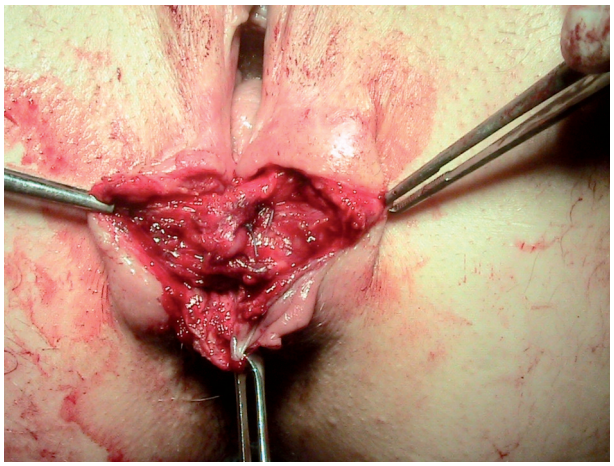

Figure 5C. – Sutured muscles.

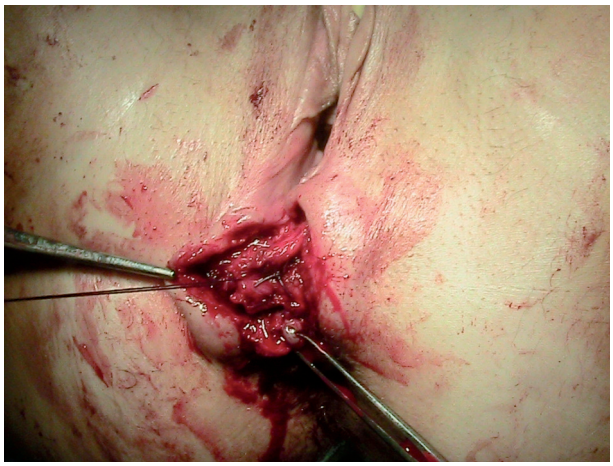

Figure 5B. – Stitch that brings the muscle closer to the wound bed.

a. anorectal examination and assessment of sphincter sufficiency according to an objective incontinence scale (e.g. Wexner's scale).

b. additional examinations:

– anorectal manometry

– anorectal endosonography or sphincter magnetic resonance imaging.

Anorectal manometry is an examination which allows for an indirect assessment of sphincteric function and sensory anorectal reactions. The basic parameters measured during the so-called static manometry include: resting and squeeze pressure in the anal canal, anal canal length, length of the increased pressure area, functional length of the internal anal sphincter as well as reflexes that are essential for, so-called, sensory functions of the anal canal and rectum, i.e. Gowers' recto-anal inhibitory reflex and reactional contractile reflex of the internal anal sphincter.[5] However, anorectal manometry does not enable to determine the cause of damage (mechanical or neurogenic). In order to specify the size and localisation of muscle defect, dynamic manometry may be applied. It allows for measuring pressure in a balloon in the rectum by means of continuous measurements and visualising these values in the form of a spatial figure. The difference between the volume of the obtained figure in the examined patient and the volume of so-called "ideal patient" is expressed in percentage and is called sphincter radial asymmetry. It allows for the localisation of the site of damage in approximation.[5]

Anorectal endosonography constitutes a supplementation of functional assessment and provides a morphological picture of the sphincters. In sphincter damage, the examination is performed to assess: the localisation of the injury with the specification of the damaged muscle (internal sphincter, external sphincter or puborectalis muscle), range of muscle defect (defect of more than 30% forces the operator to consider a protective stoma and sphincteric defect of more than 50% renders the repair surgery practically ineffective). The remaining muscle mass needed for reconstruction is assessed. The examination is performed both to qualify the patient to the procedure and to assess the efficacy of the surgery (Figures 6A, 6B, 6C, 6D).

Magnetic resonance with the use of a torso/pelvic coil or endoanal coil is rarely performed in sphincter injury diagnosis. It usually takes place in centres that do not possess endosonography or when endosonographic image is ambiguous. In the authors' own practice, MRI was performed only once when following endosonography, damage to the branch of the puborectalis muscle was suspected in a woman after a brutal rape. MRI image confirmed partial damage to the puborectalis muscle with coexistent injuries of the internal and external sphincters.

The findings of additional examinations need to be included in the documentation due to medical and legal reasons.

Similarly to emergency surgery, the scheduled procedure is conducted with the use of "overlapping" or "end-to-end" techniques. Overlapping sphincteroplasty was thoroughly described by Slade in 1977.[6] The long-term effects of planned repair surgeries are not always satisfactory but the published data related to their effectiveness are divergent.[7,8] Some authors estimate the effectiveness of such procedures at 50%,[9] others quote very high effectiveness rates.[10] Probably the reason for such discrepancies is non-uniform material of analysed patients. Next to mild injuries to the sphincters, the studies also included extensive sphincteric injuries and the other way round.

In nearly each case, surgical treatment should be followed by conservative therapy. Conservative treatment encompasses appropriate diet (avoiding foods that cause diarrhoea, diet thickening) and pharmacological therapy. Exercising sphincter muscles, frequently with the use of the biofeedback method, is also recommended. The biofeedback method uses biological feedback (visual or auditory control of the patient over contraction strength of the sphincters while exercising). The possibility to observe the reactions of the device to muscle contractions enables the patients to acquire and strengthen the ability to adequately flex and relax the muscles and the observed improvement motivates them to further exercises.

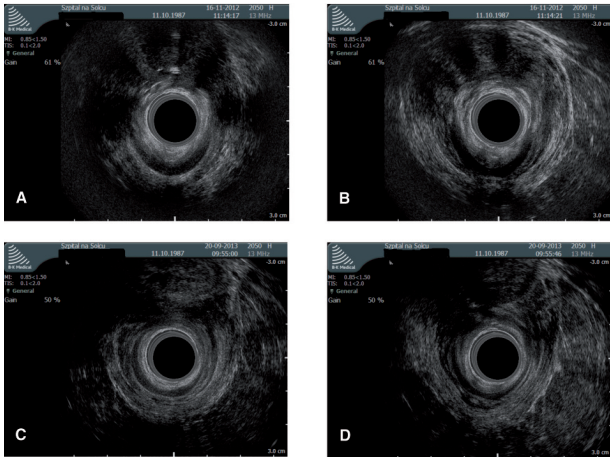

Figure 6. – Endosonographic examination of the obstetric injury of the anterior circumference of the internal and external sphincters in mid (A,C) and high (B,D) anal canal, before repair (A,B) and after sphincteroplasty (C,D) showing restored continuity of the muscles.

If defects are extensive and do not qualify to the procedure of suturing the sphincters and if the performed procedures mentioned above are ineffective, alternative surgeries should be considered, such as dynamic graciloplasty[11,12] or implantation of an artificial bowel sphincter - a hydraulic prosthesis, ABS.[13,14] The less invasive methods include: transrectal sacral nerve stimulation (SNS),[15,16] radiofrequency anal remodelling (RFAR) - Secca procedure or injecting collagen, silicone-based material, carbon microspheres and autologous fat into the sphincteric region.[17] None of these methods, however, produce long-term effects. Mixed injuries, i.e. structural defects with neurogenic component, are particularly problematic and do not have a favourable prognosis. The presence of neurogenic component may render the treatment ineffective even if the defect qualifies to sphincteroplasty.

Sphincteric injuries may also be caused by the presence of foreign bodies introduced to the anus. Sphincter damage results from: a: stretching (damaging the internal sphincter); b: direct injury by a foreign body (e.g. glass); c: movement of a foreign body, which leads to perforation or injury to the wall of the anus and rectum.[4] It is essential to take a detailed history from such a patient. Information concerning the circumstances in which the object was introduced into the rectum should be acquired. Foreign bodies are usually inserted during sexual activities. The patient frequently reports to the physician a day after sustaining damage and sometimes, due to intoxication, he or she does not remember the circumstances of the incident. If the patient does not complain about severe pain in the anus, no peritoneal symptoms are observed and the patient is in a good overall condition, anorectal examination may take place without anaesthesia in the left lateral position, during which the object may be retrieved from the anus. The knee-elbow position should be avoided since due to the force of gravity, the

foreign body may move away from the anal opening. Similarly to anal damage, anorectal examination should be preceded with abdominal x-ray, which facilitates localising the foreign body and helps determine its morphology and type. After the first unsuccessful attempt to retrieve the foreign body, the subsequent attempts should be made under anaesthesia in the operating theatre.[18] In some cases, laparotomy may be necessary. Following each removal of the foreign body, the rectal mucous membrane should be assessed via an endoscope. The patient should be monitored in hospital for at least 24 hours.

CONCLUSION

Despite the advancement of anal and rectal surgery, the most effective method of treating sphincteric injuries is primary surgical repair. The effectiveness of the procedure depends on experience of the surgical team, which is associated with proper wound debridement, correct suturing of the sphincters and factors that do not depend on the surgeon, such as: time that lapsed from sustaining the injury to sphincter repair procedure, extensiveness of damage, co-existence of damage to other organs, general condition of the patient and the degree to which the rectum is filled with stool. Scheduled sphincter repairs are performed in coloproctological centres and are preceded by functional and imaging examinations. Nevertheless, their long-term effects are worse than those of emergency procedures. Surgical procedures should be followed by conservative treatment, including biofeedback therapy or electrostimulation of the sphincter muscles.

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Review article

Mini-sling procedures in surgery of stress urinary incontinence: a literature review

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Abstract: Sling surgery has been the gold standart treatment of stress urinary incontinence. Nevertheless, the 'zero tolerance' concept has led to searching for a new technique which would be minimally invasive as well as complication free. Hence, third generation slings, namely mini-islings have been developed. A general overview has been carried out to the minislings in the light of current literature.

Key words: Minislings, single incison minisling.

INTRODUCTION

Stress urinary incontinence (SUI) is a common condition that may affect up to 20% of women.[1] Over the past several decades, various surgical procedures and techniques have been available for the treatment of SUI. Sling therapy is the enhanced surgical support of the urethra, routinely performed by vaginal or abdominal (open or laparoscopic) routes, or, most recently, by access to the obturator foramen. Kelly's 1913 anterior vaginal repair is probably the oldest described procedure for incontinence. The Marshall-Marchetti-Krantz urethropexy (1949) sought to elevate the proximal urethra directly in the same way that the Burch colposuspension (1961) did indirectly by using the vagina as a hammock.

Since Ulmsten and Petros first described in 1996 the TVT procedure, use of tension–free suburethral tapes has become the gold standard for the treatment of SUI in women.[2] This treatment was based on the Integral Theory,[3] which suggests that continence depends on urethral closure related to interplay between the pubourethral ligaments, a suburethral vaginal hammock and the pubococcygeous muscles. Its advantages include short operative time, quick postoperative recovery, low complication rate, and good effectiveness.[4] Although cure rates were excellent with the retropubic approach, there were also complications associated with the blind-needle passage through the retropubic space including bladder perforation and nevre injury as well as major vascular and bowel injuries.[5,6] In 2001, Delorme described the transobturator approach that offers similar efficacy with decreasing risk of complications.[7] However, TOT has been associated with a small but defined risk of prolonged leg pain, owing to passage of the transvaginal mesh through the obturator foramen.[8,9] Recently, a third generation of suburethral slings has been developed using a single vaginal incision and shorter polypropylene tape (8-14 cm: mini-sling).[10] They were designed to support the mid-urethra in the same fashion as has been accomplished with the TVT and TOT but without the passage of a trocar or mesh through the retropubic space or obturator foramen. The goal of the single-incision midüretral sling (SIMS) is to provide comparable cured-dry rates, with fewer side effects and adverse events. They require local analgesia and a single vaginal incision.

Because of the relatively new market introductions of the mini-slings, there are limited published data available for either of these new product. The efficacy of single incision mini slings remains unknown as the current literature regarding minisling lacks long-term results. The present paper entails the current up-to-date literature on 'mini-sling' and aims to assess the technique, safety, and efficacy of mini-slings in the surgical treatment of the female SUI.

METHODS

The Pubmed and Medline online databases were searched for the term "mini-sling" and "single-incision sling". Only papers written in English were analyzed.

DISCUSSION

Recently, many different procedures have been introduced to the market. Some of these minislings (for example, the TVT Secur®) were withdrawn when low efficacy and high complication rates based on well-designed randomized controlled trials were published.[11] A number of single incision mini-slings (SIMS) are currently used in clinical practice; MiniArc® (American Medical Systems, Minnetonka, MN, USA), Ajust® (C.R. Bard, Murray Hill, NJ, USA), Ophira® (R. Promedon, Cordoba, Argentina), TFS® (Adelaide, Australia).

Kenelly et al present a multicenter prospective study evaluating MiniArc® placement in the treatment of female SUI.[12] The study population comprised 188 women, and 157 patients had been followed up for 1 year. The primary outcomes of the study was sling efficacy. Secondary outcomes were sling safety and procedure variables. The reported 12-month success rates ranged from 85-91%, depending on the outcome measure wich were evaluated. A low rates of perioperative and postoperative adverse events were seen.

In 2011, Pickens reported on 108 patients undergoing the MiniArc® with a 94% cure rate at 12 months follow up.[13] Both studies also showed statistically significant improvements in the UDI-6 and IIQ-7 scores. Prospective randomized studies with long-term follow up are needed to evaluate whether the MiniArc with benefits of single incision technique can still guarantee satisfying continence results after 5-10 years.

The Tissue Fixation System® (TFS) consists of an adjustable polypropylene mesh that uses two small plastic anchors to fix it into the inferior surface of the pelvic muscles and tissues below the retropubic space, in an hammock-like tension-free position. The initial dissection is similar to other midurethral tapes, and para-urethral dissection carried a few millimeters beyond the urogenital diaphragm, so the applicator is placed in this space and triggered to release the TFS® anchor. Then the tape is pulled with a short, sharp movement to set the anchor prongs into the tissues. Adequate fixation was tested by pulling the free end of the tape. After performing this on both sides, the tape was tensioned until it is placed firmly against but not indenting the urethra and the free end is cut. This single-incision sling was developed by Petros and their report at medium follow-up (3 years) provides data about 36 patients with stress incontinence. Cure rates on 31 eligible patients were 80%. Complication rates are not described.[14]

Author	Type of studies	Sling	n. pts	Evaluation Criteria	F/U months	Outcomes
Kennelly et al.[12]	multicenter, prospective, single arm institutional review	Mini-Arc®	157	CST, PWT, IIQ-7, UDI-6 scores	12	Primary study outcomes included sling efficacy Secondary outcomes were sling safety and procedure variables.
Pickens et al.[13]	Prospective, observational study	Mini-Arc®	108	UDI-6,IIQ-7 scores	12	Treatment success and adverse events
Petros et al.[14]	Prospective	TFS®	36	The patients were contacted by telephone independently by a nurse	36	Symptomatic cure was reported
Sekiguchi et al.[15]	Prospective	TFS®	45	urodynamic SUI	16	de novo urgency or urge urinary incontinence
De Ridder et al.[16]	retrospective, dual-center, cohort study	Mini-Arc® Monarc®	75 56	CST, daily pad use, IIQ-7,UDI-6, and a 0-5 VAS for QoL.	12 12	Primary studi outcomes included sling efficacy
Hinoul et al.[11]	Randomized multi-centre study	TVT-Secur® TVT-O®	96 98	UDI-6, and a 0-5 VAS for QoL	12 12	Objective cure at 12 mo, patient-reported cure, operation time, postoperative hospital stay, day 1 VAS pain score, QoL, and safety
Abdel Fattah et al.[17]	Meta-Analysis	TVT-Secur®, MiniArc® and Ophira® to standard mid-urethral sling	9 studies	Meta-analysis of all randomised controlled trials (RCTs) comparing SIMS versus SMUS was performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement	6-12	Primary outcomes were patient-reported and objective cure rates. Secondary outcomes included perioperative complications, quality of life (QoL) changes, and costs to health services.
Cornu et al.[18]	Prospective	TVT-Secur®	45	PGI-I, PWT	30	objective cure, subjective cure and failure rates
Sivaslıoglu et al.[19]	prospective randomized controlled trial	TFS® I-Stop®	80	urodynamically proven stress urinary incontinence	64	objective cure, subjective cure and failure rates
Alvarez-Bandres et al.[20]	retrospective, descriptive analysis	TVT-Secur® Mini-Arc®	50 105	clinical history, physical examination and two questionnaires of QoL	6	intraoperative, early (within the first month after surgery) and late complications (after a month)

Another report on TFS®, from Tokyo, describes a prospective study on 44 women with urodynamic SUI. This cohort had an high percentage of women with poor sphincteric function (34,1%). With a mean follow-up of 16,1 months, success was noted in 91% of patients, with 4 cases considered treatment failures (9%). Pain complaint at discharge was minimal. No significant blood loss was described. Five patients (11%) had transient voiding difficulties that resolved after 48 hours of indwelling catheterization. Nine patients (20%) had occasional urge incontinence in the post-operative follow-up, that resolved spontaneously or with pelvic floor exercises.[15]

Comparisons of single-incision mini-slings with standard mid-urethral slings

In a retrospective, dual-center, cohort study on the single incision MiniArc® sling and the transobturator Monarc® sling in the treatment of stres urinary incontinence one hundred thirty-one (MiniArc® n=75, Monarc® n=56) consecutive patients were evaluated. Evaluation was performed by cough stress test (CST), daily pad use, IIQ-7, UDI-6, and a 0–5 visual analog scale for quality of life. The results of the study were compiled after a 1-year follow-up. The authors of the article conclude that the MiniArc® and Monarc® procedures are equally effective in the treatment of stress incontinence in female patients with in 1 year following treatment. A possible advantage of the MiniArc® sling which is confirmed in these study is the significant reduction of duration of the procedure (11 vs 19 min; $p<0.0001$). Another possible advantage of a minimal invasive approach could be a reduced risk of postoperative groin pain due to transobturator passage.[16]

In a recent European study, the TVT Secur® was compared to the TVT-O® in a multicenter, prospective, randomized control trial.[11] One-year follow-up for 75 TVT Secur® and 85 TVT-O® patients showed objective post-op SUI of 16.4% with TVT Secur® versus 2.4% with TVT-O® ($P = 0.002$). Subjectively, 24% of TVT Secur® patients reported SUI versus 8.3% with a TVT-O® ($P = 0.008$). Up to the 2-week post-op period, significantly less pain was noted with the TVT Secur. Although this evolution has led to a less invasive procedure with decreased post-op pain and reduced recovery time, the efficacy could be the endpoint. Additional medium- to long-term data are needed to answer this question.

Recently, Abdel-Fattah et al.[17] published a meta-analysis whose outcome was the clinical cure/ improvement of incontinence for single-incision minislings versus standard mid-urethral slings at 6- to 12-month follow-up. Moreover,

the authors evaluated the most important surgical outcomes, including perioperative and postoperative complications, impact on women's quality of life, sexual function and cost to health services. Nine studies were included comparing TVT-Secur®, MiniArc® and Ophira® to standard mid-urethral slings. On the whole, the data of the meta-analysis show that single-incision mini-slings were associated with lower patient-reported (OR: 0.83; CI: 0.70–0.99, P = 0.04) and objective (OR: 0.85; CI: 0.74–0.97, P = 0.01) cure rates on short-term follow-up when compared with standard mid-urethral slings and with significantly higher reoperation rates for SUI (RR: 6.72; 95% CI, 2.39–18.89; P = 0.0003). Abdel-fattah et al. demonstrated that repeat continence surgery and de novo urgency incontinence were significantly higher in the patients treated with mini-slings.

Data with longer follow-up are available from prospective case series. Cornu et al.[18] demonstrated recurrence of SUI in about 40% of the patients treated with TVT-Secur® at a mean follow-up of 30 months. According to the National Institute for Health and Clinical Excellence in the UK, mini-slings should only be used in the context of research studies or through submission of data to a national register.

A prospective randomized controlled trial of the TOT and TFS in patients with stres urinary incontinence published in 2012.[15] Contrary to reports in the literature of poor results with mini-slings, in this research the tissue fixation system mini-sling demonstrated a higher cure rate and lower complication rate than the transobturator tape. Total followup was 64 months. The objective cure, subjective cure and failure rates in the tissue fixation system group were 83% (30 cases), 6% (2 cases) and 11% (4 cases), respectively. The objective cure, subjective cure and failure rates in the transobturator tape group were 75% (27 cases), 3% (1 case) and 22% (8 cases), respectively. The difference in objective cure rates was statistically significant in favor of the tissue fixation system (p = 0.029). The difference in decreased cure rates between 5 and 3 years was 7% (90% to 83%) for the tissue fixation system vs 9% (84% to 75%) for the transobturator tape. The relative decrease in cure rates between the 2 groups was not statistically significant (p = 0.16).

Complications of female urinary incontinence surgery with mini-sling system

Alvarez-Bandres et al reported in a descriptive analysis of the complications of the surgery in a group of 155 women with urinary incontinence whom have had minisling surgery (50 TVTSecur® and 105 MiniArc®) from October 2006 to November 2008.[20] The complications were grouped into three categories: intraoperative, early (within the first month after surgery) and late complications (after a month). The complication rate was reported of 20% (22% TVT-Secur®, 17% MiniArc®). They reported one intraoperatory complication corresponding to a bladder perforation (0.64%), managed conservatively with catheterization. All early complications were reported in the MiniArc® group: one obturator fossa hematoma (0.64%) spontaneously resolved, groin pain in 4 patients (2.5%) successfully treated with NSAIDs and one urethral obstruction (0.64%) that required mesh cutting. Late complications included: 8 vaginal erosions (5%), 4 required tape excison and vaginal wall closure; 2 were treated with vaginal estrogens, and the other 2 were asymptomatic so they did nothing. Six patients (3.8%) showed urethral obstruction: they performed mesh cutting in 5, whereas one patient improved with intermittent catheterization. Urge symptoms were reported in 10 patients (6.45%) and successfully managed with anticholinergic agents. Two patients suffered from recurrent infections (1.3%) confirmed by antibiogram, treating isolated episodes.

Urinary incontinence surgery using suburethral mini-slings is not free of complications (20%).[21] However, such complications may be conservatively managed and are less severe than those caused by previous procedures, and this new generation of slings is therefore an effective and safe technique for correcting female stress urinary incontinence.

CONCLUSION

Single-incision slings appear to be a valid option to offer to patients with SUI. The theoretical advantage of the SIMS is the avoidance of the retropubic space and obturator fossa, and the lack of necessary thigh or suprapubic incisions. Most of the studies investigating minislings show that at best, they are not inferior when compared with the conventional TVT.

In addition, their lower complication rates as compared to our TVT and TOT series and the possibility of performing outpatient surgery under local anesthesia make this new generation of tapes a valid tool for SUI treatment. In conclusion, there is an extreme need for a high-quality randomized clinical trial.

The use of SIHS in the treatment of SUI with demonstrable urethral hypermobility and pure urodynamic SUI is established. Moreover, the indications for single incision minisling have been expanded to include other special situations such as mixed urinary incontinence, low leak-point pressures, minimal urethral hypermobility, recurrent SUI, concomitant prolapse surgery, obesity and advanced age.

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Original article

An EMG needle technique for validation of external opening of urethra by levator plate during micturition

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Abstract: Background: At present, the commonly accepted notion is that the pelvic floor muscles relax, allowing micturition and defecation to take place. Significant observational x-ray data evidence indicates that there is an active striated mechanism which opens out both the urethra and anorectum during micturition. Micturition studies with an EMG cylindrical electrode positioned in the posterior vaginal fornix demonstrated that these contractions preceded the onset of urine flow. In the 1990 Integral Theory publication and subsequently, it was hypothesized that both levator plate and conjoint longitudinal muscles of the anus activate this external opening mechanism. However, this has never been demonstrated by direct needle EMG. *Aim* to develop EMG methodology to measure levator plate contraction, thought to be a key element of this active opening mechanism. *Methods:* Using ultrasound guidance, an EMG needle was inserted halfway between the anus and coccyx, 1.5cm laterally from the midline position to a depth of approximately 1.5 cm. *Results:* The needle EMG showed that muscle contraction preceded urine flow. *Conclusions:* The technique, though successful, is not easy to perform accurately and requires ultrasound guidance for accurate needle placement. Further studies are proceeding.

Key words: EMG; Levator plate; Micturition; Pelvic floor contraction.

INTRODUCTION

In 1990, the Integral Theory of Female Urinary Incontinence[1] hypothesized that the urethral closure on stress and opening during micturition were activated by an external striated muscle mechanism, directional muscle forces stretching the surrounding tissues (Figures 1-3). Closure was activated by 3 striated muscle vectors, forward (m.pubococcygeus), backwards (levator plate) and downwards (conjoint longitudinal muscle of the anus) (Figure 2). Micturition was almost the same except that the forward vector (m.pubococcygeus) relaxed, while the posterior vectors (levator plate and the conjoint longitudinal muscle of the anus) contracted (Figures 1, 3); this causes the urethra to funnel, lowering the resistance to flow by the expulsive action of the detrusor.

All hypotheses require objective testing. Only the distal closure mechanism (Figure 2) was demonstrated in 1990. Abdominal ultrasound testing demonstrated distal urethral closure from behind on straining and coughing.[1] Video x-ray proof for closure and micturition was offered in 19932 and again in 1997.[3,4] In 1997, a cylindrical EMG located in the posterior vaginal fornix showed evidence of pelvic floor contraction during coughing and micturition, in the latter, preceding urine flow (Figure 3).[3,4] Video x-ray studies indicated that contraction of levator plate was also most likely a critical part of anorectal closure and evacuation[5] (Figures 1, 3). A finite element model based on known stretch extension characteristics of the components of the vagina and urethra indicated that the pressure generated by the detrusor during micturition was deficient by at least two orders of magnitude as regards opening pressure.[6]

Though highly suggestive of an external striated muscle action during closure and micturition, none of these investigations were able to definitively demonstrate contraction of the levator plate as hypothesized.

Our aim was to develop a repeatable method for location

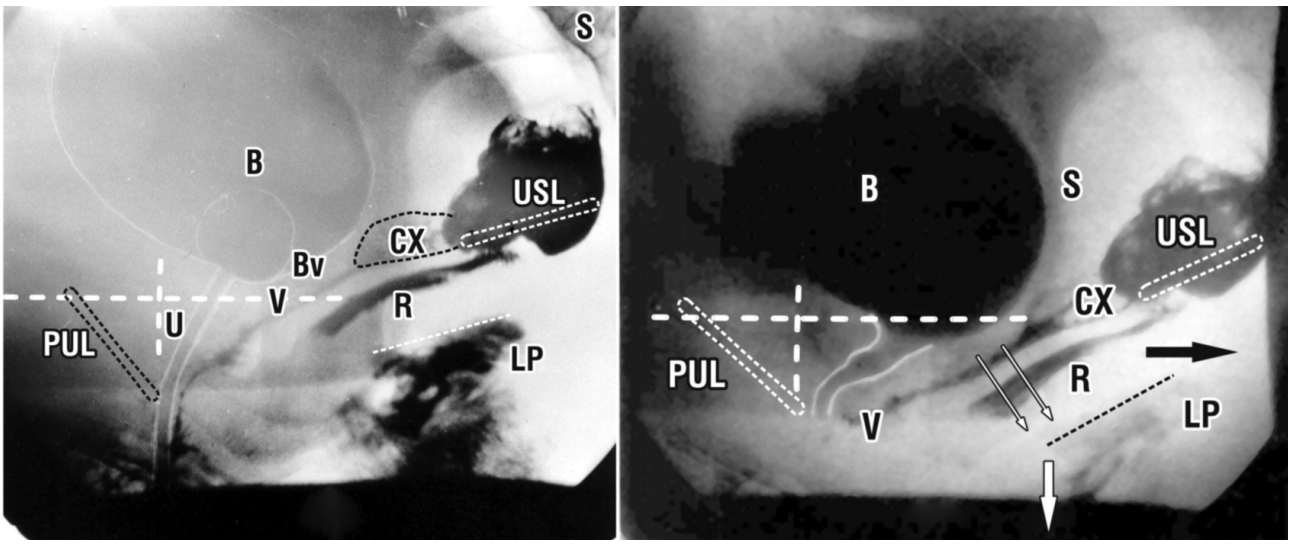

Figure 1. – **Left side.** Bladder (B) in resting position. Patient sitting. Slow twitch contractions angulate the urethra (U), vagina (V) and rectum (R) around the pubourethral ligament (PUL). 10ml dye has been injected into the levator plate (LP). CX=cervix; USL=uterosacral ligament. S=sacrum. Vertical and horizontal broken lines indicate bony co-ordinates.
Right side. Micturition. The urethra has moved backwards suggesting relaxation of the forward vector (cf. fig. 2). Vagina and rectum appear to have been stretch backwards by a backward vector (arrow) . The anterior part of LP has been angulated downwards, seemingly pulling open the posterior urethra.

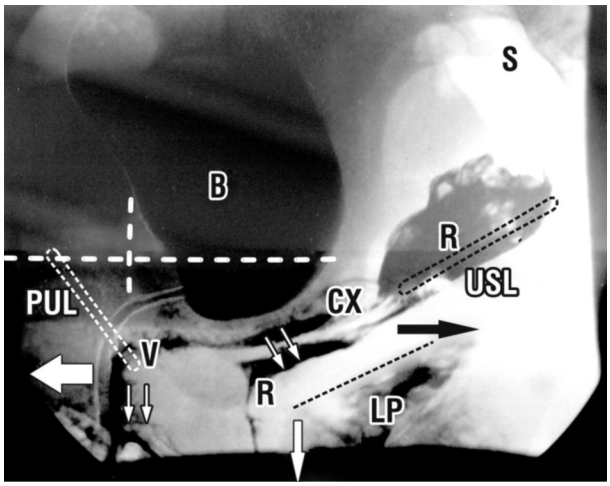

Figure 2. – **Patient straining.** Same patient and labeling as fig1. Exactly the same directional movements have occurred as in micturition: backward/downward stretching of bladder base, vagina & rectum around PUL to 'kink' the proximal urethra and anorectal angle. The distal urethra and vagina have been pulled forwards of PUL beyond the vertical co-ordinate.

and testing of levator plate contraction so as to allow us to challenge both theories[1,5] for truth or falsity. The experiment was performed under the umbrella of existing IRB approval from Nanjing University for needle EMG studies of the pelvic floor.

PATIENT AND METHODS

The EMG test was performed on a 57 year old para 1 patient who presented with chronic constipation but no urinary symptoms of incontinence or evacuation. We used the technique described by Berglas and Rubin.[7] The patient was digitally examined and asked to strain. A spot was marked halfway between the coccyx and anus. The needle was inserted 1.5 cm laterally from the midline position to a depth of approximately 1.5 cm. Its exact location was monitored initially with a 6MHz curvilinear transperineal ultrasound probe, then with a 6 MHz intravaginal probe. The position was checked on the EMG monitor by asking the patient to cough. Because of concerns for displacement of the needle, the variables were kept to a minimum for this first testing, in that the patient was asked to micturate into a commode, with no urodynamic monitoring of detrusor pressure or flow. Prior to initiating micturition, the needle position was confirmed by coughing. The initial loss of urine was marked on the graph, and the experiment was repeated on a 2nd patient.

RESULTS

The EMG (Figure 5) shows clearly that levator plate contraction precedes urine loss during micturition. We found the EMG signal was more concentrated during micturition rather than during resting, but it was weaker than the straining contraction and cough maneouvre registered.

DISCUSSION

This is the first report of levator plate contraction demonstrated directly during micturition. We found that use of the ultrasound probe was essential for accurate placement of the EMG needle. Movement of the needle during an activity was a major concern, as the patient had to come off the bed onto a commode. This issue, movement of the needle, caused us to vastly simplify our original intended methodology which was to test all the elements deemed essential for finally proving the complex series of events hypothesized to occur during micturition.[1]

Ideally, this would consist of placing an EMG needle into the anterior portion of pubococcygeus to confirm its relaxation during micturition. Also a needle needs to be located into the conjoint longitudinal muscle of the anus (LMA) to confirm its contraction. Ideally, a double transducer would also be needed in the urethra and bladder so simultaneous measurements pressure could be taken.

Adding another two EMG needles and urodynamics would have exponentially increased the complexity of measurement. As the EMG and urethral components of the pressure measurement are highly sensitive to movement, we felt that complex measurements at the initial testing were not possible. Therefore, we felt it was not possible to monitor more than one variable.

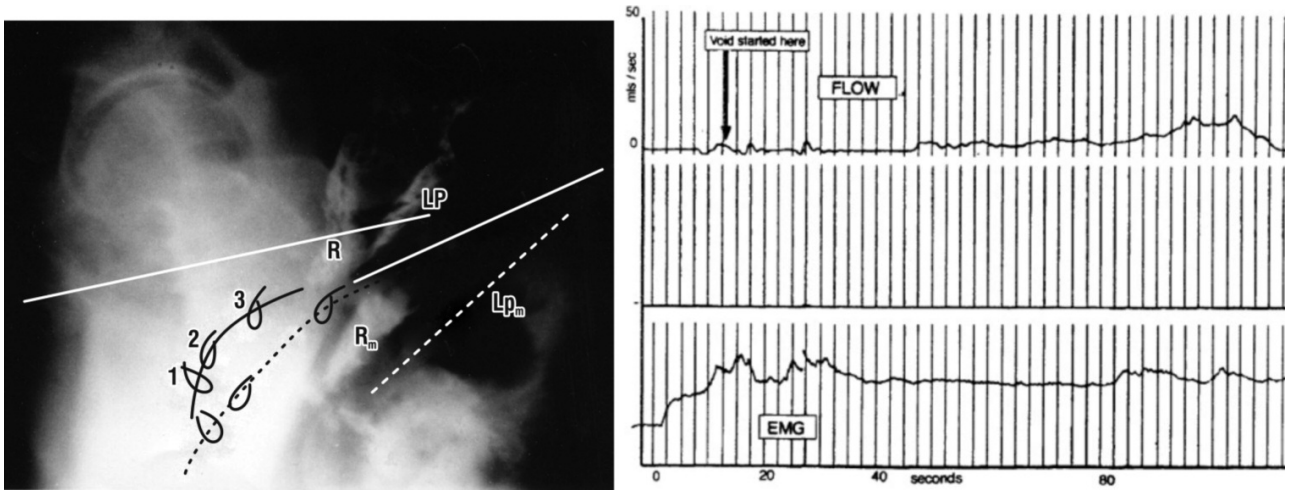

Figure 3. – **Left side.** Micturition x-ray superimposed on resting. Vascular clips have been applied to the midurethra '1'. Bladder neck '2' and bladder base '3'. Radio-opaque dye has been injected into the levator plate LP, which has been angulated downwards during micturion, as has the rectum 'R', which barium paste.
Right side. Surface EMG cylinder placed in the posterior fornix of the vagina simultaneous with uroflowmetry. The EMG shows that muscle contraction precedes urine flow.

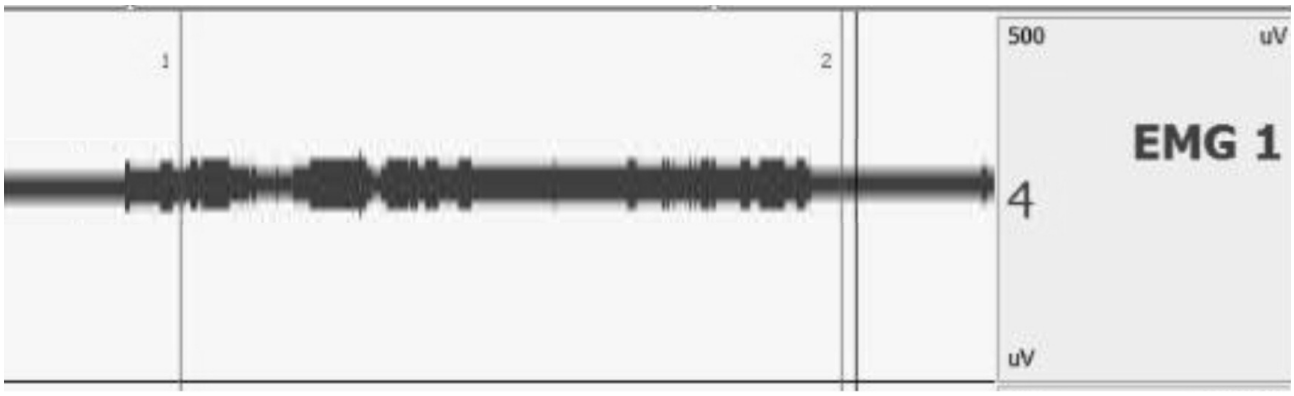

Figure 4. – **Needle EMG during micturition.** Micturition commenced at 1 and finished at 2. EMG contraction preceded urine flow.

CONCLUSION

The technique is the first step in proving the hypothesis proposed by the Integral Theory, that micturition is an active process: relaxation of the forward vector followed by contraction of he backward vector to open out the posterior wall of the urethra. Though successful, levator EMG is not easy to perform accurately. Ultrasound monitoring is an essential part of the methodology. Our initial results appear to demonstrate that levator plate contraction precedes micturition. We are proceeding with more studies which we hope will further elucidate this and other pelvic muscle actions such as coughing, straining and defecation.

There are no conflicts of interest.

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Original article

Stigma and the perception of bodily parts: Implications for help seeking

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Abstract: The present paper covers the first of a four part series that will investigate the hypothesis that people may have biased cognitive representations of the body's parts (body schema) and that this may have implications for illness behaviour, disclosure, and help seeking. In fact, seeking help for medical needs varied across body parts, with test subjects less likely to seek help for highly stigmatized and private parts but likely to seek help for parts viewed as important and vulnerable. To test if we could minimize this effect, we conducted a series of interventions aimed at changing cognitive perceptions and schemas of the body on randomly selected test subjects. We compared the various interventions and measured the efficacy of each different type of intervention in changing cognitive perceptions of test subjects. Among the interventions carried out and measured were: storytelling, group work, humour, empty chair and empowering. We discuss which of these interventions produced the greatest changes in cognitive representations of the body and the implications of these findings.

Key words: Body; Stigma; Health promotion; Intervention; Private parts

INTRODUCTION

There is a lot of research that has explored individual's concepts and attitudes about their body, especially in the field of body image distortions in eating disorders[1,2] and stereotyping of physical attributes.[3,4] What the research seems to tell us is that beliefs about the body play a major role in the effectiveness of preventative health programs such as exercise programs, as well as in a variety of pharmacologic, surgical, medical, psychotherapeutic, and behavioural medicine interventions.[5] However, attitudes about body parts are not limited to beliefs about the size and attractiveness of the body part in question, but more importantly, attitudes about the perceived privacy of a body part can affect the willingness to share information with others about any potential dysfunction or illness of that part. We hypothesize that the stigma that is associated with such private parts like the genitals and the anus, that are oftentimes viewed as "dirty"[6] can have a real effect on the propensity of individuals to seek medical attention when health issues arise to the private parts in question. This unwillingness to seek medical attention, and talk to significant others about a problem that is associated with a body part that has a social stigma attached to it can have large implications for the health of individuals and when generalized to the entire population, it can carry considerable health care bills costs. It also points to the need to develop creative and dynamic programs that address this issue, raise awareness and encourage the "airing out" of these taboo subjects in order to deconstruct the social stigma attached.

On the other hand, other body parts such as the ears are viewed as less private and sexual than the aforementioned and thus are more likely to receive greater medical attention from the patient.[7] In addition, as these body parts are viewed as neutral, any problems arising from these are more readily expressed and shared with others. In fact, we predict that for these neutral parts, disclosing medical challenges and comparing stories are frequent among individuals. These neutral body parts we define as "embarrassment free", thus medical problems such as broken bones, dental abscess, ulcers etc, we hypothesize are more freely disclosed to others than issues such as anal fissures that are viewed as highly private and "dirty." This has important medical implications.

METHOD

In our study we would like to investigate cognitive representations of the various body parts via a questionnaire administered to randomly selected individuals at the hospital of Pescara, Italy. To a certain degree, we replicated an earlier study by Klonoff & Landrine,[8] with the difference that we went one step further and carried out interventions on test subjects to measure if these cognitive representations can be changed over time and if this change can lead to a greater likelihood to seek help in the future. We decided to exclude from the study individuals that had already been screened for various pelvic perineology problems as they may have already received some form of formal or informal intervention or education and therefore the stigma and view they hold about the body part in question may already have undergone a change. We invited test subjects that had completed the surveys at T1 to take part in one of our interventions and then re-test their cognitive representations of the various body parts post intervention at T2 to investigate which intervention was more effective in changing body schemas and thus lead to changes in how the various body parts are viewed.

The various interventions carried out on test subjects included: storytelling, group work, humour, empty chair and empowering. These methods were chosen on the basis of their efficacy and practicality (only various sessions were conducted). Storytelling was chosen because research shows that our understanding of the narrative model is not just something acquired, but it seems to be genetically determined.[8] In fact, already in 1985, Fisher talked about humans as being "Homo Narrans". Moreover, the way our brain responds to stories illustrates that this is an especially effective cognitive tool. In a study conducted at Washington state university,[9] participants brain activation while reading a story was measured. The results showed that participants were living the experiences alongside the young protagonist in the story and were not just passive participants. In fact, neurons in areas related to movement correlated with the protagonists movement in the story.

Group work was chosen as an intervention modality because it enables group members to learn from the experiences of others and offer advice. In our experiments we also wanted to capitalize on this methods ability to foster working through issues together. In this manner this method provides subjects with a "peer group" of individuals that they can feel safe around to practice the new cognitive viewpoints learned.

Humor has long been used as an effective psychological intervention tool, we might all recall the physician Hunter "Patch" Adams, who used laughter as a primary tool in his treatment of cancer patients, to great success. He is just one example of many who have witnessed and reported first-hand accounts of how essential humor is to both physical and emotional health. In fact, research points out that laughing leads to increased learning, more specifically that humor produces psychological and physiological benefits that help students learn.[10]

Figure 1. – Farrah Fawcett.

The Empty chair technique was used with test subjects because it's been proven to be effective at facilitating integration of different aspects or "disowned parts" of individuals and their personality. In addition, it brings into the present or immediate, experiences, verbalizations and abstractions. There are various approaches that can be used, we decided to use the corrective dialogues approach: here the subjects' distorted cognitions or maladaptive schemas are clarified and verbalized in one chair. A counter-argument is carefully developed in a collaborative manner by the therapist and the patient.[11] The patient then goes back and forth between the two chairs – presenting the distorted thinking and then working to correct it. The dramatic and emotional quality of this work helps to counter the issue of patients understanding the new cognitions intellectually, but do not really feeling them to be true.[12]

Empowerment techniques were chosen for their ability to provide individuals with a sense of control and purpose over their lives. Empowerment is a way to encourage all people even those that are materially, psychologically or even physically disadvantaged to become responsible for their own condition and achieve a sense of control--individually and as a group. In fact, empowerment has been used in diabetes care and is specifically effective at helping patients discover and develop their inherent capacity to be responsible for their own life.[7, 13, 14]

DISCUSSION

We hypothesize that subjects that hold highly stigmatized views about certain body parts are less likely to seek help and speak to others about their medical condition. We believe this leads to a decreased propensity for prevention and higher rates of somatization which could lead to less effective post operative results and greater stress and pain.[14,15] We predict that after the interventions, the majority of test subjects will be more likely to disclose problems related to private parts and seek help in the future if problems arise.[16] Testing the various interventions for efficacy will be useful to provide direction to health care providers, government and other interested parties in the design of effective health prevention campaigns. In this way we can avoid the delay in seeking treatment, and non compliance with diagnostic and treatment interventions involving certain body parts but not others.

ADDENDUM

The numbers of anal cancer cases are rising, although experts haven't been able to pinpoint why. Cultural squeamishness about certain body areas could prevent early diagnosis and treatment of anal cancer. For example patients in the United States often hate to be examined in these areas, they like to keep their private parts even more private than in Europe. If patients hate those exams, physicians hate to do them as well and thus the examination is incomplete." Former "Charlie's Angels" actress Farrah Fawcett, 62, (Figure 1) received a diagnosis of anal cancer in 2006 and died in 2009. She brought the world's attention to a rare disease during her cancer battle which lasted for three years.[17]

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INVITED COMMENTS

Many patients with pelvic disorders have poor awareness of themselves and one's own body (body schema). This means that they still commit "Descartes' error" there is no duality between mind and body, but only wholeness unity. There is no division but unity. What we are, how we explain it, the "narrative thought" is reflected on the emotional and somatic side and vice

versa. Bodies and body parts are invested with emotion and it is the awareness or non awareness of this that avoids confusing organic pathology from somatization and leads us to understand the difference.

Very often it happens that a discomfort of psychological origin creates long term a clinical disorder. In my opinion, the cognitive error should not be treated much like a distortion but focused and re-read with the patient in order to understand the various aspects, which according to the personal history of the subject, have made it such. And through a cognitive reconstruction that enables us to understand how the latter has told himself "reality", how this has caused certain gaps in his mind, how he built certain valences of meaning and how HIS beliefs influence him and consequently, how he feels, perceives, and behaves. In this way the symptom will assume a different value but will be revisited in a neutral fashion (without judgment). In a sort of "enlightenment", what was interpreted mainly from the organic point of view, will take on characteristics articulated to reveal, to tell, to be exhausted and perhaps to be put in the right place.

I think this is the central point to keep in mind, regardless of the type of interventions that will be chosen, from time to time and according to the subjects to be evaluated, with the aim of achieving a more full self-awareness and therefore, of their own psychological- body functioning.

Given my post- rationalist training, I do not think there is a single reality, defined and pre-existing, but many realities as many as there are individuals who experience them. I do not think there are cognitive errors, distortions or dysfunctional a priori thoughts, everyone "tells it" how they can, according to their parenting attachment, and the subsequent organization of personality and finally, their personal life history. Keeping in focus these three factors together and reconstructing them with the patient, by listening to his story, one can act on "change" or on the more harmonious and articulate re-reading of the self.

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The Author's reply

It's interesting to observe how the human mind is not cognitively and emotionally equipped to overcome Descartes' error, despite our attempts to rationalize. Paradoxically, the colleague later passionately affirms that there is only wholeness (unity) and no duality between mind and body, but then invites the clinical world to avoid "confusing organic pathology from somatization"! Our approach embraces the concept that there may be cognitive distortions in our own perceptions and beliefs that may in fact restrict or impede the quality of the patients social, emotional and physical life. and when our colleague speaks of a patient who "has certain gaps in his mind" the statement seems to implicitly agree with our vision, if by gap we mean a gap between functional and dysfunctional concepts to "put in the right place". At the same time we are convinced that the human mind is not equipped to interpret any element (be it a person, event, or, in fact, a symptom) in NEUTRAL terms with no "judgment". Our mind is an extraordinary machine built to continuously emit assessments and judgments (primarily affective and then these are rationalized), the question then becomes not how to revisit the symptom without judgment but how to recondition the automatic neuro-affective associations linked to previous conditioning, thanks to a targeted and "enlightening" psychosocial intervention that combines effectiveness and efficiency/transversal (one cannot objectively carry out a deep therapeutic intervention with each patient), Moreover as explicitly stated in our paper, we are conducting interventions with healthy people and not with existing patients. Our objective is to "educate" a random set of subjects to test if we can change their cognitive perceptions of the stigma of certain types of diseases.

This research offers interesting insights. The patient's experience with pelvic and colonproctologic issues is often loaded with meanings that go far beyond the actual disease. In everyday practice, the health care worker is often faced with "unsettling" statements with regard to the perception of the problem that, should not be ignored, and should be fully understood before by the physician or the health care worker that looks after the patient and then these statements should be "deconstructed" through dialogue or other strategies that allow a "redefinition" of the disease. How many times in fact, patients with incontinence due to dyssynergia are convinced of having to tone their pelvic muscles, totally unaware of their "real" muscle tone. Often, it happens that even in cases of mild prolapse the stories of friends or relatives "worry" the patient so much to the point where the patient is certain that "everything is falling" and if nothing is done the damage will be irreparable. On the one hand "moral" resistance prevents a serene description of symptoms and on the other "deep fears" make the imagination a sort of "black hole" that catalyzes the attention of the subject.

Dialogue, diffusion without minimizing is the prescription of this research. The chair method invites a sort of role playing where the patient gets to be the "devil's advocate". The therapist's role is maieutic, to help the person find the nature of the symptoms and often the source of them as well. One example: the anal sphincter is often very tight causing a plethora of problems in individuals that tend to "hold" on not only to feces but also to deep fears and emotions. To enable the patient to perceive and talk about what they feel with their hands, joking about the tendency to "tighten the ass" in every situation are some practical examples that make us understand the direction and the purpose of this approach as useful as it is purely pragmatic.

STELLA DE CHINO
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The Author's reply

Noteworthy comments about the experience of working with patients in a live setting without the hindrances that are often present when dealing with such cases. In our research, we reviewed the literature on the topic and started with the premise that patient and public sensitization is really one very important first step in this "chain" of events. We observed that campaigns that have sensitized people to illness such as cancer, HIV etc. have been able to not only bring to light topics of "taboo", and initiated valid discussions in the public, but also and most importantly, for front line workers have enabled individuals to learn about these conditions and thus come forward without shame and get early treatment. This along with other factors has cut down considerably mortality rates and increased life expectancy prognosis of the aforementioned diseases… Similarly we hypothesize that when something comes "out" into the light of society and is no longer hidden in the shadows, that it likewise ceases to lie in the shadow of the individual, and it is no longer so viable to become a "dark hole" where patients readily somatize.

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