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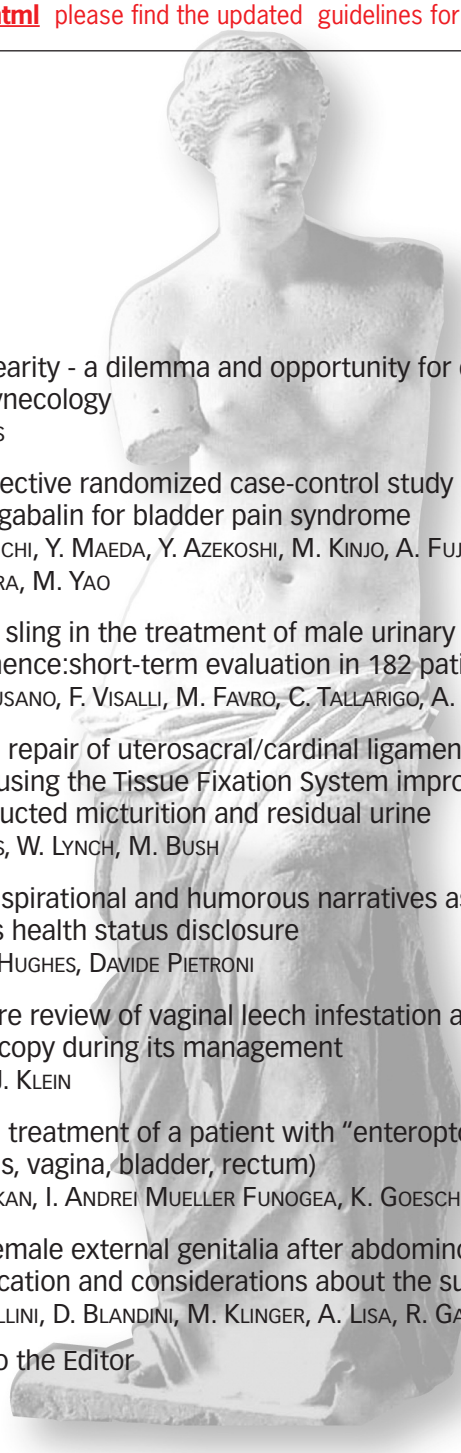

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'Taxe Perçue' 'Tassa Riscossa' - Padova C.M.P.
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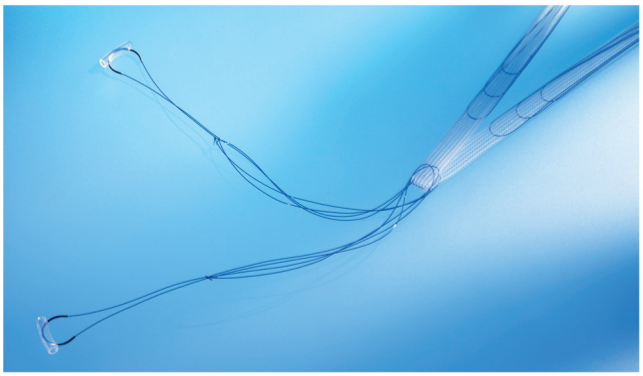
A.M.I. TOA / TVA System
for Female Stress Urinary Incontinence

Q.: Who needs an adjustable sling?



If you think adjustability for slings is just a marketing ploy, it might be time to reconsider. The data below is taken from an analysis of **six, peer-reviewed studies** published, comprising a total of **392 patients** treated with either the A.M.I. TVA or TOA System for female stress urinary incontinence.
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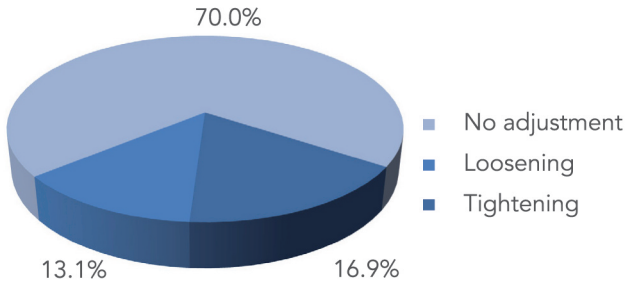
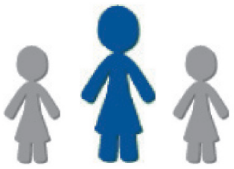
A.: About 30% of patients.

% of patients requiring adjustment





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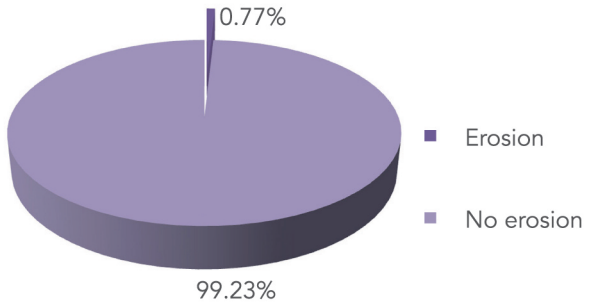

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Editorial

Non-linearity - a dilemma and opportunity for clinical research in urogynecology

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Abstract: The female pelvic floor contains the most complex interconnected nonlinear controlled system of muscles and ligaments in the body. *The dilemma* Much of the research in urogynecology today is reductionist, never ending classifications attempting to fit complex issues into simplistic reductionist boxes. Examples are the POPQ system, complex classifications of mesh complications, urodynamics used in place of urge symptoms, replacing symptoms with numbers, "scores". Use of simple language is suggested to report results and application of Occam's Razor to distinguish relevance of rival systems. *The opportunity* Complexity and Chaos are the key to understanding the variance inherent in pelvic floor function and are a rich direction for future research. The importance of 'criticality' in speedily changing the bladder phase from 'closed' to 'open' is described as are the non-linear mechanisms driving this system, an external striated muscle mechanism acting against suspensory ligaments, and the internal resistance to urine flow which, following the Law of Poiseuille, is inversely proportional to the 4th power of the change in urethral radius by this mechanism. The impossibility of pre-operatively determining the initial conditions as a guide to therapy is discussed and how this can be bypassed by repairing the ultimate cause of the dysfunction, damaged ligaments, with tensioned slings Repairing the ligaments works by reversing the non-linear cascade of events consequent upon inability of the musculoelastic control mechanisms to 'grip' on the loose ligaments. A simple research protocol for reversing these complex cascades is detailed by supporting various suspensory ligaments.

GLOSSARY
Chaos *is the generation of complicated, aperiodic, seemingly random behaviour from the iteration of a simple rule. In urogynecology it applies especially to the feedback systems inherent in control of continence, the micturition and defecation reflexes.*
Complexity *is the generation of rich, collective dynamical behaviour from simple interactions between large numbers of subunits.*
Criticality*. A system is critical if its state changes dramatically given some small input. A good example is the almost instantaneous activation of bladder/urethral closure and micturition.*
Dynamical system *– a set of interacting and interrelated elements that can change in time. The pelvic floor is a classical example, with all structures, muscles, nerves, connective tissues, blood vessels acting co-ordinatedly to achieve organ support, opening and closure.*
Integral Theory (IT). *States that POP and pelvic floor symptoms mainly derive from laxity in the vagina or its supporting ligaments because of altered collagen/elastin.*
Integral Theory System (ITS) or Integral System*. A management system based on IT which diagnoses and treats lax vagina/ligaments using squatting based exercises or small strips of tape accurately applied to damaged ligaments.*
Linear system *is simple and predictive. It is the sum of its parts. 1+1 always =2.*
Nonlinear system: *a nonlinear system in contrast to a linear system, is a system in which the output is not directly proportional to the input. Non-linear systems dominate the pelvic floor.*
QOL *Quality of life.*
Reductionism *is the practice of simplifying a complex idea to the point of minimizing, obscuring, or distorting it. Examples are new terminologies such as POPQ, urodynamics, some classifications, symptom scores, really, any artificial structure imposed on a Natural system.*
VAS *Visual analogue scale.*

The dilemma: Pelvic floor function is non-linear and therefore constantly variable

Marcus Aurelius, the Roman Emperor and Stoic philosopher described the holistic non-linear character of Nature thus: *Constantly regard the universe as one living being, having one substance and one soul; and observe how all things have reference to one perception, the perception of this one living being; and how all things act with one movement; and how all things are the cooperating causes of all things which exist; observe too the continuous spinning of the thread and the contexture of the web*[1].

This quote beautifully encapsulates the modern science of Complexity[2], that Nature works in an interconnected, holistic and non-linear way: every part of a system affects every other part, with the sum being greater than the parts. Though the pelvic floor contains the most complex interconnected system of muscles and ligaments in the body, very little has been written about the non-linear control mechanisms of these dynamical systems and how they impact on clinical and research urogynecology. Yet much of the research in urogynecology today is reductionist, never ending classifications attempting to fit complex issues into simplistic reductionist boxes. Such reductionism cannot encompass the wide variance seen in clinical conditions and symptoms, even within the same patient, fig. 1.

Karl Popper, discussing the problems of artificial model languages, stated: *"thus the method of constructing artificial model languages is incapable of tackling the problems of the growth of our knowledge"; and "It is a result of their poverty that they yield only the most crude and the most misleading model of the growth of knowledge - the model of an accumulating heap of observation statements"*[3].

Examples are the POPQ system[4], complex classifications of mesh complications and the predictive value of urodynamics[5]. Replacing symptoms with numbers, "scores", is another example of an "artificial model language"[4]. Reporting the change in the total number of episodes of frequency, urge incontinence, nocturia in a cohort[6] using standard ICS definitions is much easier to understand than a set of numbers. Furthermore symptoms are experienced differently by different patients and the QOL varies considerably even within the same patient, fig. 1. This is the dilemma. Classifications have to be productive and helpful in patient management. Non-productive classifications serve only to burden clinical practice and research.

Occam's Razor is a tool which is useful in resolving the dilemma: Occam or Ockham, a 14th century English philosopher stated that a simpler solution was more likely to be the most valid, and simpler theories are preferable to more complex ones because they are better testable and falsifiable. In urogynecology this could mean that we should use the halfway system instead of POPQ; the sign of USI instead of urodynamics; reporting the change in the total number of frequency, urge incontinence, nocturia episodes in a cohort instead of a set of numbers and describing a mesh complication instead of giving it a number.

The Opportunity

Complexity and Chaos are the key to understanding the variance inherent in pelvic floor function and are a rich direction for future research. Complex and chaotic systems are nonlinear and sensitive to initial conditions. A system is 'critical' if its phase state changes dramatically with some small input[2]. The bladder has two phases, open and closed. The bladder is always "en garde", ready to instantly open (evacuate) or close (continence) depending on circumstance. Criticality is important for rapid phase change. What makes a rapid phase transition possible is.

The external striated muscle vectors, arrows, fig. 2 which can rapidly open or close the urethral tube.

According to the Law of Poiseuille, the exponential relationship (4th power) between the radius and the resistance to urine flow[7] which exponentially accelerates 1.

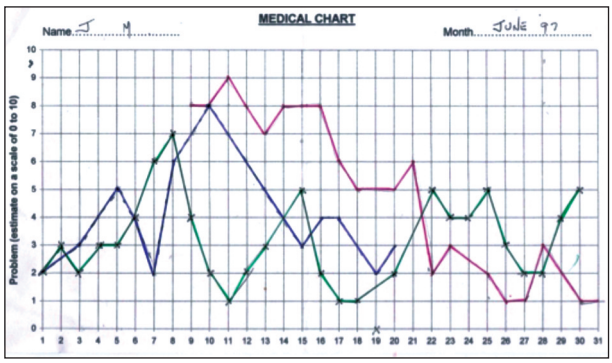

Figure 1. – This graph was constructed from a QOL which used a VAS score recorded on a daily basis by a patient who had urinary incontinence and chronic pelvic pain. The non-linearity of the VAS scores displayed question the validity of "Pelvic Floor Scores" and "validations' as performed today. Different colours denote different months. Looking at the top (red) graph, there would be an enormous difference in score depending on whether the assessment was on Day 11, or Day 26.

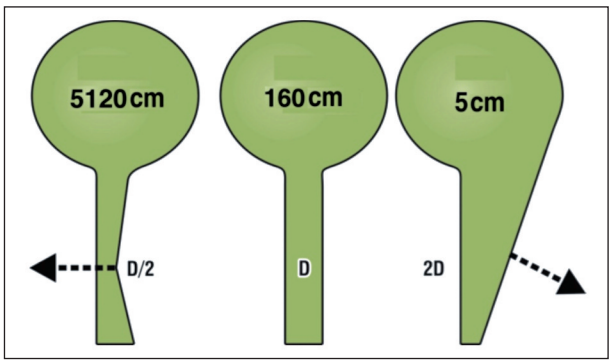

Figure 2. – The non-linear relationship of urethral resistance to continence and micturition (for non-laminar flow) according to the Law of Poiseuille. *Resting closed* (middle fig.). 160cm H_2O is a nominal pressure for leakage at radius R. *For closure (continence)* (left fig.). If the forward vector can close the radius to R/2, resistance to flow increases by the 4th power. The head of pressure required for leakage *increases* to 2560cm H_2O (the inverse of ½: 2x2x2x2=16). *For opening (micturition)* (right fig.). If the backward vectors can open the radius to 2R, resistance to flow *decreases* by the 4th power. The head of pressure required for leakage decreases to 10cm H_2O.

For example, a sudden halving of the urethral radius 'R' by vector closure, fig. 2, *increases* resistance by a factor of 16. Doubling 'R', by the vectors stretching the urethra posteriorly enables micturition by *reducing* resistance to flow by a factor of 16[7]. It is this mechanism which gives instant commencement of urination and instant stoppage of flow.

Continence Effort such as coughing activates the fast-twitch forward vectors to contract against the suspensory ligaments. This small change in initial conditions sets forth a cascade of events in associated subsystems, muscles (arrows), stretch receptors, suspensory ligaments and all their components, collagen, elastin, nerves, blood vessels. The effect is to *exponentially* narrow the urethra for closure.

Emptying At a critical point, the hydrostatic pressure of the urine stimulates the bladder base stretch receptors to set off a different cascade of events in the same subsystems to swing the system into open phase, micturition. The posterior urethral wall is stretched open by the vectors, fig. 2, *exponentially* decreasing the internal resistance; the bladder contracts and empties.

Urgency & Frequency Any loose ligament will prevent the vectors from stretching the vaginal membrane sufficiently to support the bladder base stretch receptors. Depending on their sensitivity, they may fire off at a low bladder volume to cause urgency and frequency and at night, nocturia. The control of urgency is consistent with a classic chaotic feedback mechanism[8]. This mechanism adequately explains the instability curve of urodynamics and bladder stability in the normal patient during filling; a low compliance bladder is consistent with a partly activated but controlled micturition reflex[8].

How to address non-linearity in clinical situations?

From a Complexity perspective, the exponential nature of the control system makes it difficult for any system to predict an outcome, as it requires the initial state of the system to be described with perfect accuracy, a nearly impossible task[2]. So any pre-operative test (e.g., urodynamics) is doomed to fail as a predictor. The ITS bypasses this problem by repairing the ultimate cause of the dysfunction cascade, damaged ligaments, with 'micro' tensioned slings[9].

New research directions

The ligament concept of function and dysfunction provides many opportunities for research. It can be tested without surgery by examining a patient with a full bladder. Upward pressure on one side of the urethra immediately behind the symphysis will control USI and often urgency. A large tampon in the posterior fornix will support the posterior ligaments and often diminish urgency, pelvic pain and nocturia[9]. Gentle digital support of the vagina just anterior to the cervix may diminish urge symptoms and may alter DO[8]. Performed under urodynamic or ultrasound control, these 'simulated operations' would constitute a most original research project. They work by reversing the non-linear cascade of events consequent upon disturbance of the musculoelastic control mechanisms[8,10,11].

CONCLUSIONS

Non-linearity and chaotically influenced feedback mechanisms are fundamental to Nature. They are the key to understanding the complexity of pelvic floor anatomy and function, day to day symptom variation in an individual patient. They help us make sense of anomalous and varied experimental results, and even to appreciate how the randomness of initial experimental results may influence a whole new direction in surgery in a positive or negative way.

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Original article

A prospective randomized case-control study of amitriptyline and pregabalin for bladder pain syndrome

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[2] *Yokohama City University Graduate School of Medicine - Urology*

Objective: Pregabalin is one of the standard medications for neuropathic pain. However, few studies have been conducted to evaluate pregabalin for bladder pain syndrome (BPS). We prospectively tested pregabalin against amitriptyline for BPS. *Methods:* A total of 57 patients with BPS were enrolled to the study. Patients received amitriptyline or pregabalin, alternatively. Pregabalin dose was increased from 25mg to 150mg during 2 months; amitriptyline dose was increased from 10mg to 30mg during 2 months. *Results:* Three patients in the pregabalin group and 4 in the amitriptyline group did not return to the clinic after the first consultation. Meanwhile, 6 patients in the pregabalin group discontinued drugs due to side effects (for a continuity rate of 77%), while 8 in the amitriptyline group also did so (continuity rate 65%). The change in pain scale pre- and post-treatment by pregabalin was from 4.81±2.52 to 3.25±2.88, and by amitriptyline was from 4.87±2.45 to 2.2±2.30. The difference between them was not statistically significant p=0.52 Effects of amitriptyline were statistically better than those of pregabalin in terms of urgency, pollakisuria and pain, as measured by the O'Leary and Sant IC questionnaire. p<0.05 *Conclusion:* The efficacy of pregabalin for pain relief may be same as that of amitriptyline. On the other hand, amitriptyline may be effective more than pregabalin for lower urinary symptom of BPS.

Key words: Pregabalin; Amitriptyline; Bladder pain syndrome; Interstitial cystitis.

INTRODUCTION

Bladder pain syndrome (BPS) is a chronic condition that causes several kinds of bladder pain with urgency, frequency and nocturia.[1] Its cause is not clear, and it is still a disease diagnosed by exclusion. BPS has, however, one side of chronic pain syndrome related to neuropathic pain. Several theories regarding the mechanism of neuropathic pain have been proposed, including central and peripheral nervous system sensitization, dIfferentiation neurogenic inflammation, and the pain wind-up theory. The mainstay of treatment for neuropathic pain is pharmacological, including the use of antidepressants, antiepileptics, topical anesthetics, and opioids. Non pharmacological treatments include psychological approaches, physical therapy, interventional therapy, spinal cord stimulation, and surgical procedures. Neuropathic pain is difficult to treat, and a combination of therapies may sometimes be more effective than monotherapy.

Bladder pain syndrome (BPS) is diagnosed on the basis of chronic pelvic pain, pressure, or discomfort perceived to be related to the urinary bladder, and accompanied by at least one other urinary symptom such as persistent urge to void or urinary frequency. The name "Interstitial cystitis" has been deemed misleading and has been replaced by BPS.[1] It is estimated that 3.3-7.9 million (2.70%-6.53%) of women in the United States suffer from BPS.[2] Non pharmacological treatments of BPS include psychological approaches, pelvic floor rehabilitation, spinal cord stimulation, bladder hydrodistention and transurethral surgeries. Parallel non pharmacological treatments, medicines effective for internal use and readily available include Amitriptyline, Cyclosporine A, Pentosan polysulfate sodium PPS with hydroxyzine and L-arginine.[3] On the other hand, tricyclic antidepressants (TCAs) and antiepileptic drugs (AEDs) are recommended as first-choice medicines for neuropathic pain.[4] BPS has an aspect of chronic pain syndrome. Few studies, however, have considered pregabalin for BPS.

In the current study, to evaluate the efficacy of pregabalin for BPS, we conducted the randomized prospectively designed case-control study on the use of amitriptyline and pregabalin.

PATIENTS AND METHODS

This study was randomized prospectively designed case-control study and approved by the medical corporation Women's Clinic LUNA Group ethics committee. (Approved number 16) Written informed consent was obtained from all patients.

Subjects were 57 patients diagnosed with BPS in the Women's Clinic LUNA Japan. Diagnosis was based on pelvic pain and pollakisuria by questionnaire and pain scale with no abnormal findings by urine analysis, urine culture, cytology and ultrasound.[1] Patients were given pregabalin or amitriptyline randomized prospectively. The pregabalin group included 30 patients (median age 53.5±13.8; max 80, min 32. The amitriptyline group included 27 patients (median age 63±13.8; max 75, min 23). There was no statistically significant difference in age and symptoms between groups (Table 1).

In terms of dose, pregabalin was started at 25-150mg, and amitriptyline was started at 10-30mg for 2 months, because we were interested in the early effects of the medicines.

The primary outcome measure was assessment of pain by pain scale (10-grade) and second outcome measure of urinary symptoms by the O'Leary and Sant IC questionnaire (validated by the Japanese society for the study of interstitial cystitis with 5 grades for symptoms and 4 grades for problems) before and after treatment.[5]

We used a t-test from software PASW statistics 18 (S.P.S.S.Inc.Japan) to assess statistical significance at the 2-sided 5% level ($p < 0.05$).

RESULTS

Four patients in the pregabalin group and 3 in the amitriptyline group did not return to the clinic after their first consultation. Six patients in the pregabalin group and 8 in the amitriptyline group discontinued drug treatment due to side effect. Therefore, the continuity rate for pregabalin was 77% and for amitriptyline, 65%.

To evaluate pain which is primary outcome, we used the 10-grade pain scale. The change pre- and post-treatment by pregabalin was 4.81±2.52 to 3.25±2.88. For amitriptyline, change pre- and post-treatment was 4.87±2.45 to 2.2±2.30. The difference between them was not statistically significant (Fig. 1).

Lower urinary tract symptoms (LUTS) on the O'Leary and Sant IC questionnaire which are second outcome are

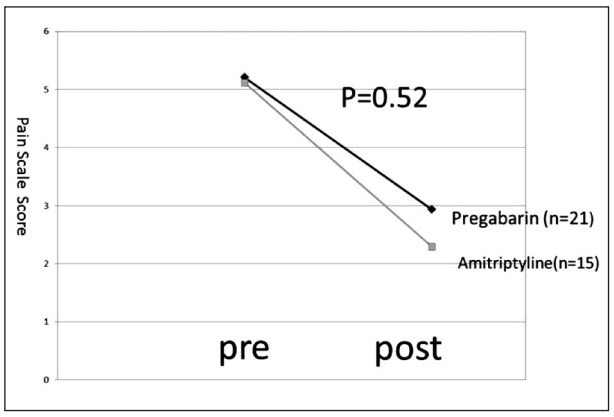

Figure 1. – This is the results of the 10-grade pain scale. The change pre- and post-treatment by pregabalin was 4.81±2.52 to 3.25±2.88. For amitriptyline, change pre- and post-treatment was 4.87±2.45 to 2.2±2.30. The difference between them was not statistically significant.

listed in Table 2. There were statistically significant differences among symptoms of urgency and pain, as well as with problems of pollakisuria and pain. In terms of side effects, patients in the pregabarin group experienced dizziness, drowsiness, nausea, loss of concentration, palpitation, and weight gain; there were also 4 cases of drowsiness 4 in the amitriptyline group, as well as continued pain, dizziness, disturbance of taste, and constipation.

DISCUSSION

Our results indicated no statistically significant difference in pain reduction between pregabarin and amitriptyline by pain scale. The main symptom which patients suffer is pain on bladder. Therefore both drugs are available to PBS for first choice of treatment

There were, however, statistically significant differences in pain reduction, urgency and pollakisuria between pregabarin and amitriptyline by the O'Leary and Sant IC questionnaire. This suggests evaluation of the pain sensation only is different from evaluation of specific symptoms including pain, urgency and pollakisuria. Amitriptyline has an anti-serotonin and adrenaline reuptake effect, as well as an anti-cholinergic effect. This may be one reason why amitriptyline was rated more effective than pregabarin on the O'Leary and Sant IC questionnaire.

The continuity rate of pregabalin within 150 mg was 77%, while that of amitriptyline within 30mg was 65%. If patients can tolerate the drug, amitriptyline may be more effective than pregabalin for BPS at first. However the usual maximum dose of pregabalin is 300mg, and that of amitriptyline is 150mg.Therefore the dropout rate of pregabalin may be estimated as lower than that of amitriptyline. And if patients cannot tolerate amitriptyline, we can take the strategy that pregabalin will be given for first choice and after reduction of pain, any cholinergic agents will be added on.

Furthermore the effective point of pregabarin is different from that of amitriptyline. Pregabarin mainly blocks the source of pain while amitriptyline mainly blocks the points of accepting pain. Therefore pregabarin which reduces the pain of peripheral injury of bladder mucosa are available first for the patients who have suffered for BPS within a few years. And amitriptyline which recovers the hypersensitivity of central neural systems are available the patients who have suffered for BPS over a few years. And serious BPS patients may need both types of medicine for combination therapies

In this study, medication doses were set at 30mg for amitriptyline and 150mg for pregabalin. These were first

Table 1. Background.

(median±st.)	pregabalin	amitriptyline	p value
age	56±13.9	62±13.9	0.9
VAS	5±2.4	5±2.3	0.3
IS-SI(total)	8±3.3	8±3.5	0.42
iS-CI(total)	8.5±4..2	8±4..8	0.46

Table 2. The results of O'Leary and Sant IC questionnaire.

	S1 Urgency	S2 Pollakisuria	S3 Nocturia	S4 Pain	P1 Pollakisuria	P2 Nocturia	P3 Urgency	P4 Pain
Pregabalin (n=21)								
Pr (average)	0.96 ±1,14	2.86 ±1.48	1.89 ±1.40	2.73 ±1.21	2.39 ±1.34	2.07 ±1.46	1.36 ±1.28	2.61 ±1.26
Post (average)	1.47 ±2.33	2.07 ±1.53	1.4 ±1.24	2.33 ±1.62	1.87 ±1,46	1.2 ±1.08	1.07 ±1.16	2.07 ±1.67
Amitriptiline (n=15)								
Pre (average)	1.1 1±1.42	2.85 ±1.70	1.81 ±1.54	3.47 ±0.99	2.29 ±1.54	1.96 ±1.63	1.7 ±1.62	3.07 ±1.11
Post (average)	0.65 ±0.76	1.18 ±0.88	1.18 ±1.34	1.4 ±1.26	1.06 ±0.90	0.71 ±0.92	0.8 2±0.88	1.12 ±1.11
P Value	0.043	0.11	0.5	0.018	0.04	0.35	0.42	0.035

treatment doses, and there was room to increase the dosage of both drugs. Therefore this paper should be considered a preliminary report, and more evaluation is needed.

In conclusion, The efficacy of pregabalin for pain relief may be same as that of amitriptyline. On the other hand, amitriptyline may be effective more than pregabalin for lower urinary symptom of BPS.

DISCLOSURE STATEMENT

We declare no conflict of interest.

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Original article

Argus-T sling in the treatment of male urinary incontinence: short-term evaluation in 182 patients

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Abstract: We evaluated short-term results of patients undergoing to positioning of Argus-T sling for the treatment of post-prostatectomy stress urinary incontinence (SUI). *Materials and Methods:* 182 patients were treated with Argus-T sling at four institutions from June 2008 to March 2013. The preoperative evaluation included medical history, pad count (1-2 pads: mild SUI; 3-5 pads: moderate SUI; >5 pads: severe SUI), VAS on continence, QoL score scale, physical examination, cystoscopy and urodynamic evaluation. Postoperative evaluation was performed four weeks postoperatively, and late follow-up (FU) was achieved in April 2013. We considered a satisfactory result cured (no pads) and or improved (1-2 pads per day). *Results:* 21 (11.8%), 96 (52.7%) and 65 patients (35.7%) were affected by mild, moderate and severe incontinence respectively. At the median FU of 22 months the overall satisfactory rate was 86.2%. Satisfactory results were 95% in mild incontinence, 78% in moderate incontinence and 70% in severe incontinence. In cured and improved patients we observed a statistically amelioration of QoL ($p<0.0001$). Sling regulation was necessary in 42.9% of cases while its removal occurred in 9.3% of cases. Postoperative complications were reported in 14.3% of patients. In patients with previous radiotherapy we observed a satisfactory result in 61.2% of cases. *Conclusions:* This study represents the first report that shows short-term results of Argus-T positioning in a large population. This device seems to offer good outcomes in patients with mild and moderate SUI while in case of previous radiotherapy it is associated with a low possibility to recover a satisfactory continence.

Key words: Sling; Urinary incontinence; Male urinary incontinence; Prostatectomy; Radical prostatectomy.

INTRODUCTION

It is well known that male stress urinary incontinence (SUI) is generally due to radical prostatectomy (RP) or in some cases to transurethral resection of prostate (TURP)[1]. In this setting several authors reported that up to 1-40% of patients who undergo prostatectomy are affected by persistent post-prostatectomy incontinence (PPI)[2,3].

As well defined in these cases the surgical treatment should be considered only 6-12 months after the radical prostatectomy and in presence of a permanent condition of SUI[4-5]. Indeed in this period it is useful employ a conservative therapy, such as lifestyle interventions, pelvic floor muscle training and biodfeedback[6].

In this way the artificial urinary sphincter (AUS) has been to offer long-term durable results in terms of continence and at present is the gold standard continence procedure[7,8]. However in recent years the use of slings is growing strongly and Argus-T adjustable male sling with transobturator approach seems to be attractive for the intrinsic characteristics of the material composition, for the easiness of the surgical implant and finally for its ability to modulate the urethral compression post-operatively. The literature on Argus-T is still lacking and to our knowledge there are only few reports with low number of patients. In this setting[9,10] in which the social continence rate reported is about 62-77%.

In this way we retrospectively evaluated the data in the short-term in a large cohort of patients regarding the efficacy, complication rate and quality of life in patients undergoing to the positioning of Argus-T male sling for the treatment of mild, moderate and severe SUI.

MATERIAL AND METHODS

Patients

The records of 182 patients treated with the Argus-T sling at 4 institutions since June 2008 to March 2013 were evaluated.

Eligible patients had SUI as a result of radical prostatectomy, transurethral resection of the prostate (TURP) and of previous failure of AUS, ProACT, urethral constrictor and other male slings. We considered eligible all patients affected by persistent SUI at least 6-12 months after the surgery. The patients quantified their SUI as mild 1-2 pads per 24 hours, moderate as 3-5 pads per 24 hours and severe more than 5 pads per 24 hours. We excluded all those affected by detrusor overactivity.

We also included patients underwent previous adjuvant radiotherapy after prostatectomy.

Pre-operative evaluation

The evaluation of male patients with SUI before the surgical procedure included medical history, pad count, VAS measurements on continence (scale of 1-severe incontinence to 10-dry) and a QoL score (scale of 1-poorest to 10-best)[11]. All patients were evaluated preoperatively with physical examination and cystoscopy. We performed urodynamic evaluation in all patients and we excluded the ones affected by overactivity.

The ARGUS-T Device

The Argus-T device includes a silicone cushion that is long 3.2-4.5 cm and large 2.9-3.5 cm along its antero-posterior axis. It is also connected to 2 silicone columns made of multiple cone-like sections and 2 silicone rings/washers. The rings are positioned on the columns to regulate the tension of the silicone cushion on the bulbar urethra. The coned structure of the columns allows regulation of sling tension by tightening or releasing the 2 silicone rings[10].

The surgical procedure

Implantation of the male sling

The surgical technique is the same well described by Romano et al[10] with some changes, as follows. Patients were previously treated with antibiotic prophylaxis (500mg vancomycin 4 times in 24h and 3mg/kg/die gentamicin in 72h) intravenously. Then they were operated upon under spinal or general anesthesia. With the patient in lithotomy position, it is prepared the suprapubic and the perineal areas and it is

positioned an 18 Ch Foley catheter. Then it is executed a 6cm median perineal incision and the tissues are dissected until the bulbocavernous muscle is seen. It is left in situ and the urethra is not mobilized from the central tendon. It unsticks the lateral borders until the bilateral identification of perineal aponeurosis and then it detaches this to the muscle fibers in order to access to the obturator foramen.

In correspondence of the inguinal fold it is executed a bilateral small incision below the insertion of the adductor magnus muscle. Finally it is made a last transverse suprapubic incision until the exposure of the muscle rectus fascia. Hence it is introduced the helical needle bilaterally with a movement "out-in" from the lateral entries until the perineal one. During this procedure the operator had to perforate the obturator aponeurosis so with an opposite movement it is possible to allocate the columns laterally (transobturator approach) and the cushion on the ventral surface of the bulbar urethra. Then the washers are introduced on the end of the columns bilaterally so the operator can adjust the tension of the sling.

At this point it is executed a cystoscopy to control and possibly to correct the tension. The regulation is obtained with the identification of "retrograde leak point pressure" at level 0 (normally it is 30-40cmH_2O). Then this procedure can identify any urethral trauma related to the needle crossing. When the tension of the sling is achieved the cushion is fixed to the muscle bulbocavernous. Finally the end of the columns are positioned crosswise deep the suprapubic subcutaneous fat and both wounds were closed in layers. The Foley catheter is repositioned at the end of the procedure and it is removed about 48 hours after the surgery.

Revision procedures

A revision procedure was performed on all patients with persistent SUI after implantation of the device. Patients were operated upon under spinal or general anesthesia and there was injected antibiotic prophylaxis (500mg vancomycin 4 times in 24h and 3mg/kg/die gentamicin in 72h) intravenously.

Suprapubic and inguinal incisions were opened and the sling tightened by pulling the coned columns through the washers over 1 or 2 cones bilaterally. Cystoscopy was performed as previously described. During the retrograde urethromanometry we aimed for an optimal retrograde leak point pressure (between 40 and 50 cm H_2O), generally 10 cm H2O higher than the previous condition.

Postoperative evaluation

Postoperative evaluation was performed 4 weeks postoperatively and late FU was achieved in April 2013.

Moreover we evaluated as satisfactory result the patients cured (no pads) and or improved (1-2 pads per day).

Patients were asked to fill out VAS measurements (1 to 10) on continence and QoL.

Complications and revision procedures were registered.

Data analysis

All statistical analyses were conducted using SAS version 9.3 software (SAS Institute, Inc., NC). Preoperative and postoperative results were compared using the paired samples t-test. Statistical significance were considered when $p \leq 0.05$ (two-tails.).

RESULTS

Patient characteristics

Between June 2008 and March 2013 an amount of 182 patients affected by SUI were treated with surgical procedure of positioning of sling Argus-T according to a transobturator approach. The median age of them is 71 years (range 50-86 years) and the median follow-up is 22 months (range 1-59 months) (Tab. 1).

TABLE 1. – Clinical characteristics of 182 patients with SUI pre-operative and post-operative Argus-T positioning.

Characteristics	N. (%)
Pre-operative	
Age (years)	
Median (range)	71 (50-86)
Follow-up (months)	
Median (range)	22 (1-59)
Type of radical prostatectomy	
Open	109 (59.9)
Laparoscopic	49 (26.9)
Robotic	3 (1.7)
TURP	21 (11.5)
Adjuvant radiotherapy	
No	133 (73.1)
Yes	49 (26.9)
Previous urinary device	
No	160 (87.9)
Artificial urinary sphincter	2 (1.1)
Other male sling	6 (3.3)
Pro ACT	12 (6.6)
Urethral constrictor	2 (1.1)
Vesico-urethral anastomosis stenosis	
No	154 (84.6)
Yes	15 (15.4)
Post-operative	
Number of regulations of Argus-T	
0	104 (57.1)
1	55 (30.2)
2	15 (8.2)
≥3	8 (4.5)
Type of complications	
No	87 (47.8)
Hyper-continence	16 (8.8)
Infections	9 (5.0)
Urethral erosion	1 (0.5)
Removal Argus-T	
No	165 (90.7)
Yes	17 (9.3)

21/182 patients (11.6%) were affected by mild incontinence (1-2 pads per day), 96/182 of them (52.7%) were affected by moderate incontinence (3-5 pads per day) and 65/182 of them (35.7%) were affected by severe incontinence (more than 5 pads per day).

Most of people were become incontinent after radical prostatectomy (161/182 patients, 88.4%), while the other ones after TURP (21/182 patients, 11.6%).

49/182 patients (26.9%) received previous adjuvant radiotherapy. Then some patients underwent to a previous surgery for SUI: 2/182 of them (1.1%) were treated with AUS, 6/182 of them (3.3%) with other kind of sling, 12/182 of them (6.6%) with ProACT and 2/182 of them (1.1%) with urethral constrictor.

At cystoscopy 28/182 patients (15%) showed vesico-urethral anastomosis stricture.

Operative outcomes and revisions

At the median follow-up of 22 months, the overall satisfactory rate was 86.2% (157/182 patients) of which 60/182 patients (33%) were cured and 97/182 patients (53.2%) were improved.

Also we observed that the reduction of number daily pads after the surgery and the improvement of the QoL (identified on the specific questionnaires) were statistically significant ($p < 0.0001$) after an analysis with T-student test (Tab. 2).

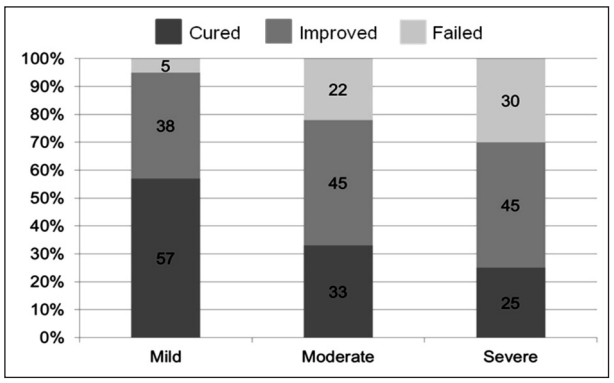

Figure 1. – Success rate by incontinence degree of 182 patients with SUI after Argus-T positioning.

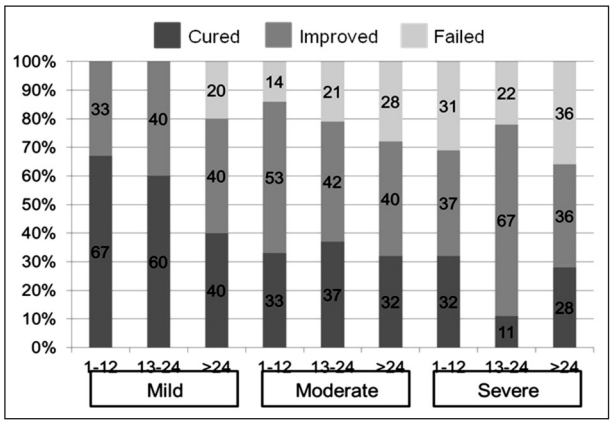

Figure 2. – Success rate by months of follow-up and incontinence degree of 182 patients with SUI after Argus-T positioning.

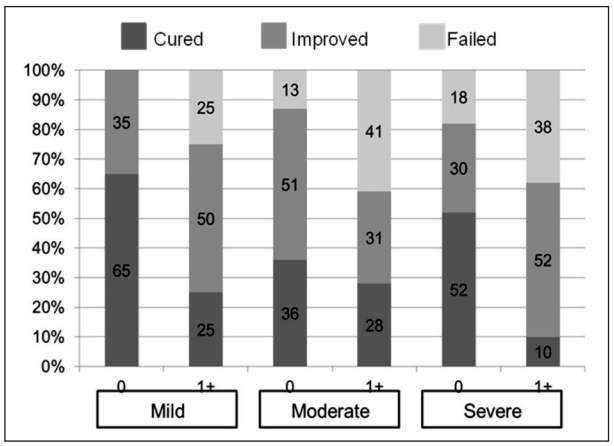

Figure 3. – Success rate by months of follow-up and incontinence degree of 182 patients with SUI after Argus-T positioning.

According the incontinence degree, we observed interesting results, as follows. 12/21 patients (57%) with mild incontinence were cured while 8/21 patients (38%) were improved. Moreover patients with moderate incontinence showed satisfactory results in 78% (33% cured and 45% improved). Finally patients with severe incontinence were cured in 25% (16/65 patients) and improved 45% (29/65 patients) (Fig. 1).

In particular, the outcomes were inversely proportional compared to the time of follow-up regardless of incontinence degree, as described in Fig. 2. We also observed the same link with the QoL score scale the VAS continence scale (data not shown).

Table 2. – Mean and standard deviation (±SD) of number of pad/die, VAS continence scale and QoL score scale of 182 patients with SUI before and after Argus-T positioning.

	Argus-T positioning		
	Before Mean (±SD)*	After Mean (±SD)*	p-value**
Number of pad/die	4.9 (±2.5)	1.6 (±1.9)	<0.0001
VAS continence scale	3.4 (±2.2)	7.5 (±2.9)	<0.0001
QoL score scale	2.9 (±1.9)	7.5 (±3.1)	<0.0001

*SD=standard deviation. **T-student pairs test

Table 3. – Clinical characteristics of 182 patients with SUI previous Argus-T positioning by adjuvant radiotherapy.

Characteristics	Adjuvant radiotherapy	
	No (N. 133)	Yes (N. 49)
Type of radical prostatectomy		
Open	80 (60.2)	29 (59.2)
Laparoscopic	35 (26.3)	14 (28.6)
Robotic	2 (1.5)	1 (2.0)
TURP	16 (12.0)	5 (10.2)
Previous urinary device		
No	114 (85.7)	46 (93.9)
Artificial urinary sphincter	2 (1.5)	--
Other male sling	5 (3.8)	1 (2.0)
Pro ACT	10 (7.5)	2 (4.1)
Urethral constrictor	2 (1.5)	--
Vesico-urethral anastomosis stenosis		
No	112 (84.2)	42 (85.7)
Yes	21 (15.8)	7 (14.3)
Number of Argus-T regulations (1)		
0	82 (61.6)	22 (44.9)
1	39 (29.3)	16 (32.7)
2	9 (6.8)	6 (12.2)
≥3	3 (2.3)	5 (10.2)1
Type of post-operative complications (2)		
No	72 (54.1)	15 (30.6)
Residual incontinence	43 (32.3)	26 (53.1)
Hyper-continence	13 (9.8)	3 (6.1)
Infections	4 (3.0)	5 (10.2)
Urethral erosion	1 (0.8)	-2
Removal Argus-T (3)		
No	126 (94.7)	39 (79.6)
Yes	7 (5.3)	10 (20.4)3

1,2,3 In comparison of the "No adjuvant radiotherapy" the p-value of the chi-square test were: p=0.04, p=0.01 and p=0.002 respectively.

In 30.2% of patients (55/182) it was necessary to perform a single regulation while in 12.6% of patients (23/182) at least two regulations (Tab. 1). The regulation of Argus-T was associated with worse outcomes regardless the incontinence degree, as described in Fig. 3.

Otherwise this study demonstrated a worse percentage of success in patients previously treated with radiotherapy: in fact only the 61.2% of patients (30/49) obtained a satisfactory result while in 38.8% of patients (19/49) the treatment failed showing that the outcomes were inversely proportional to the incontinence degree (Fig. 4). The group with previous radiant treatment was associated to high percentage of sling regulation or sling removal and post-operative complications (p=0.04, p=0.002, p=0.01) (Tab. 3). Nevertheless, these patients showed a significant reduction of daily pad number and an improvement on their QoL (p<0.0001) (Tab. 4).

TABLE 4. – Mean and standard deviation (±SD) of number of pad/die, VAS continence scale and QoL score scale of 182 patients before and after Argus-T positioning by previous adjuvant radiotherapy.

	Argus-T positioning		
	Before Mean (±SD)*	After Mean (±SD)*	p-value**
Number of pad/die			
Adjuvant radiotherapy			
No	5.9 (±2.7)	2.6 (±2.2)	<0.0001
Yes	4.5 (±2.3)	1.3 (±1.6)	<0.0001
VAS continence scale			
Adjuvant radiotherapy			
No	2.7 (±1.8)	6.0 (±3.5)	<0.0001
Yes	3.7 (±2.3)	8.1 (±2.5)	<0.0001
QoL score scale			
Adjuvant radiotherapy			
No	2.2 (±1.2)	5.9 (±3.6)	<0.0001
Yes	3.1 (±2.0)	8.2 (±2.7)	<0.0001

*SD=standard deviation. **T-student pairs test.

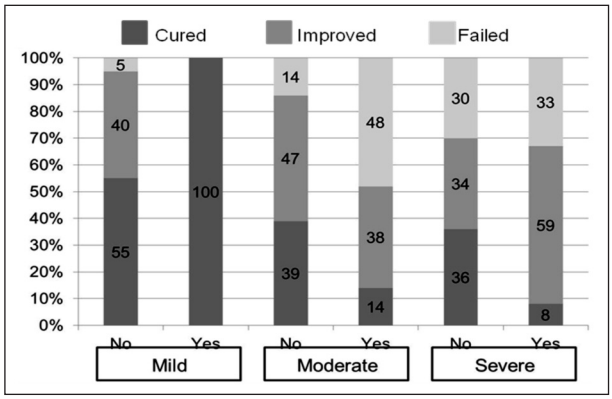

Figure 4. – Success rate by adjuvant radiotherapy and incontinence degree of 182 patients with SUI.

Complications

None complication was occurred during the intra-operative period while we observed in 26/182 patients (14.2%) a post-operative complication, such as infection (9/182 patients, 4.9%), urethral erosion (1/182 patients, 0.5%) and hypercontinence (16/182 patients, 8.8%). In some of them it was necessary to remove the device. The overall removal rate was 9.3% (17/182 patients) (Tab. 1).

Patients reported at least one complication were associated with worse outcomes regardless the incontinence degree, as described in Fig. 5.

DISCUSSION

Nevertheless mini-invasive approaches, as robotic and laparoscopic surgery, stress urinary incontinence (SUI) after radical prostatectomy represents an important post-operative complication causing remarkable troubles on QoL of these patients[1,12].

Percentage of PPI at 24 months after surgical operation ranges between 1 to 40% of patients underwent RP[2,3].

It is known that SUI is caused by a reduced urethral resistance to abdominal pressure secondary to the intrinsic sphincter deficiency[14-16].

According to the international guidelines, the surgical treatment of SUI should be offered only after the failure of conservative therapy and with a stability of the continence status for at least 12 months[4,6].

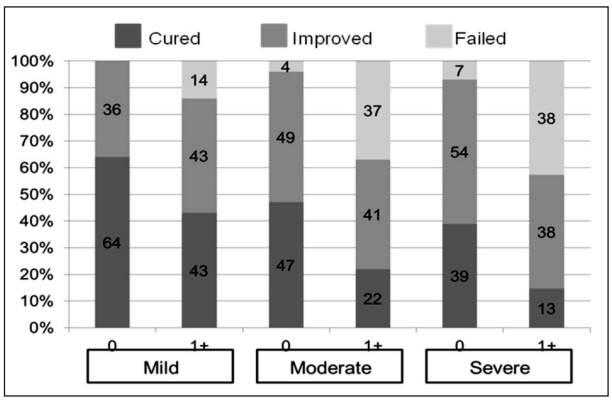

Figure 5. – Success rate by post-operative complications and incontinence degree.

In this way, the AUS offers long-term durable results in terms of social continence (73-90% at 5 years and 80-90% at 10 years) and at present it is the gold standard continence procedure[7,8] in this setting.

However in recent years the use of slings is growing strongly due to high costs of AUS that causes about 37% of post-operative complications, such as mechanical failure, erosion and or infections[17].

These issues induced several urologists to choice the sling procedure that seems to assure satisfactory results in the short-term[18,19].

In particular, according to the National Institute for Health and Clinical Excellence (NICE) in the UK the best candidates to receive a surgical treatment with male sling are the patients with mild and or moderate SUI[2].

In this way, Argus-T adjustable male sling with transobturator approach seems to be attractive for the intrinsic characteristics of the material composition, for the easiness of the surgical implant and finally for its ability to modulate the urethral compression post-operatively.

Overall results with this device showed a continence rate between 62% and 100% after a short follow-up[9,10,19] even if this variability is due to differences on continence definition.

In particular in our study, that at present represents the largest clinical series with this device, emerges a satisfactory result in 86.2% of clinical cases at 22 months of follow-up, as also confirmed by others with low clinical series[9,10,20]. In this context, our outcomes are overlapping with those published on AdVance by Bauer et al in the short-term[9].

According to the incontinence degree, our data revealed that success rate was worse in the group with severe SUI in comparison with the group with mild and moderate SUI. These results are also confirmed by Romano with a cure rate of 100% in subjects with mild and moderate SUI while 71% in severe SUI[10]. The lower efficacy of Argus-T in presence of severe incontinence confirms what it was previously described in Literature[9,13,18] where AUS remains the "gold standard" while the ideal candidates for male sling are patients with mild and moderate SUI.

At the same conclusions arrived Rehder[21] with AdVance that described a continence rate of 71% in patients with severe SUI compared to 79% in patients with lower incontinence degree.

In this context our study suggests that severe SUI has lower possibility of recovery after sling procedure.

Regarding the complication rate, at present, there are no data in Literature showing intra-operative complications with Argus-T while in the post-operative period the patients reported troubles in 15.8-19.1% of cases[22,23] as urgency de novo, hypercontinence, urethral erosion, perineal pain or infections with an high risk of sling removal in these three last conditions.

In our data we reported post-operative complications in a percentage of 14.3% and most of them were hypercontinence rather than infections. In 9.3% of patients was necessary to remove the device, especially after sling infection (7/17, 41%) and, generally, in our series patients affected by one or more complications obtained worse success rate.

Although the greatest problem on the indication for the sling procedure is related to the previous radiotherapy and in this regard many studies tried to identify predictive factors of success for male sling[12,21,24-27] and so to select ideal candidates for this surgical procedure. In particular, some Authors reported that age and adjuvant radiotherapy are not predictive factor of success[9,13]. This issue is still controversial and in our experience the patients with previous radiotherapy showed a worse outcome in comparison with patients without radiotherapy. This aspect could be related to the fibrosis of pelvic floor induced by radiation activity causing an ineffective cushion effect of the sling pad on the pelvic floor with particular reference to the sphincter complex.

On the base of our experience, we suggest that patients with previous radiotherapy should be not ideal candidates for surgical treatment of their PPI with Argus-T device.

In fact, our data showed that adiuvant radiotherapy was associated with higher number of regulation or removal of ARGUS-T ($p= 0.04$ and $p= 0.002$) and post-operative complications ($p= 0.01$).

Instead as regarding the QoL of these patients we observed a linear correlation between with the latter and the daily pads use after Argus-T. In fact the VAS continence scale and the QoL score scale showed an overall improvement of QoL in these patients about 100% after Argus-T positioning, even if this trend does not remain in the long-term in all groups of patients underwent radiotherapy.

CONCLUSION

In conclusion, PPI represents a considerable social problematic for this kind of patients.

This paper represents the first that shows functional outcomes after Argus-T positioning in a large population.

Nevertheless the lacking of results in Literature on long-term results, Argus-T sling seems to offer good outcomes at short-term, especially in patients affected by mild and or moderate SUI while adjuvant radiotherapy is associated to low possibility of recovery of the continence.

This issue is contrast with latest published works that suggest the radiotherapy is not a negative predictive factor for slings procedure.

DISCLOSURE STATEMENTS

We declare no conflict of interest and informed consent was obtained by all patients.

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Multidisciplinary Colorectal 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.

The definitions of **urinary and fecal incontinence** are similar: ability to hold urine and feces and to eliminate them when and where desired. An interdisciplinary perspective may analyze similarities and differences between the two functions in physiological and pathological conditions. In the **female** the **Integral Theory** highlights the interactions among them, the pelvic ligaments working for both. In the **male** we are often still in the dark excluding some specific muscular or neurological lesions. Maintaining or recovering fecal continence continues to be a challenge for the colorectal surgeon who is facing many failures. Surgery in the rear is much less favorable compared to urology, it deserves anyway to be discussed.

As in the anus, in the urethra the sphincter complex is composed of an inner smooth muscle and an outer rhabdosphincter of skeletal muscle. The latter is most marked around the membranous urethra and gradually less distinct toward the bladder; the former has its main part at the vesical orifice and is thinner in its further course in the urethra; the smooth muscle is primarily concerned with continence at rest (in the anus as well). The rhabdosphincter has a double genitourinary function, namely active continence during stress conditions and antegrade semen propulsion. Stress urinary incontinence is caused by a reduced urethral resistance to abdominal pressure secondary to the intrinsic sphincter deficiency, and the majority of male incontinence is secondary to sphincter weakness following prostatic surgery. With the growing number of operations for prostate cancer, incidence of male incontinence is increasing, hence, management of male incontinence is of great interest to urologists with various conservative not invasive therapies (for early postoperative and mild incontinence) and surgical approaches. The **artificial urinary sphincter** is still labeled as the gold standard despite the introduction of several more minimally invasive alternative treatments. However, as yet there is no consensus on the optimal timing and best modality for managing these patients, and well designed clinical trials are needed. The rather expensive **artificial anal sphincter** has been implanted as well, but results have been disappointing both in patients with anatomic sphincters damage and with idiopathic fecal incontinence. The authors of this article propose a transobturator adjustable sling in males with mild or moderate SUI with a short term good outcome the worst results being observed after adjuvant radiotherapy. A similar surgical alternative with an anal sling based on the success of tension-free suburethral tapes used to treat SUI has been described by Haverfield (*A pilot study: The anal sphincter support procedure for the treatment of anal incontinence, Pelviperineology 2007; 26: 108-112*) supporting the external anal sphincter with a circlage tape prosthesis. La Torre's procedure tries to create an elastic structure supporting the pelvic diaphragm placing tension free along puborectalis muscles's line a prosthetic biological mesh *(Use of anal sling in the treatment of fecal incontinence; Pelviperineology 2013; 32: 9-13*). Results have not been better than with the artificial sphincter or the so-called dynamic graciloplasty. Among the numerous factors involved in fecal incontinence (cerebral conditions, rectal compliance, peristalsis, quality of stools, anal canal sensitivity), none individually appears crucial to achieving a cure so that, after the failure of conservative therapy, surgical management of fecal incontinence in order to claim fair outcome is limited to the reconstruction by the overlapping technique, and the best results in the treatment of fecal incontinence resistant to rehabilitation, seem to be obtained by the sacral neurostimulation.

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Original article

Surgical repair of uterosacral/cardinal ligaments in the older female using the Tissue Fixation System improves symptoms of obstructed micturition and residual urine

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Abstract: Background. Previously published flow mechanics and finite element model works demonstrated that the intraurethral resistance to flow in normal micturition was exponentially determined and that the detrusor pressures required for expulsion of urine were by two orders of magnitude beyond normal available voiding pressures. Xray and EMG studies indicated the presence of directional vectors which most likely contacted against the cardinal/uterosacral ligament complex. *Objectives*. A prospective pilot study to test the hypotheses that voiding dysfunction in the female may be caused by lax cardinal/uterosacral ligaments preventing traction of the opening vectors and so is potentially curable by surgical reinforcement of these ligaments. *Patients and Methods*. The mean patient age was 61 yrs., mean BMI 23. Inclusion criteria: symptoms of emptying dysfunction, residual urine >40ml and apical/uterine prolapse to the halfway mark (stage2, Baden Walker). Exclusion criteria: nil. The TFS (Tissue Fixation System), an adjustable tape which shortens and reinforces loose ligaments was applied to the cardinal and uterosacral ligaments for cure of symptomatic uterine/apical prolapse (n=36). The sample size (n=36) was double the number required to give a 95% confidence interval with 1% significance for 50% cure rate of the "obstructed micturition". A two-tailed Student's ttest was used. *Results*. 34/36 patients were reviewed at 12 months. Emptying symptoms were cured or improved beyond a VAS self-assessed >80% level in 76% of patients (p>0.001); mean emptying time improved from 52 to 26 secs. (p.0.001); mean residual volume from 201ml to 39ml (p>0.001). *Strengths of the study*. The results appear to indicate that competent cardinal/uterosacral ligaments may be important for adequate bladder emptying. *Weakness of the study*. Single centre, non-randomized, no control group. *Conclusions*. The surgical methods described appear to have the potential to improve "obstructed micturition", a major as yet insoluble problem in older females. The results are best explained by reference to an external striated muscle mechanism reliant on firm ligamentary insertion points for the vector forces to open the urethral tube. Further more rigorous studies are required.

Key words: Obstructed micturition; Residual urine; TFS surgery; Uterosacral ligament; Cardinal ligament; Urethra.

INTRODUCTION

Inability to adequately evacuate the bladder is a major source of repeated urinary infection and pathology[1]. Catheter-associated UTI is the most common nosocomial infection, accounting for >1 million cases in hospitals and nursing homes. The risk of UTI increases with increasing duration of catheterization. In non-institutionalized elderly populations, UTIs are the second most common form of infection, accounting for nearly 25% of all infections with a cost of 1 billion dollars p.a.[1].

The traditional view of the mechanism of micturition was described by Messelink et al[1]: *"The pelvic floor muscles must relax in order to remove the passive continence mechanisms, thereby favouring normal micturition"*.

A recent Review of voiding dysfunction[2] shed little light on the problem. It stated, *"There remains a lack of consensus regarding a precise diagnosis and definition of voiding abnormalities in women"*. The Review's statement of causation[2] was limited to "*detrusor underactivity and outflow obstruction which could be either physiological or iatrogenic*." Two studies reporting improvement of bladder emptying following cystocele and fascial repair were mentioned, but no anatomical explanations were forwarded as to why[2].

We believe that the answer to these conundra is to be found in urethral resistance to urine flow which is exponentially determined and is instantaneously modified by an external striated muscle mechanism first described in 1990[4]. This mechanism, since validated with EMG and video xray studies[5,6] stretches open the posterior urethral walls during micturition, figs 1&2, and is in turn ultimately dependent on competent posterior suspensory ligaments in the position of the cervix 'CX', fig. 1[5,6].

The external opening mechanism, figs 1&2, was described as follows[4-6]: immediately prior to commencement of voiding, the forward closure vector (m.pubococcygeus) relaxes; relaxation of m.pubococcygeus releases the closure pressure of the hammock on the posterior urethral wall, thereby freeing the posterior vectors (levator plate and the conjoint longitudinal muscle of the anus, arrows, fig. 1, to actively open the urethra prior to detrusor contraction; this causes the urethra to funnel, exponentially lowering the resistance to flow immediately prior to the expulsive action of the detrusor[5,6].

According to[4], the keystone of this mechanism is the requirement for firm anchoring points for the downward opening vector, the uterosacral/cardinal ligaments (CL/USL) at 'CX', fig. 1[5,6]: the downward opening vector (white arrow, Fig. 1) contracts against the CL/USL: if the USL is loose, the vector weakens[7]; the vector cannot open out the posterior urethral wall; the detrusor contracts against an unopened urethra and therefore, a high urethral resistance; a higher detrusor pressure is required for expulsion, fig. 3; the patient will have bladder emptying difficulties because of greatly increased resistance to flow[8]. Resistance to flow is highly sensitive to this opening mechanism, as it is exponentially determined (Poiseuille's Law). For non-laminar flow, it is approximately inversely related to the 5th power of the radius 'r'[8]. With reference to fig. 1, there appears to be almost doubling of the urethral diameter during micturition. The pressure flow relationship as determined by direct laboratory measurement and computer modelling is shown in fig. 3[8]. At a diameter of 3.5 mm, a pressure head of approximately 170 cm H_2O is required to achieve a flow rate of 50 ml/sec, fig. 3. If the urethra can be opened out from 3.5 mm to 6 mm by the proposed external mechanism, the head of pressure required for a 50 ml/sec flow falls to 20 cm H_2O.

The basis of this study is that the cascade of events which leads to these voiding dysfunctions is potentially reversible by surgical strengthening of the uterosacral/cardinal ligament complex by insertion of TFS polypropylene tapes.

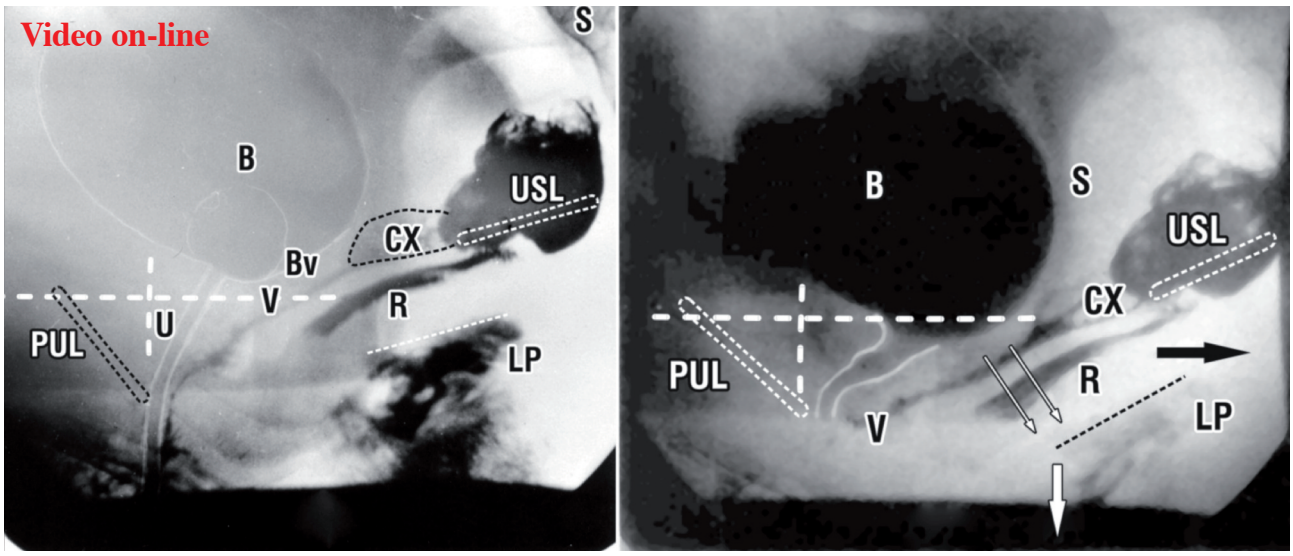


Figure 1. – Normal patient - xrays at rest (left) and during micturition (right), samepatient in sitting position At rest, slow twitch contractions angulate bladder (B), urethra (U), vagina (V) and rectum (R) around the insertion of the pubourethral ligament (PUL) at midurethra. 10ml radioopaque material has been injected into the levator plate (LP) vagina and rectum. Vertical and horizontal broken lines indicate bony co-ordinates. During micturition (right figure), the urethra has moved backwards from the vertical co-ordinate, suggesting relaxation of the forward vector. Vagina and rectum appear to have been stretched backwards by a backward vector (black arrow). The anterior part of LP has been angulated downwards apparently by the downward vector (white arrow) acting against the cervix (CX)/uterosacral ligament (USL) complex. The backward/downward vectors (thin diagonal arrows) create a diagonal vector force which seems to be pulling open the posterior urethral wall. S=sacrum. **Micturition video in the journal online.**

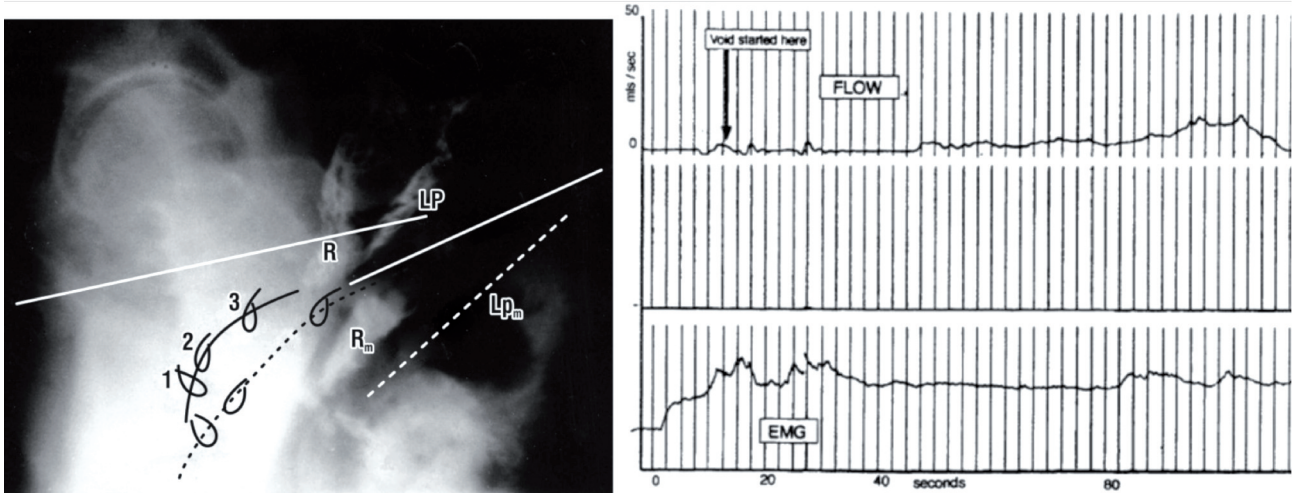


Figure 2. – Micturition x-ray superimposed on resting xray (left side), patient sitting. Vascular clips have been applied to the midurethra '1'. Bladder neck '2' and bladder base '3'. Radio-opaque dye has been injected into the levator plate 'LP', which has been angulated downwards during micturition, as has the rectum 'R', which has 10 ml of barium paste. Broken lines indicate position of organs during micturition. Subscript 'm' indicates the position of rectum 'R' and levator plate 'LP' during micturition.
Surface EMG (right side) Surface EMG cylinder placed in the posterior fornix of the vagina simultaneous with uroflowmetry. EMG shows that muscle contraction preceded urine flow.

The aim of this study was to test the hypotheses that non-surgically induced voiding dysfunction is largely a consequence of loose cardinal/uterosacral ligaments invalidating the external opening mechanism described earlier and as such, is potentially curable surgically by TFS reinforcement of these ligaments.

MATERIALS AND METHODS

We prospectively studied a cohort of 36 patients from a tertiary referral centre who met all the inclusion criteria.

Inclusion criteria.

Patients with a residual urine of 40ml or more, with uterovaginal or apical prolapse at or beyond stage 2 (Baden Walker classification) and who complained of at least one of 4 abnormal emptying symptoms from a validated questionnaire (9).

- Do you feel that your bladder isn't emptying properly?
- Do you ever have difficulty starting off your stream?
- Is it a slow stream?
- Does it stop and start involuntarily?

Exclusion criteria

None

Surgery

All patients had TFS tapes implanted for repair of the cardinal/uterosacral ligaments (Figs 4&5)[10]. The cardinal ligament TFS repaired the high transverse cystocele defect[10] and helped suspend the apex along with the USL TFS[10]. Where required, TFS perineal body repair for recto-

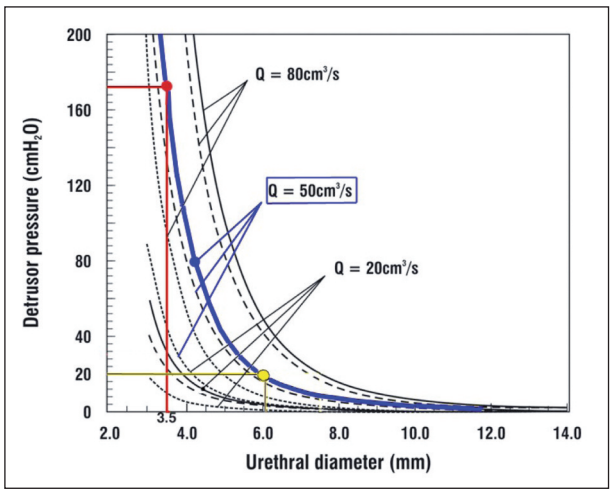


Figure 3. – Pressure flow graph – detrusor pressure as a function of urethral diameter for urethral length of 4 cm at flow rates of 20,50,80 ml/sec (8).
Total resistance to flow (unbroken line) ———————- Frictional component …….. Dynamic component - - - - - -. For a flow rate of 50 ml/sec (blue line), increasing the diameter of the urethra from 3.5 mm to 6 cm, reduces the head of pressure required to empty from approximately 170 cm H_2O to 20 cm H_2O

cele was also performed (n=8). The TFS surgical technique is the same for all ligaments in the pelvis. The ligaments are identified. A tunnel is made with Metzenbaum scissors into or adjacent to the body of the ligaments. The TFS applicator is inserted into each channel in turn and fired to release the anchor. Then the tape is tightened until a resistance is felt, a sign that denotes return of muscle contractility subsequent to return of ligament tension. The one-way tensioning system of the anchors shortens and re-attaches the elongated cardinal and uterosacral ligaments to the cervical ring and pelvic side wall, fig. 5.

Apical/uterine prolapse repair: 34 patients (4th degree n=1; 3rd degree n=10; 2nd degree n=23). All patients had TFS repair of uterosacral and cardinal ligaments, fig. 4.

Cystocele repair: 15 patients (3rd degree n=5; 2nd degree n=10) had a transverse defect repaired by a cardinal TFS sling. 3 patients with central or lateral defect had a native tissue paravaginal re-attachment to the ATFP in addition to a TFS cardinal ligament sling.

Rectocele and perineal body repair: In 8 patients a 3rd degree rectocele was repaired with a TFS perineal body operation plus rectovaginal fascial attachment to the perineal body.

Statistics

Based on results of a previous work[11] which showed a 50% success rate with a posterior sling, a sample size of 18 patients would give sufficient power (95% confidence limit), to detect a 50% success rate in emptying for a 1% significance. A two tailed Students t-test was used to compare the results. The cohort of 36 patients was deemed sufficient for these statistical requirements.

Approval for the TFS surgery was granted by the local Ethics committee. Informed consent was obtained from all patients. The Declaration of Helsinki for Medical Research Involving Human Subjects was followed.

RESULTS

Thirty-four patients attended for review at 12 months. Two patients when contacted declined to return for testing,

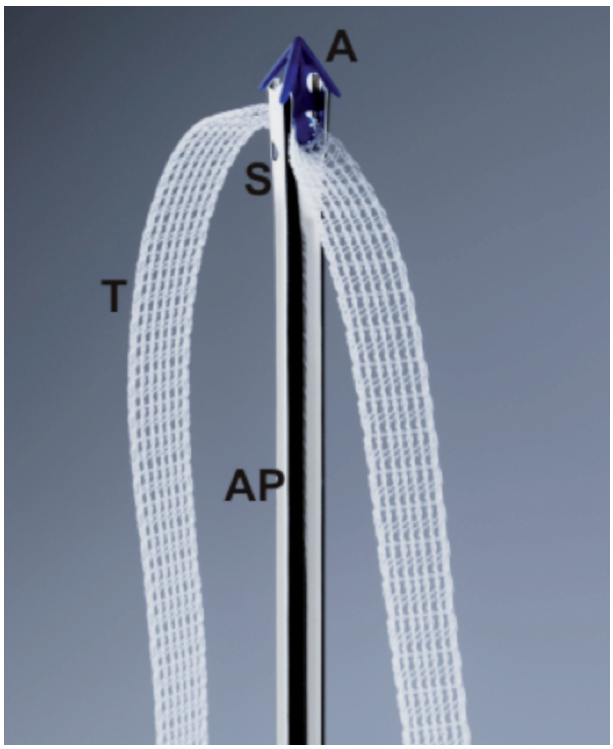


Figure 4. – The TFS system for site-specific re-inforcement of damaged suspensory ligaments. A tunnel is made into the ligament with Metzenbaum scissors; the applicator (AP) is inserted and fired to release the soft tissue anchor (A). This is repeated on the contralateral side and the tape (T) is tightened via the one-way system at the base of the anchor to restore tension and strength to the damaged ligament.

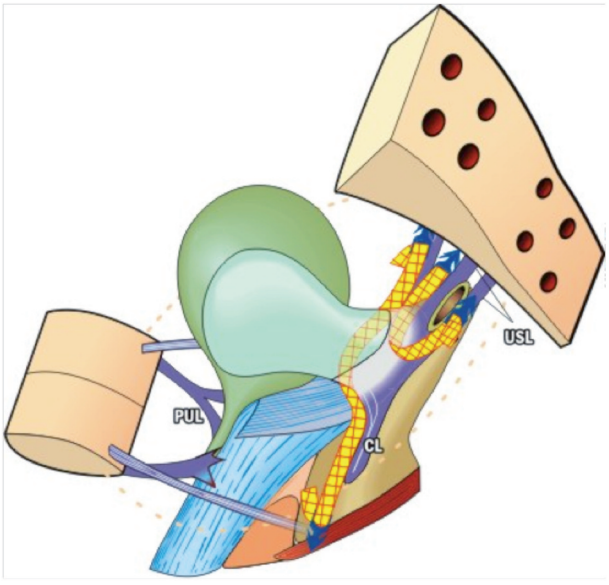
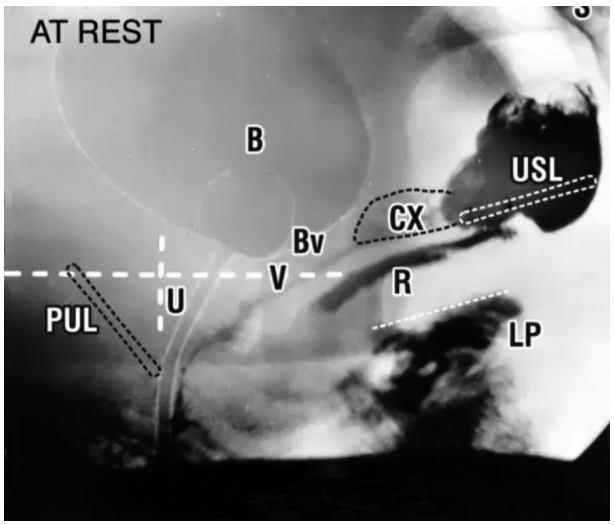


Figure 5. – TFS surgical repair of the cardinal and uterosacral ligaments, patient in standing position. The tape shortens and reinforces the lax ligaments and re-attaches them to the pelvic side wall. With reference to fig 1, the "U" configuration of the uterosacral sling potentially allows the downward movement necessary for the opening mechanism, even when fibrosed from tissue infiltration.

but stated they were happy with their result. The mean age was 61yrs (range 40-82), mean parity 3 (range 0-6), mean BMI 29 (Range 17 to 46). Eight patients had no previous pelvic surgery and 24 had prior hysterectomies. Thirty-four patients had the following TFS surgeries



This is a video xray of a patient taken during micturition in the sitting position. Barium has been inserted into the vagina and rectum and Urografin into the bladder and levator plate. Fig1 has been inserted at the start of the video to orientate the viewer. The process of micturition is clearly active: the anterior border of levator plate is angulated downwards at the commencement of micturition, apparently as a result of muscle contraction which also pulls down rectum, vagina and bladder base prior to detrusor contraction. In the video, there are 4 other observations of note.

1.There is considerable elasticity in the vertical organ movements. This elasticity is necessary for recoil to the resting position and it can only be attributed to elasticity in the suspensory ligaments.

The vector causing downward angulation can only act against the cardinal/uterosacral ligament complex as an insertion point.

In neither the xray (fig1) nor the video, is there any evidence of muscle relaxation. On the contrary, active co-ordinated organ movement is seen.

If abdominal pressure was the motive force for driving the urine to open the urethra, there would have to be indentations in the dome of the bladder and indeed, the anterior rectal wall. There are none. Loops of bowel are seen falling onto the dome of bladder in fig1, but there is no indentation.

At 12 months post-operative review (Baden Walker classification**)

Uterine/vault prolapse (n=34). One patient had 3rd degree prolapse, 3 had 1st degree and 30 had zero degree prolapse. *Cystocele repair (n=15)*. One patient had 3rd degree prolapse, one 2nd degree, four 1st degree and 9 zero degree prolapse.

Rectocele repair (n=8), one patient had 1st degree prolapse and 7 zero degree prolapse.

** 1st degree, prolapse to the mid part of the vaginal length; 2nd degree beyond midpoint; 3rd degree beyond introitus; 4th degree complete eversion.

Surgical complications. There was one tape erosion which was trimmed. There were no haematomas or infections and all patients were discharged the day after surgery.

Post-operative emptying symptoms. The patients used a self-assessed VAS improvement scale of 0-10, with 0 being zero symptoms and 10 being no change. Of 34 patients, 28 reported cure or substantial improvement, (17 reported 100% cure; 9 reported >80% improved; 2 reported >50-60% improvement). There were 6 total symptomatic failures. The improvement in symptoms was significant p>0.001 (Students t-test). Two patients who were self-catheterizing pre-operatively were restored to normal micturition, with postoperative residuals of 50 ml & 32 ml. The former was 87 years old with no cystocele, 3rd degree apical prolapse, 2nd degree rectocele and no cystocele. The latter was 82 years old, with 2nd degree uterine prolapse and 1st degree cystocele.

Objective data. The residual volume decreased from mean 203 ml pre-operative to mean 38.9 ml post-operative (p>0.001) (Students t-test). The change was significant (p>0.001) (Students t-test) as were the changes in emptying times (p>001) (Students t-test).

Pre-operative residual volume ranged from 40-600 ml and post-operative from 0-150 ml.

Thirty-four patients with >40ml residual pre-operatively reduced to 11 patients recording >40ml residual post-operatively.

Pre-operative emptying time ranged from 12-120 seconds and post-operative from 13-78 seconds.

Pre-operative bladder volume ranged from 232-1012 ml and post-operative from 220-1022 ml.

DISCUSSION

The concept of apical prolapse and symptoms of inadequate bladder emptying (12) is not new. Cole et al.[12] found a strong relationship between apical prolapse, and "pure voiding symptoms" (hesitancy, straining, positional voiding).

What was novel in this study was the intervention, repair of the apical prolapse by site-specific reinforcement cardinal/uterosacral ligament complex using the TFS tensioned sling. Bladder evacuation was symptomatically and objectively improved. Of 34 patients, 28 reported cure or substantial improvement in their emptying symptoms. The residual volume decreased from mean 203ml pre-operative to mean 38.9 ml post-operatively, (p>0.001) and the emptying times from 52 seconds to 26 seconds (p>001). Thirty-four patients with >40ml residual pre-operatively reduced to 11 patients recording >40ml residual post-operatively.

Our results cannot be explained by any "passive relaxation" theory. It can only be explained by an external opening mechanism.

The conventional muscle relaxation theory[1] has many flaws. Total relaxation of the pelvic floor would cause reciprocal laxity in the urethral tube, imposing urethral folds into the urethral cavity, further increasing resistance to urine flow, exponentially to the 5th power[8]. Furthermore, total pelvic relaxation does not accord with xray and EMG observations, figs 1&2[5,6], or the video presented as part of this work. All these observations indicate that the posterior urethral wall is actively stretched open by vector forces which are quite visible on the video xray. Active stretching of the organs by the backward/downward vectors, figs 1&2, would stretch out the longitudinal urethral folds, and pull open the urethra, vastly decreasing internal frictional resistance to flow, fig. 3[8]. Nor can the pelvic relaxation theory explain the post-surgical improvement in emptying symptoms and the objective improvements in emptying time and residual urine.

The consequences of a failed external opening mechanism are evident in patients who have a) severance of the spinal cord, b) in Burch colposuspension operations, or c) in very old patients with loose uterosacral ligaments. In a) the external mechanism is paralysed, so the urethra cannot be pulled open. In b), the vagina is sutured to Cooper's ligament; this mechanically prevents opening out of the posterior urethral wall. In c) the loose uterosacral ligaments weaken the downward opening vector. In all 3 examples, for different reasons, the detrusor is forced to contract against a high internal resistance. This is interpreted by the cortex as obstruction to flow, which is exactly what it is, but only in the functional sense, a consequence of the exponen-

tial resistance factor[8], not urethral narrowing. Our results are consistent with the conclusions from a recent finite element model of micturition (FEM)[13]. Using known anatomy, bladder pressures and stiffness of the tissue components of the urethra, it demonstrated that the detrusor pressure would need to be increased by two orders of magnitude beyond normal voiding pressures (i.e., 100 times normal micturition pressures) in order to achieve opening of the tube by detrusor contraction alone[13].

The 82 and 87 year old patients who were restored to spontaneous micturition had no significant cystoceles.

We deduce from our results that repair of the uterosacral/cardinal ligament suspensory mechanism was the key factor in the improvement of the patients' micturition and therefore, it must have a key role in the mechanics of normal and abnormal micturition.

From an anatomical perspective, the surgical cure of patients with voiding dysfunction is explained as follows: the uterosacral/cardinal ligament complex is the effective insertion point of the downward vectors which open out the posterior urethral wall into a funneled shape, figs. 1&2. A loose insertion point effectively lengthens a striated muscle, weakening its contractile force[7]; the TFS tape restored ligament tension and therefore, muscle length and contractility[7].

The basis of this study is the external opening mechanism which precedes detrusor contraction, figs. 1&2.

Using intra-anal ultrasound, Watanabe et al[14] demonstrated a similar active opening mechanism in the male which preceded micturition.

Strengths of the study

The results appear to indicate that competent cardinal/uterosacral ligaments may be important for adequate bladder emptying

Weaknesses of the study

Single centre, non -randomized, no control group.

CONCLUSIONS

The surgical methods described herein have the potential to improve or even cure "obstructed micturition" problems in the elderly female. However, confirmation by other surgeons with larger numbers will be required before these methods can become mainstream.

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Conflicts The senior author PP is the co-inventor of the TVT and the inventor of the TFS. WL and MB have no conflicts.
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Ethical standards

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Original article

Using inspirational and humorous narratives as a Nudge towards health status disclosure

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Abstract: The present paper discusses the third part of a series of papers that have investigated individuals biased cognitive and affective representations of the body's parts, specifically the anal and genital regions and how these affect disclosure and help seeking. In our current study, we measured the impact of two types of interventions aimed at mitigating the stigma associated with these body parts which has been found in the previous two papers as strongly related with help seeking resistance. We presented participants with a nudge consisting of two texts created specifically to prime individuals to perceive the body parts investigated more favorably and even in a more ironic way. We found that both interventions, humor and the inspirational story about problems in the rectal region, were equally effective in contrasting stigmatization of the body part, i.e. to mitigate the perception of dirtiness, embarrassment, and disgust associated with both the anus and the genitals. Furthermore these nudges improved participants willingness to engage in a conversation about anus/genitals problems. Unexpectedly, the simple humorous story seemed more effective than the inspirational story as the latter risked to increase a sense of weakness and vulnerability associated to the area. The effectiveness of the intervention was affected by age and gender. Implications of these findings are discussed.

Key words: Self-disclosure; Humor; Priming; Nudge; Storytelling; Body stigma.

INTRODUCTION

Humor and storytelling have been used in a variety of settings including the medical field to impact changes in individuals behavior such as help seeking, well-being and illness disclosure[1]. In order to investigate if we could change perception of the pelviperineal region which, as we identified in our previous study[2], was the body region that suffers the most from stigma, poor perception and neglect, we decided to employ a nudge consisting in the administration of two brief stories.

The concept of **Nudge** originated recently from behavioral science, political theory and economics which argues that positive reinforcement and indirect suggestions to try to achieve non-forced compliance can influence the attitudes, the behavior and the decision making of groups and individuals, at least as effectively – if not more effectively – than direct instruction, legislation, or enforcement[3].

These behavioural science principles are being used to change health behaviors and decisions by capitalizing on the fact that behavior is often influenced by subconscious cues[4]. These cues can be strategically used as primers for healthy behaviors. This strategy capitalizes on our proneness to be subtly affected (primed) by environmental and internal cues. Given the worldwide rising obesity rates, one manner in which this technique has been used is to prime individuals to eat less by changing the size of food containers. In one study, people were given different sized bowls to scoop ice cream into, some large and some small. The results show that bowl size determined how much ice cream was eaten, with the first group consuming 225 calories and the second one consuming 144 calories[5]. Another way nudges have been used in the health sector is in the arrangement of food in school cafeterias. For example, when cafeteria staff placed fruits and vegetables in prominent places such as at cafeteria bottlenecks and displayed them attractively, fruit consumption rose 54% (http://nudges.org/2010/06/09/nudging-in-new-yorklunchroom-cafeterias, accessed June 19th, 2015). In another example, placement of stairs in front of doors, with the elevators 50 feet away, caused more people to take the stairs[6]. Giving students a lecture on the risks of tetanus combined with handing out maps locating the student health center made them nine times more likely to go get a tetanus shot[3]. Even simple inquires about a person's health habits may increase healthy behaviors. Asking people whether they intended to floss and how often increased flossing; asking whether they planned to consume fatty foods in the next week made them less likely to do so[3].

In our study we would like to investigate the use of a type of nudge based on priming individuals through the use of stories.

Priming can be used to prepare people for specific thoughts or actions. It can also act as a more general nudge that encourages the target person to think in a particular way (or at least not in an undesirable way) and thus help to modify their behavior in regards to a specific matter[4].

Priming can be subtle and unconscious, such as with the use of linguistic patterning. It can also be deliberate and conscious, such as in training exercises. It can be short and take one minute or it can be long and repetitive in order to embed a prompted response into memory. In our study, the nudge consisted in participants being presented two types of stories: in one condition participants were told a humorous story making light of the body part investigated and in the other condition participants were told a real-life story about a courageous individual coming to terms with their serious problems concerning their rectal and anal disorder.

METHOD

Participants

One-hundred and fifty-four participants were randomly selected to participate in the study and asked to read a brief text and then to fill out our paper and pencil questionnaire. There were 64 men and 90 women that ranged in age from 19 to 70 years (mean = 34.45, standard deviation = 12.87). The questionnaires were administered at the University of Pescara (central Italy) and the rest in other previously identified public places such as gyms and parks. We checked whether participants had been to a medical specialist for problems concerning the anus o genitals, or had surgery (even only as an outpatient) in the last five years. In our sample, 21.1% of the participants had been to a medical specialist and 3.9% had some sort of surgery on at least one of the ten body parts investigated. More specifically visits with the specialists concerned in greater part the genitals

(14.9%) than the anus (6.2%), as well as surgery interventions concerned more the genitals (3.2%) than the anus (0.7%).

Procedure

All test subjects were current residents of Pescara, Italy. Subjects were asked to take part in a study to investigate cognitive perceptions of body parts. While waiting for the test administration participants were randomly assigned to one of three experimental conditions, where they were asked to read one of three different texts. Each text was about ten lines in length and participants took about one minute to read it. As described in greater detail below, one text consisted merely in a privacy statement (control group), the other two presented two variations of a "nudge" based on priming. The first one was aimed to make the participants grin and chuckle about problems in the anal region, the second was aimed to engage participants in a real story of a courageous individual coming out publicly about their anal area problems.

After reading the text, participants completed a questionnaire which was an evolution and an extension of the one already used by Klonoff and Landrine[7] to investigate the relationship between cognitive representations of body parts and health seeking behavior. In the questionnaire, subjects were asked to describe their genitals and their anus by rating each on 13 items: Important, Dirty, Private, Good, Sensitive to Stress, Embarrassing, Sexual, Useful, Disgusting, Easily Hurt, Erogenous, Ugly and Weak.Each of these descriptions was followed by a scale ranging from 1 (not at all) to 7 (extremely). For each body part, as an index of orientation to seek help and to reveal openly their physical problem, participants assessed on the same 7 points scale how much that body part could become object of a conversation and self-disclosure. Filling out the questionnaire required about three minutes.

Nudge Manipulation

The two nudges consisted in the following: recounting the real-life story of the actress Farrah Fawcett (one of the original Charlie's Angels's) and her battle with anal cancer that began in 2006 and ended in her death in 2009, and reading a humorous story.

Farah Fawcett was diagnosed with rectal cancer in 2006 and began treatment, including chemotherapy and surgery. Four months later, Fawcett was, at that point, cancer-free. In May 2007, she was told a malignantpolyp was found where she had been treated for the initial cancer. She traveled to Germany for treatments and initially the tumors were regressing, their reappearance a few months later necessitated a new course of treatments, this time including laser ablation therapy and chemoembolization. Aided by friend Alana Stewart, Fawcett documented her battle with the disease.

In 2009, Farah died and through the documentary movie she made during her ordeal she raised awareness about anal cancer, the danger of unprotected anal sex, which had caused her cancer and the importance of early detection and screening.

The humorous story went like this: A man urgently consults his doctor complaining of very bad diarrhea. The doctor, who prefers natural based non-invasive solutions, prescribes as treatment the use of a lemon. The result is extraordinarily effective and within hours, the man expresses satisfaction that the problem has been promptly fixed. After three days, however, the man returns to the doctor very disappointed, complaining that the problem has returned worse than before. The doctor expresses surprise since he was convinced that the lemon had worked. The man indeed confirms that in fact the problem was resolved until at a certain point the lemon came out!

RESULT

We first runned a Manova on the presence (humor and inspirational story) versus absence (mere privacy statement) of the nudge and the body parts (genitals versus anus) as the independent variables and the participants descriptions of these body parts as the dependent variable. We found no interaction effects for the factors on any decriptions so the presence of the nudge, in spite of the fact it was focused only on problems concerning the anal region affected both the perception of the anus and genitals confirming the "psychological consistency" of this body region.

We found three main effects of the nudge. It affected how much the pelviperineal region was perceived as dirty, F (1, 153) = 9.71, $p < .01$, embarassing, F (1, 153) = 39.57, $p < .001$ and disgusting, F (1, 153) = 7.77, $p < .01$.

Specifically, the nudged group rated the region as less dirty (M = 3.95, SD = 1.73) than the control group (M = 4.58, SD = 1.82), the nudged group rated the region as less embarassing (M = 4.1, SD = 1.71) than the control group (M = 5.28, SD = 1.57), and finally the nudged group rated the region as less disgusting (M = 3.39, SD = 1.62) than the control group (M = 3.91, SD = 1.7).

These three descriptive dimensions showed a strong internal consistency among them (Alpha = .76), therefore as found in earlier studies they saturated the psychological construct of Stigma associated with the body parts (Klonoff and Landrine, 1992)

Consistently with previous research (Verdi and Pietroni, 2014[b]), we found a number of main effects for the specific body part (genitals vs. anus). Since the aim of the present study is not to broaden these findings, we just listed them. The anus was perceived as less important, more dirty, less good, more embarassing, less sexual, more disgusting, less erogenous, and more ugly than the genitals.

Humor vs Inspirational story

To check the differential effects of the two types of nudges on the perception of the pelviperineal region we runned an ANOVA with the nudge typology as the independent variable. We found a main effect for typology on three genitals/anus perceptions: Sensitiveness to Stress, F (1, 57) = 8.59, $p < .01$, Easiness to Hurt, F (1, 57) = 4.94, $p < .05$, and Weakness, F (1, 57) = 7.14, $p < .01$.

Specifically, priming participants with a touching story about another individuals anus health problems lead them to perceive the region as being more sensitive to stress (M = 4.89, SD = 1.33) compared to using a joke (M = 4.08, SD = 1.62), more vulnerable (M = 5.02, SD = 1.38) compared to using a joke (M = 4.42, SD = 1.52), and weaker (M = 4.21, SD = 1.42) compared to using a joke (M = 3.53, SD = 1.32).

On the other hand, jokes and stories are equally effective compared to the control group in contrasting stigmatization of the region, i.e. to mitigate the perception of dirtiness, embarassment, and disgust.

To investigate if this effect could be mitigated by gender, age, and the clinical history of participants (medical visits and surgery interventions), an ANOVA was conducted including these factors. Results showed only a tendentially significant interation effect between nudge typology and gender on dirtiness perception, F (1, 57) = 3.74, p = .05, while the story was equally effective for men and women in mitigating the perception of dirtness, the jokes tended to be more effective for males (M = 3.18, SD = 1.88) than for females (M = 4.5, SD = 1.34).

Embarassing disclosure

Since the main goal of the present study is to facilitate individuals towards an open discussion about genital and anus health problems so as to overcome the inihibiting stigma associated to this region, we runned an ANOVA investigating the willingnes to make these body parts objects of conversation as the dependent variable and nudge presence, gender, age and clinical history as the independent factors.

We computed the age factor by spliting the participants into two groups (younger and older) on the basis of the median age of the sample (31.5 years).

We found a main effect for nudge presence, F (1, 153) = 8.52, p = .01, and a main effect for age, F (1, 153) = 5.62, p = .05. Furthermore, we found an interaction between these factors, F (1, 153) = 4.01, p = .05.

Participants primed with the nudge (both the humorous and inspirational story) were more open to speaking about their anus and genitals (M = 4.41, SD = 1.48) compared to the control group merely exposed to a privacy statement (M = 3.91, SD = 1.87). Older participants were more willing to engage in a frank conversation about this problem in the area (M = 4.25, SD = 1.84) compared to younger participants (M = 3.95, SD = 1.64). Futhermore, the presence of the nudge affected significantly more the propensity towards disclosure in the more mature participants (from M = 3.94, SD = 1.99 to M = 4.96, SD = 1.73) compared to the less mature participants (from M = 3.87, SD = 1.71 to M = 4.06, SD = 1.56).

This pattern was stable independently from gender and the clinical history of the participants.

DISCUSSION

We expected to find some differences between the inspirational and humorous story, as the former has the capacity to set an example moving individuals toward an open and brave approach in facing their health issues in a stigmatized body part, while the latter could be perceived as a rougher way to create a more relaxed and less embarrassing environment[8]. However, the humorous story appears as efficient as the inspirational story in nudging embarrassing health disclosure. Furthermore, as inspirational narratives usually recount in a more detailed manner how the problems were confronted and provide details about negative events, they indirectly could prime a sense of danger and further discomfort associated to the stigmatized body region. Actually, we found that Farrah Fawcett's story (the inspirational text) led to the perception in test subjects of their pelvic region as more vulnerable to stress, more sensitive and weaker. This perception could sensitize individuals about problems concerning this body part and to have a more responsible approach towards monitoring this region[2]. In addition, this change in perception could increase individuals empathy towards others that have problems in this body part. On the other hand, this increased awareness could add further negative sentiments, such as fear and avoidance, with respect to a body part which already easily evokes aversion. So if this increased vulnerability perception can ignite more awareness towards disease in this region and a more proactive approach in early treatment, it might have the double edged result of also producing anxiety and a feeling of danger concerning an area of the body already associated with negative emotions.

Humorous stories however seem to have the potential to mitigate the embarrassment associated with the most stigmatized body parts, to reduce negative emotions, and in encouraging positive and relaxed disclosure. The only precaution that emerges from the data concerns a part of the target audience; women associated a greater sense of dirtiness and roughness towards jokes. Given this fact, our recommendation is to create narratives that are humorous but that do not contain explicit references.

Even though the two body parts investigated are perceived differently, i.e. the anus is perceived as less important, more dirty, less good, more embarassing, less sexual, more disgusting, less erogenous, and more ugly than the genitals, it's interesting to note that the mitigation of the embarrassment as well as the promotion of disclosure had an effect on both body parts in question. Specifically, even though the humorous and the inspiration story concerned the anal region, it produced the same positive changes in perception and potential behaviour also about the genital body parts. In the end, by encouraging individuals to speak about their problems in the anal region it led them to also become more willing to speak about problems in the genital region. Further research could investigate if the same contagion effects are produced the other way around, more specifically by jokes highlighting genital parts. However, we suspect that given the fact that the genitals are perceived as cleaner and more important and are perceived in a more positive light than the anal region, that these spill over effects would not be easily found.

Verdi & Pietroni[2] found that, consistently with previous research[7], there were four factors that led individuals not to seek help including perception of areas as not important, stigmatized, not vulnerable, and sexualized. . Through a regression analysis we found that the second most important factor that inhibits help *seeking* is stigma, i.e. the association of the body parts with a sense of embarrassment, dirtiness, disgustingness and ugliness. It's reassuring that our nudge produced effects on this key factor without undermining the strength of the first one, i.e. the perception of importance of the body parts in question. Our concern was that perhaps a body part that is object of a joke could implicitly lead individuals to perceive it as less important, and consequently less deserving of health monitoring. Lastly, humorous stories seem to have the potential to be liberating without negatively impacting health disclosures of stigmatized regions.

Our studies do not allow us to generalize this claim to the most likely sensitive target, i.e. individuals who actually suffered severe health problems in the pelviperineal region and who could find the use of humorous story telling degrading. In fact, only 6 participants out of 154 (3 in the humorous condition) declared to have had a facial a surgery intervention. Our analysis did not show a different effect of the jokes on this factor but of course the statistical relevance is weak. However, a reassuring cue can be found observing that the 21,1% of participants which had at least a consultation with a specialist about health problems in the region did not respond differently towards both the inspirational and humorous stories compared to the rest of participants.

Our nudge worked maximally on the portion of the participants that was older. Meaning that the intervention produced the greatest effect on disclosure in the more mature individuals. This effect could be due to two factors: a greater sensitivity of this older group towards this type of intervention by providing a pretext to speak about this issue compared to younger people. Or on the other hand, perhaps young people have a strong aversion towards self-disclosure which makes soft facilitative interventions (like nudges) ineffective in overcoming their resistance towards open conversations concerning stigmatized body parts. This pessimistic suggestion could be hopefully confuted by future research focusing on producing more effective nudges geared specifically to different target audiences like young

women maybe through the use of group discussions and focus groups.

DISCLOSURE STATEMENTS

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

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APPENDIX

Behavioral science: the systematic analysis and investigation of human and animal behaviour through rigorous scientific experimentation.

Nudge: positive reinforcement and indirect suggestion/s to try to achieve non-forced compliance and gently influence the motives and decision making of groups and individuals.

Priming: an implicit memory effect in which exposure to one stimulus influences the response to another stimulus.

Storytelling: a universal means of entertainment, education, and cultural preservation, that aims to instill moral values and life lessons to the listener through a vivid oral illustration of significant events.

Subconscious clues: subtle messages that provide information and that impact the experiences of the receiver.

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Multidisciplinary Editorial Comment: the Physiotherapist

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.

The biggest challenge for a physical therapist who deals with pelvic floor issues is to make any direct physical contact with the body as minimally invasive as possible, not so much on the physical level as on an emotional level.

Hand contact is in fact frequently aimed at gaining awareness and therefore it takes time and there is the need to be physically in contact with the genital area and / or rectal area for thirty minutes during the session.

Telling stories or anecdotes even when handling these private parts makes the treatment more pleasant and provokes less of an emotional impact. Laughter plays down the sense of embarrassment given by the situation itself.

The body primarily benefits. The resulting muscle relaxation are proof of this.

On the other hand, telling inspirational stories can upset the individual and lead to the creation of additional fear, giving rise to questions such as: "could I also have that problem?".

We are not always able nor willing to tell our patients a joke, as described in the article, but often we simply make a few gags. For example, many times during an anal examination the patient tends to stiffen. Saying a phrase like: "I would like you to give me back my finger at the end of the visit" provokes a reaction of laughter and with it a release of the anal muscles.

The psychologists provide much food for thought for the physiotherapist. The article provides valuable insights, in particular, it focuses on a less "formal" way of relating that is more relaxed and comfortable. It stimulates the therapist to reduce the level of detachment and cultivates an attitude of empathy that takes into account not only the pathology of the person but also the emotions that are provoked as a result of it.

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Technical note and review

Literature review of vaginal leech infestation and the use of vaginoscopy during its management

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Abstract: There are few case reports in the world literature in English of vaginal leech infestation in pre-pubertal, menstrual and post-menopausal females. The usual presentation is painless continuous vaginal bleeding. Blood transfusion was required in half the published case reports. Vaginoscopy seems to be underused, as there is only one recorded case report of its use during the management of vaginal leech infestation in a teenage girl.

Key words: Vaginal leech infestation; Painless vaginal bleeding; Pre-pubertal vaginal bleeding.

LITERATURE REVIEW

Leeches are annelids (segmented worms) in the subclass Hirudinea. They can be found in most areas in Australia in both damp land and aquatic habitats. Australian leeches have two jaws and produce a V-shaped wound. Leeches of the Gnatbobdellida genus are sanguivorus and release hirudin, an anticoagulant protein which acts via direct thrombin inhibition[1].

There are few case reports in the world literature in English of vaginal bleeding secondary to leech infestation in pre-pubertal, menstrual and post-menopausal females. They generally describe continuous, painless passage of bright blood per vagina. In 1968, was the first recorded case of a 45 year Bulgarian woman who had haemorrhage secondary to a leech in the vaginal wall[2]. The severity of bleeding reported varies among case reports from mild asymptomatic bleeding to significant anaemia. The most recent publication in 2013 describes two cases of profuse vaginal bleeding and hypovolaemic shock in women aged 21 years and 20 years in South India[3]. Both women had histories of swimming in natural bodies of water and each presented after a number of days with profuse, bright vaginal bleeding and haemodynamic compromise. Their haemoglobin levels were 60g/L and 50g/L respectively and they both required blood transfusion. Rao et al described the need to pack the vagina to stop the bleeding in 48 years old woman[4]. A 45 years old woman had an unnecessary hysterectomy due to failure to diagnose the vaginal leech as the cause of her vaginal bleeding[5].

The duration of bleeding varies between reports from a few hours to days and even a report of four months of continuous vaginal bleeding. Patient demographics and clinical details of other reported cases, including the duration of bleeding, haemoglobin, method of diagnosis and treatment of vaginal leech are summarised below (Table 1).

The usual method of removing leeches involves application of salt to the skin or disruption of the attached jaw by sliding a sharp object or fingernail under the point of attachment. However, when the leech embeds within the vagina, this makes both diagnosis and management challenging. A number of cases report irrigation of the vagina with normal saline to dislodge a leech and one case describes a method of injection of the leech with lignocaine.

Previously, there were four cases published in world literature of vaginal leech bite in pre-pubertal girls, two of them required EUA and none used vaginoscopy during the diagnosis[6-8]. The examination of pre-pubertal children poses difficulty due to a small vaginal orifice, unestrogenised vaginal tissue susceptible to trauma and an intact hymen. Prior to this case, there were no reports of the use of vaginoscopy under anaesthesia for diagnosis of leech bite in a pre-pubertal child and there are no published photos of the vaginal lesion appearance caused by a leech bite. In 1983, Vallerino et al reported the use of vaginoscopy in diagnosis of vaginal leech in a teenage girl[9].

VAGINOSCOPY

Vaginoscopy seems to be underused in this clinical situation, as there is only one recorded case report of its use during the management of vaginal leech infestation in a teenage girl.

The examination of pre-pubertal children poses difficulty due to a small vaginal orifice, unestrogenised vaginal tissue susceptible to trauma and an intact hymen. There are no reported cases of the use of vaginoscopy in pre-pubertal girls.

We report the first use of vaginoscopy under anaesthesia for the diagnosis of leech bite in a pre-pubertal girl.

An 8-year-old pre-pubertal female underwent air evacuation from a remote Northern Territory community to Royal Darwin Hospital (RDH) for heavy vaginal bleeding. History revealed that she had been swimming in a local billabong and a number of had removed a leech from her vaginal introitus after experiencing a non-painful sensation. Following this event child experienced continuous bright vaginal bleeding of moderate amount. This was noticed by her aunt who sought review at the community primary

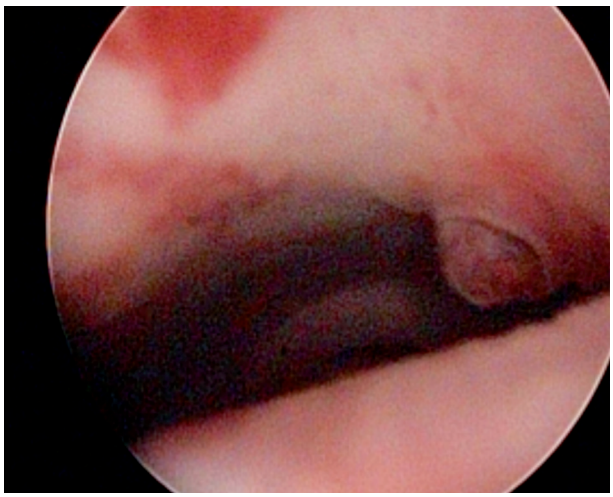

Figure 1. – Vaginoscopy revealed a 3 – 4 mm ulcer on the left side of anterior vaginal wall caused by vaginal leech (the ulcer is seen on the right side of the photo). The anterior lip of the cervix is seen (above the ulcer) at the centre of the top of vagina.

TABLE 1. – All cases of vaginal leech published in World Literatures in English up to August 2015. EUA: Examination Under Anaesthesia - Hb: Haemoglobin – BT: Blood Transfusion.

Publication	Age	Bleeding duration	Hb (g/L)	BT needed	Method of Diagnosis and Management
Senthilkumaran et al. 2013 (3)	21	2 days	60	Yes	EUA showed 3 live, engorged leeches removed with forceps.
	20	6 days	50	Yes	Initial treatment with oral contraceptive pill unsuccessful. EUA showed 2 live leeches removed with surgical forceps.
Rao et al. 2010 (4)	48	1 day		No	Per vaginal speculum examination showed a large leech extruding from the introitus that was dislodged with vaginal irrigation of NaCl. Vaginal packing of wound due to ongoing bleeding.
Shamdeen. 2007 (5)	45	4 months	70	Yes	Initially presumed to be uterine bleeding and managed unsuccessfully with oral progestagen and diagnostic curettage. Proceeded to total abdominal hysterectomy but ongoing bleeding post-operatively. EUA on day 5 post operative revealed a leech that was dislodged by injection with lignocaine and removed with sponge forceps.
Habtai et al. 2009 (6)	6	4 days	100	No	Saline vaginal irrigation and removal of leech with forceps.
Saha et al. 2005 (7)	5	2 hours	95	No	EUA and exploration of vagina with nasal speculum showed a live leech removed with surgical forceps. Vaginal packing of wound due to ongoing bleeding.
	7	14 hours	75	Yes	EUA with vaginal irrigation of NaCl via small feeding tube and extrusion of a leech. Vaginal packing for ongoing bleeding.
Ibrahim et al. 2003 (8)	9	24 hours	73	Yes	Vaginal irrigation with 20ml NaCl and extrusion of a leech. Bleeding continued for 24 hours after removal of leech and was managed conservatively.
Vallerino et al. 1983 (9)	14	8 days	110	No	Leech crawled out from vagina after admission to hospital. Bleeding ceased immediately. Vaginoscopy showed 1cm ulcerated lesion on posterior vaginal wall.

health clinic. There was no visible trauma to the external genitalia noted by the clinic staff and bleeding continued despite fifteen minutes of application of pressure with gauze pack to the introitus. In response, the clinic organised transfer of the child and her aunt to RDH for further evaluation and management.

On history taking at RDH there were no inconsistencies between the child's account and that of her aunt and no suspicion of child sexual abuse. The amount of blood loss was unable to be quantified and there was no report of dizziness, dyspnea or other symptoms of anaemia. Examination revealed the child was pre-pubertal (Tanner Stage 1) and of slight stature with weight 26kg. Her vital signs were within normal limits and her abdomen was soft and non-tender with no palpable masses. Examination of the external genitalia was unremarkable other than a large blood clot at the introitus, which was dislodged, causing a continuous trickle of bright blood per vaginum. It was therefore decided to proceed with examination under anaesthesia (EUA) and vaginoscopy. This occurred 24 hours after the child first noted the bleeding. The patient's haemoglobin was 111g/L on admission.

Findings from EUA were normal external genitalia with intact hymen and no evidence of injury. A 4mm, 30-degree Hysteroscope with irrigating sheath was used to perform vaginoscopy with Normal Saline distension of the vaginal. A large abdominal pack was held against the introitus to reduce saline leak to achieve adequate distention of the vagina. Good view was achieved, there was a 3-4 mm lesion in the form of an ulcer on left side of anterior vaginal wall at the proximal third of the vagina. The lesion was consistent with a leech bite and was not actively bleeding (Fig. 1). We provide the first ever photo showing the appearance of vaginal lesion caused by a leech bite.

Although not needed in this case but the saline jet used during vaginoscopy may be very helpful in washing out a leech that may be seen inside the vagina during the procedure.

This is the first published account of vaginal leech bite in Australia, a setting where leeches occur in all areas of the country that are non-arid.

CONCLUSION

Vaginal leech infestation is a rare event. It should be considered when encountering women especially young girls presenting with painless vaginal bleeding without history of trauma. The use of saline vaginoscopy should be considered when vaginal leech infestation is suspected especially in in pre-pubertal girls.

STATMENT

There was no conflict of interest.

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Surgical treatment of a patient with "enteroptosis" (prolapse of uterus, vagina, bladder, rectum)

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Abstract: Abstract: A 81-year-old patient with prolapse of uterus, vagina, bladder and rectum (enteroptosis) was cured anatomically and functionally by an entirely vaginal operation. During the same session all deficient connective tissue structures of the pelvic floor were repaired according to the Integral Theory. This case with excellent results demonstrate a less invasive alternative to classical surgery.

Key words: Rectal prolapse; Uterine prolapse; Enteroptosis; Integral Theory; Sacrospinous fixation; Total pelvic reconstruction.

INTRODUCTION

Understanding the anatomical basis for rectal and uterine prolapse formation is fundamental to plan surgical repair thereof. Rectocele and rectal intussusception repair has been influenced by the Integral Theory[1]. The theory states, that abnormal bladder symptoms, abnormal bowel symptoms and vaginal prolapse are related and mainly caused by connective tissue defects in 3 zones of the vagina. A normal defecation is only possible if the anterior rectal wall is stretched. With a defect in the rectovaginal fascia (RVF) or uterosacral ligaments (USL), the anterior rectal wall can not be stretched sufficiently. The stool can not escape directly to the anus, because faeces reaches first the dilated anterior rectal wall to be decelerated in the bulge. The increased pressures in the wrong direction overstretched the RVF further and generates a rectocele. The evolving outward rectocele pulls the proximal rectal wall down inside. This leads to invagination of the wall, to intussusception, and lastly to internal and external rectal prolapse. Clinically this manifests itself in incomplete emptying, symptoms of abnormal anorectal closure, rectal intussusception, external hemorrhoids or – as in our case – anorectal prolapse. Because all structures, rectum, vagina, suspensory ligaments, fascia and muscle forces work synergistically, all deficient connective tissue structures need to be repaired for adequate restoration of anatomy and function.

PATIENT AND METHOD

A 81-year-old patient came with complaints of a palpable mass in the vagina and anus, obstructive defecation symptoms, rectal bleeding, stress and faecal incontinence. She had a uterine and posterior vaginal wall prolapse III° according to the halfway classification system, an entero/rectocele III° and a full-tickness rectal prolapse (Fig. 1). On admission she was asked to fill a questionaire developed by P. Petros[2].

According to this questionnaire she suffered from

- discomfort and pain due to prolapse dragging
- nocturia (>2 per night)
- bladder emptying problems
- stool outlet obstruction
- discharge of mucus and blood from the anus
- faecal incontinence
- urine incontinence.

Therapy

1. In consideration of replacing the rectal prolapse and normalizing the anatomy of the posterior wall we performed a posterior IVS operation in combination with bilateral sacrospinous tape fixation, a posterior bridge repair and a perineal body repair.

2. In order to restore the uterine and anterior vaginal wall prolapse we used an anterior 4-arms mesh. The anterior 2 arms we inserted transobturatorially. Than the cervix was surrounded by the posterior 2 arms, which were fixed to the sacrospinous ligament both sides.

3. Concerning the stress incontinence we inserted a suburethral transobturatorial sling.

Local estrogens were administered six week before surgery and a proper informed consent was obtained for the operation.

Procedure in detail

Level I repair: After local injection of bupivacain with adrenalin a transverse incision approximately 4-5 cm long was made in the posterior vaginal wall 1,5 cm below the cervix and opened antero-posteriorly. A Sims speculum was inserted to open out the incision. A rectal examination was performed to identify the limits of the rectocele and enterocele. Adherent enterocele was freed from adjoining tissues so as to avoid damage by the tunneller. The laterally displaced uterosacral ligament remnants were localized. The enterocele sac was reduced with a pursestring suture.

With a digital blunt preparation the sacrospinous ligament was freed from adhearent tissue and 2 prolene sutures 2-0 were inserted into the ligament on both sides with a sacrofix device according to Goeschen.

Bilateral incisions 0.5 cm long were made in the perianal skin at 4 and 8 o clock, halfway between the coccyx and the

Figure 1. – Uterine and posterior vaginal wall prolapse III° combined with a full-tickness rectal prolapse.

external anal sphincter (EAS) in a line 2 cm lateral the EAS. Starting at the left side the IVS Tunneler was placed into the ischiorectal fossa for a distance of 6 cm. Under direct vision, with a finger placed into the rectum, the tip of the tunneler was gently pushed through the levator plate, inclined medially towards the vaginal vault by rotating the delta wing and brought just behind the uterosacral ligament. The tip penetrated through the recto-vaginal fascia and reached the transverse incision. 1 prolene suture from each side was stiched through the middle of the tape in a distance of 4 cm.

Then the procedure was repeated on the contralateral right side, leaving the tape as U entirely unfixed at the sacral end. The tape was secured to the vaginal vault, also to the remnants of the uterosacral ligaments and the cervix with interrupted no. 1 vicryl. The tape was then gently stretched by pulling on each perineal end.

Level II and III repair: **Repair of the anterior vaginal wall:** After local injection of bupivacain with adrenalin a full thickness elliptical incision, 3 cm wide, over the herniation of the cystocele was made, extending from 2 cm distal of the bladder neck to the cervix. The cut edges of the incision were grasped with Allis forceps and the space between bladder and vaginal wall was opened out with a scissors and blunt dissection up to the arcus tendineus fasciae pelvis (ATFP).

Extensive diathermy was used to destroy the superficial vaginal epithelium overlying the bridge. The anterior part of the bridge was anchored by burrowing 0.5 cm below the anterior border of the incision, the posterior part in the cervix. The cystocele was reduced with 4 mattress sutures extending from one to the other side and attached to the bridge in two layers.

Anterior transobturator mesh support: Because of the poor tissue a ribbon of polypropylene mesh (Premilene LP) 5 cm wide, 30 cm long was cut in a figure with two arms on each side. The anterior two arms of both sides were placed with a special instrument between the pubococcygeous muscle and the vaginal skin, running from the arcus tendineus of one side to the arcus of the other side and pulled out transobtoratorially. It was placed without tension across the midline defect to reinforce the weakened tissue. The mesh was sutured with Ethibond 0 lateral to the pubococcyc was muscle and to the cervix in order to get the mesh flat. The posterior two arms were placed around the cervix subepithelially and than connected with the remaining sacrospinous sutures, one right, one left. The pubocervical fascia was narrowed with U-sutures to cover the mesh. The skin incision was closed by a continuous longitudinal no. 1 Dexon locked running suture.

Repair of the posterior vaginal wall: After aquadissection using bupivacain with adrenalin in the posterior vaginal wall two full-thickness parallel longitudinal incisions, 2cm wide, were made along the posterior vaginal wall, extending from the transverse incision to 1 cm distal to the introitus. Extensive diathermy was used to destroy the superficial vaginal epithelium overlying the bridge. The margins of the bridge were sutured with interrupted sutures resulting in a double layer bridge. Adherent rectum was freed from the vaginal wall and perineal body (PB) over the distal 3-4 cm of vagina. The rectocele was reduced by using laterally placed horizontal mattress sutures. These sutures run through the bridge and were tied without tension so that the rectum-tube had a normal width and strength. Two transverse vaginal holding sutures (1 PDS) were placed as laterally as possible, one at the level of the uterosacral ligaments and the other at the level of the rectovaginal fascia (RVF) and left untied. These sutures run subepithelially as a horizontal mattress suture through the bridge. The bridge was anchored separately at the tape above and at the perineal body below.

The horizontal limbs of the "Y" were sutured with interrupted no. 1 vicryl sutures, followed by a continuous longitudinal one. The four sacrospinous and the PDS sutures were tied only with so much tension, that was necessary to bring all pelvic organs in normal position. Finally one vicryl unlocked running suture was placed which approximated the lateral cut edges. The bridge was buried below the lateral flaps. The coccygeal and obturatorial ends of tape were cut, and left tension-free.

Paraurethral transobturator IVS: After local injection of bupivacain with adrenalin paraurethrally two full-thickness longitudinal incisions were made in the lateral urethral sulcus, extending from just below the level of the external urethral meatus to the level of midurethra. A suburethral tunnel was created between vagina and urethra. On the left side a small skin incision was made at the level of the clitoris. A special Deschamp was inserted transobturatorially into the paraurethral cut. Then an 8 mm polypropylene tape was threaded into the eye of the instrument, and pulled out through the skin cut. By inserting an Overholt forceps into the suburethral tunnel the tape was brought into the right contralateral vaginal incision. The tape insertion was completed on the contralateral right side. On both sides the

Figure 2. – Final result after the operation.

Figure 3. – Seven days postoperatively the anorectal and vaginal anatomy has already become normal.

Figure 4. – Anatomical result one year after operation.

hammock was attached with vicryl No 1 to the anterior portion of pubococcygeus muscle. The incisions were closed with a continous suture.

The bladder was filled with 300 ml fluid and the catheter removed. In order to avoid excessive tension and urethral constriction by the tape the tunneler was inserted into the urethral cavity when tightening the two limbs of the tape. While testing for continence by tapping on the bladder no urine leakage was observed.

RESULTS

Anatomy: The final anatomical result immediately after surgery is demonstrated in Fig. 2. Seven days postoperatively the ano/rectal and vaginal anatomy has already become normal (Fig. 3).

Clinical Course: The patient had no complications and only less pain during the hospital stay and later on. Bladder- and ano/rectal-function were normal without any signs of incontinence. Discharge from hospital was on the third day postoperatively.

Follow up: A follow up check was performed 3 months and one year after surgery. Both examinations showed a normal anatomy (Fig. 4.) In addition to the preoperative examination the patient was encouraged to fill the questionaire again with the result that now bladder and anorectal function were physiological and the quality of life excellent.

DISCUSSION

Rectal prolapse is a rare entity which is formed by an intussusception of all rectum layers due to lax USL[3]. With lax USL levator plate cannot tension the RVF. The force of gravity and pressure from above during defaecation causes the rectal wall to prolapse inwards[3] and finally throughout the anus (Fig. 5).

Despite its rarity more than 100 surgical procedures have been described and there are no good evidence based recommendations for these surgical procedures[4,5,6]. According to Graf et al.[7] the defecation improved only in 5%, fecal incontinence only in 16% after conventional operations. Overall good or excellent surgical outcomes were only achieved in 16% of all cases.

A recent publication from Koscinski et al.[8] showed good anatomical and functional results after a combined abdomino/vaginal perineocolporectopexy using a polypropylene mesh. We tried to cure our patient suffering from complex pelvic floor pathology entirely with an much less invasive vaginal approach.

Our patient had a combined prolapse of all pelvic organs (uterus, vagina, bladder, rectum). The better description for this situation is "evisceration or enteroptosis" as a result of weakening in the complete ligamentary holding system.

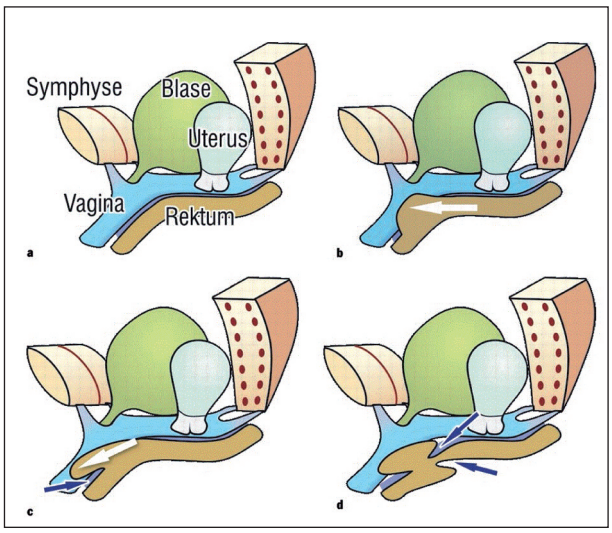

Figure 5. – Development of a rectocele, intussusception and rectal prolapse. a) With intact rectovaginal fascia and tight uterosacral ligaments the anterior rectal wall is stretched and faeces freely can pass through the rectum. b) If a defect in the rectovaginal fascia press the stool the anterior rectal wall to the front and slow down (white arrow). The patient must press increased, in order to empty the intestine. c) Due to increased pressure intensified the rectocele (white arrow), leading to the notch in the intact rectovaginal fascia (blue Arrow) and pulls at the proximal rectum. d) In case of defective uterosacral ligaments, the rectum can be curl inward, to narrowing of the lumen lead (blue arrows) and the increase constipation (9).

Therefore our aim was not to excide herniated tissue, but to repair all deficient connective tissue structures for adequate restoration of function according to the Integral Theory of Petros[1,2]. This concept is consistent with the Baden and Walker (1992)[10] developed tent theory. They have postulated that if a tent roof incident, the walls will follow.

The Integral Theory states that abnormal bladder and bowel symptoms as well as vaginal and rectal prolapse are related and mainly caused by connective tissue defects in the 3 zones of the vagina. Lax connective tissue structures invalidate the muscle forces involved in opening and closure of urethra and anorectum, leading to incontinence (abnormal closure) or retention (abnormal opening). Normal defecation thus is only possible if the anterior rectal wall is stretched.

The posterior vaginal wall is suspended between perineal body (PB), which underlies half its length, and USL, which also support the anterior wall of rectum[1,2]. These structures are at least 6 times stronger than the vaginal or rectal mucosa which they support[11]. Loose USL and lateraly displaced RVF therefore leads to entero-/rectocele and anorectal prolapse in a high percentage.

Understanding these interelationships we repaired all 3 zones of the vagina in our patient. In analogy to the tent theory we renewed the USL at level 1 and all defective structures in level 2 and 3. This stretched the RVF, eliminated the bulge of the anterior rectal wall and pulled the rectum back in normal position.

We added sacrospinous fixation of the posterior tape and the 2 cervical mesh arms for a higher apical support. Excision of exessive vaginal mucosa was avoided. This procedure is not able to cure a genital prolapse, but will only narrow and shorten the vagina. A short vagina cannot be properly angulated backwards and downwards around the perineal body and leads to bad functional results.

CONCLUSIONS

In the presence of intussusception or rectal prolapse, transanal, open or laparoscopic rectopexy, with or without resection, still is most popular. The Integral Theory states that these problems are mainly caused by connectiv tissue defects and can not be solved by excision of herniated tissue.We learned from our patient with enteroptosis (prolapse of uterus, vagina, bladder and rectum), that adequate restoration of all deficient connective tissue structures leads to perfect anatomical and funtional results and can be reached only by a less invasive vaginal approach.

DISCLOSURE STATMENT

We declare no conflict of interest.

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Multidisciplinary Colorectal 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.

The *tetralogy of fallout* is another interesting definition of the *total pelvic organ prolapse* or *enteroptosi* as the Author of this article names this quite incapacitating condition involving the descent of the anterior, central and posterior compartments of the pelvis in the female. Caliskan et al. describe a surgical procedure where all the three levels of pelvic support are considered and repaired. Conforming to the Integral Theory the rectal prolapse is due to a lax uterosacral ligament. Colorectal surgeons, who obviously face also in males the problem of the total rectal prolapse and of the rectal intussusception, usualyy perform sacrorectopexies through an abdominal approach or transanally resecting the prolapse (Altemayer procedure), or reducing it into the rectum itself (Delorme). It has been an interesting surprise for the colorectal surgeon applying the CR-Mesh transvaginally (Farnsworth's procedure) in patiens with the "tetralogy of fallout" to observe the complete and definitive cure of the rectal prolapse without any apparent surgical involvement of the rectum itself. But one has to be careful! Actually this technique works, but only in the cases where the rectal invagination starts at the level of the recto-vaginal septum, where the posterior mesh is placed. A rectopexy or any other posterior approach will be needed if the intussusception starts above it, like when the proximal rectum or even the sigmoid colon prolapses into the rectum all the way through the anus.

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Original article

Lift of female external genitalia after abdominoplasty: quantification and considerations about the surgical planning

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Background: weight gain and loss cause mons pubis ptosis and labia majora enlargement. This deformity may cause sexual impairment, difficult personal hygiene and discomfort. Abdominoplasty inevitably causes a lift of anterior commissure and may be sufficient to treat this condition. *Aims:* In this study we evaluate the amount of the lift of the anterior commissure. *Methods:* we analyzed seven women that underwent abdominoplasty in the last year. We measured the sternal notch – anterior commissure distance and the ground – anterior commissure distance before and 6 months after the procedure. Wilcoxon test for related samples was employed to analyze the differences after the procedure. *Results:* The sternal notch – anterior commissure distance decreased after surgery of 2.8 cm (p 0.028) and the ground – anterior commissure distance increased after surgery of 2.8 cm (p 0.028). The patients were discharged 6 days post-operatively and healed uneventfully in three weeks. *Conclusion:* Abdominoplasty could effectively correct mons pubis enlargement and ptosis of mons pubis and labia majora. We believe that the surgeon should know exactly the amount of lift of pubis after this procedure. This issue is essential to predict the results after abdominoplasty and for planning of possible suspension of mons pubis if required.

Keywords: Abdominoplasty; Labia majora; Mons pubis; Anterior commissure; Lifting.

INTRODUCTION

Several aesthetic procedures address the female genitalia. These procedures comprise those for vaginal prolapse as long as external genitalia. This kind of surgery has both a functional and aesthetic indication in most cases, although this distinction could not be clearly performed in many cases. Moreover literature is lacking about statistical and objective data concerning the true functional improvement of any single procedure on external genitalia. The border between these two indications is greatly influenced by sociocultural issues. According to some African cultures, protruding and elongated labia minora are considered attractive.[1] On the contrary, the same characteristic is often indication to surgery in western countries causing sexual embarrassment and impairment even at younger ages.[2]

In this setting, weight gain could upset and worsen the aspect of external genitalia. In fact mons pubis ptosis and labia majora enlargement are common effects of weight fluctuations. Compared to the previous mentioned hypertrophy of the labia minora alone, this deformity may cause even difficult personal hygiene, discomfort and concerns.

Several techniques have been described to correct the ptotic skin, the fatty labia majora and ptosis of the anterior commissure,[3] although this issue could be addressed also by other procedures not specifically designed for this purpose like abdominoplasty. Considering the high number of procedures, the importance of this phenomenon is high: in fact abdominoplasty is the fourth most common procedure in 2013. According to the American Society for Aesthetic Plastic Surgery, 160,077 abdominoplasty procedures are performed yearly in the U.S and 151,200 of these are performed on women.[4]

This procedure aims to correct the excess of abdominal skin and diastasis of recti muscles. However the lift of skin and subcutaneous tissue during this procedure inevitably causes a lift of the anterior commissure and mons pubis.

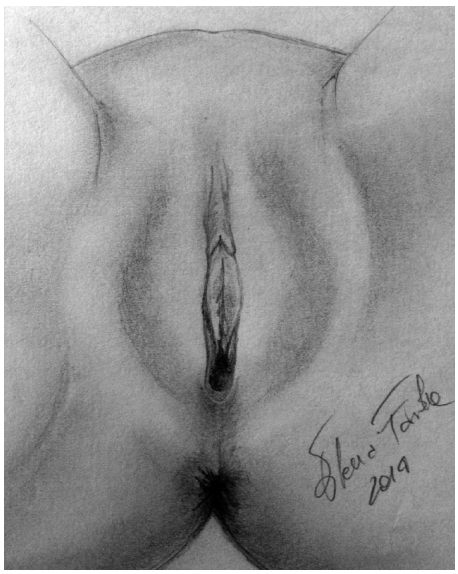
Moreover, as long as the pubis usually lengthens with age, a resection below the horizontal pubic hairline may reduce pubis height and width conferring a more youthful appearance.[5] This fact is able to positively influence the sexuality and body image of the patients changing the position of the clitoris, which becomes more exposed.[6] However literature is poor concerning the description of this important phenomenon. In our opinion the surgeon should be able to inform and indicate the patient about the grade of lift of the anterior commissure.

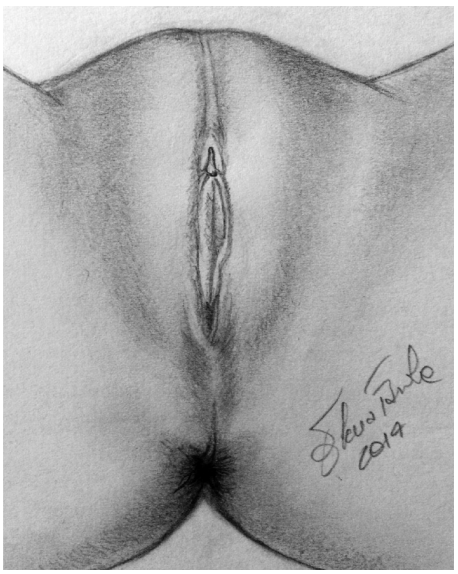
In this study we aim to study the amount of this phenomenon after a standard abdominoplasty.

MATERIALS AND METHODS

Seven women were enrolled for this study from March to December 2012. These patients underwent consistent weight loss in the past 12 months. Patients under psychiatric medication and/or affected by body dysmorphic disorders were excluded from the study. A proper informed consent was obtained in all cases.

The patients were evaluated pre-operatively and followed for 6 months after surgery. We evaluated the lift of the anterior commissure by evaluating of the sternal notch – anterior commissure distance and the ground – anterior commissure distance. In all cases a suprapubic incision extended to the supero-anterior iliac crest was performed. All the patients presented with no diastasis of the rectus abdominis muscle except one case. After correction of the cutaneous and subcutaneous excess, the umbilicus was transposed, the muscular diastasis corrected and the abdominal wall was closed in layers. Changes of the height of the anterior commissure after the procedure were analyzed with Wilcoxon test for related samples. Chi-square test was applied to study the relation between age, weight, height, BMI and commissure lift.





Figures 1-2. – The figures illustrate the changes of the anterior commissure after abdominoplasty. In some cases clitoral hood and labia majora are stretched along the antero-posterior axis, causing a better exposition of the clitoris. The mons pubis could be reduced and flattened. The posterior commissure is stretched and narrowed as well, although to a lesser degree than the anterior commissure. The changes may be transient in the post-operative period until the skin and subcutaneous layer stabilize. Illustration by Elena Fasola, MD instruments.

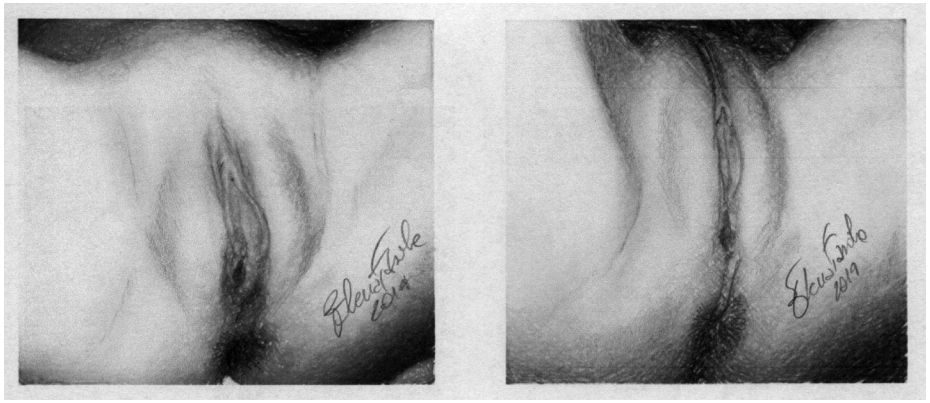


Figure 3. – The figures illustrate the changes of the anterior commissure after abdominoplasty. In some cases clitoral hood and labia majora are stretched along the antero-posterior axis, causing a better exposition of the clitoris. The mons pubis could be reduced and flattened.
The posterior commissure is stretched and narrowed as well, although to a lesser degree than the anterior commissure.
The changes may be transient in the post-operative period until the skin and subcutaneous layer stabilize.
Illustration by Elena Fasola, MD

RESULTS

The patients aged 52 years (33-71) and weighted an average of 75.2 Kg. All the patients experienced a consistent weight loss in the past two years and the mean BMI at surgery was 28.1 (Table 1).

The sternal notch – anterior commissure distance decreased after surgery of 2.8 cm (p 0.028) and the ground – anterior commissure distance increased after surgery of 2.8 cm (p 0.028) (Table 2, Figures 1-4). No significant association between age, weight, height, BMI and commissure lift was observed.

The patients were discharged 6 days post-operatively and healed uneventfully in three weeks (Figures 5-7).

DISCUSSION

The enlargement of the mons pubis and labia majora (and subsequent ptosis) are common effects of obesity in women. This condition could heavily affect the quality of life, causing sexual impairment and discomfort during the everyday life.

This issue could be addressed by a labia minora labiaplasty and clitoral hood reduction. Labiaplasty is the most common among these. Several variations of these techniques have been described since the first reports in the early ’80s.[7] These techniques mainly differ from the type of excision. The classical wedge of excision commonly produced scar adherences and contraction and was therefore replaced by different interrupted incisions, even in association with laser and radiofrequency.[8]

Instead clitoral hood reduction aims to eliminate the excess skin in the fold surrounding the clitoris, improving both the sexual function and the aesthetic appearance.[9]

Although the purpose of abdominoplasty is completely different, it could improve the aspect of ptotic external genitalia by lifting the anterior commissure. This action could be compared both to a labiaplasty and clitoral hood resection. The tightening of the abdominal skin inevitably produces the lift of the anterior commissure, better exposing clitoris and lifting labia minora.[3] This phenomenon corrects ptosis and confers a more juvenile aspect to the external genitalia. However abdominoplasty procedure could be coupled with dermal-fascial suspension, liposuction, and mons dermolipectomy to improve and stabilize the results over time.[10]

We believe that the surgeon should know exactly the lift of pubis after abdominoplasty. This is essential to predict the results after abdominoplasty, correctly inform the patient about surgery and for planning of possible suspension of mons pubis if required. In this study we observed a significant lift of 2.8 cm of the anterior commissure. The amount of lift does not depend on age, weight, height, BMI (no significant difference was found). We believe that the lift of external genitalia depends on the surgical technique and the cutaneous laxity.

The lift that we observed requires no fascial suspension, liposuction or other cutaneous excision beyond that required for the abdominoplasty. Excessive lift of the anterior commissure is to be avoided. In fact the umbilicus to pubis

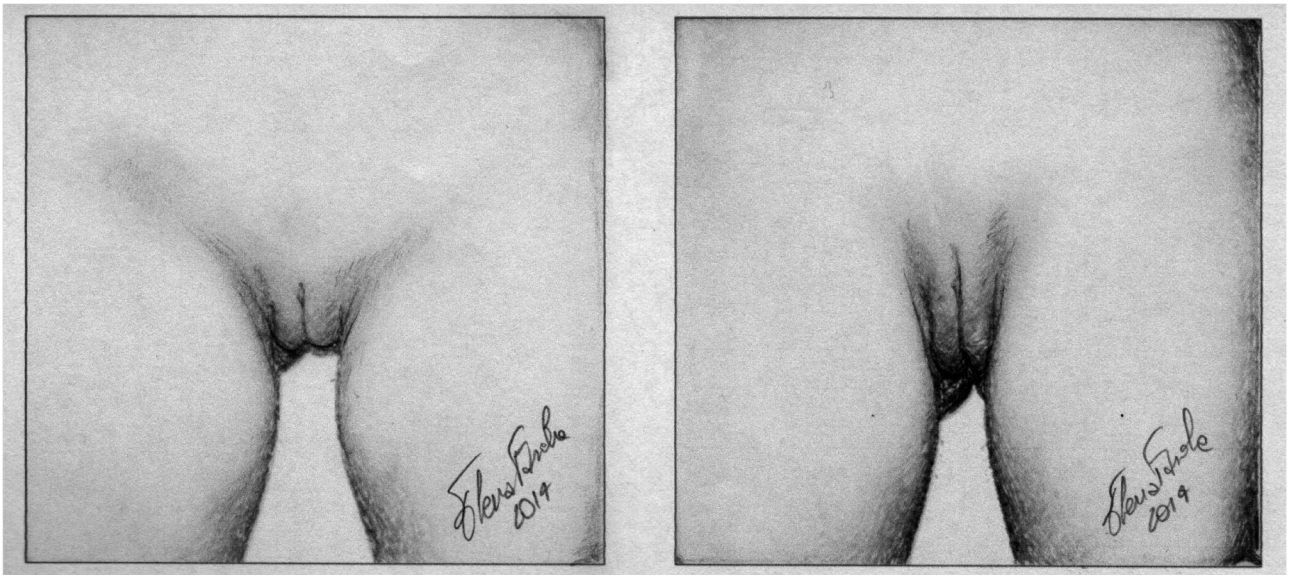
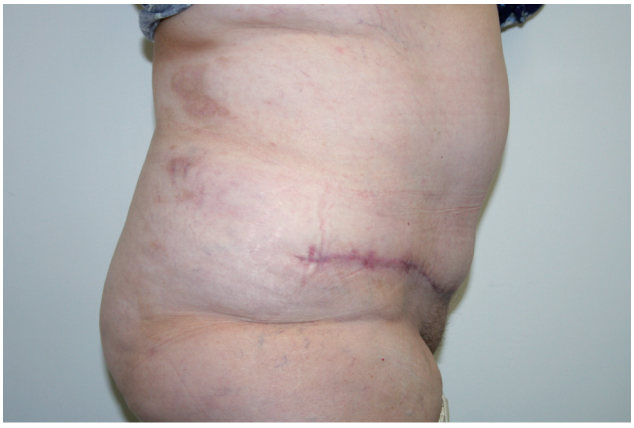


Figure 4. – Modification of the anterior commissure in orthostatism. Illustration by Elena Fasola, MD



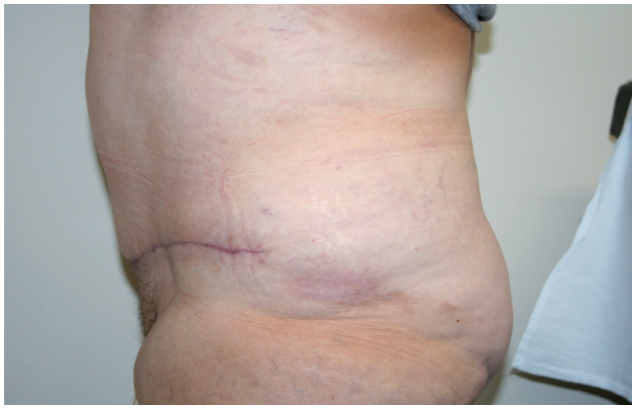


Figure 5-7. – 54 years old woman underwent abdominoplasty for cutaneous laxity after consistent weight loss (more than 20 kg). After surgery a lift of the anterior commissure of 2 cm was observed.

distance should not be inferior to 10 cm to have a natural appearance.[11]

The surgeon should be able to calculate and inform the patient concerning the amount of pubic lift and thus discuss with her the necessity of further procedures to correct the ptosis of this region.

Abdominoplasty is a procedure that can produce a lift of the anterior commissure and the mons pubis. The amount of the lift is 2.8 cm by mean. This value is fundamental and should be considered during the surgical planning in order to state the necessity of further corrective surgeries for genital rejuvenation.

Table 1.

	Average	Range
Age	52	33 - 71
Height (cm)	163.1	148 - 180
Weight (Kg)	75.2	56 - 85
BMI	28.1	22.7 - 30.1

Table 2.

	Pre-op	6 months post-op	Difference	P – Wilcoxon test
Sternal notch – anterior commissure	64	61.2	- 2,8	0.028
Ground – anterior commissure	71.3	74.1	2,8	0.028

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We acknowledge Dr. Elena Fasola MD for the illustrations of figures 1-4 and or declare no conflict of interest.

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EDITORIAL COMMENT

The problem of the prominent Mons Pubis has been tackled in various ways with liposuction, abdominoplasty, and non-surgical fat reduction (such as with laser diode, ultrasound, infrared light, radiofrequency, and injected agents) or a combination of these modalities. Success rates and patient satisfaction for these surgeries is generally high. With significant weight loss there is loose skin on the abdomen and Mons and also on the labia majora. The labia minora is much less affected by weight loss and typically should be addressed both functionally and aesthetically as a separate unit from both the abdomen/Mons and the labia majora. As gynecologists and plastic surgeons gain skills and confidence in performing aesthetic vulvovaginal procedures it is tempting to combine abdominal surgery and liposuction with genital surgery all at the same date and time. Abdominal surgery and liposuction has a long established history of clinical research but aesthetic vulvovaginal surgery is newer and certainly not an established surgery taught and learned in surgical and gynecologic training programs. This results in a dilemma on knowing what to do first in terms of surgical sequencing when dealing with abdominal and genital surgery. Trying to do both body regions (abdomen and genital surgery) at the same time can be disastrous. For example, doing abdominal and Mons liposuction at the same time as labial surgery is filled with potential pitfalls. The edema that occurs after a Mons liposuction can often extend to the labia majora and minora that makes these areas quite puffy and can cause a dramatic pulling of surgical edges. Labia majora tissues can puff up and look like large testicles and any labial reduction effects can be lost due to the stretching of skin post liposuction.

In the series of patients presented, the quantification of results is admirable as there is no current method of assessing degrees of improvement. Currently an “eyeballing” method is used worldwide. Arguably, in some patients, modified abdominoplasty is sufficient to pull up on the Mons and eliminate the need for labia majoraplasty. However, in my opinion, the majority of patients will not be satisfied with a pulling up of labia majora since there will still be loose skin and sagging with the potential of fatty material below the majora skin. The “Camel Toe” remains. In these patients a formal labia majoraplasty with fat pad reduction is recommended. In most cases, labial issues should be managed on the labia and not from above on the abdomen except when a prominent Mons is present such as in this series. I personally favor the approach the authors have made in addressing the abdominal and Mons issue first and then deciding if labial surgery is warranted. Lastly, 6 days of hospitalization is much longer than the outpatient surgery abdominoplasty has become in the United States with the advent of both pain pumps and the use of Exparel.

To complete the whole vulvovaginal and abdominal rejuvenation aesthetics, labia minora and clitoral hood issues should be considered once the abdominoplasty and liposuction are done and the labia majoraplasty has been completed. I would personally perform labial surgery immediately after abdominoplasty if no liposuction is used but wait at least 2 months if liposuction of the Mons is performed. Liposuction can cause edema that affects the labia minora and majora.

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Letter to the Editor

Dear Editor,

in a recent issue of Pelviperineology (2015; 34: 60-66) the article by A. Meneghini et al. "*Chronic pelvic pain syndrome in women. Review and preliminary results with low-energy extracorporeal shock wave therapy*" deserves a comment concerning the chronic pelvic pain syndrome (CPPS) and the use of Extracorporeal Shock Wave Therapy (ESWT). Research into CPPS is plagued by dilemmas of inconsistent definitions, misleading terminology and a lack of insight into the mechanisms of pain. Persistent symptoms of long-standing duration, a lack of demonstrable pathology as well as a history of unsuccessful consultations, result in high levels of frustration for patient and health care provider. Insights into predisposing factors and triggers continue to improve, however, the many potential causes of chronic pelvic pain, making CPPS patients a very heterogeneous group to study and the exclusion of medical causes is not always a simple process. On this account, trials of interventions and the management of CPPS becomes a challenge. Likewise, understanding of mechanisms of chronic pelvic pain appears to lag well behind. In this study each of the three patients discussed underwent multiple surgical procedures giving rise to the real possibility of iatrogenic triggers being implicated in chronic pain. Certainly palpation of the levator muscle identified tenderness and presence of trigger points as well as increased sensitivity in various pelvic structures. Given the apparent involvement of the musculoskeletal system ESWT becomes an optional intervention. As difficult as it is draw any conclusions from a study of three patients, each experiencing a different level of response, this paper provides a good overview of the classification of CPPS and brings to attention the need to further study of the potential benefits of ESWT use in chronic pain. Most of the earlier utilising ESWT have shown benefit and further research into its use with CPPS clients is warranted.

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Author's response

I agree that the treatment of CPPS is extremely hard due to a multifactorial etiopathogenesis; I also agree that a scientific medicine cannot draw conclusions from a case report, and I think we need an approach to management of the CPPS that primarily considers an improvement in the quality of life of the patient. In fact, not knowing the cause, is very difficult to propose a remedy. A more humanistic and anthropocentric medicine may more easily accept the results of a case report however.

The pain therapists often use the word *treat* by acting on the pain, not the word *cure* that suggests the possibility of healing. This distinction is important because it recognizes the difficulty of being able to act on the cause; then they try to manage the effects. In this perspective we have to consider the approach with ESWT, that can be a tool to improve the quality of life of the patient.

I thank Marek Jantos for his comments which are shared and that lead me to the above beliefs.

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