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A multidisciplinary pelvic floor journal

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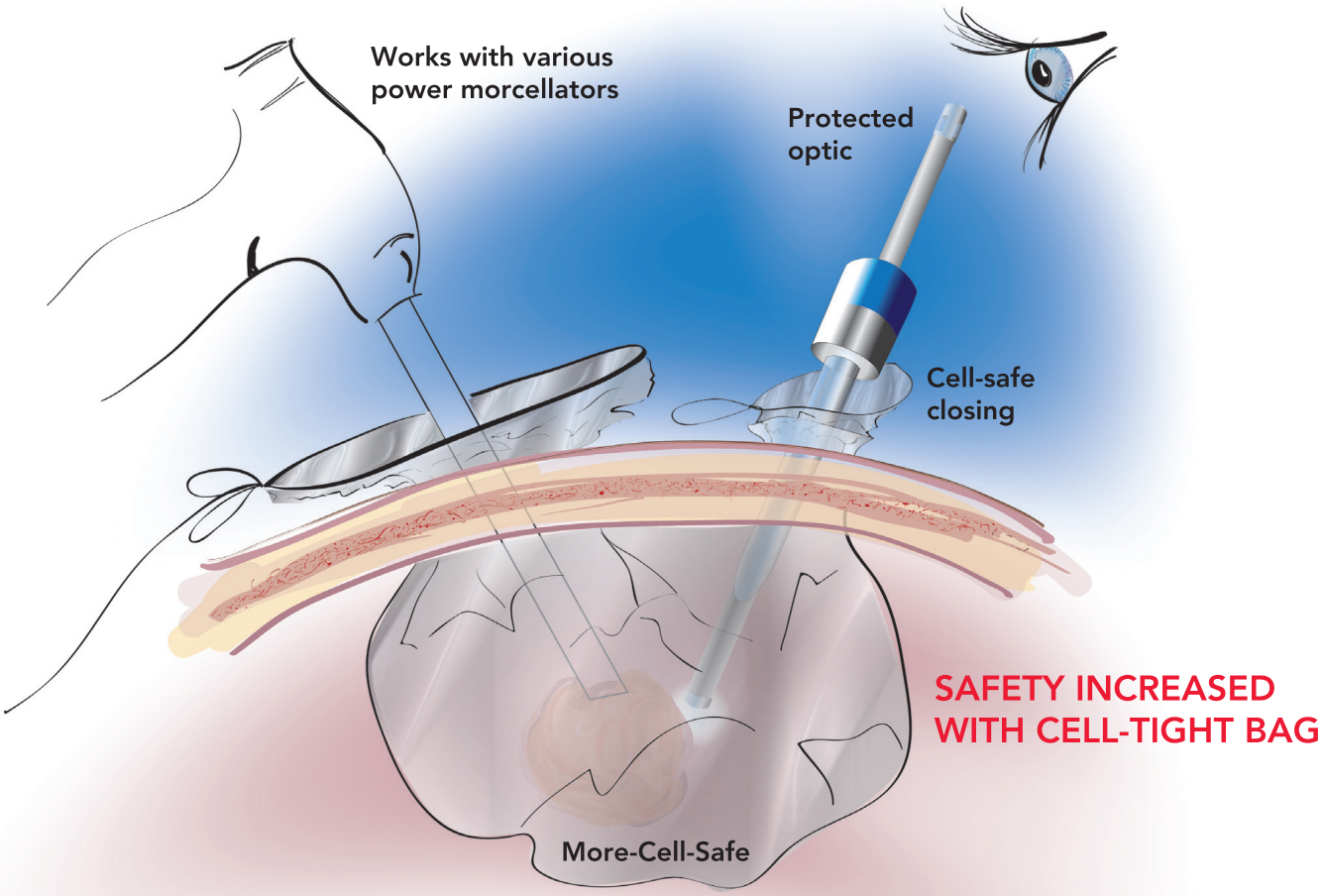

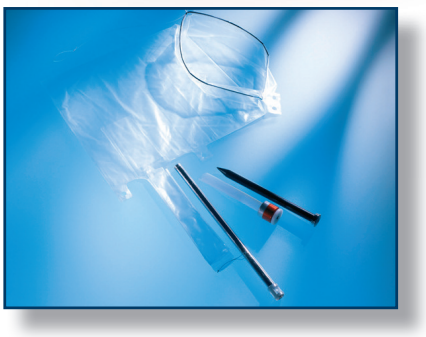

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Editorial

Pelviperineology and the Associaciòn Latinoamericana de Piso Pelvico

ALAPP is the official pelvic floor society for all the Spanish and Portugese speaking societies of North, Central and South Americas which represent some 600 million people. ALAPP is a broad church. It brings together, urologists, gynaecologists, coloproctologists, physiotherapists, nurses, physical therapists, indeed any specialty which concerns the pelvic floor in the male, female and all ages, paediatric to geriatric.

The aims of ALAPP are to bring together the constituent national societies on a yearly basis, to share knowledge, to provide a forum for research through lectures and abstracts and to upskill the members of each society.

As our official journal, Pelviperineology Journal is an essential part of this plan. Last year PPJ printed all the abstracts presented online in the Spanish and Portuguese languages with an English summary. Several research papers were of high quality and the authors were encouraged to present their work in English for the main journal. This is another educational function of PPJ, to link ALAPP researchers to the broader English language scientific community .

As President of ALAPP, I am pleased to announce that the 2nd ALAPP Congress will be held in Sao Paulo Brazil between 9-11 March. It will be held in conjunction with ISPP, the International Society for Pelviperineology. Our first ALAPP meeting in Bogota Colombia attracted 500 delegates. We expect more than 1000 for our 2nd meeting in Sao Paulo.

PAULO PALMA
President ALAPP and Professor Titular da Universidade Estadual de Campinas.

NUCELIO LEMOS
Chairman Scientific Committee ALAPP

Editorial

Bariatric surgery and the pelvic floor

Bariatric surgery improves pelvic floor disorders (Piñango-Luna S., Level-Cordova L., Marquez M., Chaves L.) is published in this issue of Pelviperineology. Since its inception, this journal has emphasized the holistic anatomical nature of pelvic floor dysfunctions. In this regard, we frequently seek articles and comments from 3 separate specialties, Urology, Gynecology, Coloproctology. Admittedly we have published ground-breaking dynamic MRI anatomy studies, physiotherapy studies and in depth articles on chronic pelvic pain (an important area we hope to explore further in the future with an issue dedicated to chronic pelvic pain).

However, we have never wandered as far from our core as we do in this issue, publication of an article on the role of obesity and bariatric surgery on incontinence.

It is overdue. Statistics show that more than 1/3 of men and women in Western nations are obese.

In the current journal, we publish a well-documented article on the causative role of obesity in urinary and fecal incontinence. It is quite convincing. The importance of this article is that for the first time, an anatomical cause has been advanced as to why obesity cause incontinence: the increased abdominal weight places an extra burden on the three directional forces which close the urethra and anorectal tubes. The article is consistent with the ongoing theme of this journal, that pelvic floor dysfunctions have an anatomical basis and that even the effect of obesity can be explained in anatomical terms.

Some questions arise from this article. Should each clinician make a determined effort to induce every obese patient to lose weight? Some of us who have tried have found this is a fruitless pursuit, often losing the patient in the process! Should bariatric surgery be considered as a treatment per se of incontinence? Alternatively, what weight should a clinician give to incontinence when bariatric surgery is being considered? Admittedly the improvement in urinary incontinence is impressive, but how negative a factor is the worsening of fecal incontinence? This article opens yet another door for pelviperineology research and we look forward to further studies and comments on this subject.

GIUSEPPE DODI
Editor

Original article

Vaginal apical prolapse repair using two different sling techniques improves chronic pelvic pain, urgency and nocturia – a multicentre study of 1420 patients

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Abstract: Introduction: Chronic pelvic pain (CPP) occurs in approximately 20% of women. Pathophysiology includes peripheral and central hypersensitisation. The CPP syndrome variously encompasses chronic pelvic pain, urinary urgency, frequency, nocturia or faecal incontinence, causally linked to lax apical support of the vagina. *Aim:* To test the hypothesis that surgical repair of the apical support of the vagina improves CPP, urinary urgency, frequency, nocturia and/ or faecal incontinence. *Materials and methods:* Multicenter, multinational, prospective cohort study including female patients attending pelvic floor centers, presenting with apical vaginal prolapse and at least two symptoms of CPP, urinary urgency, frequency or nocturia. Pelvic floor reconstruction performed vaginally, using two different posterior sling techniques restoring apical support: Infracoccygeal sacropexy (PIVS) and Tissue Fixation System (TFS) of uterosacral and cardinal ligaments. Assessments at baseline and 12 months after surgery using the Integral Theory Symptom Questionaire and the half-way system. Primary endpoint was improvement of symptoms. Statistical analysis by paired binary response data (per-patient presence/absence of specific sign/symptom before vs. after surgery) using McNemar's test, with null hypothesis of no treatment effect. *Results:* 1420 patients from 8 pelvic floor centers were included. 809 patients had PIVS, 611 TFS surgery. % cure/improvement at 12 months in the PIVS (TFS) cohort was as follows: pelvic pain 68 (78) nocturia 63 (83), urge incontinence 70 (85), frequency 79 (82), faecal incontinence 76 (65), apical prolapse 93 (90). Limitation was the non-randomized design. *Conclusions:* Restoration of apical support improves CPP, nocturia, urgency/ urge incontinence and/or non-sphincteric fecal incontinence.

Key words: Integral theory; Apical prolapse; Posterior fornix syndrome; Chronic pelvic pain; Nocturia; Urgency.

Abbreviations: CPP – chronic pelvic pain; PIVS – Infracoccygeal sacropexy; TFS – Tissue Fixation System; ICS – International Continence Society; USL – uterosacral ligament; CL – cardinal ligament; PUL – pubourethral ligament; EUL – extraurethral ligament; ATFP – arcus tendineus fasciae pelvis; PB – perineal body; ODS – Obstructive Defecation Syndrome,; PC – m. pubococcygeus; V – vagina; PB – perineal body; LP – m. levator plate; R – rectum; IS – ischial spine; PS – pubic symphysis; S – sacrum.

INTRODUCTION

Chronic pelvic pain (CPP) syndrome is a major health and societal problem[1-2]. The 2002 definition by the International Continence Society (ICS) includes concomitant complaints of lower urinary tract, bowel, sexual or gynecological in nature where there is no infection or other obvious pathology"[1,3]. It is thought that CPPS is associated with changes in the central nervous system (CNS) that may maintain the perception of pain in the absence of acute injury and magnify its perception so that non-painful stimuli are perceived as painful (allodynia) and painful stimuli are perceived as more painful than expected (hyperalgesia)[2].

Chronic pain of moderate to severe intensity occurs in 19% of adult Europeans, seriously affecting the quality of their social and working lives[4]. Significant health costs are attributed to this problem. In a 1996 study, the estimated direct medical costs for outpatient visits alone for this group in the U.S. was $881.5 million per year. In addition, 15% reported time lost from paid work and 45% reported reduced work productivity[5].

The pathogenesis of chronic pelvic pain is still incompletely understood. Mechanisms proposed include peripheral and central hypersensitization of the nervous system[2]. Peripheral hypersensitization describes an augmented sensory pain input from the peripheral nervous system and central hypersensitization describes a predisposition of a dysfunctional central regulation of the sensory input[6]. In parallel, accompanying symptoms such as urinary symptoms or psycho-social symptoms are also frequently found.

Up to now there is no gold treatment standard of CPP in women. Currently the main approaches to treatment in women include counseling or psychotherapy, surgery to interrupt nerve pathways such as laparoscopic uterine nerve ablation and presacral neurectomy, or hysterectomy - with or without removal of the ovaries[7] – and, more recently, neuromodulation, where patients reported 40% improvement in their pain symptoms and 26% improvement in their urinary symptoms at 15 months mean follow-up[8]. Recent developments aim to diagnose and treat the clinical phenotypes of patients by different approaches, including physical therapy, medications and psychosomatic therapy amongst others.

As part of the 1993 publication of the Integral Theory, chronic pelvic pain was linked to a specific symptom complex known as the "posterior fornix syndrome" caused by lax apical support of the vagina[9]. The syndrome variously

encompassed chronic pelvic pain and bladder symptoms of urgency, abnormal emptying, nocturia[9]. Patients rarely presented with single symptoms[9]. Essential to this theory, is the concept that loose ligaments interfere with the muscle-mediated central-peripheral control reflexes. For symptoms of overactive bladder (e.g. urgency, frequency, nocturia), loose ligaments prematurely activate the micturition reflex[10]. For pain, inability to support the sympathetic and parasympathetic nerves is expressed by referred pain to various sites and symptoms are not always proportional to the degree of the anatomical failure[11]. In 1996, a description of the pain was published. This included site (lower abdomen, sacral, deep dyspareunia) severity, variability, relieve on lying down. Surgical intervention consisted of the approximation of the uterosacral ligaments (USL) under local anesthesia. This resulted in an initial 85% cure/ improvement of CPP at 3 months[11], Figure 1. The cause of the pain was hypothesized to be inability of lax USLs to support the nerves in the USL[11]. The ultimate etiology of USL laxity is attributed to age or birth related collagen, in association with smooth muscle and sympathetic nerve fiber damage[8,9], aided by hormone induced depolymerization during pregnancy[12].

The primary aim of the present study was to investigate whether lax apical support (uterosacral and cardinal ligaments) was a causative factor in CPP and other symptoms of the posterior fornix syndrome (e.g. urinary urgency, nocturia, faecal incontinence) by prospectively evaluating these symptoms using two different surgical techniques which restored apical support of the vagina. Inherent in this work was our hypothesis that the peripheral hypersensitisation of the CPP and micturition circuits might be potentially reversible by treating the underlying cause as hypothesized, lax uterosacral ligaments.

MATERIAL AND METHODS

Eight Female Pelvic Floor tertiary referral centres participated in the study. Ethical approval for data acquisition was received by the ethics committee of the Justus-Liebig-University Giessen, Germany (ethical vote 74/10).

At the first consultation, all patients completed a self-administered validated patient questionnaire[13], whose answers were transferred to the Pictorial Diagnostic Algorithm [Figure 2], which served as a guide to surgery. All patients underwent a vaginal examination to assess the degree of prolapse and to detect specific anatomical defects. Given the fact that there are no routine tests to diagnose peripheral and/or central hypersensitisation, patients with symptomatic vaginal prolapse were included in this study. No attempt was made in the present study to differentiate between peripheral and central hypersensitisation.

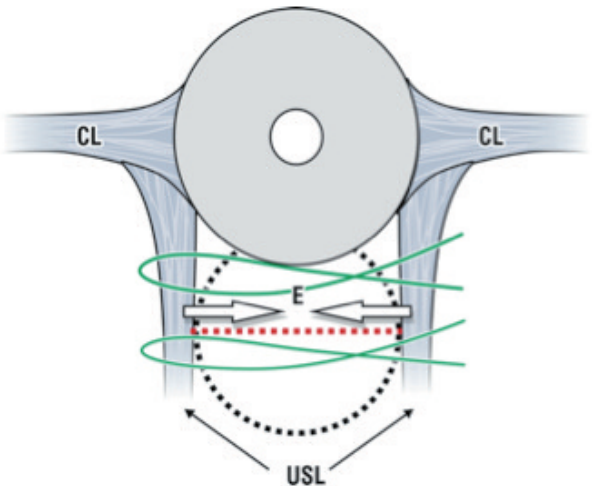

Figure 1. – Simple posterior fornix repair[11]. A transverse incision is made in the posterior fornix 3-4cm below the cervix, A large No1 needle is inserted widely laterally below the vaginal skin and the loose uterosacral ligaments (USL) are approximated (arrows) with strong sutures. USL= uterosacral ligament; CL=cardinal ligament; E=enterocele.

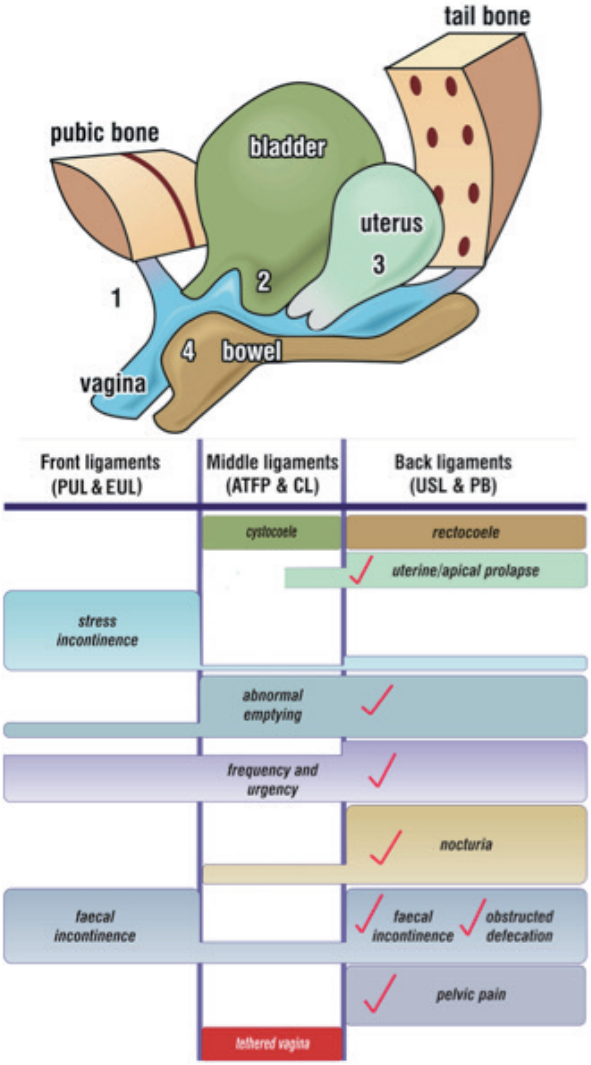

Figure 2. – Simplified diagnostic algorithm. As applied in this study, it related symptoms (ticks) to prolapse and damaged ligaments in the apical parts of the vagina. PUL=pubourethral ligament, EUL=extraurethral ligament (anatomical zone 1); ATFP=arcus tendineus fasciae pelvis, CL= cardinal ligament (2); USL=uterosacral ligament, PB=perineal body (3 and 4).
The height of the bar indicates prevalence of a symptom caused by the respective anatomical region.

Inclusion criteria

Consecutive patients with apical prolapse of any degree[14] and two or more posterior fornix syndrome symptoms (e.g. chronic pelvic pain, urgency, abnormal urine emptying, or nocturia) were included.

Exclusion criteria

Patients with endometriosis, proven organ infection or other conditions known to cause chronic pelvic pain were excluded. Patients not suitable or not willing to undergo surgical pelvic reconstruction were also excluded.

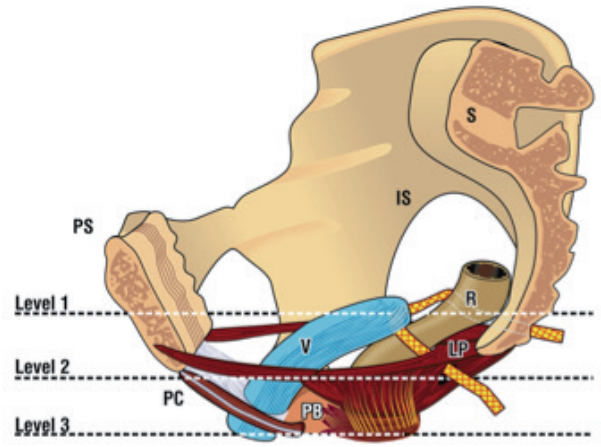

Figure 3. – Infracoccygeal sacropexy or "Posterior IVS". The apex is suspended to the sacrospinous ligaments. PC=m. pubococcygeus; V=vagina; PB=perineal body; LP=m. levator plate; R=rectum; IS=ischial spine; PS=pubic symphysis; S=sacrum.

Symptoms were defined as follows:

– Pelvic pain; consistent with the 1996[11] and other descriptions[1-3].

– Nocturia was defined as by the ICS: two or more episodes of micturition per night[1,3].

– Urge incontinence: at least one episode per day of wetting prior to arrival at the toilet.

– Fecal incontinence (non sphincteric): Loss of either gas, liquid or solid feces more than once per week.

Intervention

All patients underwent a posterior sling operation, depending on the standard operation performed at the participating centre, an infracoccygeal sacropexy (posterior IVS)[15-16] (Fig. 3), or a TFS sling operation of the cardinal and/ or uterosacral ligaments[17] (Fig. 4).

Data acquisition

Between January 2007 and January 2012, eight pelvic floor centres with experience either in the infracoccygeal sacropexy or TFS sling techniques participated in this trial.

Follow-up and end point measurements

Outcome measures were assessed at the individual study level. At 12 months follow up a full assessment was made using the self-administered Integral Theory System Questionaire[13], as well as vaginal examination.

Criteria for a positive response

– Pain: Because of widely varying pain intensity, often from day to day, patients were asked to give a global self-assessed 80% improvement over the baseline symptom at the 12 month visit.

– Nocturia: Reduction from 2 or more episodes per night to one or none.

– Urge incontinence: Zero episodes of wetting prior to arrival at the toilet.

– Fecal incontinence: Zero episodes of soiling prior to arrival at the toilet.

Every centre used the Integral Theory System Questionaire[13], examination technique, intervention algorithm and either the infracoccygeal sacropexy with tapes attached to the sacrospinous ligament,[15-16] or posterior TFS technique, with tapes directly applied to the cardinal/uterosacral ligaments[17].

In patients who were subjected to infracoccygeal sacropexy, a special tunneller was inserted into the perineum on both sides, through the ischiorectal fossa and was brought up medial to the ischial spine just below or through the sacrospinous ligament, attached to the cervix or vaginal apex and tightened, as previously described (Figure 3)[15-16].

In patients who were subjected to TFS sling[18], the cardinal and uterosacral ligaments (USL) were identified, incorporating a horizontal transvaginal incision approximately 3 to 4 cm in length. A channel was created through or adjacent to the ligaments to the pelvic skeleton, the applicator carrying the TFS tape was inserted into the channel, and the anchor released. The procedure was repeated on the contralateral side and the tape was tensioned in the midline until a resistance was felt. The excess tapes were trimmed and the vaginal mucosa closed in layers, figure 4.

Cystocele, rectocele and perineal body repairs were performed using native tissue or TFS as required.

Statistical analysis

Paired binary response data (per-patient presence/absence of a specific sign/symptom before vs. after surgery) in the total study cohort were analyzed with a McNemar's test, with a null hypothesis of no treatment effect[19].

The GraphPad Quickcalcs platform was used for this analysis (http://graphpad.com/quickcalcs/mcNemar1/). The sample size (https://www.statstodo.com/SSizMcNemar_Pgm.php) was deemed sufficient to assume a Chi-squared distribution. The Chi-square was calculated with one degree of freedom.

Post-hoc estimation of the study power was performed, assuming an alpha error equal to 0.01 (https://www.statstodo.com/SSizMcNemar_Pgm.php). In all cases the estimated power for this comparison exceeded 0.95 (table 1).

To evaluate differences between the proportions of patients showing or not a specific sign/symptom when treated with different surgical techniques (posterior intravaginal slingplasty vs. tissue fixation system), the Z-ratio and the 95% confidence interval for the difference between independent proportions were calculated[20].

The VassarStats platform was used for this analysis (www.vassarstats.net).

RESULTS

1420 patients presenting with pelvic floor dysfunction due to apical prolapse and amenable to pelvic floor recon-

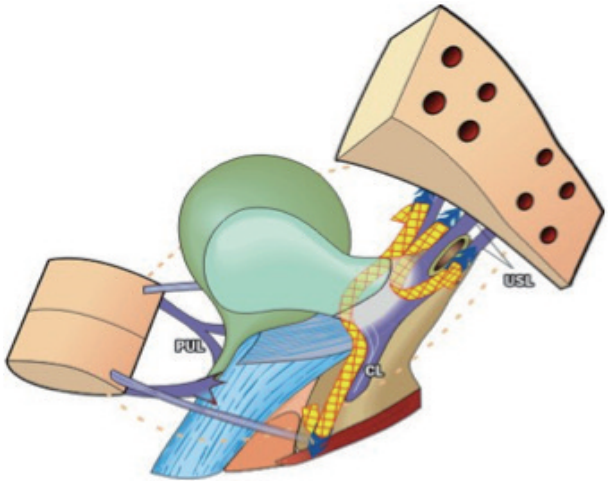

Figure 4. – Reconstruction of the cardinal and uterosacral ligaments with the TFS mini sling procedure.
PUL=pubourethral ligament, CL= cardinal ligament; USL=uterosacral ligament

TABLE 1. Signs and symptoms (pelvic pain, nocturia, urge incontinence, frequency, faecal incontinence, apical prolapse) at baseline and after 12 months in patients operated by Infracoccygeal Sacropexy (PIVS) or Tissue Fixation System (TFS).

	Number of patients with symptom or condition/total patients (%)				Confidence interval of difference between proportions*		Probability (two-tailed)**	
	pre-PIVS	pre-TFS	post-PIVS	post-TFS	pre-PIVS vs pre-TFS	post-PIVS vs post-TFS	pre-PIVS vs pre-TFS	post-PIVS vs post-TFS
Pelvic pain	405/809 (50)	194/611 (31)	131/809 (16)	42/611 (7)	0.13 to 0.23	0.06 to 0.12	< 0.0001	< 0.0002
Nocturia	286/809 (35)	254/611 (41)	59/809 (13)	77/611 (7)	0.011 to 0.11	0.021 to 0.085	0.017	0.0008
Urge/ Urge incontinence	322/809 (40)	317/611 (52)	100/809 (12)	51/611 (8)	0.069 to 0.17	0.007 to 0.071	< 0.0002	0.015
Frequency	233/549 (42)	310/611 (51)	48/549 (9)	55/611 (9)	0.025 to 0.14	-0.03 to 0.035	0.0047	0.87
Fecal incontinence	69/324 (21)	93/532 (17)	17/324 (5)	34/532 (6)	-0.015 to 0.094	-0.023 to 0.042	0.167	0.49
Apical prolapse	809/809 (100)	611/611 (100)	56/809 (7)	63/611 (10)	-0.006 to 0.005	0.0047 to 0.064	//	0.022

*No continuity correction
**Z-test comparing PIVS vs TFS, before or after surgery (www.vassarstats.net)

structive surgery were consecutively included by the centres from January 2007 to January 2012, Table 1. Only data of patients presenting for a 12 months follow up are presented. Mean age was 64.62 ± 13.17 years (grand mean ± square-rooted pooled variance).

% cure/improvement at 12 months in the PIVS (TFS) cohort was as follows: pelvic pain 68 (78), nocturia 63 (83), urge incontinence 70 (85), frequency 79 (82), faecal incontinence 76 (65), apical prolapse 93 (90).

Due to the non-randomized design of this study, baseline symptoms – with the exception of faecal incontinence – were characterized by statistically significant imbalances between patients undergoing PIVS or TFS surgery.

In particular:

- pelvic pain was present at baseline in a higher fraction of PIVS-treated patients vs. TFS;
- nocturia was present in a higher fraction of TFS patients at baseline vs. PIVS;
- urge incontinence was present in a significantly higher fraction of TFS patients at baseline vs. PIVS;
- frequency was present in a higher fraction of TFS patients at baseline vs. PIVS.

Due to this baseline imbalance, the postsurgical results in the follow up after 12 months of the two different cohorts (patient undergoing PIVS and TFS, respectively) are evaluated separately and presented individually for each cohort (table 1).

DISCUSSION

This is the first large scale multicentre study to report on the improvement of chronic pelvic pain and other "Posterior Fornix Syndrome" symptoms by repair of prolapsed vaginal fornix. The data supports our hypothesis that damaged pelvic ligaments could be a potentially curable cause of chronic pelvic pain, bladder and bowel symptoms. The data from both cohorts indicates that if central hypersensitisation circuits had been activated in the pain, bladder and bowel domains, they were most probably secondary to peripheral (ligament) defects and not permanent, at least for the majority of our patients.

The native tissue method, figure 1, was initially effective, however cure rates had deteriorated by 12 months and rapidly thereafter[11]. It was therefore replaced by sling techniques using alloplastic material. In 2008, Abendstein et al. expanded the scope of Posterior Fornix Syndrome symptom causation with their report of cure/improvement of Obstructive Defecation Syndrome (ODS), severe sacral and abdominal CPP and non-sphincteric fecal incontinence with a posterior sling[11,21-22]. Though apical support with sling techniques had previously successfully cured chronic pelvic pain and other posterior fornix symptoms[15,18,21-25], these studies were from single units, with small numbers. The strength of this study was the application of two different surgical methods with large numbers collected from multiple centers, giving greater statistical validity to its conclusions: loose posterior suspensory ligaments are most likely an important cause of chronic pelvic pain and other pelvic symptoms. A limitation of this study is the baseline imbalance between the two study cohorts, which is presumably due to the non-randomized design of the study. However both (PIVS and TFS) gave very significant cure/improvement rates for chronic pelvic symptoms. From an anatomical perspective, both PIVS and TFS techniques restore apical support, albeit differently[16-17,23].

Heinrich Martius stated that in about 30% of cases, backaches are provoked by damaged suspending or supporting ligaments of the pelvic organs[26-27]. He did however not associate CPP with other "Posterior Fornix Syndrome" symptoms such as urgency, nocturia, abnormal bladder emptying. Martius described two pathways for CPP, visceral and mechanical. The visceral pathway was transmitted from Frankenhauser's plexus which is situated approximately 2cm lateral to the cervix. It lies at the distal end of the hypogastric plexus. These pains radiate mainly to the lumbosacral region, the anterior and lateral abdominal wall, the inguinal region and the thighs.

The second pathway involves stimulation of the sacral plexus pains. These pains radiate mainly to the lumbosacral region, characterized by low dragging abdominal pain or deep sacral backache. The pelvic pain addressed by this study, is consistent with both of these descriptions.

Other possible causal relationships to deficient apical support

It is possible that other pain conditions may have a similar etiology.

In a group of 408 patients, Butrick et al reported findings on 4 equal groups: Interstitial Cystitis, CPP, Vulvodynia/ dyspareunia and "Other". They found a high rate of complaints of voiding dysfunction, dyspareunia, pain, urgency, frequency[28]. These are similar to the descriptions of the Posterior Fornix Syndrome[9].

The question of loose USL as an etiological factor was tested in 10 patients with chronic extreme vulvodynia. Two ml of 2% lidocaine was injected transvaginally at the junction of USL to cervix. On retesting after 5 minutes, 8 pa-

tients reported complete disappearance of introital sensitivity and this was confirmed by two separate examiners. In the other two patients, direct testing confirmed that the allodynia (exaggerated sensitivity) had disappeared on one side, but remained on the other. Re-testing the patients at 30 minutes confirmed that the blocking effect on the pain had disappeared[29].

A similar test was made in 3 patients with CPP and symptoms of bladder pain syndrome. The abdominal, urethral, introital and cervical tenderness which were demonstrated objectively on pre-testing in all 3 patients, improved significantly shortly after the injection[30].

A simple office 'simulated operation' test, insertion of a 6x3x3cm pessary in the vaginal apex, normally used to determine apical cause of urgency[31], or gentle insertion of the bottom part of a bivalve speculum into the posterior fornix often immediately improves the urge and pain symptoms[32-33]. All these observations suggest that central hypersensitisation may be secondary and the cause of the symptoms potentially reversible.

In summary, defective adequate apical support of the vagina seems to be an important cause for CPP and also, nocturia, urgency and non-sphincteric fecal incontinence.

These symptoms are potentially curable by reconstructing the apical ligamentous supports of the vagina.

Summary

Chronic Pelvic Pain, nocturia, urgency/ urge incontinence and/or non-sphincteric fecal incontinence can be improved by surgical reconstruction of the apical ligamentous supports of the vagina. Both surgical techniques evaluated in this study (Infracoccygeal sacropexy or Tissue Fixation System) achieved similar improvements.

CONFLICT OF INTEREST, FINANCIAL DISCLOSURES

All authors indicate that they have no conflict of interest regarding this publication.

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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 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.

Uro... According to the Standardisation of Terminology in lower urinary tract function proposed on 2002 by the International Continence Society (ICS), Pelvic Pain Syndromes (PPSs) are all chronic in their nature. Pain is the major complaint but concomitant complaints are of lower urinary tract, bowel, sexual or gynaecological nature. Pelvic organ prolapse (POP) can occur in association with urinary incontinence and other lower urinary tract and pelvic dysfunction and it is difficult, if not impossible, to find cause and effect in that. The Integral Theory proposed by Petros, argues that laxity of the uterosacral ligaments and uterus supporting structures can lead to PPSs. Thus, restoring these supporting structures, could represent a therapeutic option for addressing pelvic pain. Both Infracoccygeal Sacropexy (PIVS) and posterior Tissue Fixation System (TFS), gave very significant cure/improvement rates for chronic pelvic pain symptoms in women with vaginal apical prolapse. Unfortunately there is a lack of scientific data from good quality published reports on this topic in the literature. Moreover, although this approach may be beneficial for this kind of patient, it can be largely dependent on the accurate identification of patients with pain, reproducible upon traction of the prolapsing structures. Because POP is typically not associated with pain primarily, patients should be well counselled on the possibility of persistence of pain despite surgical anatomic correction. On the other hand, it is not know whether or not the insertion of a polypropylene tape, could be complicated by the occurrence of pain in women without this complaint before surgery.

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Gyneco... This article emphasizes how ligamentous laxity is important in the onset of syndromes involving the three compartments front, middle and rear. In particular the weakening of the utero-sacral ligaments is responsible for pelvic pain and functional symptoms as well in bladder and rectal emptying, regardless of the degree of genital prolapse. Patients with lesser degrees of prolapse associated with these symptoms are usually recommended for rehabilitation or pharmacological therapy or to wait for a more severe anatomical defect in order to indicate surgery. The restoration of the apical vaginal support with the TFS sling represents a minimally invasive innovative approach allowing cure in symptomatic cases, which are not particularly severe from the anatomical point of view, thus expanding the surgical indications in case of chronic pelvic pain and bladder symptoms (hyperactivity and abnormal emptying). This multicenter study suggests that in the evolution of the clinical picture, early surgery might prevent chronicity of symptoms that probably occurs through the peripheral and subsequently central hypersensitivity. What remains unexplained is that there are patients with higher degree pelvic organs prolapse, and thus with ligaments definitely weak and inefficient in countering muscle action, that do not report symptoms except vaginal fullness.

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Procto... Pelviperineal chronic pain (PPCP) is often observed in a proctologic practice both in males and females, being simply named as proctalgia. Nevertheless it may affect other nearby organs, and it occurs with variable intensity, dysfunctions and emotional involvement. Nosography itself is imprecise and ill-defined in the various forms extending from the pubic bone (pubalgia) to the coccyx (coccydynia). The choice of therapy is difficult as well, being a real challenge for all specialists interested to the pelvic floor. A recent unpublished study (Pelvis Center, Padua, Italy) between 2015 and 2016 has selected 100 female patients with PPCP over a population of 812 women (12.3%), average age 49 (16 -82), mean NRS 4 (2-7), 48 in menopause (8 HRT), with the following localizations: vulva-vagina 90, dyspareunia 60 (sexually active 80), anus and rectum 48; 80 parous, average deliveries 1.7 (1-5). Patients claimed to be anxious in 56%, appearing actually anxious in 46%, admitted to be depressed in 12%, appearing depressed in 24%. The trigger points most frequently mentioned as painful were: vaginal vestibule (60), posterior fornix (35), anal canal (30), Douglas pouch (25), bladder (20), coccyx (12), pudendal nerve /ischial spine (10); in 19 women a descending perineum was observed. The main pathologic conditions in the anterior/central compartment were POP/2-4 Half Way System (14), urinary incontinence (12), hysterectomy (6), endometriosis (6), recurrent cystitis (1), interstitial cystitis (1); in the posterior compartment constipation (55), fecal incontinence (18), dyssynergia (10), rectal mucosal prolapse (32), rectal intussusception (20), low rectocele (14). At present only the Integral Theory (IT) helps us to interpret these cases in which there are no lesions evident at physical examination or imaging. The Integral Theory System offers as well a chance of surgical treatment after 'simulating' the proper operative procedure as follows: by insertion of the lower blade of a bivalve speculum to mechanically support the apex. If the pain improves, surgery to reinforce the posterior ligaments is indicated.

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Original article

Competent uterosacral ligaments are required for normal bladder evacuation - testing a hypothesis evolving from finite element studies on micturition mechanisms in the female

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Abstract: *Background:* Our mathematical models for micturition indicate that micturition is only possible by active opening of urethra by posterior vectors acting against uterosacral ligaments, relaxation being confined to the anterior pelvic muscles. *Aim:* To test this hypothesis in a retrospective study. *Patients and Methods:* Sixty-four patients aged 27-83 years were studied. Inclusion criteria. Posterior sling (infracoccygeal sacropexy),1st or 2nd degree prolapse, one or more emptying symptoms, pre and post-operative urodynamics. Exclusion criteria: none. *Results:* A total of 159 abnormal emptying symptoms was reduced to a total of 83 postoperatively. Mean residual urine in the 38 patients with residuals >50 ml was reduced from 110ml (SD 128 ml) to 63ml (SD +/- 97ml), p = < 0.02, paired t-test. There was no significant change in flow rate post-operatively. 10/64 patients had also undergone pre-operative video-xrays and combined EMG/ urine flow tests. EMG indicated that pelvic muscle contraction preceded urine flow. Xrays data was consistent with contraction of posterior pelvic muscles in the region of the cervix during micturition. Main limitation: retrospective study. *Conclusions:* The main outcome was that competent ligaments appear to have a role in bladder emptying, possibly by restoring the posterior muscle forces hypothesized to open out the urethra. A secondary outcome was improvement in 50% of 'obstructive micturition' symptoms, a condition not previously considered as being surgically curable.

Key words: Mechanism of micturition; Obstructive micturition; Residual urine; Posterior sling.

INTRODUCTION

Incomplete bladder emptying is considered to be an important cause of recurrent urinary tract infections. It is especially a problem in Nursing Homes, where inability to empty often results in indwelling urinary catheters.

It was found that there was a stepwise increase in mortality with duration of catheterization. Patients who were catheterized for 76% or more of their days in the nursing home were three times more likely to die within a year[1].

Though understanding the mechanism of micturition is fundamental to finding a solution to such clinical problems, there is a lack of consensus regarding a precise diagnosis and definition of voiding abnormalities in women[2]. The existing mechanism as presented by the 2005 Standardization of Terminology report of the International Continence Society was that the pelvic floor muscles must relax in order to remove the passive continence mechanisms, thereby favouring normal micturition[3]. To our knowledge, no EMG or imaging proof has ever been offered to validate this assertion.

There are several logical inconsistencies as regards the pelvic relaxation theory. Many patients without previous surgery present with "*outflow obstruction*". On testing with Hegar dilators, urethral stricture is rarely found in such patients.

Urethral obstruction is rarely found on inserting Hegar dilators in patients with voiding dysfunction following the Burch colposuspension[4], indicating absence of mechanical obstruction. The question then arises "how does the Burch operation alter the pelvic relaxation process if there is no mechanical obstruction."

If micturition is viewed from a flow mechanics perspective, the obstruction to flow is functional, not mechanical, a result of the detrusor having to push the urine through a urethra which now has a much higher frictional resistance to flow. According to Poiseuille's Law, the frictional resistance to laminar flow through the urethra is inversely proportional to the 4th power of radius. In our laboratory[5] and finite element modelling[6] of non-laminar (turbulent) flow through a 4cm urethral analogue, the necessary inclusion of the Darcy friction factor into the relationship makes the resistance inversely proportional to approximately the 3rd power of the radius. Therefore, regardless of whether the flow is laminar or turbulent even a minor reduction in diameter of the urethra during micturition will cause symptoms of obstruction. In this context, relaxation of the pelvic muscles would cause the urethral walls to sag inwards, further obstructing urine flow*, in an exponential manner,* ac-

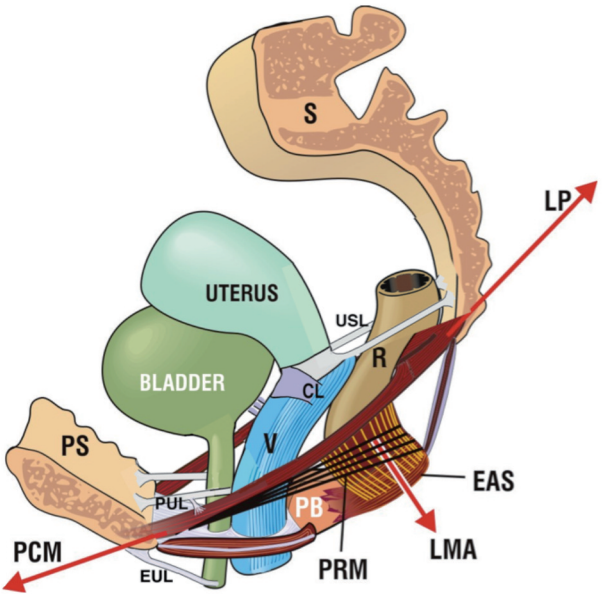

Figure 1. – Muscle-ligament interaction
The 3 directional muscle vectors (arrows) lie below the ligaments and contract against them. Forward vectors: m.pubococccygeus (PCM). Backward vectors: levator plate (LP) and conjoint longitudinal muscle of the anus (LMA). These 3 vectors control the involuntary opening and closure of the urethral and anal tubes and therefore, continence and evacuation.
PRM is a special case. It contracts involuntarily to retain the anorectal angle and is the voluntary muscle activated during 'squeezing'.

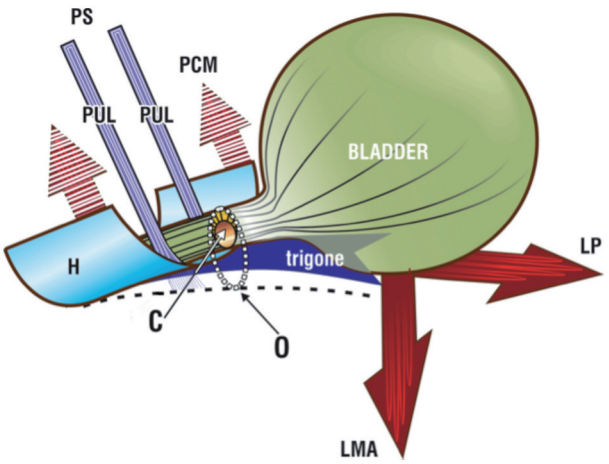

Figure 2. – Hypothesis on the mechanics of micturition. During closure, m.pubococcygeus (PCM) pulls the suburethral vaginal hammock (H) forwards against the pubourethral ligament (PUL) to close the distal urethra. During micturition, PCM relaxes (broken lines). PUL lengthens. LP/LMA vectors pull open the posterior wall via a semirigid trigone from 'C' (closed) to 'O' (open). This vastly decreases resistance to urine flow exponentially, inversely by the 5th power of radius change (5). Bladder contracts and empties. LP=levator plate; LMA=conjoint longitudinal muscle of the anus.

cording to Poiseuille's Law. On this basis alone, it is our view that the pelvic relaxation theory is unsustainable.

Our view is based on the concept that the pelvic muscles contract against the suspensory ligaments to give the organs shape and strength, much like a suspension bridge (Fig. 1). In the normal state the pelvic muscles interact with the bladder/urethra so that the urethral tube is closed (Fig. 1). During micturition, it is our hypothesis that only the anterior muscles relax. This unbalances the system, so that the posterior vectors open out ('funnel') the bladder base urethra to vastly reduce the frictional resistance to urine flow. The consequence of this is that a much smaller head of pressure is required to empty the bladder[5].

Our hypothesis is summarized in figure 2. Only the anterior pelvic muscles relax. The posterior pelvic floor muscles contract against competent suspensory ligaments to open out the vesicourethral outflow tract. According to Gordon's Law[7], if the insertion points (uterosacral ligaments, figure 1) of the posterior muscle force are loose, the striated muscles effectively lengthen, thereby losing much of the contractile force required to actively open out the posterior urethral wall. Our hypothesis predicts that reinforcing the uterosacral ligaments surgically would improve symptoms and objective criteria of bladder evacuation.

Aim. To challenge this hypothesis with a retrospective review of the fate of patients with 'obstructive micturition' symptoms who had a posterior sling. To this end we undertook a retrospective study of 64 patients who had symptoms of 'obstructive micturition' and who had undergone a posterior sling operation for uterine or apical prolapse. We reasoned that if the hypothesis was correct, we would observe improvement in subjective symptoms and objective measures of 'obstructive micturition'.

PATIENTS AND METHODS

A retrospective data search was carried out in a 15 year period ending 2009 to locate patients who had undergone posterior sling for minimal apical prolapse (1st or 2nd degree Baden-Walker classification), who had 12 month post-operative data, with pre-operative 'obstructive micturition' symptoms, pre-operative residual urine >50ml, and who had undergone pre and post-operative urodynamics.

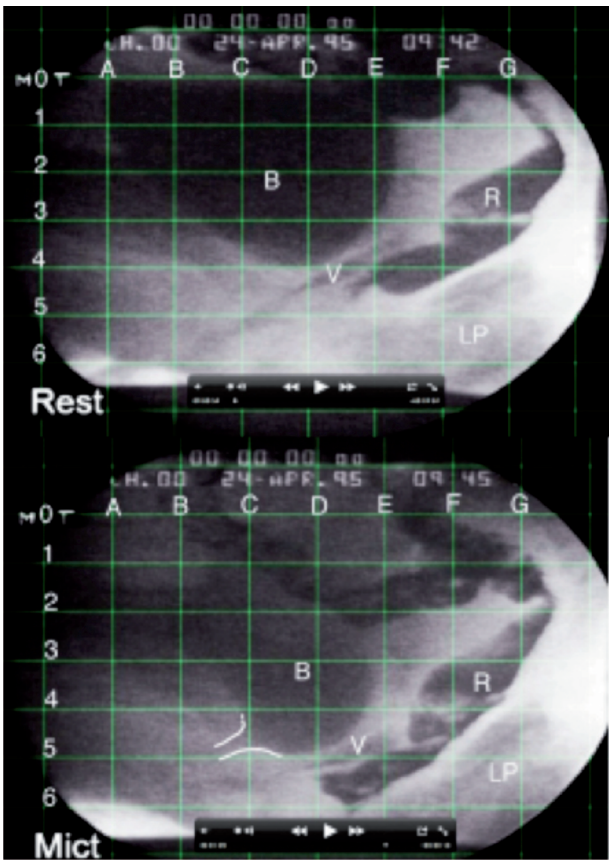

Figure 3. – Active opening of the urethra. Video xray. The upper xray is at rest. The lower Xray was taken during micturition. Dye has been injected into bladder 'B',vagina 'V', rectum 'R', levator plate 'LP'. The grid allows direct comparison of organ movement during micturition. *Micturition* The bladder base, vagina and rectum have been pulled down from level 4 to level 5, apparently by contraction and downward angulation of the levator plate by a downward vector (arrow) contracting against the cervix (CX). Compare square F-G, levels 4-5, 'Rest' & 'Mict.'

Sixty-four patients, aged 27-83 years were studied, 32 with 2nd degree prolapse and 32 with 1st degree prolapse (Baden-Walker). Four abnormal emptying symptoms were assessed, namely 'Does your bladder empty properly?' 'Do you have a slow stream?' 'Does your stream involuntarily stop and start?' 'Do you have difficulty starting flow?' Ten patients from this group had undergone video-xray studies and EMG micturition studies.

The EMG micturition studies were performed using a modified cylindrical electrode (gain 0.5 mV f.s., time constant 2.0 s: Electromed, UK) inserted into the posterior fornix of the vagina during uroflow testing.

A posterior sling operation, the infracoccygeal sacropexy, was used to repair uterine prolapse (n = 31) or post-hysterectomy apical prolapse (n = 33), as previously described[8].

All operations were performed under local ethics committee approval with informed patient consent.

RESULTS

A total of 159 abnormal emptying symptoms was reduced to a total of 83 postoperatively. Mean residual urine in the 38 patients with residuals >50 ml was reduced from 110ml (SD 128 ml) to 63ml (SD +/- 97ml), p = < 0.02, paired t-test.

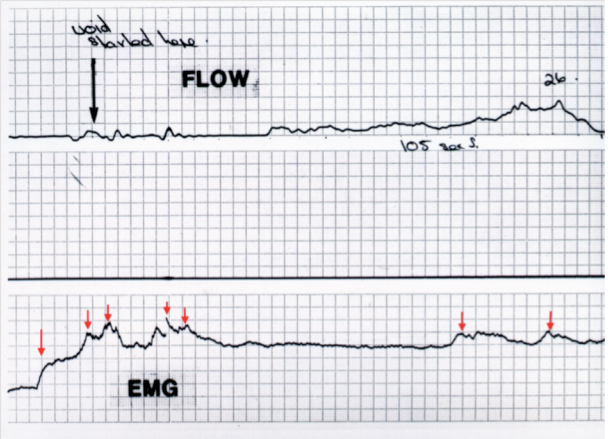

Figure 4. – Active opening of the urethra- 'obstructed micturition'. *Lower figure.* The EMG probe was placed in the posterior fornix of the vagina. Slow prolonged flow consistent with 'obstructed micturition'. The graph demonstrates commencement of muscle contraction in the region of the posterior fornix of vagina (small arrows) prior to commencement of and during voiding. The repeated contractions (small arrows) are consistent with the pelvic muscles repeatedly trying to 'grip' onto a loose ligament so as to open out the urethra.

Peak flow rate was measured in 62 patients postoperatively. Preoperative mean value for this group was 29.5 ml/s (range 8-52 ml/s), and postoperative mean 30.4 ml/s (range 18-56 ml/s), i.e. not statistically significant. Mean bladder volumes preoperatively were equivalent, 447 ml and postoperatively 465 ml.

Almost all patients were discharged within 24 hours of surgery, without postoperative catheterization, returning to fairly normal activities within 7-14 days. At (minimum) 12-month follow-up cure rates were apical prolapse, 95%, emptying symptoms 50% mean residual urine >50 ml from 110 ml to 63 ml, P = <0.02.

The still photos (Fig. 3) taken from the video xrays are consistent with the hypothesis. Active stretching of the rectum, vagina and opening out of the posterior urethral wall are seen, apparently in response to the downward angulation of a contracted levator plate.

The EMG recordings (Fig. 4), generally confirmed that muscle contraction precedes urine flow.

DISCUSSION

Only patients with minimal prolapse were chosen so as to avoid any issues arising from mechanical obstruction from

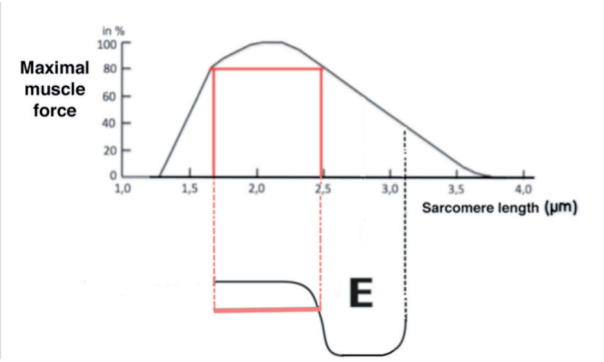

Figure 5. – Gordon' Law. A striated muscle can only contract efficiently over a small distance (outlined by the red square). If, say, the muscle lengthens over distance 'E', from 2.5 to 3.2 µm because of a loose insertion point, the muscle forces generated fall dramatically.

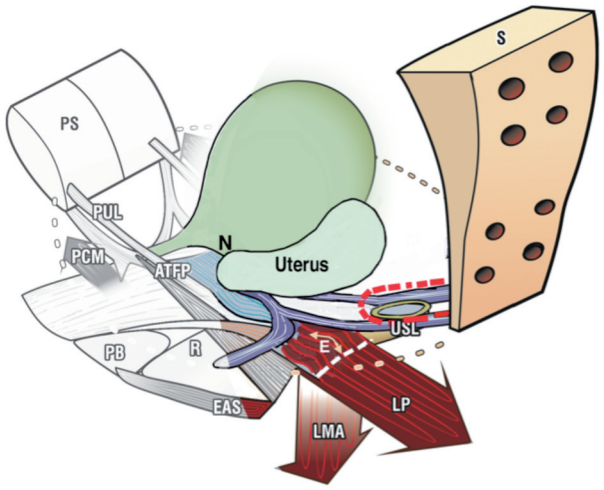

Figure 6. – Repair of loose ligaments restores prolapse and muscle power. The uterosacral ligaments (USL) have lengthened due to prolapse of the uterus. LP/LMA also effectively lengthen from 'E', white broken lines to the posterior ring of cervix. The broken red lines lines show how the tape shortens and reinforces the loose uterosacral ligaments to repair the prolapse. This restores length of LP/LMA to their normal length and contractile efficiency. LP = levator plate; LMA=longitudinal muscle of the anus; N=stretch receptors at bladder base; EAS=external anal sphincter; S=sacrum.

the prolapse. The only intervention was a posterior sling. The results cannot be explained by existing pelvic floor relaxation theories. They are, however, consistent with an external opening mechanism reliant on competent insertion points, in this instance, reinforced uterosacral ligaments. The results are consistent with Gordon's Law which states that a firm insertion point is required for optimum force generation by striated muscles (Figures 5, 6) diagramatically explains how a loose uterosacral ligament would effectively lengthen the levator plate (LP) by 'E'. This would diminish muscle force according to Gordon's Law[7]. The posterior sling (broken lines, figure 6), shows how the tape shortens and reinforces the loose uterosacral ligaments to repair the prolapse. At the same time, this would restore LP/LMA to their normal length and contractile efficiency as predicted by Gordon's Law[7].

The video xrays (Fig. 3) and EMGs, are consistent with previous studies[8] which indicated that the organs are stretched backwards and downwards during micturition. This active stretching would tension the urethral walls and the longitudinal folds of the urethra, further reducing the frictional resistance to flow. Relaxation of the forward muscle vectors, m.pubococcygeus (PCM, figure 2) is a logical requirement for this backward stretching to occur. In the context of the muscle relaxation theory, relaxation of the pelvic muscles in figures 1-3 would cause all the organs to sag downwards. The urethral walls would also sag inwards, narrowing the urethral tube, this further obstructing urine flow, *but in an exponential manner according to Poissueille's Law.* On this basis alone, it is our view that the pelvic relaxation theory is unsustainable.

Further evidence against the relaxation hypothesis came from our recent Finite Element Study[6]. We used known anatomy, bladder pressures and stiffness of the tissue components of the urethra to mathematically model the forces required to achieve the well known funnel shape seen during normal micturition. We found that the detrusor pressure would need to be increased by two orders of magnitude beyond normal voiding pressures (i.e., 100 times normal mic-

turition pressures) in order to achieve opening of the tube by detrusor contraction alone[6]. The importance of this study was that it added another layer of evidence in favour of an active musculo-elastic mechanism occurring during micturition.

Strengths of the study. We demonstrated that repairing the uterosacral ligaments also improved "obstructive micturition" symptoms and residual urine. The EMG and video x-rays indicate contraction not relaxation of the posterior pelvic floor and opening out of the posterior urethral wall.

Limitations of the study. The main limitation was that the data was retrospectively obtained, albeit with definite inclusion criteria.

DISCLOSURES

Author contributions: The authors contributed equally to all aspects of the paper.

Conflicts of interest. None.

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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 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.

Uro... The authors report a mathematical model for micturition in female indicating that it is only possible by an active opening of the posterior urethra by vectors acting against uterosacral ligaments. This hypothesis on the mechanics of micturition is an extension of what reported by the authors in the 90's where they focused on the importance of the force vectors mediated by the interaction of the PUL, PCM, LP and LMA. In this context it is evident that the posterior support of the bladder, activated by a reinforcement of the loose uterosacral ligaments, allows the system to obtain a rectilinear urethra and so achieve an unobstructed voiding.

From a urological point of view, this principle is applied before orthotopic bladder replacement after radical cystectomy in the female. In this way, pelvic organ prolapses are currently considered contraindications to orthotopic neobladder so as to avoid complications such as incontinence or, more frequently, chronic urinary retention, which leads to intermittent self-catheterization. There are many possible causes of chronic retention in female neobladder. A mechanical factor is frequently advocated given the position and fixation of the pouch in the pelvis, the handling of the urethropelvic ligaments and the acute angulation of the pouch-urethral junction. In this context, the creation of a posterior support to the neobladder has been reported by Ali-El-Dein (1) who described a peritoneal flap from the peritoneal cul-de-sac fixed to the vaginal stump. Similarly Stein (2) and Stenzl (3) proposed an omental flap interposed between the vagina and the pouch. The functional results in these cases are excellent, thanks to the restoration of a functional posterior support to the neobladder that allows it to achieve a non-obstructed micturition.

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Procto... Reading Liedl's interesting article, a colorectal surgeon is stimulated to apply the same Integral Theory criteria described by Liedl and Bush for micturition to mechanisms for defecation and emptying of the rectum. It is not uncommon to see that patients who complain of symptoms of obstructed defecation or fecal incontinence do not show any pathological data with diagnostic tests. Defecography, anorectal manometry, EMG, transit time study, traditionally considered important for those two functions may all show results within normal limits indicating that the role of traditional elements such as the internal and external sphincters, rectal compliance, etc. may not actually be essential. Furthermore it is well known that in patients surgically treated for constipation or fecal incontinence correcting the above mentioned factors, the long term functional results are not satisfactory, with a significant worsening of the quality of life within 5-10 years after surgery, symptoms being as before the treatment. Starting from these concepts, the application and validation of this theory in relation to the defecatory dynamics should better known by colorectal surgeons and proctologists as it could highlight a new interpretation of the pathophysiology of the posterior compartment and consequently give rise to new therapeutic applications.

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Original article

Male sexual dysfunction after surgery for rectal cancer

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Abstract: Introduction: Sexual dysfunction is a quite frequent complication of surgery for rectal cancer mostly related to the intraoperative autonomic nerves injury. *Aim*: To investigate sexual dysfunctions after surgery for rectal cancer comparing two different surgical techniques. *Methods*: 85 male patients who had undergone surgery for rectal cancer were divided into two groups: group A (1995-1999), rectal excision associated to preaortic and caval lymphadenectomy and group B (2000-2011), mesorectal excision (TME) with careful autonomic nerve preservation. All patients were surveyed regarding their postsurgical sexual function and results were compared in the two groups. *Results*: The erectile dysfunction was reduced from 10% in group A to 5% in group B. The ejaculation dysfunction was 10% in group A and almost 0 in group B; coupled ejaculation and erection disorder was 10% in group A and 15% in B. The local recurrence rate was similar in the two series of patients (5.8% vs 5%). *Conclusions:* Analysis of our data shows that in rectal cancer surgery, a technique particularly focused to nerve preservation has reduced the percentage of isolated disorders of the ejaculation that are related to a lesion of the hypogastric plexus during the lymphadenectomy. Nonetheless in 15% of the patients coupled disorders of ejaculation and erection remain as unavoidable because related to a lesion of the pelvic plexus due to oncologic radicality in presence of locally advanced tumors.

Keywords: Rectal cancer surgery; Erectile dysfunction; Male sexual dysfunction; Total mesorectal excision.

INTRODUCTION

Sexual dysfunction is a quite frequent consequence of surgery for rectal cancer. The incidence of erectile or ejaculation disorders has been reported to be 15-70%[1-3] due to the intraoperative nerve injury. Preservation of pelvic autonomic nerves such as the pelvic plexus and superior hypogastric plexus seems to lower the incidence of sexual morbidity[4-5]. Some authors address the importance of preservation of the pelvic autonomic nerves in the prevention of sexual dysfunction after surgery for rectal cancer and imply that more radical excision carry a higher risk of nerve damage[6-8].

Clearly, adequate removal of the tumor is the first priority of surgery. This goal can be achieved until the mid-80's with organ excision and extensive lymphadenectomy (preaortic and caval). Subsequently was shown that TME (Total Mesorectal Excision) procedure was equally radical[9-10].

The principle of this technique is en bloc removal of the complete rectum and mesorectum together with any potential spread of cancer into perirectal fat, leaving negative surgical margins.

TME demanding a more precise dissection, respecting the anatomical planes and preserving the autonomic pelvic nerves that are adjacent to the resection plane seems to be able to preserve the autonomic innervation and the sexual function[2,6,11].

The purpose of this study is to assess the incidence of erectile and ejaculation dysfunction after rectal surgery for cancer analyzing this complication in relation to the surgical technique employed: rectal resection with preaortic and caval lymphadenectomy vs TME.

MATERIALS AND METHODS

From January 1995 to December 2011, 232 consecutive patients with histologically proven adenocarcinoma of the rectum underwent surgery at the VI Clinic of Surgery, "Sapienza" University, Policlinico "Umberto I", Rome. In all patients, one senior surgeon (C.M.) performed the operations.

139 patients were eligible for the study after applying the criteria of exclusion: female gender, death, abdomino-perineal amputation. 85 were eligible for follow-up of at least 3 years and were investigated for age, type of resection (high, low, ultra-low anterior resection, or coloanal anastomosis), tumor stage (T), postoperative pelvic complications, pre or postoperative chemo/radiotherapy and pelvic recurrence.

The study comprised 2 groups of patients: 65 patients (group A) were underwent TME o PME (partial mesorectal excision) associated with preaortic and caval lymphadenectomy from January 1995 to December 1999, 20 patients (group B) were underwent TME with particular attention to autonomic nerve preservation from January 2000 to December 2011.

The technique of TME as described by Heald involved complete removal of mesorectum containing lymph nodes through a sharp dissection along the avascular plane between the parietal and visceral pelvic fascia and leaving intact Denonvillier's fascia whenever the tumor allowed it.

Autonomic nerve preservation is done by identifying and sparing of the preaortic superior hypogastric plexus and the bilateral hypogastric nerves that join the sacral parasympathetic nerves to form the inferior hypogastric plexus anterolateral on both side from which originate the nerves erigentes.

In our experience we were unable to identify the nerves erigentes lying in a more anterior plane than the rectum. The chance to save the innervation of urogenital function exists, in our opinion, only when excision is contained in a space within the hypogastric plexus whose branches can be identified with careful preparation. Locally advanced rectal tumors with adherence or infiltration necessitated sacrifice of these pelvic nerve structures to obtain a clear lateral resection margin.

All 85 male patients were interviewed at last 1 year to the surgery and asked to answer a standardized questionnaire (IIEF, International Index of Erectile Function)[11] regarding their postoperative sexual function. Among these 85 patients, we extracted a sample of 40 patients with age ≤70 yrs., 20 for each group (A and B), homogeneous for all variables investigated.

The questionnaire comprises 15 questions and aimed at gathering data about sexual disorders in male patients; it is used in medical literature mostly after radical prostatectomy. In this study, two items concerning erection and ejaculation were selected from the IIEF items in identify patients with active sexual function before surgery.

We synthetically grouped the results obtained from the questionnaire as:

– presence of the disorder of erection only
– presence of the disorder of ejaculation only
– presence of both disorders of erection and ejaculation.

We compared the two groups of patients stratified also in relation to type of resection, tumor stage, pre or postoperative chemo-radiotherapy, pelvic postoperative complications and local recurrence.

The statistical evaluation was carried out using the SPSS 15 statistics program. The univariate analysis was performed using the chi-square test (exact Fisher Test). Statistical significance was accepted at $p \leq 0,05$.

RESULTS

The characteristics of the 85 patients eligible for follow up ≥ 3 years were shown in *Table 1*. Results of comparison of the sexual function in the two group of patients were shown in *Table 2*. The disorder of erection was reduced from 10% in group A (1995-1999) to 5% in group B (2000-2011) and the disorder of ejaculation was reduced from 15% in group A to zero in B; the incidence of both erection and ejaculation disorders was 10% in group A and 15% in group B. The local recurrence rate was similar in the two periods (5.8% vs 5%).

DISCUSSION

The rate of sexual dysfunction reported after surgery for rectal cancer varies from 15% to 70% and it is related to damage of the sympathetic and parasympathetic autonomic innervatio[1-3].

The retrograde ejaculation is reported in a range from 14% to 69% of the patients, while the impotence from the 11% to the 76%[1,13-16].

Damage of the superior hypogastric plexus and hypogastric nerves could lead to disturbed ejaculation. Disruption of the pelvic splanchnic nerves or the pelvic plexus could lead to erectile dysfunction.

Our results show ejaculation disorders in 10% of patients treated with traditional surgery, when the preaortic and caval lymphadenectomy was performed systematically.

Disorders of the ejaculation that may consist in the absence of the ejaculation, retrograde ejaculation, and painful ejaculation can result from damage of the superior hypogastric plexus or the hypogastric nerves, even if unilateral[7].

Section of the superior hypogastric plexus laterally to the aorta can occur during the preaortic lymphadenectomy or during the ligature of mesenteric artery at its origin. Sometimes the superior hypogastric plexus and the adjacent lymph nodes were deliberately sacrificed for oncologic radicalism.

At the level of the sacral promontory, the hypogastric nerve is clearly visible when it splits itself in the two lateral branches that lay on a plane immediately adjacent to the endopelvic fascia and easily separable from the mesorectal one[17-19].

In our patients treated with only TME without preaortic lymphadenectomy, retrograde ejaculation disorders goes to 0.

TME, preserving the integrity of the mesorectal fascia and obtaining negative circular margins of section, is the assumption to minimize the risk of a pelvic recurrence. Even with the total mesorectal resection, it is possible to save the autonomic innervation when a plane of cleavage is accurately performed between the endopelvic fascia and the mesorectal one (fascia propria), cutting in almost completely bloodless plane. This plane represents an important landmark, since it contains structures of the pelvic plexus that if excessively stretched, tending them upwards or medially, may cause a nervous damage[20-22].

At this level, the damage results to be mixed since it involves both sympathetic and parasympathetic structures. In other words, avoiding to "hooking" both the middle rectal artery and the lateral ligament of the rectum, the possibility of complications may be reduced.

Every time the tumor site and extension allow it, the plane of excision to be followed, has to be the one behind the Denonvillier's fascia. In this way, it is almost certain not to include the nerves in the section. The Denonvillier's fascia has a variable thickness but sometimes the thickness is such that it can cover the prostate and the seminal vesicles with a layer of tissues so dense not to make these organs visible.

Our experience for what concerns only the erectile dysfunctions shows a trend in reducing (from the 15% to the 5%), even if the difference was non statistically significative because of the size of the sample.

Nonetheless, it is to notice that in the second period the coupled erectile and ejaculation disorders stay high (15%) and are similar to the ones in the first period. This leads us to consider that the lateral dissection of the pelvic cavity is the time in which the lesion of plexus has more likely happened. Indeed analyzing the sexual disorders in the ileoanal pouches, that in our experience do not exceed the 1.5%, we observe that the technical difference fundamentally consists in the fact that in the pouches the lateral excision of the rectum is extended beyond the levator ani muscles floor, along a plane close to the organ.

One of the most striking findings in our experience was that, in contrast to conventional rectal cancer surgery, TME completely avoided the problem of retrograde ejaculation. Apparently, the hypogastric nerve descending on both sides from the preaortic superior hypogastric plexus is at high risk of damage during conventional blunt dissection of the rectum. Furthermore, if the surgeon is not familiar with the TME technique there may a some difficulty entering the correct plane at the pelvic brim and preserving a thin layer of preaortic connective tissue that contains the superior hypogastric plexus and hypogastric nerves. Lateral lymph node dissection is an important factor involved in sexual dysfunction and was the only surgical factor that influenced postoperative sexual function in patients.

Introduction of the well-defined and standardized technique of TME led to a significant reduction in sexual dysfunction in men compared with the results obtained with the conventional technique.

Particularly 5 anatomical danger zones should be considered in TME with respect to functional postoperative results: I) protection of the superior hypogastric plexus, II) protection of the hypogastric nerves, III) protection of the inferior hypogastric plexus on both sides in the area of so-called T-junction, IV) preparation behind Denonvillier's fascia without violation of the capsule of the vesicles to avoid urogenital malfunction, V) protection of the dorsolateral region of sacral nerves S2-S4.

The exact preparation within the visceral and parietal fascia is essential to protect the structures of the autonomous nerves to avoid postoperative dysfunction.

TABLE 1. Characteristics of the 85 patients eligible for follow-up≥ 3 years assessed in relation to sexual function (85/139).

N patients	**1995-1999 (65)**	**2000-2011 (20)**
Median F-up ± SD (years)	*11±5*	*8±4*
Mean Age (range)	64,4 years (22-85)	59,1 years (40-76)
Type of Resection:		
High ARR	16 (24, 6%)	4 (20%)
Low and Ultralow ARR	36 (55, 4%)	9 (45%)
Coloanal ARR	13 (20%)	7 (35%)
Tumor Stage (T):		
T0- T2	24 (36, 9%)	7(35%)
T3	40 (61, 6%)	10 (50%)
T4	1 (1, 5%)	3 (15%)
Septic complications in the pelvis	8 (12, 3%)	3 (15%)
Chemo /Radiation Therapy	25 (38, 4%)	12 (60%)

ARR= anterior rectal resection

TABLE 2. Sexual dysfunction: comparison between the two periods examined.

	1995-1999 (20 pts)	**2000-2011 (20 pts)**	
Median Follow-up years (range)	10,5 (18-12)	8,0 (14-3)	
Mean Age years (range)	56.5 (40-70)	59 (49-70)	
erectile dysfunction	**3 (15%)**	**1 (5%)**	**P=n.s.**
Ultralow and Coloanal ARR	3	1	
Stage: T3-T4	0	1	
Septic Complications in the pelvis	0	0	
Chemo and Radiation Therapy	0	1	
ejaculation disorders	**2 (10%)**	**0**	**P=n.s.**
-Ultralow and Coloanal ARR	1	0	
- Stage: T3-T4	0	0	
- Septic Complications in the pelvis	1	0	
- Chemo / Radiation Therapy	0	0	
both erectile and ejaculation disorders	**2 (10%)**	**3 (15%)**	**P=n.s.**
- Ultralow and Coloanal ARR	2	1	
- Stage: T3-T4	2	2	
- Septic Complications in the pelvis	0	0	
- Chemo / Radiation Therapy	1	3	

ARR= anterior rectal resection

The main goal in the rectal surgery, on the other side, remains the oncologic radicalism with specific regard to the local recurrence. The reported incidence of pelvic recurrence is an average of 30%, between 14% and 35% performing the traditional surgery (not TME). In patients that undergo a TME that incidence is drastically cut with values between 1.6% and 9,8%[9, 22-30].

In almost all the patients, since the first half of the 80's, our excision technique has included the TME. This fact has allowed us to obtain a very low incidence of pelvic recurrence that remain similar in the two periods examined (5.8% vs 5%).

From the analysis of our data it emerges that in the surgery for the cure of rectal cancer, the usage of a technique particularly focused on the preservation of the nerves has reduced the % of isolated disorders of the ejaculation that are related to a lesion of the hypogastric plexus during the lymphadenectomy.

Particular attention has to be paid also to this type of problem because the surgeon nowadays has to try to guarantee also the maintenance of a good sexual activity that is considered – at all ages – an important area of the quality of life.

Nonetheless, in the 15% of the patients coupled disorders of ejaculation and erection remain as inevitable because related to a lesion of the pelvic plexus determined by reasons of oncologic radicalism in presence of locally advanced tumors.

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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 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.

Procto… An interesting point of view in rectal surgical oncology is related to QoL. Particularly attention must be cared to sexual and urinary disorders in male. As well as reported in this paper, there are many factors that may have effect on this aspect: 1) first of all the neo-adjuvant treatment (radiotherapy, in particular, has negative influence on both, urinary and sexual function, immediately and in the middle-long term). A functional recovery is very difficult. 2) Extension of rectal excision (related, of course, to the stage and subsequent radical procedure). 3) Total Mesorectal Excision (TME). 4) Nerve Sparing Technique (NST). TME and NST, when correctly performed, have significant influence on QoL. There are a lot of recent trials, also reported in the attached references, that demonstrate better results in the F.U. of patients treated, also related to "function". The surgeons need to choose and perform a correct radical procedure before but, not secondary, must observe particular attention to preserve a long-term QoL.

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Every patient knows whether his sexuality is experienced with joy, confidence and pleasure or rather with fear, consuetude, duty or even pain. As therapists, do we know it? Are we aware of the basic characteristics of the sexual life of our patients, or our team only deals with biological data? The WHO's definition of sexual health considers also the relational, emotional, and psychic aspects of sexual life. Those aspects existing well prior to the inner earthquake suffered when a cancer is diagnosed, shake the individual from the foundations of his being, and a scream awakens his ancestral instinct for self-preservation. Each component of his sexuality and personality that we didactically split, becomes altered, damaged and mixed with fear of death, primum movens of all biochemical storms that unhinge us and fling us into those stress mechanisms that also undermine sexual life. Let's not forget that this fear has also a strong relational component, as well as sexuality: the fear of facing a tumor is not only of disappearing, but also that death ends every emotional relationship, all tenderness, every mutual nurturance. For this reason it is very important to remember the role of the sex therapist in supporting and rebuilding a happy sex life, beyond the biological symptom. This task should be carried out starting from the maximum stress represented by facing death, followed by an activity predominantly parasympathetic which is biologically managed by a number of chemical mediators, but humanly by skin contact, emotion, sharing of themselves and their fears. It's a fascinating endeavour, but difficult, in which the patient has an absolute need not to be left alone.

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Original Article

Effectiveness of sacral neuromodulation in the management of refractory bladder pain syndrome

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Abstract: INTRODUCTION AND AIM OF THE STUDY. Bladder Pain Syndrome (BPS) is a complex pathology, with a prevalence ranging from 0.06% to 30%. In patients refractory to first line treatment, sacral neuromodulation (SNM) can reduce BPS symptoms and improve patients' lower urinary tract symptoms (LUTS) associated. The aim of this study was to evaluate the effectiveness of SNM for the treatment of symptoms in patients with refractory BPS. *Materials and methods:* The data regarding patients undergoing SNM refractory to medical/conservative therapy, who underwent InterStim® SNM 2012 and 2014 in a single Italian centre, were retrospectively evaluated. Bladder pain was assessed with a 0-10 Visual Analogue Scale (VAS) before and one year after the treatment and at the last follow-up visit, whereas LUTS were evaluated using a three-day bladder diary. *Results:* Twenty-three patients underwent first stage unilateral S3 stimulation; median age was 56 years and mean follow-up was 32 months; 78% of the patients showed a significant improvement and underwent a definitive implant. Patients' reported pain score decreased from a mean of 8 at baseline to 3 at one-year follow-up ($p < 0.001$). Urgency decreased from 4.6 ± 2.4 up to 1.3 ± 1.9 ($p < 0.001$). Daily urinary frequency improved from 12.7 ± 4.8 times up to 8.7 ± 2.8 ($p < 0.001$) and nocturia decreased from 2.5 ± 1.9 up to 0.7 ± 1 ($p < 0.001$). Mean voided volume increased from 145.4 ± 70.5 ml to 208.2 ± 73.4 ml ($p < 0.001$). Clinical effectiveness was maintained in the last follow-up visit. Conclusions: SNM appears to be effective and safe in treating refractory BPS with associated LUTS.

Keywords: Sacral neuromodulation; Bladder pain syndrome; Pelvic pain; Interstitial cystitis; Effectiveness.

INTRODUCTION

Bladder Pain Syndrome (BPS), formerly known as interstitial cystitis (IC) and painful bladder syndrome, was defined in 2008 by The European Society for the Study of Bladder Pain Syndrome (ESSIC) as the presence of chronic (more than 6 months) pelvic pain, pressure or discomfort perceived to be related to bladder, accompanied by at least one urinary symptom such as persistent urgency to the emptying or frequency. [1] At the moment, there is no agreement how this complex syndrome should be referred to.This disease is a multidimensional and invalidating pathology; it is difficult to evaluate BPS prevalence, because this condition is underestimated. Reports of BPS prevalence have varied greatly, along with the diagnostic criteria and populations studied. Prevalence of BPS ranges from 0.06% to 30%,[2] whereas a survey conducted in USA in 2004 on the female members of the University of California (San Diego) identified a probable IC in 30.6% of the young women and a documented IC in a minimum of 10% of the female medical students.[3] A review conducted by Buffington in 2004 supposed, moreover, that this pathology is not a single disease, but a member of large clinical conditions, due to a stress response pattern of increased sympathetic nervous system function.[4] IC/BPS patients are, moreover, more frequent affected by irritable bowel syndrome (38.6% versus 5.2%), fibromyalgia (17.7% versus 2.6%) and chronic fatigue syndrome (9.5% versus 1.7%; all $p < 0.001$), in comparison with asymptomatic control subjects.[5] Management of BPS symptoms is a therapeutic challenge and needs a multi-disciplinary management; unfortunately, available studies, due to the great heterogeneity of methodology, give only limited evidence on several options proposed for the treatment of PBS/IC. [6]

First-line treatments of BPS/IC are conservative and includes: education and patient support, dietary and behavioural changes, stress reduction, dietary changes, relaxation techniques and pelvic floor muscle training.[2]

Second line treatments include both oral (antidepressant, pentosanpolysulphate sodium, and anti-convulsivants) and intravesical therapies (pentosanpolysulphate sodium, heparin, hyaluronic acid). When intravesical instillation therapies have failed, it is possible to consider intravesical bladder wall and trigonal injection of botulinum toxin A. Actually, in refractory patients sacral neuromodulation (SNM) may be a further option, as well. SNM can reduce BPS symptoms and improves voids and over 90% of patients treated with neuromodulation would undergo the implant again.[7]

Moreover, SNM decreases Interstitial Cystitis Symptom and Problem Index scores decreased from 16.5 to 6.8 and 14.5 to 5.4, respectively ($p < 0.01$), showing safety and efficacy of this treatment.[8]

The aim of this study was to evaluate safety and effectiveness of SNM for the treatment of patients with refractory BPS.

MATERIALS AND METHODS

We retrospectively collected and analysed the data regarding a cohort of patients undergone SNM with InterStim® for refractory bladder pain syndrome (BPS) between March 2012 and July 2014.

All patients fulfilled the diagnostic criteria for BPS:

- chronic presence (more than six months) of pelvic pain, pressure or discomfort perceived to the bladder
- association with at least one lower urinary tract symptom, such as urgency or frequency)
- not results responsive to oral and intravesical therapy.

All patients were older than 18 years and organic causes of BPS were ruled out.

All patients affected by neurological diseases, stress urinary incontinence or pelvic organ prolapse, were excluded from the study. Each patient was evaluated by medical history, urologic physical examination and bladder diary. Both

the first stage and the definitive implant of SNM were conducted by the same surgeon (FC).

The first stage of the procedure was conducted using the tined lead[9] of InterStim (Medtronic, Inc., Minneapolis, MN, USA).

All responders patients, that showed an improvement of pain and urinary symptoms > 50%, underwent a definitive implant. Bladder pain was evaluated with a a 0-10 point scale visual analogue scale (VAS) and all patients completed preoperatively a 3-day voiding diary, with the aim to evaluated frequency of micturition, episodes of urgency or incontinence and voided volume.

Moreover, all patients were evaluated at 12 months after the procedure with history, physical examination and voiding diary.

After a minimum follow up of 12 months a global evaluation was conducted and patients filled VAS score and voiding diary. All complications were recorded and evaluated. Statistical analysis was performed using the Statistical Package for Social Science (SPSS Inc, Chicago, IL) version 18.0. Continuous variables with normal distribution were reported as means and standard deviations; non-normally distributed continuous variables were reported as medians and interquartilic range (IQR) or range; the t-test and the Wilcoxon tests were used to compare the continuous variables, as appropriate. A $p \leq 0,05$ was considered statistically significant.

RESULTS

The data regarding 23 patients (18 females and 5 males), diagnosed with refractory BPS and treated with SNM were collected and retrospectively evaluated. A uro-gynaecological physical examination excluded organic diseases in all patients.

After the first stage procedure, 18/23 patients (78.3%), all females, showed an improvement of at least 50% in pain relief and LUTS. Therefore, these patients were candidates for definitive implant with InterStim® (Medtronic, Inc., Minneapolis, MN, USA).

Median age of the patients was 56 years (range 43-75 years), with a median time from diagnosis of 2.5 years (range 1 to 6.5 years).

Median follow up was 32 months (range 12-38 months). In 85% of cases the electrode was placed at the S3 nerve root, on the right side, in the standard manner. VAS score decreased significantly from a median value of 8 at the baseline (range: 8-10) to 3 (range: 2-5) at one-year-follow up ($p < 0.001$) (Figure 1). The pain reduction was, therefore, statistically significant.

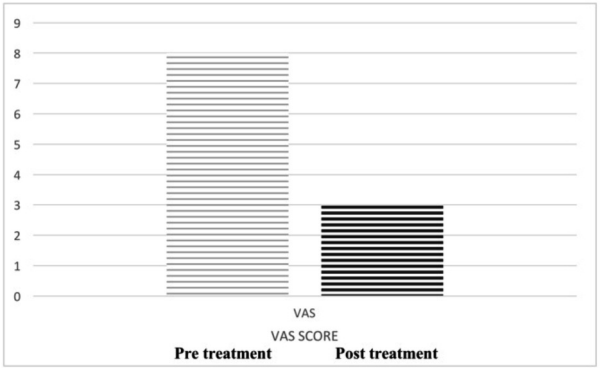

Figure 1. – Median pain reduction from baseline to one-year follow-up after SNM.

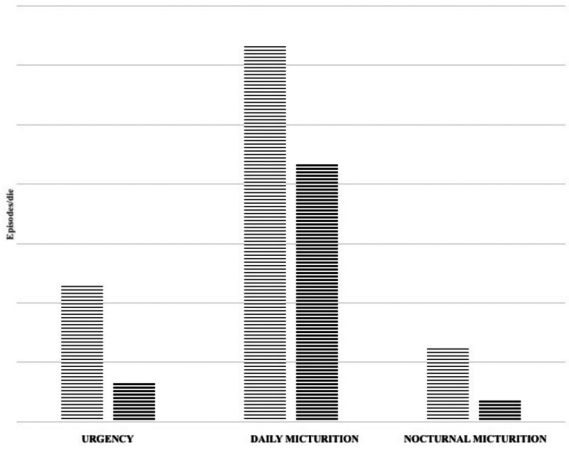

Figure 2. – LUTS reduction from baseline to one-year-follow-up after SNM.

With regard to the associated LUTS, urgency episodes decreased from 4.6 ± 2.4 to 1.3 ± 1.9 ($p < 0.001$) (Figure 2), daily micturitions improved from 12.7 ± 4.8 to 8.7 ± 2.8 ($p < 0.001$) (Figure 2) and nocturnal micturitions from 2.5 ± 1.9 to 0.7 ± 1 ($p < 0.001$) (Figure 2).

The mean voided volume, moreover, increased after SNM from 145.4 ± 70.5 ml to 208.2 ± 73.4 ml ($p < 0.001$) (Figure 3).

Overall, SNM showed a statistically significant improvement in both VAS score and LUTS.

During the analysed follow-up, no patient has replaced the impulse generator because of battery depletion or developed pain or infection at the site of the definitive implant. No complications led to the extraction of either the electrode or the impulse generator.

DISCUSSION

The aim of our study was to evaluate safety and effectiveness of SNM in a cohort of patients affected by refractory BPS at a mid term follow up; SNM demonstrated a statistically significant improvement in reducing both bladder pain and LUTS.

Median VAS score was reduced from 8 (range: 3-10) to 3 (2-5) (62%) at one year follow up after treatment; moreover, daily frequency reduced from 12.7 ± 4.8 to 8.7 ± 2.8 (31%), whereas nocturnal micturition from 2.5 ± 1.9 to 0.7 ± 1 (72%), urgency episodes from 4.6 ± 2.4 to 1.3 ± 1.9 (71%) and voided volume increased from 145.4 ± 70.5 ml

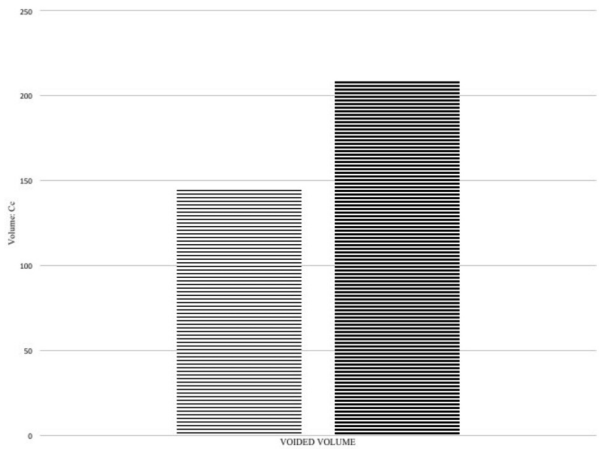

Figure 3. – Voided volume improvement from baseline to one-year-follow-up after SNM.

to 208.2 ± 73.4 (50%). Our results seem to be at least overlapping to those from the most recent literature.

Marinkovic *et al* conducted a observational, retrospective, case controlled review on a small series of 34 female patients undergone SNM for IC and documented a reduction of the visual analogue pain scale from 6.5 ± 2.9 at the baseline to 2.4 ± 1.1 ($p < 0.01$) at 86 months of follow up.[10]

Patients from Marinkovic's series were younger than our patients (median age 41 versus 56 years) with a significantly longer follow up (86 months versus 32 months); moreover, SNM confirmed its effectiveness also on LUTS, showing a reduction of urgency/frequency scores from 21.61 ± 8.6 to 9.22 ± 6.6 ($p < 0.01$), thus confirming the effectiveness of this technique also in a long term follow up.[10]

In 2010 Gajewski et al carried out a larger study on 78 patients treated with SNM for BPS; at a mean follow up of 61.5 months, they showed an improvement at the Global Response Assessment (GRA) and a good long term success in 72% of patients, confirming the good effectiveness of this technique.[11] The Authors supposed that the presence of urgency was a positive predictor of the long term successful effects of the SNM.[11]

The only randomized trial that evaluated SNM and pudendal neurodulation (PNS) in the treatment of IC was conducted by Peters et al in 2007.[7] This study was a prospective randomized, single blind, crossover trial, conducted on 22 patients (19 women and 3 men), with a mean age of 46 years; 77% of them experienced a significant symptoms improvement after tined leads placement and underwent a definite implant. Bladder pain was evaluated with a 10-cm VA and decreased by 49% in the SNM group (from 7.9 to 4.0) and by 29% in the PNS group (from 4.5 to 3.2), whereas in our series bladder pain decreased of 62% (8 to 3).[7] Patients' satisfaction was high, because all patients treated with SNM and 90% of those treated with PNS answered "yes" when asked if they would undergo the implantation again.[7]

Both SNM and PNS were effective also in the management of LUTS, showing a reduction of micturition frequency by 41% for PNS and 33% for SNM, whereas mean voided volume increased by 95% and 21%, and incontinence decreased by 92% and 17%, respectively.[7]

In our series, with a longer follow up (32 versus 6 months), daily frequency reduced by 31%, nocturnal micturition by 72%, urgency episodes by 71% and voided volume by 50%, confirming the results from Peters et al.

Bladder pain evaluation is, unfortunately, heterogeneous; Whitmore showed a bladder pain reduction from 2.2 + 0.7 to 1.6 + 0.8 (0: none; 3: severe pain),[12] whereas Steinberg showed a UDI-6 mean change between the preoperative and postoperative values of 5 ($p = 0.001$).[13]

Despite the heterogeneity in BPS evaluation and the low number of patients treated in the present series, our data are at least overlapping to those from the literature, and confirmed the effectiveness of SNM in the treatment of BPS at a mid term follow up.

CONCLUSION

SNM is a safe and effective treatment in patients affected by refractory BPS, improving both bladder pain and LUTS. Larger randomized study are needed to confirm the long term effectiveness of this technique.

DISCLOSURE STATEMENTS

There was no conflict of interest, informed patient consent was obtained, and the study was approved by the local ethical committee

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Original article

A cystocele may compensate for latent stress incontinence by artificially restoring the urethral and bladder neck closure mechanisms - a critical biomechanical perspective

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Abstract: Existing hypotheses for latent stress incontinence involve kinking of the urethra by the cystocele or compression by an organ. The biomechanical hypothesis is based on dynamic transperineal ultrasound observations which showed downward stretching of the anterior vaginal wall. This was shown to stretch and narrow the urethra, restore the urethrovesical angle and tension the suburethral vagina. It is hypothesized that the key factor in restoration of continence by the extruded cystocele was the exponential increase in frictional resistance to flow caused by the urethral narrowing, inversely by the 4thpower of the decrease in radius, according to Poiseuille's Law, but also the increased tension of the urethral walls (Laplace's Law) and restoration of the distal urethral closure mechanism by the now tensioned suburethral vagina.

Keywords: Latent stress incontinence; Cystocele; Biomechanics.

INTRODUCTION

Recent studies performing concomitant stress incontinence (SI) and pelvic organ prolapse (POP) surgery have highlighted the condition of latent stress incontinence.[1] Stress incontinence is said to co-occur in up to 80% of patients with POP.[1] In a randomized trial of 600 patients in women assigned to concomitant Burch colposuspension or to no Burch colposuspension (control) along with sacrocolpopexy surgery for prolapse, after surgery, women in the control group were more likely to report bothersome symptoms of stress incontinence at 3 months than those in the Burch group who had stress incontinence (24.5 percent vs. 6.1 percent).[1]

The precise mechanism for concealment of occult stress incontinence by a vaginal prolapse is disputed. One theory is the urethral "kinking" hypothesis:[2] uterovaginal prolapse was able to prevent stress incontinence by actually obstructing ("kinking") the urethra.

Others[3] favour the traditional concept of direct compression of the urethra by the pelvic organs.

This work presents a biomechanical hypothesis based on dynamic transperineal ultrasound studies.

METHODS

Under transperineal ultrasound control, 5 patients examined in the semirecumbent sitting position were asked to strain and cough before and after using a sponge holding forceps to manually support the cystocele.[4]

Curvilinear sector scanner probes 3.75 MHz and 5.5 MHz (Capasee, Toshiba) were sited at the vaginal introitus, taking care to avoid any undue pressure on the vulva.

All testing was performed in the sitting semi-recumbent position. The patients had a comfortably full bladder. All patients lost urine on coughing with the cystocele reduced, fig1, but all were dry on coughing with the cystocele extruded. Photographs were taken on straining both before and after support of the cystocele. The ultrasound probe was positioned to observe the events at bladder neck before and after the cystocele was reduced.

OBSERVATIONS/RESULTS

As the cystocele began to extrude, the anterior vaginal wall appeared to slide downward, with apparent tensioning of the suburethral vagina and reconstitution of the urethrovesical angle, figure 2, with urethral narrowing. No kinking of the urethral tube was observed. The biomechanical processes hypothesized to restore the anatomy, figure 2 and continence, are described in figure 3.

The biomechanical hypothesis

Viewed from a biomechanical perspective, the urethra is a tube which in the continence phase, must resist the bladder emptying pressure. Figure3 explains how stretching the anterior vaginal wall downwards would also stretch and narrow the proximal urethra. Restoration of continence in the absence of urethral kinking is explained in terms of the urethra being sufficiently narrowed to resist the pressure seeking to empty the bladder. Stretching and narrowing the urethra increases the closure acting on its walls (Laplace's Law). It also increases intracavity frictional resistance to urine flow inversely by the 4th power of the radius[5] (Hagen-Poisseuille's Law). e.g., halving the radius would increase the resistance by a factor of 16.

In addition to these mechanisms, another mechanism is hypothesized, restoration of the hammock closure mechanism: stretching and tensioning the suburethral vagina enables the forward vector 'PCM', figure 3, to close the urethra from behind.[6]

Lax Connective Tissue and Diminution of the Force of Muscle Contraction

Even at rest, sufficient tension is required in the vaginal membrane to close the urethra and support the stretch receptors (N) (Figure 4) to prevent their 'firing off 'prematurely. Vaginal tension is maintained by tissue elasticity and slow-twitch pelvic muscle contraction. Connective tissue laxity 'L' in the pubourethral ligaments (PUL)(lower part, Figure 4) may cause dysfunction. As the 'trampoline analogy' shows, laxity in the ligaments (springs) or vagina (trampoline membrane) will not permit tensioning of the vagina by the muscles. The muscle forces (arrows) can only be transmitted to open or close the urethra when point 'SE' has been reached on the stress-extension curve (upper part, figure 4). With damaged connective tissue, the muscle forces (arrows) must first 'take up the slack' (L). To accommodate this, at SEL, has to be reached on the stress extension curve. As a muscle can only contract over a finite length (E), SEL cannot be reached, the muscle forces cannot close the urethra, and stress incontinence occurs. A lax vaginal

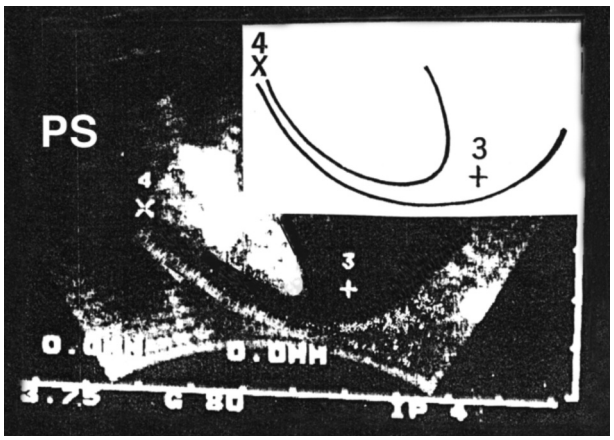

Figure 1. – Cystocele reduced Diagrammatic copy of transperineal ultrasound, patient semirecumbent. Patient leaked urine on coughing. Bladder neck funnelled on straining in a typical USI pattern: rotation of bladder with funnelling of bladder neck.

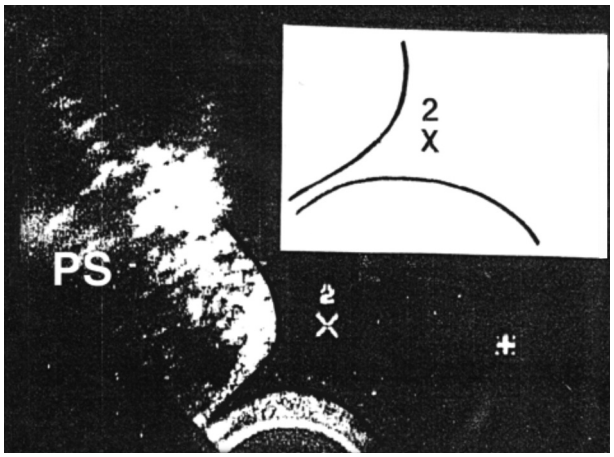

Figure 2. – Cystocele support removed. Diagrammatic copy of transperineal ultrasound, same patient as in fig1. Patient straining, cystocele descending. As the anterior wall of the cystocele descended during straining (curved arrow), the urethrovesical angle changed from funnelled to normal. Bladder neck showed closure on straining. No leakage on coughing was observed.

membrane may not adequately support the stretch receptors (N), so these may prematurely activate the micturition reflex to cause urgency.

CONCLUSIONS

Latent SI is a biomechanical consequence of cystocle.

Contributions. All authors contributed equally to the planning and writing of this paper.

Conflicts. There are no conflicts by any of the authors

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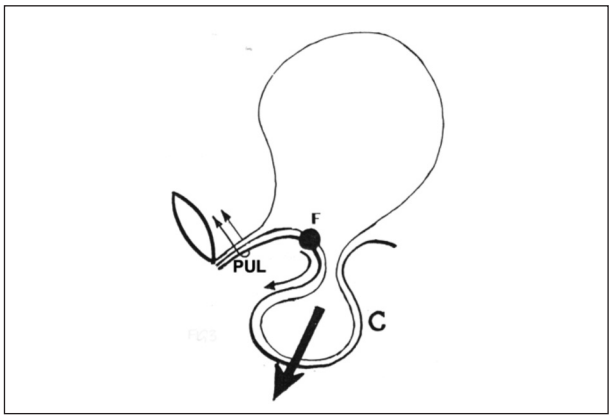

Figure 3. – Simplified Mechanism for closure in patients with latent incontinence. 'F' represents the detachment point of pubocervical fascia to anterior cervical ring. With F detached, the cystocele 'C' is free to descend (large arrow); it stretches the anterior vaginal wall and proximal urethra backwards and downwards (curved arrow). This action also stretches the loose pubourethral ligaments 'PUL', so 'C' now rotates the proximal urethra around PUL to close it. The PDF forward vectors at midurethra (twin arrows) contract to close the distal urethra.

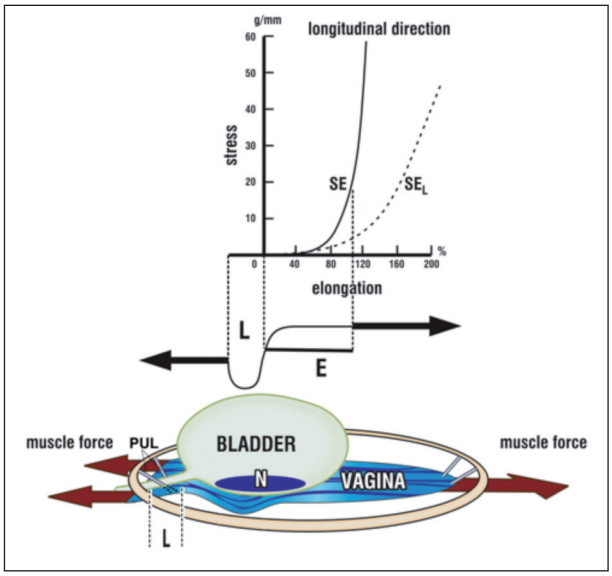

Figure 4. – Laxity in the pubourethral ligament (PUL) is indicated by broken lines 'L'. A muscle can contract only along a finite length 'E'. Some of the contraction is spent in stretching the laxity 'L', so at maximum contraction 'E', there is insufficient force remaining to reach SEL which is required to close the urethra. As the cystocele descends, it sretches out "L", so that the muscles can now contract normally 'E' to close the urethra.
(After Yamada 1970)

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Original article

Bariatric surgery improves pelvic floor disorders

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Abstract: Objective: To determine the frequency of pelvic floor disorders in patients with body mass index (BMI) greater than 30 Kg/m^2 and patients who underwent a bariatric surgery with a weight loss greater than 10% of their initial BMI. *Methods:* Self-administered questionnaires assessing pelvic floor disorders were applied. Statistical analysis was performed using Chi-square and ANOVA results to determine statistical significance. *Results:* 98 and 53 patients were included, with a mean age (SD) of 37.49 (10.65) and 38.95 (7.86) and average BMI of 42.957 (5.98) and 28.18 (5.86) for Obesity and PBS groups respectively. The analysis of questionnaires for Obesity and PBS groups demonstrated: ICIQ-SF (UI 50% - 30.9%) p = 0.022, Sandvik (SUI: Mild: 44.1% - 87% Moderate: 47.5% - 13%, Severe: 1.7% -0% Very Severe: 6.8% -0%) p = 0.00, B-SAQ ("symptom": 29,2% - 0%, "discomfort": 27% - 1.8%) p = 0.00, OAB-V8 (49.5% -14.8%) p = 0.00, Wexner (10.7% - 1.9%) p = 0.05, PISQ-12 (Female sexual response: 46% - 35.2%, Female sexual Limitation 12.6% - 13%, Male sexual Limitation 17.2% - 7.4%) p = 0.05, p = 0.00, p = 0.00 respectively. *Conclusion:* Our results confirm that the Obesity group reported more pelvic floor disorders such as UI, SUI, OAB, Severe Fecal Incontinence and Sexual Dysfunctions. The PBS patients with weight loss ≥ 10% of initial BMI had less pelvic floor disorders. The overall FI including mild symptoms of fecal incontinence and flatus incontinence increased in the PBS group.

Keywords: Body Mass Index; Bariatric surgery; Urinary Incontinence; Fecal Incontinence; Overactive Bladder; Pelvic floor disorders; Obesity.

INTRODUCTION

Obesity is a health problem whose frequency is increasing globally in an accelerated way[1].

Pelvic floor disorders are also very common and comprise a spectrum of conditions such as UI, FI, sexual dysfunction and pelvic organ prolapse. These dysfunctions affect the quality of life of at least one third of women[2].

Obesity constitutes a major risk factor for pelvic floor pathology. Morbid obesity affects the pelvic floor[3-4] with the presence of some degree of dysfunction in 90% of patients[5]. The prevalence of pelvic floor disorders increases with the degree of obesity[6], so its presence produces a four-fold increase or twice or FI and UI, respectively[7]. Obesity is associated with higher rates of FI and diarrhea[8] compared to the general population.

Pelvic floor pathology is a result of weakening of the supporting structures of the different pelvic organs[9]. These support structures should counteract the intra abdominal pressure for proper maintenance of continence and pelvic mechanisms functioning.

Overweight and obesity produce a progressive increase in intra-abdominal pressure which results in elevated hemi diaphragms and development of abdominal wall hernias and its recurrence, among other alterations[10-12]. Obesity exerts a pressure increase chronically sustained in the pelvic floor[12-13]. Noblett et al. found a strong correlation between BMI, intra abdominal pressure and bladder pressure.

Thus overweight affects the continence mechanisms and operation of the pelvic floor[3, 14-15] and increased abdominal pressure caused by increased BMI alters dynamic functional pelvic floor[13].

The weight is a modifiable factor by surgical or nonsurgical approach. Weight control is effective for the management of pelvic floor dysfunction in obese patients[16-17]. Whitcomb and Subak demonstrated that obesity is a strong independent risk factor for the prevalence and incidence of UI. 5% increments on BMI leads to an increase of 20-70% of UI, on the other hand weight loss improves significantly the prevalence, frequency and UI symptoms[18-19].

Bariatric surgery has gained more and more space in the treatment of obesity by decreasing concomitant diseases such as cardiovascular risk, diabetes and osteoarthropathies. Bariatric surgery has also shown to have a positive effect on different pelvic floor dysfunctions[20-22]. The influence of bariatric surgery in FI is unclear. Scozzari et al. described increased flatus incontinence in patients undergoing bariatric surgery[23] while Sileri et al. described decrease on defecation disorders in patients evaluated by the PBS Wexner Scale and the Scale of Severity of FI[24].

Currently, bariatric surgery is an effective treatment option for weight control in selected patients and could become the first choice of treatment for obese patients with associated pelvic floor disorders. It could reduce symptoms and prevent surgeries improving global conditions of the patient and where symptoms persist reduce surgical complications and relapses.

The aim of this study is to evaluate and compare the frequency of different symptoms of pelvic floor disorders in obese patients and patients who underwent bariatric surgery with a weight loss greater than 10% of initial BMI.

MATERIALS AND METHODS

This is a prospective and descriptive study. Self-assessment, pelvic floor symptoms tests were applied to study groups. Obesity group: patients with BMI > 30 Kg/m^2 who attend preoperative consultation for bariatric surgery, and PBS group: patients who underwent a bariatric surgery with a weight loss greater than 10% of their initial BMI. Both groups consisting of patients who attended Barosalud and Dr. Miguel Perez Carreño Hospital, Caracas – Venezuela Bariatric Surgery preoperative consult, between January 2015 and June 2016.

The inclusion criteria for obesity group were female patients with BMI > 30 Kg/m^2 with standard criteria for bariatric surgery and informed consent for the study. For the PBS group inclusion criteria were patients who underwent bariatric surgery with a weight loss of at least 10% of initial BMI.

The epidemiological data collected were Age and BMI in kg/m^2 (calculated as weight divided by the square of height).

The applied tests were International Consultation of Incontinence Questionnaire - Short Form (ICIQ-SF), Evaluation of SUI Sandvik, Self Assessment Bladder Control Questionnaire (B-SAQ), Evaluation Questionnaire of OAB (OAB-V8), Wexner Evaluation of Fecal Incontinence and the Pelvic organ prolapse / Urinary incontinence Sexual Questionnaire (PISQ-12).

The tests were analyzed for global scores and in some cases for different specific domains of each one.

ICIQ-SF: Geared for detecting UI consists of three questions ("frequency", "quantity", "affectation"), plus a group of 8 questions that are not part of the questionnaire score, and are descriptive and guiding on the type of UI[25]. The total score is obtained from the sum of the points of the first three questions and ranges from 0-21 points. It is taken as UI presence any score greater than 0.

Sandvik Scale: This test assesses the severity of UI based on the frequency (4 options) and the amount of leakage (3 options). The value is obtained by multiplying both scores and is categorized into 4 levels: mild (1-2), moderate (3-6), severe[8-9] and very severe[12, 26].

Self-Assessment Bladder Control Questionnaire (B-SAQ): This questionnaire was developed for patients with OAB who can identify this problem or for be used in medical consultation. It consists of 8 questions grouped in two scales ("discomfort" and "symptom"). The cutoff point was less than 6 points on the scale of "symptom" with a sensitivity of 84.8% and a specificity of 39.7% and a sensitivity of 81.8% and a specificity of 27% for the scale of "discomfort[27].

OAB Questionnaire (OAB-V8): Allows diagnosis of probable OAB. It consists of 8 questions each with 6 possible answers with scores of 1 to 6. OAB is probable with scores greater than 8 points with sensitivity of 82.8% and specificity of 73.5%[28].

Wexner Scale: Evaluates 5 parameters including type of loss and impaired quality of life, on a scale from 0 to 4 according to the frequency of occurrence episodes of fecal incontinence. It is interpreted with the sum of each parameter being 0 perfect continence and 20 when there is complete incontinence. The cutoff point between mild and severe FI is the presence of 9 or more points[29].

PISQ-12: Evaluates sexual function in women with UI and / or pelvic organ prolapse. It consists of 12 questions measuring three parameters: a) female sexual response (1 to 4 and 12), female sexual limitation (5-9) and male sexual or partner limitation (10-11). The answers are assigned on a scale from 0-4 points ranging from "never" to "always". Obtaining 0 or 1 point in any of the questions of the evaluated parameters is suggestive of dysfunction in the evaluated domain[30].

STATISTIC ANALYSIS

The mean and standard deviation of continuous variables were calculated. In the case of nominal variables, it frequencies and percentages were calculated. BMI contrast compared to the analyzed variables was assessed with the chi-square test.

For hypothesis testing in this research it was considered significant a value of $p < 0.05$. SPSS 22 for the application data analysis was used.

Finally tests analysis of variance (ANOVA) was performed to determine the actual effect of bariatric surgery (improvement or deterioration) and direct influence on symptoms evidenced and evaluated in the test described above. The analysis of variance p-value was 0.05.

RESULTS

Numbers, age and BMI.

98 Patients were included in the obesity group with an average age of 37.49 years (range of 15.93 to 65.03), mean BMI 42.95 kg / m^2 (range from 31.48 to 62.5). 53 patients were included in the PBS group with a mean age of 38.95 years (range 24.03 to 54.82), BMI average of 28,185 kg / m^2 (range from 20.96 to 45.77) (Table 1). For age the Chi-square test resulted in a p-value of 0.41 with a significance level of 5%. The test of independence of the variable BMI resulted in a p-value of 0.10.

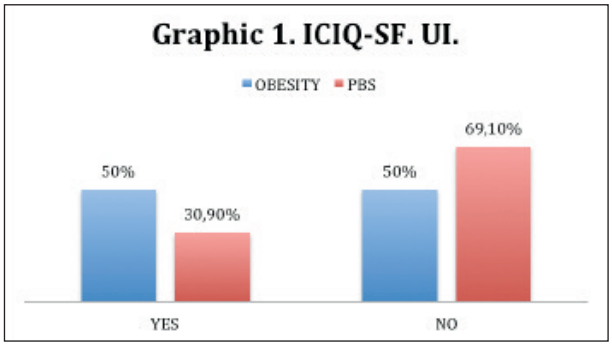
ICIQ-SF

The analysis of this questionnaire in obese patients showed presence of UI in 50.0% and absence of UI in 50.0%, while in the PBS group 30.9% reported UI and 69.1% did not refer UI symptoms (Graphic 1).

Chi-square analysis showed a p-value of 0.022. Contrasting it with a significance level of 5%, we can say that overweight and bariatric surgery significantly influence UI (Table 2). The result of p-value in the ANOVA for the variable UI was 0,022.

Sandvik scale

In Obesity group the following percentage was obtained according to severity: 44.1% had mild UI, 47.5% moderate, 1.7% severe and 6.8% very severe.



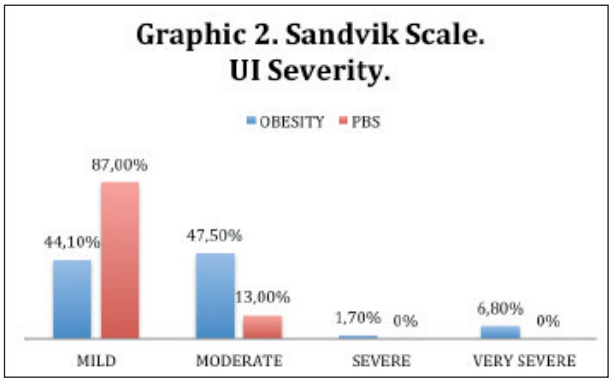


TABLE 1. Main characteristics of the two groups of women included in the study.

	Obesity			PBS		
	N	**Mean**	**SD**	**N**	**Mean**	**SD**
Age	98	37.49	10.65	53	38.95	7.86
BMI	99	42.957	5,98	32	28,185	5.86

N number, BMI body mass index, SD Standard Deviation

Table 2. Relationship between Questionnaires and State.

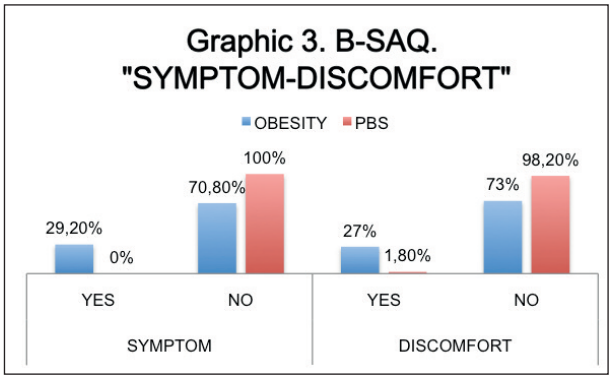
	DOMAIN		STATE		TOTAL	P value
			OBESITY	PBS		
ICIQ-SF	IU	Yes	49	8	57	p = 0.022
		No	50	46	96	
	Total		**99**	**54**	**153**	S
SANDVIK SCALE	Mild		26	47	73	p = 0.00
	Moderate		28	7	35	
	Severe		1	0	1	
	Very severe		4	0	4	S
	Total		**59**	**54**	**113**	
B-SAQ	Symptom	Yes	26	0	26	
		No	63	55	118	
	Total		**89**	**55**	**144**	p = 0.00 S
	Discomfort	Yes	24	1	25	p = 0.00
		No	65	54	119	
	Total		**89**	**55**	**144**	S
OAB-V8	OAB	Yes	49	8	57	p = 0.00
		No	50	46	96	
	Total		**99**	**54**	**153**	S
WEXNER SCALE	SFI	Yes	9	1	10	p = 0.05
		No	75	53	128	
	Total		**84**	**54**	**138**	S
	Mild FI	Yes	30	39	69	p = 0.00
		No	54	15	69	
	Total		**84**	**54**	**138**	S
	Flatus incontinence	Yes	29	39	68	p = 0.00
		No	55	15	70	
	Total		**84**	**54**	**138**	S
	Liquid incontinence	Yes	11	11	22	p = 0.255
		No	73	43	116	
	Total		**84**	**54**	**138**	NS
	Solid incontinence	Yes	6	3	9	p = 0.712
		No	78	51	129	
	Total		**84**	**54**	**138**	NS
	Using diapers	Yes	14	1	15	p = 0.006
		No	70	53	123	
	Total		**84**	**54**	**138**	S
	Quality of life	Yes	12	12	24	p = 0.230
		No	72	42	114	
	Total		**84**	**54**	**138**	NS
	Only flatus incontinence	Yes	7	18	25	p = 0.208
		No	47	66	113	
	Total		**54**	**84**	**138**	NS
PISQ-12	Disf Female Sexual Response	Yes	40	19	59	p < 0.05
		No	47	35	82	
	Total		**87**	**54**	**141**	S
	Disf Female Sexual Limitation	Yes	11	7	18	p = 0.00
		No	76	47	123	
	Total		**87**	**54**	**141**	S
	Disf Male Sexual Limitation	Yes	15	4	19	p = 0.00
		No	72	50	122	
	Total		**87**	**54**	**141**	S
Significance level 5%, S significant, NS not significant						

In PBS group we observed 87% mild UI, 13% moderate, 0% severe and 0% very severe (Graphic 2).

The analysis showed a statistically significant difference (p = 0.00), the p-value indicates that there is a relationship between the state variables (obesity and PBS) and presentation of UI (Table 2). The analysis of variance shows that the variable severity has a p-value of 0.00.

Self-assessment bladder control questionnaire (B-SAQ)

In Obesity group 29.2% had "symptom" and 27% "discomfort"; and in PBS 0% had "symptom" and 1.8% "discomfort" (Graphic 3).



The Chi-square statistical analysis showed a statistically significant difference for "symptom" (p = 0.00) and "discomfort" (p = 0.00), this means that there is a relationship of dependency between before and after bariatric surgery in the domains of "symptom" and perceived "discomfort".

The analysis of variance yields p-value of the variable "discomfort" and "symptom" of 0.351 and 0.00 respectively (Table 2).

OAB questionnaire (OAB-V8)

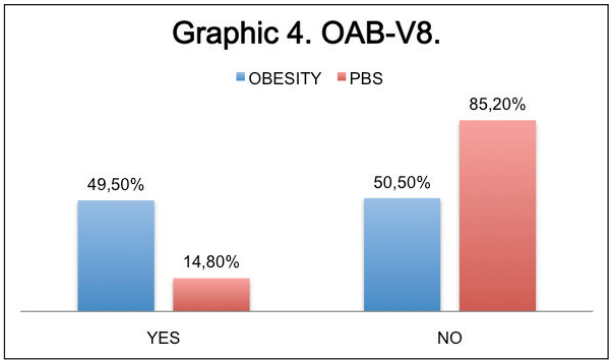
OAB questionnaire was applied on both groups obtaining the following percentages: Obesity group presented 49.5% OAB, while the PBS group presented 14.8% (Graphic 4). The obtained p-value of 0.00 reveals that obesity and bariatric surgery significantly influence the variable OAB (Table 2).

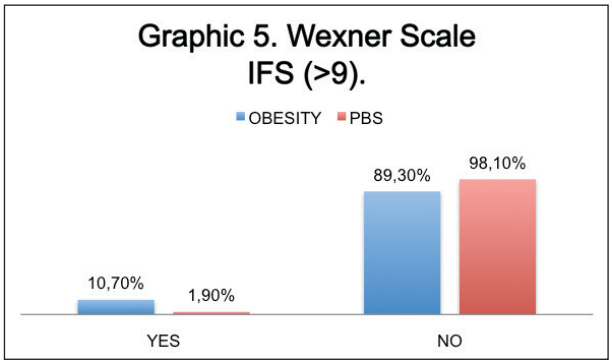
The ANOVA yields a p-value of 0.000 for the results of the OAB questionnaire.

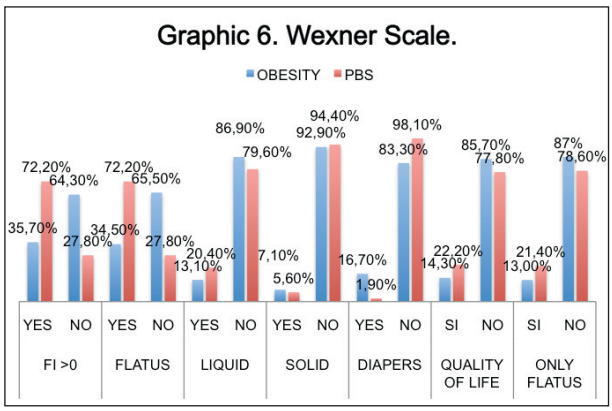
Wexner scale

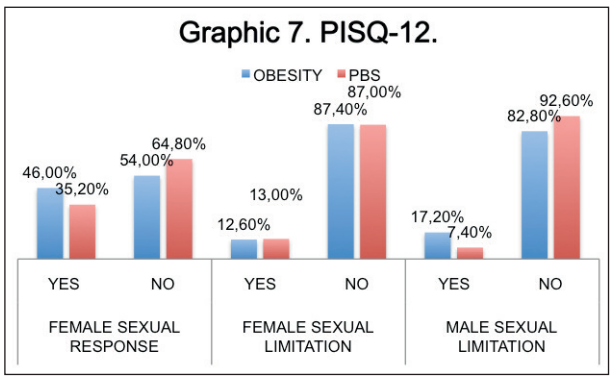
The Obesity group presented SFI in 10.7% of patients, while in the PBS group was observed in 1.9% of patients (Graphic 5).

Statistical analysis showed a p-value of 0.05 (Table 2), so the state variables (Obesity and PBS) are independent of the presence of SFI according to Wexner Scale. However,









being 0.05 so close to the rejection region we proceeded to apply the chi-square analysis for each of the items that build the Wexner scale, in order to evaluate which of these items were significant and which were not.

In Graphic 6, it is observed that PBS group has higher rates of overall FI interpreted as greater than 0 (72.2%), flatus incontinence (72.2%), liquid stool incontinence scores (20.4 %), impaired quality of life (22.2%) and higher frequency of flatus incontinence exclusively (21.4%) than Obesity group.

Statistical analysis of the presence of FI as scores grater than 0 result in a p-value of 0.00, the state variables Obesity and PBS are related to the FI evaluated in all domains of Wexner Scale.

The assessment of the Incontinence to flatus yielded a p-value of 0.00, bariatric surgery statistically impacts on incontinence to flatus.

The statistical analysis of incontinence to liquid or solid stool yielded a p-value of 0.255 and 0.712 respectively with a significance level of 5% therefore the fact of presenting incontinence to liquid stool or solid is not influenced statistically by bariatric surgery.

The domain Using Diaper showed a p-value of 0.006, bariatric surgery affects reducing the use of diapers in patients with FI.

Square chi test in the domain of affection of Quality of Life on Wexner Scale test yields a p-value of 0.230, the variables are independent, bariatric surgery did not affect the quality of life of patients with FI.

The ANOVA reveals that the p-value of the FI variables, flatus and use of diapers is 0,000; other domains presented at the Wexner Scale showed p-values greater than 0.05.

There was a strong correlation between the variables liquid stool, solid stool and continence to flatus with variable quality of life. Patients feel that having symptoms of incontinence to liquid stools and incontinence of flatus reduces their quality of life much more than the other domains listed in the Wexner test.

TABLE 3. Relationship between dysfunction and used questionnaire.

UI	ICIQ-UI SF	Bariatric surgery influence with statistically significance improving UI
SUI	Sandvik	Bariatric surgery influence with statistically significance improving SUI
OAB	Self-assessment questionnaire on Bladder control (B - SAQ)	Bariatric surgery influence with statistically significance improving "symptom", while for the domain of "discomfort» there was no statistically significant influence.
	Questionnaire OAB (OAB - V8)	Bariatric surgery influence with statistically significance improving OAB
FI	FI Wexner Scale (Wexner)	Bariatric surgery influence with statistically significance reducing SFI and the use of diapers, and increase global FI, predominantly FI to flatus.
Sexual Dysfunction	PISQ 12	Bariatric surgery influence with statistically significance but has not direct impact improving sexual dysfunction domains such as response or limitation.

PISQ-12

In the Obesity group domains Female Sexual Response, Female Sexual Limitation and Male Sexual Limitation reported 46.0%, 12.6% and 17.2% respectively, while in the PBS group showed 35.2 %, 13.0% and 7.4% for Female Sexual Response, Female Sexual Limitation and Male Sexual Limitation (Graphic 7).

A Chi-square analysis demonstrated that bariatric surgery is related to female sexual response since the p-value is less than 0.05 (Table 2).

The evaluation of Female Sexual Limitation reflects a p-value of 0.00, so bariatric surgery affects the female sexual limitation.

By analyzing the domain Male Sexual Limitation with a significance level of 5%, the null hypothesis is rejected because the chi-square statistic shows a p-value of 0.00. This represents that bariatric surgery is related to male sexual limitation.

The general p-value shown by ANOVA was 0.529.

DISCUSSION

Pelvic floor disorders are the product of weakening and dysfunction of ligamentous muscle support structure,

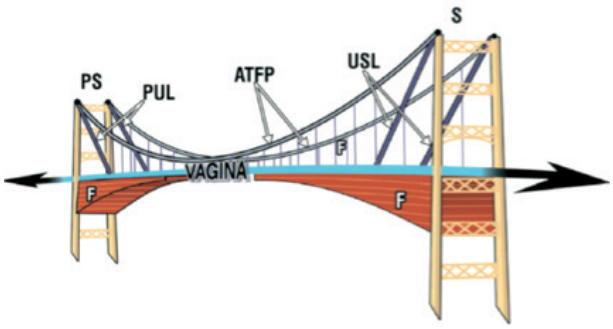


Figure 1. – Pelvic Floor Structure. Suspension bridge analogy. It represents that pelvic floor structures are interdependent. In a suspension bridge force it is maintained through the tension of the steel lines (arrows). The weakening of any part of the structure can alter the balance, strength and overall function. PS pubis, PUL Pubourethral Ligament, ATFP Tendinous arch of Endopelvic fascia, USL uterus sacral ligament, S sacrum. By permission, PE Petros.

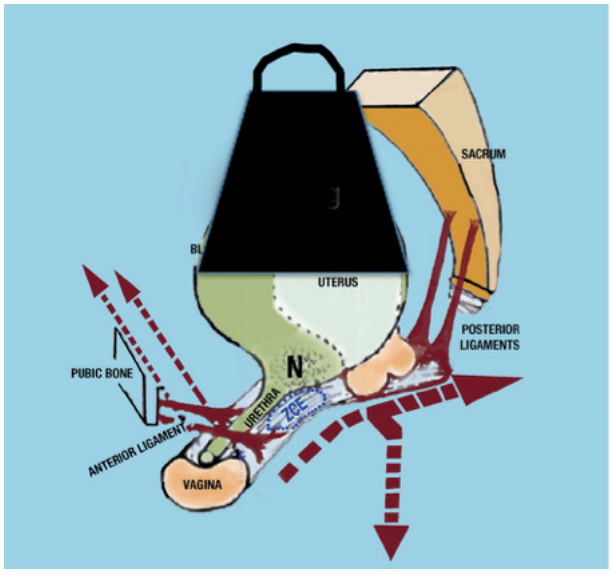


Figure 2. – Pelvic Floor with chronic overload pressure by high BMI. Modified by Piñango. By permission, PE Petros

which forms the lower end of the abdominal cavity (Figure 1)[9] and through which urinary system, the digestive system and the female genital organs communicate with the exterior. Thus we believe that the increase of intra-abdominal pressure affects the overall function of the pelvic floor whose symptoms include UI, FI and sexual dysfunction.

Increasing the intra-abdominal pressure chronically product of obesity, also increases the pressure on the support structure of the pelvic floor[13] causing suboptimal performance in the mechanisms of continence and the overall activity of the pelvic floor (Figure 2).

The additional load on the anterior wall of the vagina requires additional muscle strength to close the urethra, tighten the vaginal membrane receptors to support the "N" and then prevent activation of the micturition reflex (Urge incontinence).

We demonstrated that the UI, SUI, OAB, Several Fecal Incontinence and use of diapers showed a statistically significant improvement in direct relation to the weight reduction after bariatric surgery.

UI assessment according to ICIQ-SF showed the direct impact of surgery on the decline in the presentation of the UI. These results are consistent with the published literature where weight loss is considered an effective conservative approach for reducing symptoms[21, 31].

The evaluation of SUI with Sandvik Scale reflects a shift of patients in the categories of severe incontinence and very severe to mild to moderate levels. The analysis of variance showed the effectiveness of bariatric surgery to reduce the severity of UI in the post-bariatric group[20].

The evaluation of the OAB showed statistical difference direct impact of bariatric surgery in reducing the OAB, which coincide with the published literature[19, 32].

FI analysis showed decreased frequency of SFI in PBS group and increase of low severity FI and flatus incontinence. The findings in the literature yield controversial results[20, 23-24]. The SFI with scores ≥ 9 points decreased statistically significantly in the PBS group although ANOVA analysis showed no direct influence leading to the conclusion that although there was a statistically significant decrease by Chi-square, this may not necessarily be a direct result of surgery per se, as there are other potential variables (intestinal malabsorption, dietary changes, etc.) that can be added and also affect continence in PBS patients.

The assessment of sexual dysfunctions through the PISQ-12 instrument showed that bariatric surgery affects with statistical significance decreasing symptoms (according Chi-square) but it does not occur as a direct relation to the PBS state. These data are consistent with Oliveira et al who showed improvement in sexual function in relation to the impact on urinary incontinence[20]. There are other factors that must be evaluated in the PBS patients such as increased self-esteem, physical conditions and the interrelation with the couple that could influence more importantly, directly, in improving sexual function[33-35].

We can conclude that loss of at least 10% of initial BMI post bariatric surgery results in significant decrease of symptoms including UI, SUI, OAB, SFI and Sexual Dysfunctions. Clinical improvement in sexual dysfunction is not produced directly by bariatric surgery (Table 3).

There are changes in gastrointestinal function on PBS group that make both groups different in their characteristics with major episodes of flatulence and diarrhea in the PBS group probably consequence of alterations of gastrointestinal tract and malabsorption associated with surgery. To measure the impact of weight loss in voiding function continence study groups should have similar characteristics in gastrointestinal functioning.

DISCLOSURES

Authorship: Piñango-Luna SM. participated in the initial research design, data collection and data analysis, manuscript drafting and final approval; Level-Cordova LR. participated in the initial research design, data collection, manuscript drafting and final approval; Márquez M. participated in the initial research design, data collection; Chaves L. participated in the initial research design, data collection. Delgadillo J. Statistician: jorge.estadistica14@gmail.com.

Conflict of interest: None. Funding: None. Ethical approval: All procedures were in accordance with the ethical standards of institutional research and the declaration of Helsinki 1964 and its subsequent amendments or comparable ethical standards. Informed consent: informed consent was obtained from all individual participants included in the study.

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Original article

A simple morpho-functional evaluation leads to a high transanal irrigation success rate in neurogenic bowel management

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Abstract: AIMS: In January 2010, we introduced a simple morphofunctional evaluation method to evaluate patients candidate to use transanal irrigation (TAI). We report long term follow up on the first 100 patients with high success rate. *Methods*: We analysed data from 106 spinal cord injury patients enrolled from January 2010 to October 2013. Six patients were rejected at the start of the study due to the presence of anatomical situation at risk, 100 patients all followed the study protocol. The method consists of diluting an iodinated contrast medium (hexabrix 320) in the water of the container. After rectal examination, the irrigation fluid, with the contrast medium, is subsequently introduced in increasing quantities, to wash the left part of the colon, with a fluoroscopic examination being performed every 100 mL. The same procedure was performed after 2 weeks to check results of TAI and to define a personalized program. *Conclusions*: the introduction of an easy method that promotes better-reasoned use of this approach leads to a higher percentage of positive results. The efficacy of TAI is referred in data published around 50%, a correct protocol for selection and follow up of patients is not clear and no evidencies are reported on the dose of water to be used. On the other hand complictions as bowel perforation are reported. This approach permits to simply resolve problems related on patients selection and to avoid complications. Actually we have more than 250 patients maintaining good results with this approach, none had complications.

Keywords: Constipation; Fecal Incontinence; Neurogenic bowel disfunction; Spinal cord injury; Transanal irrigation

INTRODUCTION

Spinal cord injury (SCI) has a series of impacts on sensory and motor functions of multiple organ systems. Bowel and bladder dysfunction affects about 80% of all SCI patients[1]; it has a major negative impact on the patient's quality of life due to voiding and bowel difficulties, and the social restrictions such dysfunctions imposes on the patient[2-3].

The introduction of intermittent catheterisation (IC) by Lapides in 1972 improved the urologic morbidity and mortality considerable although recurrent urinary tract infections (UTI) is still the most common pathology linked to IC[4]. Therefore, routine examinations of the genitourinary system are mandatory for the SCI patient population.

The bowel dysfunctions consist of constipation, faecal impaction and incontinence[5], but the examination and treatment of the bowel problems has not obtained any larger degree of medical attention; one of the potential treatment modalities that has been used for thousands of years is transanal irrigation (TAI)[1] which only lately was introduced for managing neurogenic bowel dysfunction[6-9].

Several trials have shown that TAI is efficacious in terms of improving constipation, faecal incontinence and symptom related quality of life in adult SCI patients[7-11] but practical experience shows that the adherence to the procedure appears to be limited over time.

No studies has examined how to improve the practical approach to the irrigation procedure and, in particular, determined eligibility of patients, the optimal amount and speed of irrigation volume.

On this background we decided to use a fluoroscopic approach to perform a simple morpho-functional evaluation of the TAI procedure for individuals who were candidates to its use; the purpose was to define eligibility of patients, determine optimal speed and volume of irrigation and to have a basis for repeatable evaluation.

METHODS

Patient selection

From January 2010 to October 2013, potential participants were identified at scheduled urological control visits at the department of neuro-urology of Niguarda Hospital in Milan, Italy. During this visit (baseline visit), patients were additionally screened for significant bowel dysfunction, irrespective of the present conservative bowel management. In case of bowel problems and if they met the in- and exclusion criteria's, they were invited to participate in the study, whose length is 6 months. Inclusion and exclusion criteria's were as follows:

Inclusion criteria

- History of SCI (full or partial section, myelitis, multiple sclerosis, spina bifida)
- Bowel evacuation difficulties in spite of conservative bowel programs
- History of symptomatic and frequent urinary tract infections despite a good bladder management

Exclusion criteria

- History of ano-rectal disease causing pain or bleed such as anal fissures, III or IV grade hemorrhoids, fistulae
- Previous abdominal or pelvic radiotherapy
- History of diverticulitis or diverticular abcess
- History of ano-rectal or pelvic surgery
- History of severe autonomic dysreflexia
- Long term corticosteroid treatment
- Coagulation disorders or anticoagulation therapy (excl. clopidogrel and aspirin)

Study flow

Baseline visit: a dedicated physician explained and discussed all aspects around the various procedures and, if the patient was willing to participate, retrieved informed consent. In case of minor patients (Tab. 1), informed consent was obtained by the parents. The physician retrieved patients' medical history, presence of fecal incontinence or impaction, stool frequency, usual bowel management (type and quantity of laxatives) as well as occurrence of UTIs. All patients were asked before dismissal to fill-up, over a 3-4 days period, a diary of evacuations and to bring it to the next visit.

Visit 1: the first TAI under fluoroscopic control was performed. For a two weeks period, until visit 2, patients were

Table 1. Minor patients involved in the study.

Age	Pathology
17	Spina bifida
12	Spina bifida
17	Lipomyelingocele
16	Spina bifida
12	Spina bifida

Table 2. Patient flow chart.

Screened for study: 106 patients
- Rectal prolapses = 1
- No accept of irrigation procedure = 5

Informed consent: 100 patients
- Hemorrhoids = 1

Access to visit 1: 99 patients
- Bowel occlusion = 1
- Pain = 1
- Bowel over-distension = 1

Access to visit 2: 96 patients
- Autonomic dysreflexia = 2
- Fistula = 1
- No compliance or loss of caregiver = 5

Access to visit 3: Long term follow up - Finalized study: 88 patients

asked to perform TAI daily with an individualized program of laxatives (Macrogol®), and to continue their usual lifestyle. The patient was instructed to use the irrigation volume which corresponded to the volume required to opacify the left colic flexure (see below)

Visit 2: (2 weeks after visit 1), a similar TAI procedure was performed. Hereafter the patients were asked to perform irrigation three times a week, using Macrogol® if appropriate, until the next scheduled visit. The patient was instructed to use the irrigation volume which corresponded to the volume required to opacify the left colic flexure (see below).

Visit 3: (long term follow up at 6 months). During this visit, that is part of our scheduled urological follow up, a dedicated physician evaluates the patient and his bowel management using a bowel diary.

Further visits were not part of this study. Not part were scheduled as any other outpatient in our clinic every half year over (earlier controls could be obtained on patient request in case of onset of new problems (bowel linked or non).

Transanal irrigation and Fluoroscopic procedure

TAI: performed with the Peristeen® device (Coloplast; Humlebaek, Denmark), which has been marketed since 2004. It consists of a rectal catheter with a balloon, connected to a control unit, which further is connected to a water bag containing 1L. A pump attached to the control unit allows both balloon inflation and water instillation. Once the water has been installed in the bowel, the rectal catheter is removed enabling faeces evacuation. For the purpose of this study, iodinated contrast medium (Hexabrix®, 100 ml) was added to the 1L irrigation water enabling visualization of colon through fluoroscopy (BV Pulsera, Philips Medical Systems, Sweden,)

Fluoroscopy: lying on the examination bed a digital rectal examination was performed to exclude anal-rectal pathologies. Hereafter the rectal catheter was inserted and the balloon inflated. The irrigation fluid is subsequently introduced in increasing quantities, with a fluoroscopic examination being performed before and after every 100 ml of water installed. The volume of irrigation were reported at opacification of the left colic flexure.

Table 3. Patient demographics-

Patients who signed informed consent	100
Men	54
Women	46
Patients undergoing full protocol	88
Age (mean) - range 12-77 year	40
Acquired Lesion	78
Congenital Lesion	22
Time since Injury (years) 1<t<5	36
Time since Injury (years) 6<t<16	23
Time since Injury (years) t>16	41
Upper Motor Neuron lesion	60
Lower Motor Neuron lesion	45
Peripheral lesion	41
Laxatives	87
Macrogol®	60
Other laxatives	72
Faecal incontinence	30
Incomplete evacuation	71
Pain for evacuation	16
Blood in the stool	3
Mucus in the stool	3
Frequency of evacuations (n° for week) 0	41
Frequency of evacuations (n° for week) 1	34
Frequency of evacuations (n° for week) 2-3	8
Frequency of evacuations (n° for week) 7	17
Solid Stool	22
Faecal impaction (faecoliths)	76
≥ 1 UTI requiring antibiotics in previous year	85
history of symptomatic and frequent urinary tract infections despite a good bladder management	100
Self-reliant patients	93
Patients with nerve stimulator	19

When the filling phase was completed, study participants were transferred to the toilet (in a sitting position) to evacuate. After evacuation the patient was replaced on examination bed to fluoroscopically determine the amount of faecal residues.

During the whole procedure, the patient were asked to report any abnormal sensation to allow for early identification of autonomic dysreflexia.

During the fluoroscopy, the X-ray exposition is less or equivalent than the one during a routine videourodynamic evaluation.

The ability to directly assist in the procedure and display the bowel situation during the sessions of TAI with fluoroscopic control, seeing the positive effects of the control

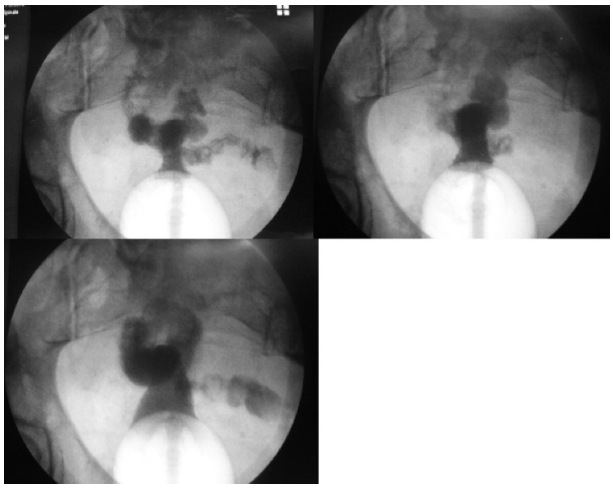

Figure 1. – Fistula.

TABLE 4. Volume of water at the first visit – 99 patients.
* 3 cases of dilation of the ampulla during the filling phase.

	Sigma	Transverse (Slit left colic)	Slit right colic	Ciecum
Volume H_2O average (ml)	200	300	520	620
N° of patients that reach the mentioned irrigation level	99*	80	28	22

TABLE 5. Long Term Follow up (after undergoing visit 3 on 88 patients).

Average volume of H2O irrigation (ml)	430
Number of patients using laxatives (%)	54 (61,4%)
Number of evacuations (programmed with TAI)	3
Number of patients symptomatic UTI requiring antibiotics	4 (4,5%)
Number of faecal incontinent patients (%)	2 (2,3%)

TABLE 6. Comparison of pre- and post-protocol patients.

	Before TAI	After TAI
UTI's	85 %	4,5 %
Use of Laxatives	87%	61,4 %
Referred Incontinence	30%	2,3 %
Mean Time for evacuation (min/day)	>60	<30
Faecal impaction (faecoliths)	76%	22 %

procedure was one of the characteristics of this method. The direct involvement of the patient allowed a high adherence to the program.

Bowel fluoroscopic evaluations and bowel diary

With the fluoroscopy we can evaluate: the presence of faecoliths, the dilation of the ampulla, the presence of bowel peristalsis.

All patients involved in the study are followed in our centre, for this reason the population of this study was submitted to scheduled neuro-urological follow up, which include even bowel evaluations, performed by a dedicated physician using a bowel diary.

RESULTS

Patient flow through study

The patient flow is described in detail in Table 2. Of the 106 patients screened, 100 agreed to participate and signed informed consent. In 1 patient haemorrhoids (grade III-IV) were detected before starting the first irrigation and another 3 and 8 patients were excluded respectively during the first or second irrigation procedure, leaving 88 to fulfil the protocol (per protocol population).

Demographic data

The demographic data of the 100 patients who gave informed consent are presented in detail in Table 3. In short, 54 were men and 46 women with a mean age of 40 (12-77) years; of these 5 were minor (12-17 years), the specific data of this group of patients are presented in Table 1. Seventy-eight patients had acquired lesions whereas the remaining 22 were congenital. Time since injury varied between 1 to 15 years.

Regarding the bowel management, 87 used laxatives, mainly Macrogol®. The weekly stool frequency was < 2 in 75 patients and ≥ 2 in the remaining 25 patients. Ninety-three patients were self-reliant with respect to their bowel management. Faecal incontinence and impaction was reported by 30 and 76 patients, respectively.

In terms of bladder emptying, all patients used intermittent catheterization. Eighty-five of patients reported at least one episode of antibiotic requiring UTI in the year prior to study inclusion.

A subpopulation consisted of 19 patients with an implanted sacral or pudendal neurostimulator (urological indication) in whom bowel function was not altered after implantation.

Transanal irrigation

Table 4 shows data about the volume of water and the bowel level reached with the irrigation, detected at the first visit (99 patients).

After the first evaluation, we recommend the patients to use the volume of water necessary to reach the left flexure in order to reproduce a physiological bowel avoiding. The data about the volume of water don't change a lot between visit 2 and 3.

At visit 3 (long term follow up at 6 months), the mean irrigation volume for reaching the left flexure was 430 ml, range 200 _ 500 YY.

Table 5 shows the results at long term follow up (visit 3, performed at 6 months).

Results before and after use of TAI

The results after use of the TAI procedure:
- 61,4% continued to take oral laxatives the previous day
- Significant decrease of faecal incontinence
- Significant decrease of number of symptomatic UTI's
- Significant reduction of faecal impaction

DISCUSSION

Correct bowel rehabilitation following SCI requires a programme to promote faecal movement and permit complete evacuation.

Proper hydration and the introduction of dietary fibre, together with a planned evacuation programme, is the basis of the rehabilitation programme. This should be associated with the evaluation of correct evacuation times in relation to bowel activity linked to the gastrocolic reflex. Various methods can be used to encourage evacuation: from me-

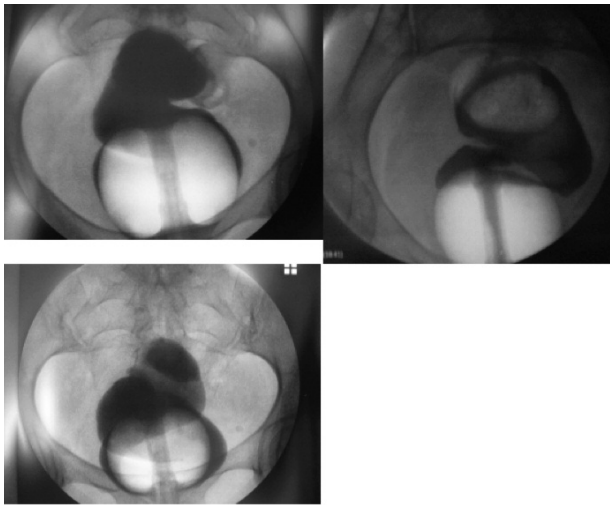

Figure 2. – The presence of fecaloma causes intestinal blockage and does not allow the liquid to go up again.

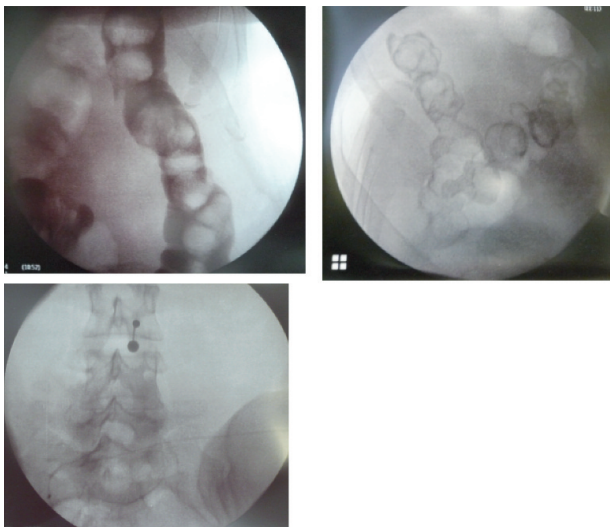

Figure 3. – Bowel before and after TAI.

chanical stimulation to rectal exploration, and the use of laxative or glycerine suppositories.

Numerous methods have been proposed to encourage normal stool consistency and promote complete evacuation. Abdominal massage, the use of the Valsalva manoeuvre, the combination of laxatives and drugs that reduce stool consistency, and prokinetic drugs are all suggested aids.

The introduction of TAI has been found to be a possible effective alternative, although the level of evidence is not high yet. In our experience, the introduction of an easy method that promotes better-reasoned use of this approach leads to a higher percentage of positive results. There is no data in the literature regarding the reasons for abandoning the procedure or on side effects associated with TAI (about 50%).

Following this, it is possible to describe the TAI procedure as an excellent alternative capable of aiding intestinal evacuation allowing complete evacuation of the left colic flexure.

Observation of this case study lets us make the following considerations:

the method of transanal irrigation is safe for the patient once anatomical changes such as fistulas, stenoses or diverticula are excluded while introducing liquids. This situation is possible after a long story of incomplete intestinal evacuation which is frequent in these patients.

This procedure must be chosen with caution in situations where medical treatment has had no effect on the presence of elevated intestinal blockage by fecaloma which do not allow the liquid to go up again. The presence of fecal matter with a blockage of the sigmoid colon and with dilation of the rectal ampulla at the beginning of the procedure must include as precaution a daily program of washing with low doses of macrogol.

After a new morphological check, it is possible to proceed with an increase in the washing dose and to alternate days.

The presence of peristalsis during irrigation can cause painful symptoms and delay the following evacuation for a possible activation of retrograde peristalsis. These visuals observations are in contrast with the theory that the efficacy of TAI is related on an activation of peristalsis due to water effect. In these patients however the presence of peristalsis favours an efficient evacuation afterwards. Analysing the mechanisms which are lost under the neurophysiologic profile following medullary lesions, it is possible to assume that the situation of lack of peristalsis in the patient with inveterate medullary lesions can be attributed to a situation of persistent intestinal overflow with anatomical changes from the wall and the myenteric plexus.

The use of sacral and pudendal neuromodulation falls within the recommended methodologies in terms of research into the treatment of constipation in neurogenic situations (ICI 2009).

CONCLUSIONS

These data describe the first group of individuals who followed the protocol. 72 individuals are currently enrolled and a long-term analysis of the entire population is underway. The current finding is that this approach makes it possible to offer a genuine, measured and effective response to neurogenic bowel dysfunction.

With this approach we are able to perform an objective evaluation during the use of TAI. This approach allows to clarify a lot of aspects and questions about the use of TAI.

We would like to underline the following topics in the study:

1. Consensus review open questions:

• Diagnostic approach before TAI to avoid side effects: with our method we don't have adverse events because we can exclude cases at risk

• Amount of water: with our method we find the specific volume of water for every person to promote a physiological evacuation, emptying the bowel until the left flexure. The media amount of water is less than recommended one.

• In the consensus review is suggested a pyramidal approach, but the study shows the need of a multimodal approach that can involve TAI, neurostimulation and laxatives.

• Repeatability of the approach to simplify follow up.

For all these reasons, our success rate with TAI is high, even in patients that started to use TAI in other centers without showing results.

2. This method bring us to have many information about TAI and its use. A lot of these findings, for example the amount of water and the combined use of TAI and laxatives, can be useful even with the standard use of TAI.

3. Morphological control of TAI effects allows a really better understanding of bowel dysfunction after spinal cord injury.

1 The procedure is known under a number of synonyms like colonic irrigation, rectal irrigation, enema clyster.

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Comment

The study aims to investigate different aspects related to the action and the improved effectiveness of TAI, performed with modern "positive and constant air pressure" devices such as Coloplast Peristeen®. This is an important issue because the reasons leading to the patients' progressive drop-out are not clearly defined yet: leaving aside the causes due to bureaucratic and organizational problems (the absence of these devices in the National Health Care Range of Fees and the resulting reimbursement difficulty in some Local Health Authorities, etc.), the most frequent reasons are associated to changes over time of the feasibility of TAI and/or of its effectiveness in producing a satisfactory and complete evacuation.

Moreover, a proper patient selection is certainly an important factor in determining the continuity of adherence to treatment, so the fluoroscopic procedure, that allows to evaluate the characteristics of the rise of irrigation water in the colon, is extremely useful to collect any patient's peculiarities that, if not properly corrected or removed, could undermine the effectiveness of TAI.

The method, proposed by Michele Spinelli's group of Niguarda and described in the article, proves to be a convincing approach to allow a more rational patient selection to start the procedure, to identify the main causes of its low effectiveness and to define which parameters will ensure the best use: the amount of irrigation water and its ways of spreading in the large intestine.

The physiopathological interpretation of these phenomena is certainly "affected" by the neurourological background of the authors (as a proof of that please note that the presence of the enteric nervous system in the colon wall, while it is absent in the bladder, makes the response mechanisms to the endoluminal increase in volume or pressure on its basal tone even more complicated. To this end, please see many studies with the barostat by Camilleri and Aspiroz), but the phenomena described undoubtedly convey the "operational" aspects of the bowel which are necessary to differentiate all circumstances produced by TAI with a device such as Peristeen®.

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