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A multidisciplinary pelvic floor journal

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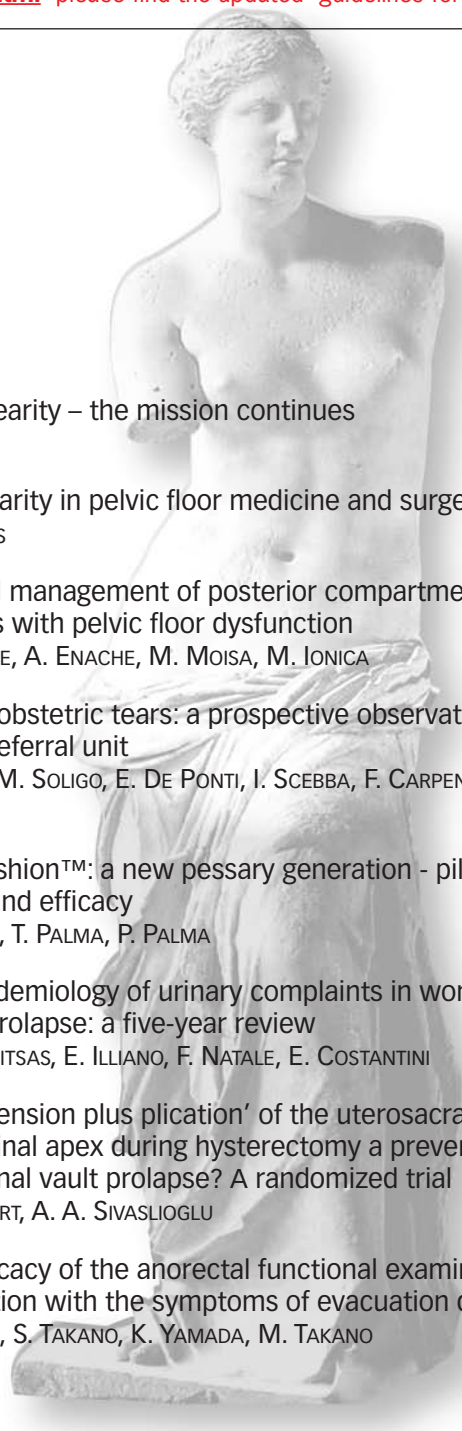

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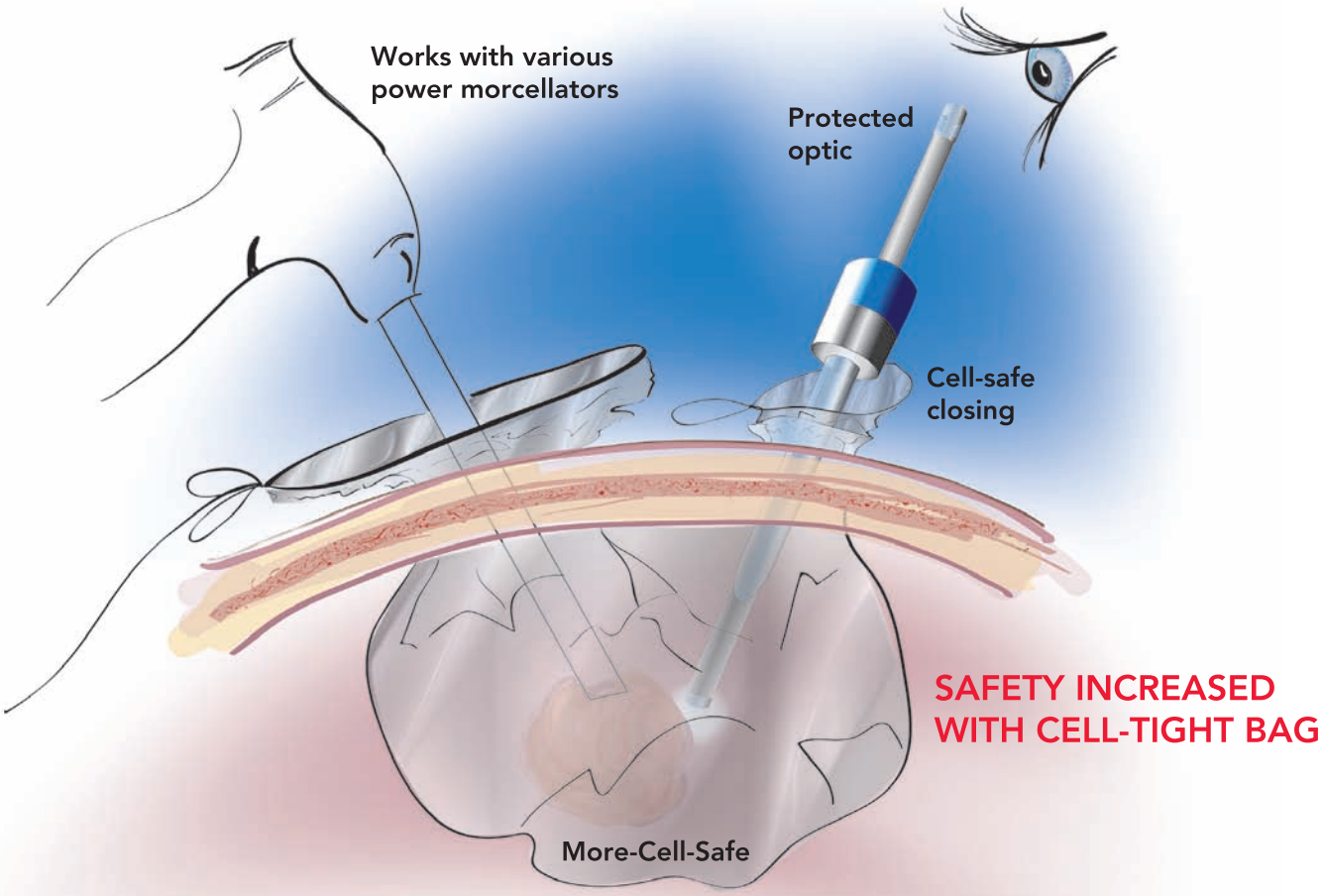

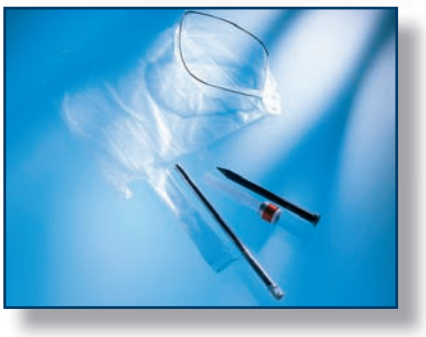

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Editorial

Non-linearity – the mission continues

GIUSEPPE DODI

University of Padova, Italy

Since its first English edition some 10 years ago, Pelviperineology Journal has actively promoted innovation and discovery. This editorial continues a mission which this journal considers critical for all future medical research, recognition that the control systems of the pelvic floor and the body in general are non-linear and holistic.

Non-linearity in medicine is not a new concept. The interaction of all parts of the Universe as a unified interactive whole is an essential part of Stoic philosophy and indeed, medicine since the time of Hippocrates. This holistic perspective lies at the heart of our "Art of Medicine" tradition. Yet medicine as practiced today is essentially reductionist. For older physicians this change has happened during their lifetime. Increasingly, all classes of physicians rely on '*objective'* evidence, imaging of all types, blood tests and in the pelvic floor, urodynamics and anal manometry; these two 'objective' tests, are but snapshots in time, pressure endpoints of complex exponential control mechanisms. Clinical pelvic floor conditions are classified and fractally subclassified. Many such as urinary incontinence are reduced to number 'scores'. All these 'innovations' require the learning of new terms and 'definitions', 'new languages'. These were described by Karl Popper as follows:

"Thus the method of constructing artificial model languages is incapable of tackling the problems of the growth of our knowledge; and it is even less able to do so than the method of analysing ordinary languages, simply because these model languages are poorer than ordinary languages. 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".

Some reasons for this reductionist trend could be the explosion of medical technology, the emphasis on rigorous evidence, the imperative of statistical analysis. Then there are computers. The whole substance of the computer age is Boolean. It is built on the binary concept of 0 or 1. Our brains have become trained in this way of thinking, black or white, reductionist. All these advances are essential. However, they do conspire to a reductionist way of thought. There is no room for variation or 'shades of grey'. There needs to be if medicine is to advance.

Pelviperineology journal sees *non-linearity* as both a dilemma and an opportunity. A *dilemma*, because the present reductionist thinking in medicine seems to have no space for the non-linear mechanisms which control the pelvic floor. An *opportunity*, because of the opportunities this line of research offers.

Advances in computer science such as parallel processing, incorporation of positive and negative feedback systems, may be seminal in advancing non-linear science in the future.

Pelviperineology journal continues its mission to encourage a more holistic perspective of the pelvic floor with a further article by P. Petros, which we hope will stimulate further debate and research.

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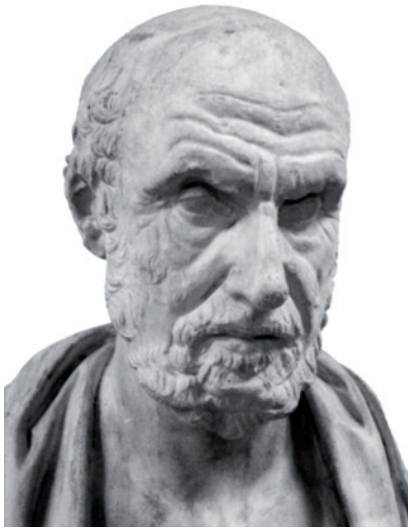
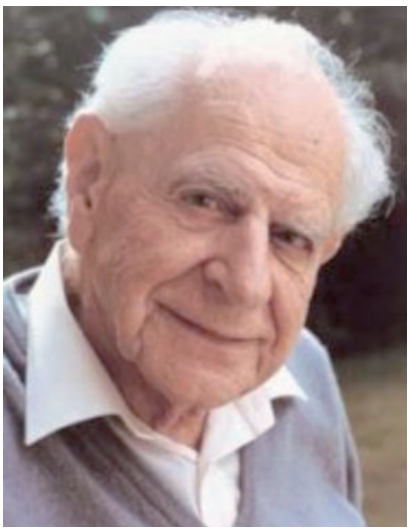


Hippocrates 460 - 377 b.C.

Marcus Aurelius 121 - 180 a.C.



Karl Popper 1902-1994

Focus on

Nonlinearity in pelvic floor medicine and surgery

PETER PETROS

DSc DS (UWA) PhD (Uppsala) MB BS MD (Sydney) FRCOG (London) FRANZCOG CU, University of New South Wales, St Vincent's Hospital, Sydney Australia

Non-linearity involves a lack of linearity between two related qualities such as input and output. For example, in a linear system, 1+1=2 always. In a non-linear system, the answer varies depending on inputs may be 1.9 one day; 2.05 another day.

Modern medicine has become increasingly reductionist and linear. Arbitrary cut-offs for definitions are the norm. But this is not how the body works. Everything in nature is related and subject to physical laws. These laws are universally non-linear. Simple systems give rise to complex behaviour which are regulated by non-linear feedback control systems. One faulty component may unleash a major cascade of dysfunctions. This is especially so in the pelvic floor, as described by the Integral Theory (1), figure 1. Nor is this a new concept.

Marcus Aurelius, the Roman Emperor and Stoic philosopher expressed a holistic view of Nature almost 2000 years ago (2).

"Always think of the Universe as one living organism,
with a single substance, and a single soul;
and observe how all things are submitted
to the single perceptivity of this one whole;
all are moved by its single impulse,
and all play their part in the causation
of every event that happens.
Remark the intricacy of the skein,
and the complexity of the web."

The pelvic floor is a holistic subsystem of Marcus Aurelius's Universe. Every component, ligaments, muscles, nerves work in a collaborative interactive way regulated by a cortical or subcortical function.

Variation,the Gaussian curve, figure 2, is at the heart of non-linearity of the female pelvic floor as each structure affects the other physical laws differently for each patient.

Power Law of Poisseuille Is a key determinant of non-linearity in the pelvic floor as it is an exponential function. Resistance within a tube is inversely proportional to its length and the radius to the 4th power. The urethra and anus are tubes. When the muscles contract against the ligaments to close or open these tubes, the resistance alters exponentially as does continence and evacuation. Thus even minor laxity in the ligaments can cause major symptoms of incontinence or evacuation difficulties such as urinary retention or obstructive defecation.

Gordon's Law of muscle power These functions, opening and closure, are mediated by striated muscle contraction. A striated muscle contracts only over a limited distance. The contractile force falls exponentially if the muscle becomes lengthened. If the ligaments are loose, the muscle effectively lengthens and some of the contractile force is expended to the loose ligament prior to opening or closing the outlet tube.

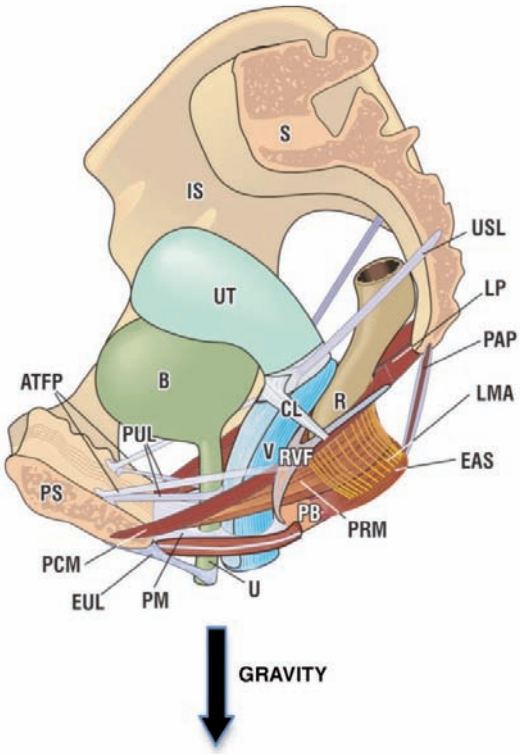


Figure 1. – Functional anatomy of the pelvic floor. Muscles (red) pull against the suspensory ligaments (grey) to support the pelvic organs, bladder 'B', rectum 'R' uterus 'UT', vagina 'V'. The cortex co-ordinates muscle contraction and relaxation to close the urethral ('U') and anal tubes (continence) and to open them (evacuation). Each structure contributes to these functions, differently for every woman. *Ligaments* External urethral 'EUL'; pubourethral 'PUL'; cardinal 'CL'; uterosacral 'USL'; perineal body 'PB'.*Muscles* Pubococcygeus 'PCM'; puborectalis 'PRM'; levator plate 'LP'; conjoint longitudinal muscle of the anus 'LMA'.

Neurological feedback control systems function like an electronic feedback circuit. They are non-linear chaotically determined by peripheral sensors (bladder and rectal stretch receptors) giving afferent signals to the cortex, which reflexly responds to either activate or suppress the micturition or defecation reflexes. These sophisticated feedback systems control vaginal tension opening and closure of the urethra via muscle spindles. Stretch receptors vary in sensitivity. Central control varies. Vaginal tension varies.

It is interesting to examine the basic anatomy of the female pelvic floor through each of these components. The organs, bladder, uterus, rectum are storage containers for urine, the fetus and feces, communicating with the outside via outlet tubes, urethra, vagina and anus. The organs vary widely in size and shape as do the outlet tubes, as per the Gaussian curve with all its standard deviations and statistics

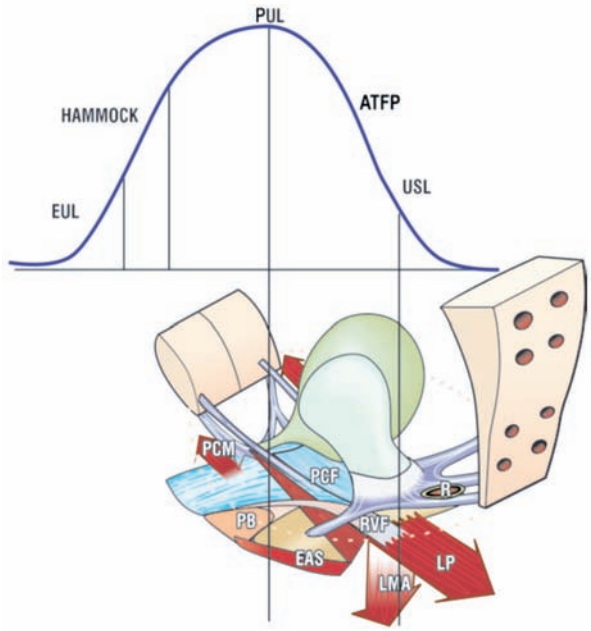


Figure 2. – *The Gaussian Curve*. The contribution of each structure varies with each person and from day to day within that person. Different structures impact synergistically to control bowel and bladder function in the individual patient.The impact of each structure differs between patients. The variance follows a normal distribution curve. This perspective is derived from application of the concepts of non-linearity to the dynamics of the pelvic floor. Labelling as in figure 1.

The ligaments suspend the organs and vary in shape, size, direction and strength.

The muscles contract against the ligaments. The muscle forces act differently, according to the position, standing, sitting, lying. The force of gravity acts differently, according to the position, standing, sitting, lying.

As regards the nerves, sophisticated feedback systems control vaginal tension opening and closure of the urethra. Stretch receptors vary in sensitivity. Central control varies. Vaginal tension varies.

Reductionist thought can be dangerous for the patient. In the 1970's, many infant deaths were caused by premature intervention purely on the basis of low oestriol results. This is but one tragic example of how grasping "scientific medicine" and ignoring the complexity and non-linearity of biological control mechanisms may lead to wrong management or even disaster.

Homeostasis is a term which has almost disappeared in this era of 'scientific medicine", how the body's system work together in balance. Yet this concept lies at the core of the "Art of Medicine" as practiced and handed down right from the time of Hippocrates. Older physicians always recognized the concept of non-linearity, how even a small intervention may set off a chain of events in the body which may profoundly disturb this balance. Hence the use of expressions such as "masterly inactivity", "first do no harm", "treat the patient then treat the disease".

The way forward All the pelvic floor mechanisms are non-linear. Understanding this concept is the key to understanding variation in patient symptoms, for example, why a patient may get up to urinate 6 times one night (nocturia) and once or twice another night. Even more important is to understand how repairing one structure, for example pubourethral ligament for urinary stress incontinence may unbalance the other ligaments to cause other symptoms, pain, bladder or bowel. All of this begs the question: do we treat the pelvic floor holistically, and if so, how?

CONFLICTS

None

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Original Article

Surgical management of posterior compartment defect in patients with pelvic floor dysfunction

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Abstract: Objective. To find and assess a new surgical way of correcting posterior compartment defects according to the Integral System. *Method:* We performed a prospective study involving 82 patients with posterior compartment defects. We compared the results of 2 surgical methods: posterior intravaginal sling with sacrospinous fixation (PIVSSF) vs. posterior "patch" with sacrospinous fixation (PPSF). The research took place in The Clinical Hospital of Obstetrics and Gynaecology, Bucharest, Romania. *Results:* All patients who presented frequency and urgency improved their symptoms in both study groups. In all groups, there was a statistically significant reduction of pelvic pains and sacral pains. In those patients operated with PPSF, we found a significant improvement of haemorrhoids and urinary dysfunction compared with those operated with PPSF, with $p < 0,03$. *Conclusion:* PPSF might be an alternative method to solve posterior compartment defects, with fewer complications.

Keywords: Urogynecology; Pelvic floor; Posterior intravaginal sling; Posterior patch.

INTRODUCTION

The posterior compartment defects are the most challenging ones because the difficult anatomical spaces require complex surgical ways of approach and with serious potential complications.[5] According to the Integral System, the aim of surgical treatment should be the recreation of the physiological disposition of ligaments.[6] The keystone in re-establishing the apical anchoring system - level I in De Lancey classification is the posterior suspension of the uterus or the vaginal vault.[1] As we presented briefly in figure 1, there are 2 ligaments involved in the proper suspension level I: uterosacral ligaments and cardinal ligaments.

Biophysically, there are 2 vectors, one oriented posteriorly and one laterally, so the vectorial resultant should be oriented more or less in a lateral - posterior direction. The surgery must tend to fulfil this aim: the new structure must have a resulting suspension force oriented as mentioned before.

The posterior compartment approach is almost always intriguing. Laparoscopic sacrocolpopexy does not realize a convenient suspension of posterior vaginal fornix, because the final position is vertical, and does not respect the Integral System principles.[7] The most appreciated element used in surgical repair is the sacrospinous ligament. There are different techniques that use it for posterior suspension, using or not meshes. The first operation is Amreich – Richter, but now there are various techniques that require meshes.

The significant rate of complications limited this techniques worldwide, and especially in the USA.[3] There is a possibility of rectal injury, haemorrhage in the ischiorectal fossa, nerve damage. Besides those, one may encounter infection or erosion of the mesh inserted.Considering this, we tried to find a simpler way of approaching the posterior compartment defects.

METHODS

The research took place in The Clinical Hospital of Obstetrics and Gynaecology "Prof. Dr. Panait Sârbu" in Bucharest. We performed a prospective study, involving 82 patients with pelvic floor dysfunction consisting in posterior defects. In this study we used 2 surgical techniques. The first one was posterior intravaginal sling with sacrospinous fixation (PIVSSF).[4] It involves insertion of a posterior tape with the tunneller. This tape is afterwards suspended to the

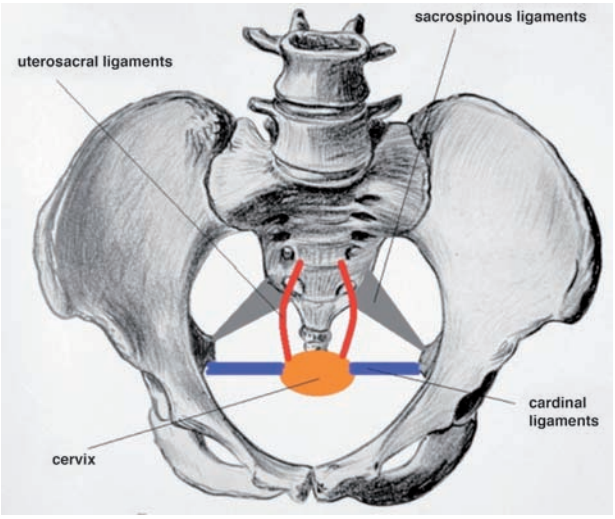

Figure 1. – The cardinal and uterosacral ligaments.

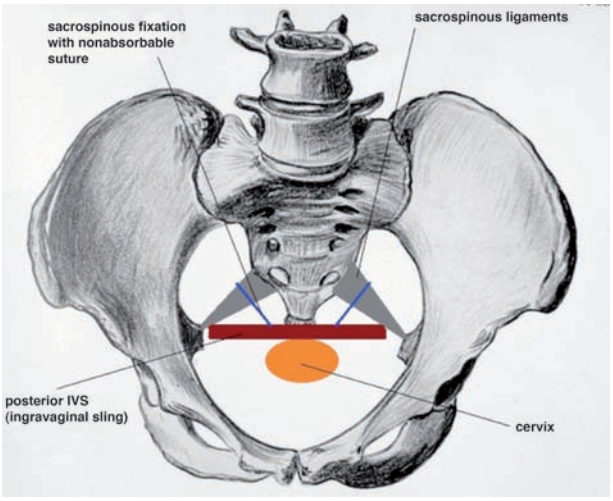

Figure 2. – The "in situ" disposition of posterior sling with sacrospinous fixation.

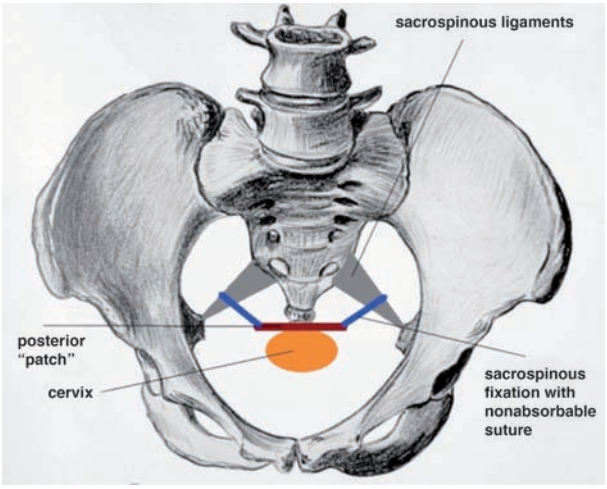

Figure 3. – The "in situ" disposition of posterior "patch" with sacrospinous fixation.

sacrospinous ligaments using the viper specially designed by Prof. Klaus Goeschen. There are few disadvantages with this method: the blind passage through the ischiorectal fossa and the possibility of vascular and nerve damage, the potential injury of the rectum.

Even though, the final disposition respects the biomechanical targets - a posterior-lateral direction of suspension as we see in figure 2.

In attempting of avoiding those difficulties we tried to find a method which may provide an easier way of correcting these defects. We propose a method called posterior "patch" with sacrospinous fixation (PPSF). Thus, we used a polypropylene "patch" which was attached to the posterior side of the cervix or the vaginal fornix in cases with vaginal vault prolapse. This patch was also suspended to the sacrospinous ligaments - Figures 3 and 4.

We respected the biomechanical purpose, so we tried to evaluate the outcome. The initial group was divided in 2 subgroups: the first operated with PIVSSF, and the second one with PPSF. The statistics used student odd tests.

RESULTS

We analyzed both subgroups before and 6 months after surgery. All patients completed a pre- and postoperatory questionnaire, beneficiated of clinical examination, preoperatory urodynamics, pre- and postoperatory echography.

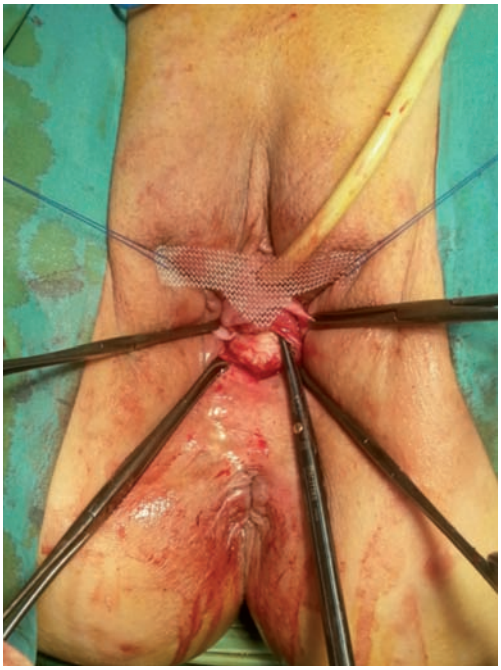

Figure 4. – The posterior "patch" - surgical view.

The anatomical results were similar in both groups - Figures 5 and 6.[2]

All patients presented symptoms like frequency, urgency and nocturia, pelvic pains or haemorrhoids. We studied the preoperatory and postoperatory dynamics of these variables within each group. We quantified frequency and nocturia with number of episodes per day and urgency, haemorrhoids and pelvic pains on a scale ranging from 0 to 3 in intensity as perceived by the patient.

After statistic analysis, with $p < 0.005$ in all subgroups, we found a postoperatory improvement in these symptoms - Table 1. Analysing the uterine arteries velocimetry, we found a significant lowering of resistivity index in PPSF subgroup. A primary conclusion might be that this procedure significantly increases pericervical blood circulation.

Analysing both groups, we discovered a reduction of resistance index of uterine arteries in the PPSF subgroup.

Comparing the surgical outcome in these patients, we discovered a significant improvement in PPSF subgroup, with $p < 0.01$. All the other parameters taken into the discussion, did not differ significantly.

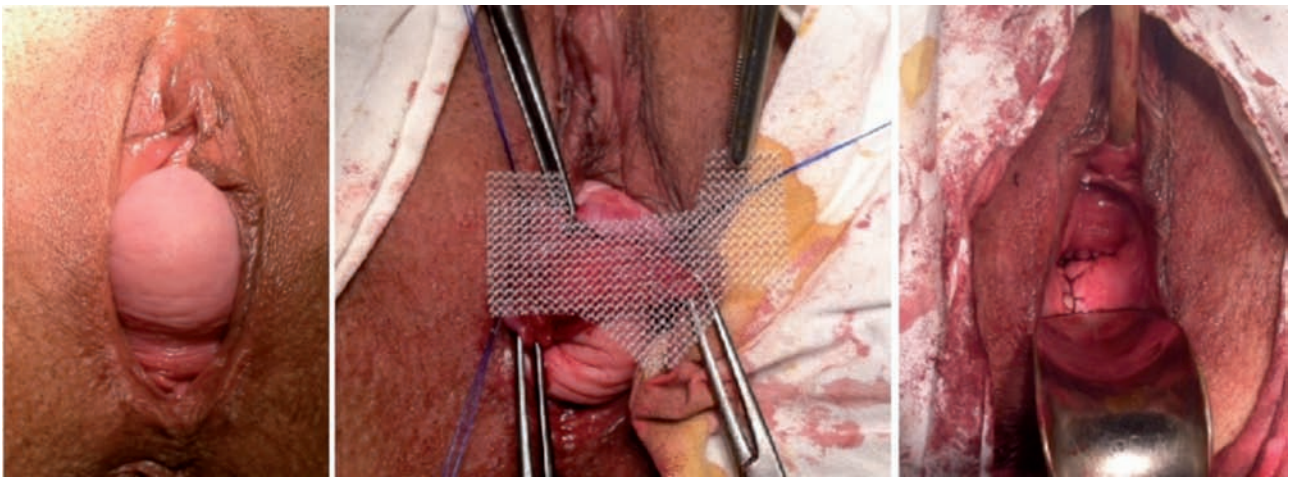

Figure 5. – PPSF in a patient with high degree of enterocoele.

Statistics analysis of patients' variables.

M - mean value; SD - standard deviation; MSD - mean standard deviation; p - probability.

Variable	Probabilistic invariants	PIVSSF		PPSF	
		Pre	Post	Pre	Post
Frequency	M	8.12	6.06	9.57	6.79
	SD	3.84	1.85	5.09	1.99
	MSD	0.66	0.32	0.96	0.38
	p	0.000565		0.000554	
Nocturia	M	2.03	1.24	3.0	1.32
	SD	1.59	0.87	3.37	0.94
	MSD	0.28	0.15	0.64	0.18
	p	0.000285		0.00783	
Urgency	M	1.67	0.58	1.82	0.89
	SD	1.19	0.61	1.12	0.8
	MSD	0.21	0.1	0.21	0.15
	p	6.15E-07		8.5E-05	
Haemorrhoids	M	0.91	0.42	0.57	0.18
	SD	0.88	0.61	0.63	0.39
	MSD	0.15	0.1	0.12	0.07
	p	0.000214		0.00529	
Pelvic pains	M	1.03	0.17	0.82	0.25
	SD	0.73	0.27	0.55	0.52
	MSD	0.127	0.52	0.10	0.1
	p	4.84E-08		5.68E-05	
Right uterine artery RI	M	0.84	0.83	0.88	0.83
	SD	0.1	0.08	0.06	0.05
	MSD	0.02	0.02	0.01	0.01
	p	0.465224		0.000134	
Left uterine artery RI	M	0.84	0.83	0.88	0.84
	SD	0.08	0.08	0.07	0.05
	MSD	0.01	0.02	0.02	0.01
	p	0.325242		0.00924	

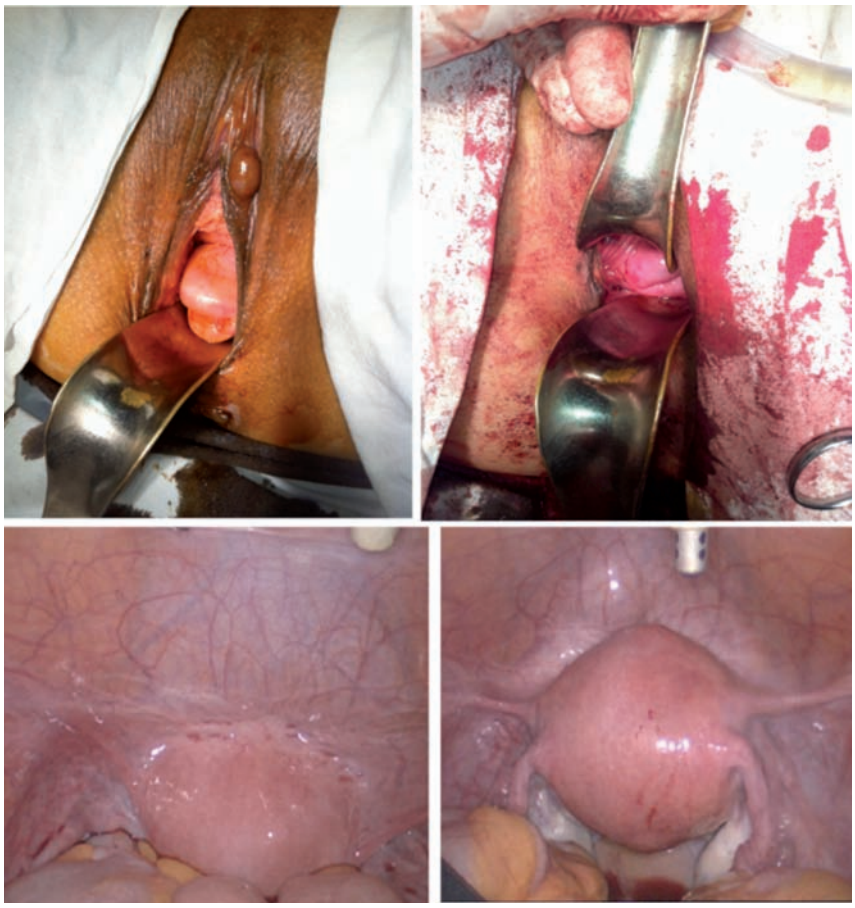

Figure 6. – 28 Years old patient with uterine prolapse, operated vaginally with PPSF.

CONCLUSION

There are some symptoms related to the posterior compartment defect that significantly improve after vaginal surgery. Apparently, correcting anatomy we may achieve restoration of function. This observation is conformable with Integral System. We may conclude that when these symptoms associate with pelvic floor disorders, they are surgically curable. They also presented a significant improvement in pelvic pains in both groups.

PPSF proved to be an easy way of correcting level I defect, with minimum complications. In this way we avoided the theoretical injuries associated with PIVSSF. It also provides a satisfactory anatomical result, yet to be verified after a longer period of time.

PPSF might have a better result in pelvic and pericervical blood circulation. The better cure of haemorrhoids and the improvement of uterine velocimetry plead for that idea.

Larger studies, multicentric and randomized, are required to a more profound understanding and for a validation of this surgical method.

ACKNOWLEDGEMENT

This paper is part of Dr. Enache Traian's PhD thesis, defended on 30.10.2014 at the "Carol Davila" University of Medicine and Pharmacy, Bucharest, Romania, with the title: "Surgical reconstruction techniques using alloplastic material in pelvic floor disorders"

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Original article

Severe obstetric tears: a prospective observational study in an Italian referral unit

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Abstract: Vaginal birth can be accompanied by pelvic complications: vaginal tears, cervical and perineal lacerations, which are commonly classified in four categories with ano-rectal involvement starting from the IIIrd degree. The objective of this study is to analyze the incidence of severe perineal lacerations and to identify possible risk factors within an Italian Tertiary Referral Maternity Hospital. This is a prospective observational cohort study based on women ≥ 32 weeks gestational age who delivered between July 2014-December 2014. Univariate analysis for parameters in relation to severe perineal tears was first performed and then logistic stepwise multivariate analysis was used including all the risk factors significant at univariate analysis (using Stata 9.0, Texas, USA). A total of 1677 women delivered in the period considered: 430 women were excluded, due to gestational age < 32 weeks (6 women) or because of abdominal delivery in 424 cases; 1247 women were included in the study. Integrum perineum was found in 233 women (18.7%), while 676 (54.2%) sustained perineal tears and 338 (27.1%) had an episiotomy. Only 15 women (1.2%) had a severe laceration, among which one IVth degree. The risk factors for severe perineal lacerations emerging in this cohort are: ethnicity, younger age, nulliparity, oxytocin augmentation and orthostatic maternal position at delivery; maternal position is the only independent risk factor emerging as significant in our multivariate logistic stepwise analysis. Above all a 1.2% prevalence rate of severe perineal laceration has been observed in an Italian Tertiary Referral maternity Hospital.

Key words: Vaginal delivery; Severe perineal lacerations; Anal sphincter; Risk factors; Orthostatic position.

INTRODUCTION

Vaginal birth can be associated with pelvic complications such as vaginal tears, cervical lacerations and perineal lacerations. Perineal tears are commonly divided in four categories, between which IIIrd and IVth degree tears are commonly considered as severe: third degree lacerations involve anal sphincter complex, while fourth degree tears are extended to the rectal mucosa[1]. The incidence of severe lacerations shows a wide variability in the literature, according to the different settings and populations, thus there is no consensus regarding preventive measures and clinical management of severe perineal tears.

Demography and obstetrical practice can differ from one context to another: this is why data analysis of risk factor for each particular setting is so important to drive clinical approach in this particular field[2,3].

Ethnicity[4], nulliparity[2], maternal BMI[5], fetal macrosomy[6], previous history of fecal incontinence or severe perineal laceration in prior deliveries[7,8] are the most frequently associated risk factors to this kind of lacerations in many retrospective studies in literature.

While concerning risk factors strictly related to labour and delivery the following are highlighted in many papers: operative delivery with vacuum or forceps[9], persistent occiput posterior position of fetus[10], prolonged second stage of labour[11], induction of labour[12] and epidural analgesia[13].

As far as concerns different maternal positions during labour and delivery in relation to severe perineal lacerations the literature is controversial. Meyvis et al[14] consider the lateral position as the most protective for perineum, while others disagree with this point of view[15,16]. Water births, instead, are universally considered at low risk of perineal trauma[17,18].

As a general rule the management of pushing phase in labour has an essential role for preventing perianal trauma: if possible it is important to respect the correct timing for the tissue to stretch, slowly, gradually and less traumatically. Manual pressure on the uterus (Kristeller maneuver) is on the other hand associated with a major risk of severe perineal lacerations[19,20].

The most discussed factor related to perineal lacerations is episiotomy: routine use of episiotomy is associated with an increased risk of anal sphincter complex damage[21] and it increases morbidity in women that could otherwise deliver with integrum perineum or with minor lacerations[22]. In addition it seems that patients with episiotomy are at higher risk to have any perineal lacerations in further deliveries[23]. Therefore to reduce iatrogenic severe perianal trauma episiotomy should be strictly performed under clear indications: fastening pushing phase because of non reassuring CTG trace, maternal pathology that contraindicate excessively prolonged second active phase of labor, treatment of shoulder dystocia[2]. If needed a mediolateral episiotomy is preferable than a median one, being the last one at higher risk of extension to sphincter area[24].

In the light of improving postpartum pelvic functional outcomes great attention has been focused on the assistance immediately after baby delivery: to assess the perineum carefully, including rectal examination under optimal conditions (adequate lighting, lithotomic position with legs flexed on supports). Andrews et al. report doubling rate of prevalence of severe perineal trauma thanks to a deeper exam of perineum after delivery[25]. Then perineal repair should be also performed under optimal conditions: epidural or general anaesthesia to obtain adequate muscle relaxation and appropriate pain control, wide spectrum antibiotic prophylaxis, vescical catheter for at least 24 hours and laxative for about ten days. Accurate layers repair should be performed and external anal sphincter reconstructed either with an overlapping or an end-to-end approach, being outcomes equivalent. Special attention has to be payed to the internal anal sphincter recognition and separate suture[26,27].

Patient with severe perineal trauma should be revaluated in a dedicated clinic within two or three months after delivery, to consider the possibility of pelvic floor rehabilitation.

The objective of this study is to analyze the incidence of severe perineal lacerations and to identify possible risk factors within a Tertiary Obstetric Italian Referral Unit.

MATERIAL AND METHODS

This was a prospective observational cohort study based on women ≥ 32 weeks gestational age that delivered in an

TABLE 1. – Distribution of perineal laceration and episiotomy.

Parameter		1247 vaginal deliveries n (%)
Integrum perineum		233 (18.7%)
Episiotomy		338 (27.1%)
	Median	12 (3.7%)
	Mediolateral	326 (96.3%)
Spontaneous perineal laceration		
	Ist-IInd degree	661 (53%)
	Seevere degree	15 (1.2%)*

Italian Tertiary Referral Maternity Hospital between July 2014 and December 2014.

The Institutional Review Board has approved the protocol of the study and privacy law was strictly observed.

All the staff working in the Unit was involved in entering data concerning pregnancy history, labour and delivery in an electronic database. Relevant parameters were then anonymously extracted from the original database to build-up a specifically designed one for the study.

A univariate analysis for categorical and continuous parameters in relation to severe perineal tears was performed with exact *Fisher* and parametric *t-Student* tests respectively. A logistic stepwise multivariate analysis was then also performed including all the parameters that resulted significant at univariate analysis. A level of $p<0.05$ was considered for significance and software Stata 9.0 was adopted (Stata Corporation, College Station, Texas, USA).

RESULTS

A total of 1677 women delivered in the six months-period considered: 430 women were excluded, due to gestational age < 32 weeks (6 women) or because of abdominal delivery (424 Caesarean Sections - 25% of all deliveries). Finally 1247 women were included in the study.

In table 1 the distribution of perineal lacerations and episiotomy is reported: only 15 women (1.2%) had a severe laceration, among which one IV degree.

Nulliparous women significantly differed from multiparous for all parameters. As only one multiparous woman sustained a severe laceration, univariate statistical analysis was performed on all eligible women (table 2).

It's important to underline that 24% (120 nulliparous and 179 pluriparous) of our population have been managed under a special protocol for non complicated deliveries and labour (spontaneous onset of labour, no epidural anaesthesia, no meconium-stained amniotic fluid, no oxytocin augmentation, CTG classified as ACOG class I in labour [28] and Piquard class 0 [29] during pushing phase) and then were managed autonomously by midwives.

Unfortunately data on fetal position at delivery are scarcely recorded in our database, thus a statistical analysis on this parameter was impossible to be obtained.

Length of pushing second stage major than a hour is indicated considering all vaginal deliveries (spontaneous and operative ones): it is possible to distinguish between the two categories, with an average time for spontaneous deliveries of 28 minutes (SD ±36.4 minutes) compared to 55 minutes of vacuum assisted deliveries (SD ±40 minutes).

In table 2 the risk factors emerging from this group of patients can be observed. Significant factors were then tested with stepwise multivariate analysis to identify the independent ones; results are reported in table 3.

The only risk factor that resists as significant after this analysis is orthostatic position of the mother at delivery.

DISCUSSION

The extreme variability in the incidence of severe perineal tears after delivery is one of the most disappointing remark concerninig this consistent body of literature.

Among possible explanations one is represented by substantial differences in obstetrical management within different context. It is therefore of extreme importance to contex-

TABLE 2. – Demographics and obstetrical parameter with univariate analysis.

Parameter		No perineal lacerations +Ist and IInd degree (n=1232)	Severe perineal lacerations (≥IIIrd degree) (n=15)	*p-value*
Ethnicity	Caucasian	979 (79.8%)	9 (60%)	
	Asiatic	99 (8.1%)	5 (33.3%)	
	South American	81 (6.6%)	1 (6.7%)	*0.048*
	Middle-Eastern	35 (2.9%)	0	
	African	33 (2.7%)	0	
Age	Average ± SD	32.8 ± 5.3	29.7 ± 6.9	*0.013 §*
BMI	Average ± SD	26.1 ± 3.8	26.1 ± 3.1	*0.499 §*
Nulliparity		694 (56.3%)	14 (93.3%)	*0.002 **
Mode of Delivery	Vaginal	1022 (83.0%)	11 (73.3%)	*0.248 **
	Vacuum extractor	210 (17.1%)	4 (26.7%)	
GA (weeks)	Average ± SD	39.4 ± 1.3	39.7 ± 1.1	*0.183 §*
Onset of labour	Induction	354 (28.7%)	2 (13.3%)	*0.152 **
	Spontaneous	878 (71.3%)	13 (86.7%)	
Lenght of induction (h)				
	≤24 h	277 (83.2%)	1 (50%)	*0.312 **
	>24 h	56 (16.8%)	1 (50%)	
Pushing second stage > 1h		216 (17.7%)	3 (20.0%)	*0.514 **
Oxytocin augmentation		296 (24.0%)	7 (46.7%)	*0.048 **
Epidural analgesia		462 (37.5%)	6 (40.0%)	*0.519 **
Maternal position Orthostatic	Lithotomic	77 (7.6%)	3 (27.3%)	*0.047 **
		941 (92.4%)	8 (72.7%)	
Neonatal birth weight (g)	Average ± SD	3333 ± 437	3367 ± 223	*0.385 §*

TABLE 3. – Results of multivariate logistic stepwise analysis.

Risk Factor	Univariate		Multivariate	
	OR (95% IC)	*p*	OR (95% IC)	*p*
Age	0.90 (0.83-0.99)	*0.028*	0.90 (0.81-1.01)	*0.071*
Mother's position at delivery	0.22 (0.06-0.84)	*0.027*	0.20 (0.05-0.79)	*0.022*
Nulliparity	0.09 (0.01-0.70)	*0.021*	0.16 (0.02-1.26)	*0.082*

tualize these data within every particular obstetrical management. As can be extracted from our data presentation we have a 25% caesarean section rate, 27% episiotomy rate (almost all mediolateral) and 17% operative deliveries with vacuum extractor (no forceps adoption). Under these conditions we observed a 1.2% rate of severe lacerations in our study, which is in accordance with the average values commonly observed. Nevertheless it can be considered a low incidence rate, and it could be possibly underestimated. In fact as Gurol-Urganci et al demonstrated in the United Kingdom[30] increasing awareness of the problem leads to a higher detection rate of severe perineal tears. The present study is part of an internal audit programme and is going to be accompanied by formal teaching practical hands-on courses on this topic to improve the perception of doctors and midwives on this clinical issue. We therefore expect, in the next future, an increase from the present 1.2% rate of severe perineal trauma in our unit.

Our risk factors analysis overlaps with that from several other authors, such as ethnicity[4], younger age[4], nulliparity[2], oxytocin augmentation[11] and orthostatic maternal position at delivery[14]. Data on maternal position at delivery are of interest from our study being the orthostatic position at higher risk for severe tears. This has to be cautiously considered due to the small number of severe lacerations that we detected and some missing data on maternal position in our sample size. In the literature both lithotomic and squatting position at birth are associated with an increased risk for severe lacerations and in our series squatting was included in the orthostatic group. Moreover this is the only independent risk factor emerging as significant in our multivariate logistic stepwise analysis, even though both younger age and nulliparity are close to significance, being therefore relevant in the prediction model. Further data are needed to clarify our results, since considering orthostatic maternal position at delivery as a risk factor would have an impact on midwifery practice.

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Multidisciplinary Uro-Gyne-Procto Editorial Comment

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

Uro... This prospective observational study by Livio et al. in 1247 women with devliveries investigated the birth trauma upon vaginal delivery. Interestingly only 18.7% of women had an intact perineum, whereas 27.1% needed an episotomy and 54.2% had a spontaneous perineal laceration with 1.2% of severe degree. These data clearly show that vaginal delivery results in a constant trauma of the perineal body and most probably of many other pelvic structures as well. Another interesting aspect was that the only risk factor for severe lacerations in the multivariate analysis was the mothers position at delivery, where orthostatic position showed a higher risk.

From an urological point of view, this study raises two important aspects:

1 - First the high percentage of birth trauma at least to the perineum calls for research also in the field of micturition and bladder emptying. Given the fact that according to the integral theory posterior defects also interfere with urinary continence, as well as bladder emptying, it is currently not clear what exact role the perineal body plays and what urinary symptoms a traumatic perineal body might cause.

2 - The fact that the mothers position at delivery was the only risk factor for severe laceration and apparently orthostatic position should be avoided, this could be translated also to other "evacuating manoevers" of the pelvis, such as bladder emptying. Perhaps an orthostatic position could be associated with a higher resistance power, whereas a sitting position might be preferable. Especially in men bladder emptying is frequently performed in the orthostatic position, in a less relaxed state of the pelvic floor.

In summary this study delivers good data with regards to the trauma associated in vaginal delivery. Certain impact to other disciplines active in the pelvic floor could be drawn with regards to prevention, diagnostics and perhaps treatment strategies, if the full role of the perineal body in the pelvic floor is elucidated.

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Procto-Colorectal... This prospective observational study in an Italian referral unit looks at the incidence of severe obstetric tears. A very interesting data is the report of only 1,2% of post-delivery severe perineal trauma, though, as correctly commented by the Authors, this data could be underestimated. Colorectal surgeons' point of view basically concerns the importance of the trauma and its relationship between the degree of laceration and the functional as well as the anatomic damage. All the risk factors cited can be expected, so the warning is quite important. Often the reported degree of the perineal trauma does not seem to be related with to the lesion observed in a proctological setting. A follow-up observational study in this group of women could be very useful, finding out how many "ghost" lesions will appear in the long term also in the "other degree" groups, i.e. not related with the high degree post-delivery severe perineal trauma. Colo-rectal surgeon are often involved for an urgent or deferred intervention in different postpartum lesions besides anal sphincter rupture, such as recto-vaginal fistula or severe anal/rectal prolapse that may be seen even without a very important perineal trauma.

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Original article

Femicushion™: a new pessary generation - pilot study for safety and efficacy

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Abstract: *Introduction and Objective:* Pelvic Organ Prolapse (POP) is a condition related to loss of anatomical support of pelvic organs. A non-invasive treatment option is a pessary, intravaginal device that provides anatomical support. Femicushion™ is a device that works as an external pessary and was developed for easier placement and reduction of complications that might happen from pessary use. Our aim is to assess the efficacy of Femicushion™ in the vaginal symptoms caused by prolapse and their impact in Quality of Life. Patients and method: We evaluated five women with symptomatic POP. The ICIQ-VS questionnaire was chosen for assessment of symptoms and Quality of Life impact caused by the prolapse. Patients were assessed at baseline and received the device and required use orientations. Femicushion™ was used for three months and patients were re-assessed after this period. *Results:* We observed a decrease in the ICIQ-VS score with the use of Femicushion™. The greatest differences were observed in question 1 (pain in lower abdomen), question 5 (lump or bulge presence) and question 6 (visual lump or bulge outside the vagina). After a period of three months of Femicushion use, we observed improvement in the vaginal symptoms and in the impact they cause in the Quality of Life of the patients. *Conclusion:* Femicushion™ was effective in the reduction of symptoms and impact in Quality of Life caused by pelvic organ prolapse.

Key words: Pessary; Femicushion™; Prolapse.

INTRODUCTION

The aging process results from successive damage to the molecular structures of the body along time. An individual's aging speed is a direct result from molecular damage, maintenance and repair and is influenced by genetics, environmental factors and comorbidities.[1]

The increase of female longevity, observed as a trend lately, has led to an increase in pelvic organ conditions, affecting quality of life, family bonds, sexuality and self-esteem.[2]

It is estimated that a 79-year-old woman has a chance of 11 to 12% of undergoing surgery for prolapse correction or urinary incontinence, and the reoperation ratio is 29.2%.[3]

Prolapses are classified in anterior, posterior or apical and they are graded from I to IV. Usually symptomatic prolapses are the ones that reach (or go beyond) the hymen (Grade ≥ II), observed during Valsalva Maneuver.[4]

Pessaries are indicated by over 85% of gynecologists and almost 98% of urologists. These devices provide anatomical support and may be used as a temporary treatment or provide a solution for women who do not have indication for surgery, as a conservative treatment option.[5]

In this project we assessed the efficacy of a novel external pessary (Femicushion™) in the vaginal symptoms caused by prolapse and their impact in Quality of Life.

PATIENTS AND METHOD

We conducted a prospective trial to assess efficacy of a novel external pessary for conservative treatment of Pelvic Organs Prolapse. Following IRB approval and obtainment of informed consent, women were screened before enrollment. Inclusion criteria were: Women with POP grade II or above and presence of at least one of the following symptoms: pain or pressure in lower abdomen, vaginal soreness caused by POP, reduced sensation in or around vaginaorfeeling of loose vagina. Exclusion criteria were POP < II, vaginitis, tissue buildup and presence of lesions with suspected malignancy.

Vaginal symptoms and Quality of Life were assessed through validated Portuguese version of International Consultation on Incontinence Questionnaire - Vaginal Symptoms (ICIQ-VS).[6] Questionnaires were filled during baseline assessment and three months after daily Femicushion™ use.This tool evaluates the vaginal symptoms caused by prolapse and its score is directly proportional to the symptom presence. It also measures Quality of Life impact in a scale of 0 to 10 (0 being not bothersome at all and 10 being extremely bothersome).

The ICIQ-VS consists of 14 questions, but only questions 1 to 8 were used in this study, since they are the ones related to vaginal symptoms. Questions regarding sexual activity were not completed since all participants reported not being active, due to advanced age or widowhood.

Femicushion™is made of silicone and comes in three different sizes, to be chosen according to the size of the introitus (Figure 1 A). Upon size definition, the prolapse reduction is performed, inserting it into the vagina and placing Femicushion™ in the correct position (Figure 1 B).

The device is kept in place by a specific pad with Velcro that is attached tothe adjustable underwear (Figure 2).

The correct placement of the device keeps the prolapse from descending beyond the vaginal introitus, as seen in Figure 3.

Following device placement, all participants were advised on hygiene and maintenance. They were instructed to wear the device during the day and remove it at night for cleaning. The product is made of a fast-drying material, which allows for use the following morning.

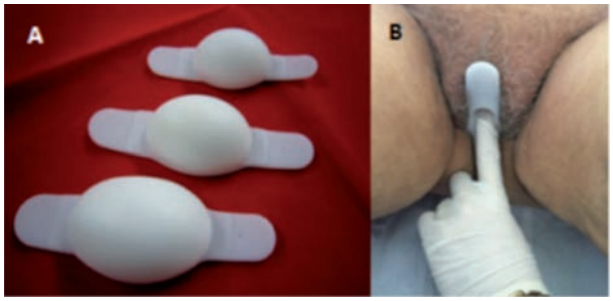

Figure 1. – A) Femicushion in 3 different sizes. B) Placement of Femicushion.

Figure 2. – Adjustable underwear.

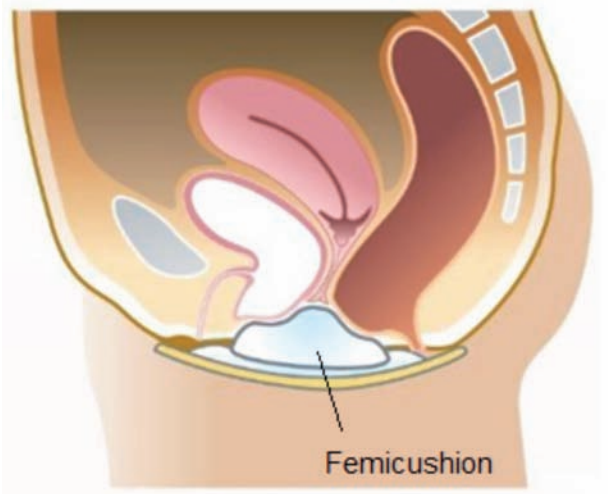

Figure 3. – Femicushion™ placement.

RESULTS

Five women aged 60 to 79 (average 71) were assessed. Four of them presented anterior prolapse grade IV. One woman presented associated posterior prolapse grade II andone of them presented posterior prolapse grade III.

At baseline, ICIQ-VS score varied from 10 to 44, as seen inTable 1.

The final assessment was performed after three months of daily Femicushion™use. Participants reported improvement in vaginal symptoms, mainly regarding lower abdomen pain, descending lump and visualization of lump. ICIQ-VS score range was reduced from 10-44 to 10-22, as seen in Table 2.

All patients but one achieved a reduction in the total score, as seen in Figure 4.These results show great improvement in symptoms after Femicushion™ use.

The impact of symptoms in Quality of Life was reduced after three months of use, as seen in Figure 5. In two of the patients, the impact degree was 9-10 and at baseline and at the final assessment it was reduced to 0.

Besides the symptoms assessed in ICIQ-VS, we observed that one participant who presented infravesical obstruction caused by the prolapse at baseline was able to pass urine normally at final assessment.

Table 1. Baseline assessment: ICIQ-VS Score.

ICIQ-VS Question	*Participants/Score*				
	1	**2**	**3**	**4**	**5**
Q1. dragging pain in lower abdomen	2	4	6	0	0
Q2. soreness in vagina	0	2	0	2	2
Q3. reduced sensation or feeling in or around vagina	0	2	0	0	0
Q4. vagina too loose or lax	6	0	6	6	0
Q5. lump or bulge coming down	8	8	8	8	4
Q6. visualize lump or bulge coming out	8	4	8	4	4
Q7. vagina too dry	8	0	8	4	0
Q8. difficulty emptying bowels	0	0	8	0	0
Score	32	20	44	24	10

Table 2. Final assessment: ICIQ-VS Score.

ICIQ-VS Question	*Participants/Score*				
	1	**2**	**3**	**4**	**5**
Q1. dragging pain in lower abdomen	0	2	4	0	0
Q2. soreness in vagina	0	0	0	0	2
Q3. reduced sensation or feeling in or around vagina	0	2	0	0	0
Q4. vagina too loose or lax	6	0	6	6	0
Q5. lump or bulge coming down	4	4	2	2	8
Q6. visualize lump or bulge coming out	4	4	2	2	4
Q7. vagina too dry	8	0	0	0	0
Q8. difficulty emptying bowels	0	0	4	0	0
Score	22	12	18	10	14

DISCUSSION

Pelvic Organ Prolapse is perceived as a very sensitive descending lump in the vagina. It worsens by the end of the day and improves when the woman lies down.Some patients refer pelvic or lower abdomen pain. Dyspareunia, vaginal bleeding and urinary symptoms such as infravesical obstruction or urinary incontinence have also been reported.Some patients also report difficulty emptying their bowels.[2]

Within three months of Femicushion™ use, a decrease in vaginal symptoms caused by POP was observed. The symptoms that presented the largest change in score were lower abdomen pain, feeling of descending lump in the vagina and visualization of descending lump outside the vagina.

In the present study mean age of participants was 71. In a retrospective epidemiologic study, Olsen *et. al.* have found a strong relation between POP and age, showing that 11% of females will be submitted toat least one surgical procedure for correction of pelvic floor defect.Relapse and need for reintervention reach 29.2% of these women and the period of time between interventions tends to be smaller as time goes by.[7]

Kapoor *et. al.* observed that when offered a pessary for initial treatment of POP, almost 2/3 of women have accepted it.[8]

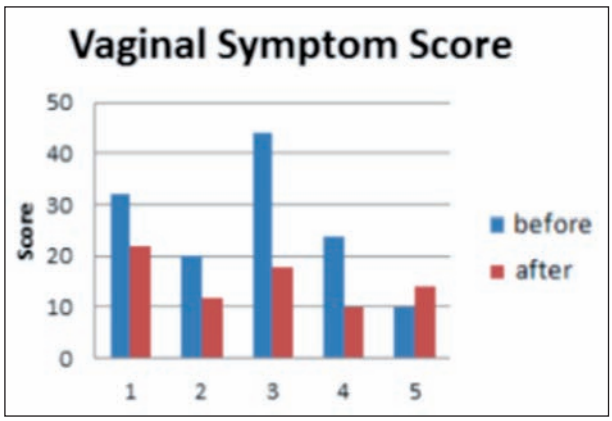

Figure 4. – ICIQ-VS score before and after Femicushion™ use, per patient.

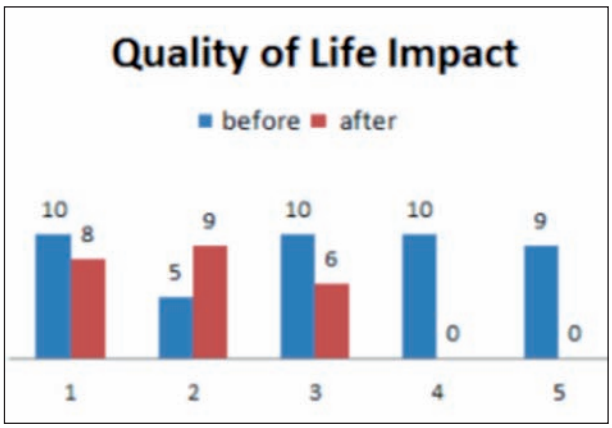

Figure 5. – Impact of vaginal symptoms in Quality of Life before and after Femicushion™ use, per patient.

In a systematic review from 2015, different complications due to the use of vaginal pessaries were observed: Vaginal discharge, bleeding and odor were the most frequent ones; however, rare cases of serious complications were observed, such as vesicovaginal or rectovaginal fistulae, difficulty emptying bowels, hydronephrosis and even death.It is estimated that 91% of the cases of serious complications are due to pessary negligence, and patients with dementia are at a higher risk. [9]

The use of Femicushion™ presents lower risk of complications when compared to pessaries, due to the fact that itis not placed inside the vagina and itis removed daily for hygiene, reducing the risk of infections and negligence. In the present study no complications were reported.

Studies with Pessaries have showed decrease in vaginal symptoms and improvement in Quality of Life.[10,11]Similar results were observed with Femicushion™.

Femicushion™ was developed aiming for better Quality of Life and decrease in vaginal symptoms in women with POP grades II or higher. These results are achieved by the use of the device, which keeps the prolapse inside the vagina, above the vaginal introitus. It is indicated for patients without surgical indication or for those who are waiting for the surgery.We have presented our preliminary results, and a longer follow-up time is needed, as well as a larger number of patients.In some cases, a decrease in prolapse degree was also observed, and more studies should be performed in order to investigate how this decrease happened. One of the hypotheses is the reflex contraction caused by the use of Femicushion™ and the absence of prolapse distension outside the vaginal introitus during daily activities.

CONCLUSION

Femicushion™ has proven to be effective in the decrease of vaginal symptoms caused by Pelvic Organ prolapse. It has consequently reduced the impact of these symptoms in the Quality of Life of these women.

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Multidisciplinary Uro-Gyne-Procto Editorial Comment

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

Rehabilitation... Traditionally, vaginal pessaries are worn to contain prolapse of the organs in women who are too ill or who do not desire surgical repair. Pessaries are not used to control symptoms of bladder dysfunction and pain.

The Femicushion™ is an interesting evolution of this conservative treatment method. This pessary could be considered as a direct application of the Integral Theory which states that bladder, bowel and pain symptoms are mainly caused by laxity in the vagina or its supporting ligaments. The shape supports the bladder base and the apex of the vagina, in particular, loose cardinal (CL) and uterosacral (USL) ligaments which of course cause uterine prolapse. The initial data for pain relief, though in only 5 patients, is quite promising. We could anticipate that this pessary would substantially reduce other symptoms deriving from loose CL/USL ligaments, for example nocturia, abnormal bladder emptying, even some bowel symptoms such as obstructive defecation and fecal incontinence. However, more extensive studies will be required to establish its usefulness as regards symptom relief. I have some comments on its use in reducing pelvic organ prolapse. The traditional ring pessary works by over distending an already damaged vagina. Hence its long-term use is accompanied by vaginal ulcerations and even damage to the vagina. Larger and larger pessaries are required. The Femicushion™ avoids such problems but it requires an external support to keep it in place. We need to know how effective this would be in the longer term. In summary, this is an interesting and novel method which does not damage the vagina and uniquely addresses disturbing pelvic floor symptoms. I look forward to seeing its use in patients with minimal prolapse and major symptoms such as chronic pelvic pain, urgency, nocturia, especially in patients who do not respond to the squatting-based Integral System PFR methods (1).

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Urologist... The authors report an interesting pilot study on an innovative pessary model based on an adjustable suspension system. Pessaries do not cure pelvic organ prolapse, but in selected cases they help slowing the progression of prolapse. With some risk of damaging the vaginal walls they add support to the vagina tightening tissues and pelvic muscles around it. From a urological point of view the Femicushion™ acts in comparable way to the most recent female or male slings whose action are related to the creation of a new biological system of urethral and pelvic floor suspension. In urodynamic practice the pessary is sometimes used to exclude an urethral obstruction during the analysis of voiding phase. In conclusion the use of the pessary in urological field is rare and when applied it is not free from complications. The traditional pessary should be limited to specific clinical cases in which the surgical reconstruction of pelvic floor is not possible due to the advanced age or bad general conditions of the patient.The the Femicushion may open new perspectives.

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Figure 1.

Procto/Colorectal... The term pelvic organ prolapse (POP) is widely used by uro-gynecologists for genital prolapse. Anal prolapse should be included in "POP" as well, being due to hemorrhoids, and mucosal or rectal descent outside the anal orifice. It affects negatively the quality of life, and patients fear the operation because of pain or considerable risk of relapse. A conservative approach would be highly appreciated when surgery is needed, but besides elastic band ligation of lower degrees (2nd, sometimes 3rd) of hemorrhoids and mucosal prolapse, nothing serious is available. An anal pessary does not exist and cerclage is the simplest procedure to avoid complete rectal prolapse. Treatment of vaginal prolapse with Femicushion is interesting because less invasive and non traumatic compared to the traditional pessaries. A similar solution has been proposed years ago in Italy for prolapsing 4th degree hemorrhoids with a so-called *Anti-hemorrhoidal Suspender* (Fig.1), a non-invasive mechanical barrier with suspenders resting on the shoulders, Its popularity has been short as it is now impossible to buy it anywhere. General surgeons have experience of patients with inguinal hernia using elastic pant with ball bearing top, instead of the trusses.

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החברה הישראלית לאורוגינקולוגיה ורצפת האגן

THEME for 2016 CHRONIC PELVIC PAIN

Preliminary program

Wednesday 21 September

08:00-12:00 **Workshops**

08:00-09:00 Workshop registration

1 The Integral System - *Peter Petros*

2 Pelvic floor Ultrasound - *TBD*

3 Chronic Urogenital Pain (CUP), Diagnosis and treatment - *Marek Jantos*

4 Urology for urogyneclogiests

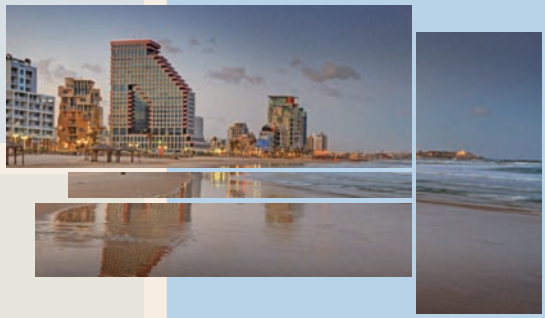
Fistula repair - *Dimitri Pushkar*

Male SUI - *TBD*

IC and Painful bladder - *TBD*

5 Colorectal surgery for urogynecologists - *Daren Gold*

Lunch



ISPP Annual conference

14:00-15:00 Registration

15:00-15:15 Opening

15:15-18:00 First Plenary session - Chronic pelvic pain

Thursday 22 September

10:30-11:00 Second plenary session - for Urology pain (OAB, IC)

11:00-13:00 Coffee break

13:00-14:00 Third plenary session - Posterior compartment

14:00-16:00 Lunch

16:00-16:30 Forth plenary session - Implants for POP and SUI repair

16:30-18:00 Coffee break

Fifth plenary session - Tips and Tricks in urogynecology

Gala dinner

Friday 23 September

08:00-13:00 **Live surgery**

* Urinary incontinence - different TVT slings

  Emanuel Delorm & David Waltregny

* Pelvic organ prolapse: vaginal mesh, Starr operation

  Michel Cosson & Antonio Longo

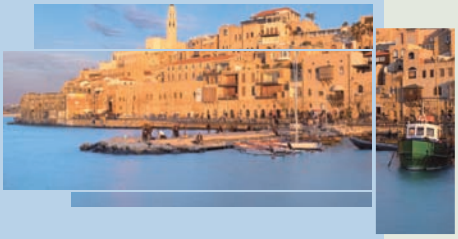
* Lap Sacrocolpopexy

  Peter von Theobald & Joerg Neymeyer

* Fistula repair

  Dimitri Pushkar

Lunch



Saturday 24 September

Jerusalem tour

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Original article

The epidemiology of urinary complaints in women with pelvic organ prolapse: a five-year review

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Abstract: *Aim*: The relationship between Pelvic Organ Prolapse (POP) and Lower Urinary Tract Symptoms (LUTS) remains unclear. Our aim was to update evidence on the prevalence of LUTS in patients with POP. *Method*: Pub Med was searched for English-language manuscripts reporting on the prevalence of LUTS in women with POP, published from 2010 onwards. *Results*: 7 cross-sectional studies and 15 surgical series of prolapse repair reported on the prevalence LUTS. Focus on different symptoms and various methods of diagnosing them do not allow direct comparisons or grouping of the studies. Stress Urinary Incontinence (SUI) is the most commonly assessed symptom with a prevalence ranging from 25 to 64% in surgical series and from 40 to 56% in epidemiologic studies. The prevalence of occult SUI, demonstrable only after prolapse reduction, is reported to be as high as 35.8%. Voiding symptoms are also prevalent particularly in patients with advanced prolapse. Overactive bladder (OAB) affects more than half of women with prolapse. *Conclusions*: Lower urinary tract symptoms are common in women with pelvic organ prolapse. The exact pathophysiology of the symptoms remains to be elucidated.

Keywords: Epidemiology; Lower urinary tract symptoms; Prevalence; Pelvic organ prolapse.

INTRODUCTION

Pelvic Organ Prolapse (POP) has been defined by the International Urogynecological Association (IUGA) - International Continence Society (ICS) joint report[1], as the descent of one or more of the anterior vaginal wall, posterior vaginal wall, the uterus or the apex of the vagina, in cases of previous hysterectomy. The exact prolapsing vaginal compartment and the degree of descent are described and quantified using the Pelvic Organ Prolapse - Quantification system (POP-Q)[2]. The sign of prolapse is accompanied by a variety of symptoms that include complaints of the prolapse itself, as well as urinary, anorectal dysfunction and sexual dysfunction symptoms. POP is an increasingly common female health problem and has a significant, negative impact on all aspects of daily life[3, 4].

As both POP and Lower Urinary Tract Symptoms (LUTS) are common[5] they frequently coexist. Available evidence, which has been summarized in previous reviews[6], suggests that this coexistence is not random and there is a pathophysiologic link between the two conditions. Nevertheless the exact relationship between POP characteristics and LUTS remains unclear.

One of the reasons for the existence of gaps in our understanding of the epidemiology and pathogenesis of various LUTS in women with POP is the variety of methods of diagnosing and reporting them: clinical interviews as well as validated questionnaires have been used. It is often that signs and urodynamic observations are sought and reported instead of the symptoms themselves.

This review aims to summarize recent evidence on the epidemiology of urinary complaints in women with pelvic organ prolapse.

MATERIALS AND METHODS

Pub Med was searched in September 2015 for English language papers reporting on the prevalence of LUTS in women with prolapse using the following terms: "lower urinary tract symptoms" OR "voiding symptoms" OR "voiding dysfunction" OR "overactive bladder" OR "incontinence" AND "pelvic organ prolapse" OR "cystocele". Search was limited to manuscripts published from 2010 onwards.

213 eligible papers were identified. 181 were excluded after reading the abstract as not relevant. 37 full papers were read and reference lists checked for missed manuscripts. In total 22 papers were included.

RESULTS

Twenty-two manuscripts are included in this review and summarized hereunder. The majority of evidence for the prevalence of urinary complaints in patients with pelvic organ prolapse comes from retrospective surgical series of prolapse repair. Seven population-based, cross-sectional studies were also identified.

1. Population based studies

Lowder *et al*.[7] conducted a cross-sectional study of women with at least stage I, according to POP-Q, prolapse, aiming to describe incontinence and other lower urinary tract symptoms. Three hundred thirty-six women attending a pelvic floor dysfunction clinic were enrolled; most of them with stage II (38%) or stage III (53%) prolapse. Lower urinary tract symptoms were assessed by the Urogenital Distress Inventory (UDI)[8] and Medical, Epidemiological and Social Aspects of Aging (MESA) questionnaire[9]. The UDI has subscales for stress, "irritative", and "obstructive" urinary symptoms and the MESA has subscales for stress and urge symptoms. Patients were categorized as having stress-only, urge-only, mixed, urge-predominant mixed, and stress-predominant mixed urinary incontinence based on UDI and MESA subscales. Only 4% of subjects reported no urinary symptoms on UDI. Based on questionnaire scores, 72% of women had mixed UI symptoms, 24% had urge-only symptoms, and only one had stress-only symptoms. In subjects with mixed UI symptoms, 57% had stress-predominant and 43% urge-predominant mixed symptoms. Despite the high prevalence of urge-relate symptoms only 9% of the patients had overactive detrusor contractions on urodynamic testing. Thirty-four percent had no urodynamic abnormality. Another observation in this study was that women with prior hysterectomy had more severe "irritative" urinary symptoms and greater symptoms bother.

Salvatore *et al*.[10] used a computer-based model analysis (Artificial Neural Network Analysis)[11] to assess the rela-

tionship between lower urinary tract symptoms, pelvic organ prolapse stage and other patient characteristics. They conducted a cross-sectional, observational study of women seeking care for lower urinary tract symptoms and POP which enrolled 1.344 subjects. Authors found that age, Body Mass Index (BMI), POP-Q stage I, and previous surgery for urinary incontinence were predictors of urgency and stress incontinence. POP-Q stages III-IV were related to voiding dysfunction and prolapse symptoms.

In a cross-sectional study evaluating the epidemiologic relation of OAB and pelvic organ prolapse, conducted in Dutch women 45 to 85years old by de Boer *et al*.[12], 1397 participants filled-out a self-reported questionnaire. The questionnaire used was a composite of validated questionnaires. Prevalence of urgency was 34%, frequency 28.7%, urge incontinence 29.8% and any OAB symptom 49%. Pelvic organ prolapse was reported by 11.4% of the women. Among women with symptomatic prolapse 69.4% had at least one of the OAB symptoms compared to 46.6% of subjects without POP: this difference was statistically significant. Frequency and urge incontinence were reported by 41.8% and 40.3% of women with POP versus 26.9% and 28.3% in women without POP, respectively. In a multivariate logistic regression model symptomatic POP was an independent risk factor for OAB with an odds ratio of 2.6.

Lien *et al*.[13] reported a cross-sectional study evaluating the prevalence of POP and associated risk factors for POP and LUTS, in Nepal. 174 women were included in the analysis. Sixty-eight (39.1%) had normal pelvic floor support or stage I prolapse and 106 (60.9%) had stage II POP or greater. Among the 106 women with prolapse stages II to IV, anterior compartment prolapse, posterior compartment prolapse and uterine or vaginal vault prolapse were reported in 53.4%, 36.2% and 21.3% respectively. Lower urinary tract symptoms were assessed using the Short form of the UDI questionnaire (UDI-6). It was found that 53.4% of women had urinary frequency, 56.3% stress incontinence, 46.6% urgency incontinence and 39.1% difficulty emptying the bladder. Authors noted that, as their analyses were conducted in women seeking care for pelvic problems, their results may not represent the general population of Nepal.

Cetinkaya *et al*.[14] evaluated the relationship between POP staging and lower urinary tract symptoms. They conducted a cross-sectional study of women attending a urogynecology unit with LUTS and/or vaginal bulging symptoms. Three hundred eighty-eight women were enrolled. Their distribution to POP stages was 27.8%, 21.4%, 38.9 % and 11.8 % for stages 0, I, II, and III or greater respectively. LUTS were evaluated using the short form of Urinary Distress Inventory (UDI-6) total and subscale scores. Incontinence was clinically assessed with the cough stress test. The stress test was positive in 167 patients (43 %) and positivity was highest in stages I and II compared to stages III and IV. Total scores for the UDI-6 did not differ among the POP stages, but "irritative", stress and obstructive subscales did: "irritative" and stress symptom scores were significantly higher in patients with stage II or greater POP, while "obstructive" symptom scores were higher in patients with stage III or greater.

A multicenter cross-sectional study of 521 women seeking treatment for pelvic floor dysfunction was reported by Espuña-Pons *et al*.[15]. Among the 521 women 224 had POP of grades II-IV (102 with stage II and 122 with stages III&IV). Urinary symptoms were assessed with the EPIQ questionnaire[16]. Stress incontinence, urge incontinence, frequency and nocturia were present in 52.2, 66.5, 61.6 and 36.6% of the patients respectively. Difficulty emptying the bladder was reported by 30% of patients with grade II and 52.4% of patients with grades III&IV POP. The positive association of urinary symptoms to prolapse was not confirmed in the multivariate analysis suggesting that other factors apart from the POP stage are involved in the pathogenesis of urinary symptoms in POP.

In a cross-sectional study of incontinent female patients older than 55 years, Casteleijn *et al*.[17] investigated the prevalence of voiding dysfunction in women with POP. Two hundred thirty- three incontinent women with POP stages I to III, were included. Ninety one % of the women had POP stages I and II. Urinary symptoms were assessed by the UDI-6 and voiding dysfunction by free uroflowmetry and post void residual (PVR). "Obstructive" urinary symptoms were present in 39.7% according to the UDI-6 and 24.8% of patients had voiding dysfunction, defined as a maximum flow rate ≤15 ml/s and-or a PVR ≥50 ml. No significant differences in urinary symptoms were observed between the POP-Q stages. Increasing age and anterior as well as posterior wall prolapse were predictors for voiding dysfunction.

2. POP repair series

In a series of 233 continent women planned for POP repair, Jundt *et al*.[18] performed a stress test with the prolapse reduced and reported a 35.8% prevalence of occult incontinence.

Elser *et al*.[19] evaluated the use of preoperative urodynamics in determining the need for an anti-incontinence procedure at the time of abdominal sacrocolpopexy. They conducted a retrospective review of 441 patients and reported preoperative urodymamic diagnoses. The distribution to prolapse stages was 23.4% stage II, 43.9% stage III and 32.7% stage IV. Two hundred-four patients (43.6%) had SUI on preoperative urodynamics: 122 without prolapse reduction during the urodynamic study and 82 had occult SUI which became evident with prolapse reduction. Two hundred thirty-seven patients had no demonstrable SUI. Detrusor overactivity was diagnosed in 88 patients (20%). Women with urodynamic SUI were significantly younger and had a higher percentage of patients with stage II prolapse, compared to women without SUI.

In a retrospective cohort study of 88 patients undergoing anterior compartment prolapse surgery Fletcher *et al*.[20] analyzed demographic and urodymamic data as predictors of postoperative outcomes. The presence of and bother from individual LUTS, including frequency, urge incontinence and difficulty voiding, was assessed using individual questions from the UDI-6 (questions 1, 2 and 5 respectively). POP was objectively graded according to the Baden-Walker halfway system[21]. There were 74 (71%) patients with moderate/severe urinary frequency, 67 (64%) with moderate/severe urgency incontinence, and 30 (29%) with difficulty emptying their bladder. Authors reported that there was no correlation between prolapse grade and baseline complaints of frequency or urge incontinence. There was a significant correlation between prolapse grade and complaints of difficulty emptying, with 87% of patients reporting moderate/severe difficulty emptying having advanced prolapse.

Dain *et al*.[22] reviewed preoperative data of 81 women scheduled for pelvic reconstructive surgery for POP aiming to determine whether "obstructive" voiding symptoms in women with advanced pelvic organ prolapse are associated with objective bladder outflow obstruction. Forty of 81 (49.4%) women reported incomplete bladder emptying preoperatively, according to the Pelvic Floor Distress Inventory (PFDI)-20 questionnaire[23]. Interestingly only 7 (17.5%) had obstructive uroflowmetry, defined as a maximal flow below 15 ml/s. These women did not differ from those without subjective voiding difficulty in terms of ob-

structive uroflowmetry, mean postvoid residual volume, maximum and average flow rates.

Wolter *et al*.[24] retrospectively analyzed the records of 111 female patients who underwent grade 3 or 4 cystocele repair and a concomitant midurethral sling procedure. All patients had a history of previous hysterectomy. 12% of the patients were asymptomatic as far as incontinence is concerned. Based on patient history and voiding diary at presentation mixed, urgency and stress incontinence were present at 54%, 9% and 25% respectively. Ten women with urgency incontinence and 13 asymptomatic patients were found to have occult SUI.

In order to understand the relationships between urinary symptoms, urodynamic findings and POP staging, Serati *et al*.[25] used the Artificial Neural Network Analysis to process data from a prospective cohort of women with pelvic floor dysfunction. Eight hundred- two women were included in the analysis. As far as symptoms are concerned 61.8% (496) had stress incontinence 68.6% (550) had overactive bladder with or without urgency incontinence and 33.3% (267) had voiding dysfunction. On urodynamic evaluation urodynamic stress incontinence, detrusor overactivity and mixed incontinence were found in 33.8% (271), 18.7% (150) and 24.3% (195) of the patients, respectively. The remaining 23.2% (186) women had normal urodynamic studies. Authors found that urodynamic diagnosis and anatomic findings were poorly correlated. They concluded that urodynamics is still superior to any sophisticated statistical method of predicting outcomes and the associations between baseline data, symptoms, anatomic findings, and urodynamic diagnosis, even if statistically significant, cannot be used in the clinical setting.

Chermansky *et al*.[26] analyzed the records of 30 patients who underwent POP-Q stage III or IV prolapse repair. Preoperative evaluation included a supine or standing stress test with prolapse reduction to check for urine leakage. Prolapse was reduced with a single speculum blade when supine and vaginal packing when standing. In patients without demonstrable SUI urodynamic testing with and without prolapse reduction was performed. During filling cystometry Valsalva testing was performed at 150 ml and at 50 ml increments thereafter until SUI was recorded or cystometric capacity was reached. Stress incontinence was revealed during stress test or urodynamics in 16 of 30 women. In the remainder 14 no stress leakage could be demonstrated.

In a retrospective cohort study of 183 women undergoing repair for anterior or apical compartment prolapse, Miranne *et al*.[27] found no difference in prevalence of urinary frequency and urge incontinence between patients with stage I and II prolapse (91% and 72% respectively) and patient with stage III and IV prolapse (89% and 75% respectively). Nevertheless, the urodynamic observation of detrusor overactivity was significantly more common in patients with more severe prolapse (35% in women with stages III and IV compared to 17 % in women with stages I and II POP). Similarly, in a series of 43 women with a prominent posterior compartment prolapse Costantini *et al*.[28] reported a 76.74% (33 patients) prevalence of urgency. Nevertheless detrusor overactivity was found in 25.6% (11 patients).

Smith *et al*.[29] conducted a secondary analysis of a prospectively enrolled case-control study to evaluate differences in levator ani defects and pelvic floor function among women with prolapse and controls. Inclusion criteria were either anterior or posterior predominant prolapse, at least to the level of the hymen, and a stress incontinence testing with prolapse reduction. 214 women were included. An overall rate of 9.8% for a positive stress test was reported. Rates of positive stress test for the anterior (n=169) and the posterior (n=45) compartment prolapse group were 11.2% and 4.4% respectively without prolapse reduction and 10.7% and 13.3% respectively with prolapse reduction.

In a retrospective review of the medical records of 308 women with stage III or IV prolapse, Liang *et al*.[30] assessed urinary symptoms during patient interviews. Authors reported daytime frequency in 73.4%, nocturia in 42.8%, urgency in 47%, urgency incontinence in 26%, stress incontinence in 46.1%, straining to void in 22.4% and difficulty in voiding in 38% of the patients. Authors were particularly interested in the cystoscopic finding of bladder trabeculation which was present in 54.9% (169) patients. Patients with bladder trabeculation had more detrusor overactivity and greater post-void residual volumes than patients without, but other urodynamic parameters, including bladder outflow obstruction, did not differ significantly. As far as symptoms are concerned, patients with bladder trabeculation had more urgency and urge incontinence than patients without.

Gowda *et al*.[31] also conducted a retrospective cohort study to investigate the association between urinary symptoms, prolapse stage and bladder trabeculation. 551 women who underwent cystoscopy for various indications in a urogynecology center were included and 86 were found to have bladder trabeculation. Overall there was no association between presence of trabeculation and stage of POP, even though women with stage IV anterior compartment prolapse had grater odds of having bladder trabeculation compared to women with stage 0 prolapse. Urodynamic data, available for 357 women, were not conclusive for the relation of BOO and trabeculation. As far as symptoms are concerned women who reported urge urinary incontinence had 4 times grated risk of trabeculation compared to women without.

Kanasaki *et al*.[32] analyzed the records of 105 Japanese women who underwent transvaginal mesh repair for pelvic organ prolapse between 2009 and 2012. POP-Q stage III was the most common stage (73 patients), followed by stage II (23 patients). Anterior prolapse (cystocele) was the predominant prolapsing compartment in 60% of the study population. The presence of preoperative SUI was confirmed at the time of surgery in 50 of the 105 patients. There was no significant association between patients' age, POP-Q stage or predominant prolapsed organ and the presence of SUI.

The clinical and urodynamic records of 66 women who underwent anterior vaginal prolapse surgery for grade III or IV cystocele and a concomitant midurethral sling, were retrospectively analyzed by Chae *et al*.[33]. Of the 66 women, 36 had voiding dysfunction preoperatively, defined objectively as maximal flow rate below 15 ml/s and/or postvoid residual urine volume >50 ml on uroflowmetry. Women with voiding dysfunction were further categorized as having bladder outflow obstruction [23 patients (64%)] or detrusor underactivity [13 patients (36%)] using a cutoff of 20 cmH_2O for the detrusor pressure at maximum flow. POP-Q stage was significantly higher, and points Aa and Ba were significantly longer in the voiding dysfunction group. There were no significant differences between patients with and without voiding dysfunction in age, parity, body mass index, SUI grade, presence of urgency and urge incontinence, and urodynamic parameters, except in uroflowmetry.

Majkusiak *et al*.[34] assessed in a prospective study the quality-of-life changes in 40 women with POP stage III or IV who underwent prolapse correction with supracervical hysterectomy and cervicosacropexy with polypropylene mesh. Stress urinary incontinence was diagnosed in 42% (21) of the patients preoperatively, overactive bladder (OAB) in 50% of women, and postvoid residual urine greater than 100 ml in 32.36%.

Tomoe H.[35] prospectively evaluated 100 consecutive women with POP stage II or greater and an associated cystocele. Overactive bladder was diagnosed in 53 of 100 patients preoperatively while detrusor overactivity was observed in 52.8% of overactive bladder cases.

DISCUSSION

The results of this review confirm that the epidemiology of lower urinary tract symptoms in women with pelvic organ prolapse is not extensively studied. From 2010 onwards only seven cross-sectional studies have been identified in the literature involving 4,000 patients. Despite the fact that these studies used validated questionnaires, most often the Urogenital Distress Inventory, to diagnose and quantify the symptoms, they focus on different symptoms or combinations of symptoms. As a consequence, their results are not directly comparable. Nevertheless, it seems that all studies agree that lower urinary tract dysfunction is highly prevalent in female populations with pelvic organ prolapse. The most commonly addressed symptom is that of incontinence with stress incontinence reported in 40-56% and urgency incontinence reported in 29-66% of the studied populations. Prevalence of overactive bladder symptoms is also reported with urgency rates ranging between 35% and 72%. A formal diagnosis of Overactive Bladder (OAB) can be made in more than half the women with POP. Interestingly voiding symptoms are not often addressed by their prevalence ranges between 18 and 39%.

The prevalence of urinary complaints has also been reported by several recent surgical series of women undergoing treatment for prolapse. In theses series patient populations are small and urinary symptoms are almost invariably reported and analyzed retrospectively. In surgical series the focus is clearly on stress incontinence and, in particular, occult stress incontinence which is demonstrated only when prolapse is reduced. For this reason some studies report on the symptom of stress incontinence while the majority report the urodynamic observation or the clinical sign of incontinence during a stress test. In any case, the prevalence of SUI in surgical series ranges from as low as 20% to as high 64% while occult stress incontinence is reported to affect approximately 20%-35% of women for whom a prolapse repair is planned. Voiding difficulty is another dysfunction often addresses in surgical series and is reported for 23 to 60% of women.

The correlation of urinary symptoms to stage of prolapse showed contradictory results but, in general, lower stages of prolapse are associated with overactive bladder symptoms and stress incontinence while advanced prolapse is associated with more voiding difficulty and less stress incontinence. This finding is in line with the presumed pathophysiology of urinary dysfunction in advanced prolapse where the proximal and mid-urethra are compressed against the pubic bone causing increased outlet resistance and "protecting" from stress incontinence[36].The unmasking of SUI with prolapse reduction has been reported in more than half of clinically continent women with severe POP[37] and the need for prophylactic anti-incontinence surgery has been one of the most interesting topics of research in recent years.

In summary, despite differences in assessment methods and reporting of urinary symptoms in women with pelvic organ prolapse, lower urinary tract dysfunction is highly prevalent in this growing female population. Further research is needed for a better understanding of the pathophysiology of urinary symptoms in relation to prolapse which will hopefully improve our ability to efficiently address them during prolapse management.

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Multidisciplinary Uro-Gyne-Procto Editorial Comment

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

Gynecologist... Thank you for asking me to comment this article. The review provides a good summary of the relationship between bladder symptoms and prolapse, but no anatomical solutions are offered to explain this link. The authors conclude "Further research is needed for a better understanding of the pathophysiology of urinary symptoms in relation to prolapse which will hopefully improve our ability to efficiently address them during prolapse management." It is unfortunate that this otherwise excellent review did not extend to the 1997 IUJ article.[1] This was the first article to challenge the Integral Theory[2] which now states Pelvic organ prolapse, bladder and bowel dysfunction and some types of pelvic pain, mainly derive, for different reasons, from laxity in the vagina or its supporting ligaments a result of altered, collagen/elastin. The abstract of the 1997 paper is reproduced with two figures from the original paper

Abstract: The aim of the study was to introduce an anatomical classification for the management of urinary dysfunction based on the Integral Theory, a new connective tissue theory for female incontinence. Eighty-five unselected patients were classified as having laxity in the anterior, middle or posterior zones of the vagina, using specific symptoms, signs and urodynamic parameters summarized in a pictorial algorithm. Special ambulatory surgical techniques, which included the creation of neoligaments, repaired specific connective tissue defects in the anterior (intravaginal slingplasty (IVS), n = 85), middle (cystocele repair, n = 6), or posterior zones (uterine prolapse repair, n = 31, or infracoccygeal sacropexy, n = 33). Almost all patients were discharged within 24 hours of surgery, without postoperative catheterization, returning to fairly normal activities within 7-14 days. At (mean) 21-month follow-up cure rates were: stress incontinence 88% (n = 85), frequency 85% (n = 42), nocturia 80% (n = 30), urge incontinence 86% (n = 74), emptying symptoms 50% (n = 65). Mean objective urine loss (cough stress test) was reduced from 8.9 g preoperatively to 0.3 g postoperatively, and mean residual urine >50 ml from 110 ml to 63 ml, P = <0.02. Pre- and postoperative urodynamics indicated that detrusor instability was not associated with surgical failure. Two new directions, based on the Integral Theory, are presented for the management of female urinary dysfunction, an anatomical classification which delineates three zones of vaginal damage, and a series of ambulatory surgical operations which repair these defects. The operations are fairly simple, safe, effective and easily learnt by any practising gynecologist.

The mechanism for ligament damage is shown in figure 1 and the relationship of damaged ligaments to symptoms in figure 2.

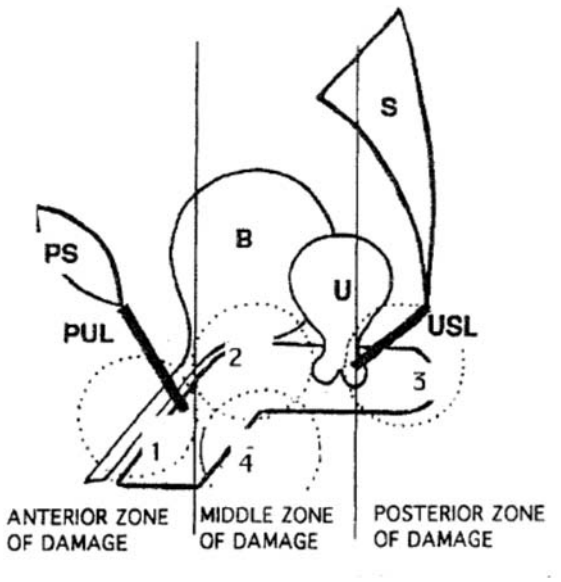

Figure 1. – Damage to vagina at childbirth. The circles represent the fetal head overstretching the connective tissue of the vagina and its supporting ligaments as it descends through the birth canal. 1. hammock and pubourethral ligament laxity; 2. cystocele and arcus tendineus fasciae pelvis defect; 3. uterine prolapse, enterocele; 4. rectocele.

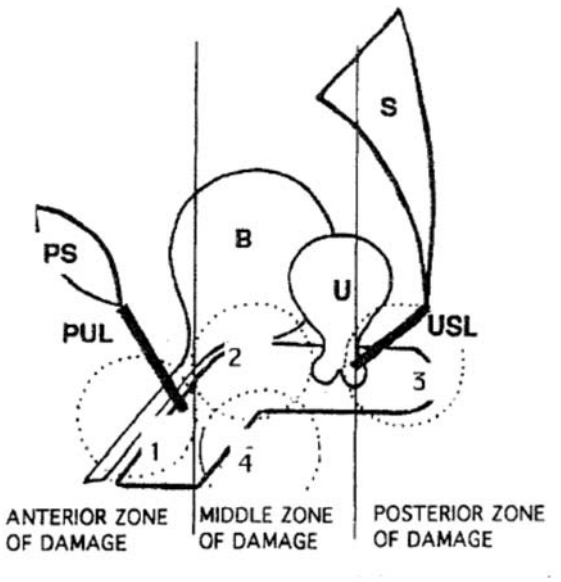

Figure 2. – Relationship between symptoms and damaged ligaments.

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Proctologists/Colo Rectal Surgeons... The paper by Giannitsas et al is an excellent attempt at trying to make sense of associated urinary symptoms in pelvic floor dysfunction, the causes of which are considered unknown, despite being highly prevalent and well-recognised. The findings of the paper can, in my opinion, be succinctly described as follows:

1. urinary symptoms such as over active bladder, urinary urgency, urinary urge incontinence, incomplete bladder emptying and stress urinary incontinence are common and frequently occur in combination.
2. These symptoms appear to be more prevalent in those who have pelvic organ prolapse.
3. There does not appear to be a direct correlation between symptom prevalence and stage of pelvic organ prolapse.
4. Other than for stress urinary incontinence, surgery is performed predominantly for prolapse but not with the intention of curing symptoms.
5. Urodynamics is not predictive nor helpful in the clinical setting.

Globally, urogynaecologists (and not to mention colorectal surgeons, urologists and gynaecologists) remain perplexed by these five well recognised observations and continue to strive to make sense of the situation. They appear to believe that these bladder and other symptoms are mutually exclusive and almost certainly have their own unique cause, which is as yet unknown. Interestingly, they choose to use ever increasingly complex urodynamic and manometric assessment, definitions and analysis to solve the mystery. These practitioners, who I shall call the "*Urodynamicists*" make up in excess of 99% of pelvic floor specialists and in recent years, have made little progress in finding a cure for these symptoms.

By contrast, and by far in the tiny minority are those that have already accepted that the above five statements are true and have looked for an alternative hypothesis by which they can be explained. They have chosen to familiarise themselves with the Integral Theory by Petros and Ulmsten, which theorises that pelvic floor dysfunction is due not to an abnormality in the bladder (or for that matter, rectum) but due to a lack of support of those organs. Depending upon the degree and site of loss of support, and as with most biological systems by introducing a degree of chaos, can produce any of the symptoms outlined above. Not only that, it further explains the coexistence of posterior compartment symptoms such as obstructed defecation, faecal incontinence and pelvic pain which are also well-recognised as occurring not only in combination with each other, but in combination with multiple bladder symptoms. The "*Integral Theorists*" as they may be called use the prevalence and combinations of these symptoms to determine where the weakness in support may lie, and approach treatment by trying to reconstruct the native anatomy. It is a symptom-based approach, the prolapse taking care of itself as part of the treatment. Interestingly, all the "*Urodynamicists*" who insert mid-urethral slings for stress urinary incontinence already practice the Integral Theory. They may simply not be aware of it.

At some point, hopefully in the near future pelvic floor medicine will reach a crossroads where we will either continue to try and make sense of the situation with urodynamics or in contrast look more closely at adopting the Integral Theory. It will be interesting to see who turns left and who turns right.

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Original Article

Is 'suspension plus plication' of the uterosacral ligaments to the vaginal apex during hysterectomy a preventive measure for vaginal vault prolapse? A randomized trial

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Abstract: OBJECTIVE. The purpose of this study is to investigate the effectiveness of 'suspending+plicating' of the uterosacral ligaments to the vaginal apex during transabdominal total hysterectomy as regards development of postoperative vaginal vault prolapse. *Materials and methods:* The study has been carried out on 60 women who have had total abdominal hysterectomy due to benign reasons between the dates of April 2013 and April 2014. The patients were randomly allocated either to 'suspension + plication' group (SP, Group 1) or 'suspension' group (S, Group 2). Pelvic Organ Prolapse Quantification (POP-Q) system was applied to all patients before and at 6th months after the surgeries. Preoperative and postoperative C point and transvaginal length (TVL) values were compared within and and between groups. Wilcoxon Signed Ranks test has been used for the statistical analysis of the data. P value was set at <0.05 for statistical significance. *Results:* There were no statistically significant differences between the groups in terms of C point and TVL values before the operations ($p > 0.05$). The comparison between C points (preoperatively and at the 6th month follow up) showed statistically significant difference ($p = 0.0002$) in group 1, whereas no difference was found in group 2 regarding C point ($p = 0.1433$). However, the comparison between TVL measurements (preoperatively and at the 6th months follow up) showed no statistically significant difference in group 1 ($p = 0.4539$), but statistically significant difference was observed in group 2 concerning TVL measurements ($p = 0.0001$). *Conclusion:* The 'suspension + plication' of the uterosacral ligaments is prophylactic on vault prolapse in the short term.

Keywords: Vault prolapse; Uterosacral ligament; Suspension; Plication; Prevention.

INTRODUCTION

The uterosacral-cardinal ligament complex is the basic structure that supports the uterus in its normal anatomic position and the effect of uterosacral ligament (USL) is very prominent with respect to cardinal ligament regarding the De Lancey Level 1 suppport.[1] Actually, the cardinal ligament (CL) is a fascial envelope which entails internal iliac vessels and uterine vessels, fuses to the cervix, lower uterine segment and upper vagina. On the other hand, the USL is much denser and stronger than the CL. Hence, the USL has been becoming an important structure of interest in the management and prevention of pelvic organ prolapse. While 33% of the USL originates only from the cervix, 63% originates from both the cervix and vagina and 4% originates only from the vagina; 82% of the USL terminates at the sacrospinous ligamanent/coccygeus muscle complex, 7% terminates at the sacrum and 11% terminates at the m.piriformis.[2] The origin of the USL is fanlike at the sacrum, narrowing to its smallest width just proximal to the cervix.

The length of the USL ranges between 12-14 cm. Based on the thickness and attachments of the ligament, it can be subdivided into three sections: distal (cervical, 2-3 cm), intermediate (5 cm) and proximal (sacral, 5-6 cm).[3] The intermediate part is wide, thick and has a distance of 2 cm from the ureter which makes it the most appropriate section for surgery.[3]

Hysterectomy is the most commonly performed surgical procedure, approximately 600,000 hysterectomies are being undertaken in each year in the United States.[4] One of the complications of hysterectomy is the vaginal vault prolapse. Although the exact incidence is not known, the incidence ranges between 0.2% to 43%.[5]

Various surgical techniques have been proposed in order to prevent postoperative vault prolapse. The suspensions of vault to the USL or USL/CL complex are one of those techniques that can be done easily concomitant with the abdominal hysterectomy.[6-8]

In this study, we aimed to compare effectiveness of the suspension + plication of vaginal vault to the USL with the suspension of vault to the USL/CL complex (described by Richardson) on the potential development of cuff prolapse.

MATERIALS AND METHODS

This prospective, randomised study has been carried out in the Gynecology and Obstetrics clinics of the Izmir Katip Çelebi University, Atatürk Training and Research Hospital between April 2013-April 2014. The ethics committee of the hospital accepted the study (Decision Number/Date: 62 / 25.April.2013). All of the patients have signed an informed consent before participating to the study.

The study group consisted of 60 women who underwent total abdominal hysterectomy (type 1) due to benign pathologies. Once the uterus has been removed a group of patients had their vaginal apex being 'suspended' to the USLs, in addition to that the USLs were plicated to each other. This group was named as 'suspension + plication group' or Group 1. Another group of patients only had their vaginal apex being 'suspended' to the USL/CL complex (described by Richardson).[7] This group was named as 'suspension group' or Group 2. Each group entailed 30 patients and the patients were allocated to the groups by a computer programme randomly. The study flow chart has been given (Figure 1).

Surgical procedures

Plication + suspension technigue: once the uterus has been removed, a nonabsorbable suture starting from the ipsilateral cervical USL and ending at the ipsilateral vaginal vault angle was tied. The same kind of suture was repeated on the contralateral side [(first and second suture) (Figure 2)]. Then a nonabsorbale suture (1 cm. caudal to the first suture) starting from ipsilateral USL passing through the posterior vaginal wall (not entering to the vagina) and end-

Figure 1. – The study flow chart.

ing at the contralateral USL (1 cm caudal to the ipsilateral second suture) was placed [(third suture) (Figure 2)]. Lastly another nonabsorbable suture (1 cm caudal to the third suture) starting form ipsilateral USL passing through the posterior vaginal without entering to the vagina and ending at the contralateral USL (1 cm caudal to the third suture) was placed [(fourth suture) (Figure 2)]. Then all the sutures were tied without any tension on the uterosacral ligaments so that the apical and posterior vaginal compartment support have been sustained aiming to prevent apical prolapse and/or enterocele formation.

Suspension technique: the vaginal vault angles were suspended to the ipsilteral USL/CL complex with one nonabsorbable suture which was placed and tied on each corner as described by Richardson.[7]

All patients have had Pelvic Organ Prolapse Quantification (POP-Q) system before, 3 months and 6 months after hysterectomy. The primary end point of the study was to compare the C point and total vaginal length (TVL) between the groups at the end of 6 month follow ups.

Inclusion criteria were 1) the women between the ages of 35-70, 2) having a benign pathology necessitating removal of uterus with/without ovaries abdominally.

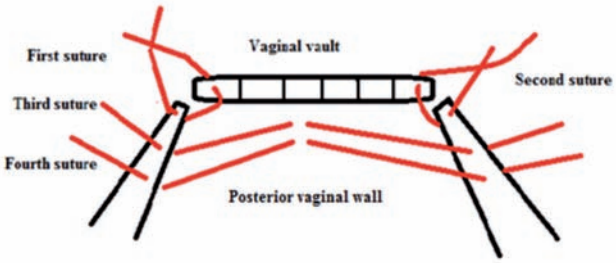

Figure 2. – The schematic drawing of the 'suspending' and 'plicating' sutures.

Exclusion criteria were 1) undergoing hysterectomy due to malign pathologies, 2) having a uterus larger than 20 weeks of gestation, 3) the leading edge of C point is <+1 or > -1cm compared to hymenal ring (Stage II), 4) having stress urinary incontinence.

Statistical analysis

SPSS 15.0 for Windows package program was used for the analysis of the data. The defining statistics for continous variables has been defined as mean±standard deviation (min-max). Wilcoxon Signed Ranks test was used for the comparison of the data. The P value was set at <0.05 for statistical significance.

RESULTS

The mean follow up time was 5.7 ± 1.02 months (min. 4.5 - max. 6 months). The demographic parameters of the patients are given in table 1.

The preoperative POP-Q scoring of the patients is given at table 2. There were no statistically significant difference between the groups in terms of C point and TVL before the operation ($p > 0.05$).

At the 6th month follow up; the C point and TVL values in the suspension + plication group (Group 1) were -5.30 ± 0.25 and 8.76 ± 0.23, respectively (Table 3). The comparison between preoperative C point value and the C point value at the 6th month follow up in this group showed statistically significant difference ($p = 0.0002$). Whereas the comparison between preoperative TVL and the TVL at the 6th month follow up in this group did not show statistically significant difference ($p = 0.4539$).

Moreover, at the 6th month follow up, the C point and TVL values were -4.46 ± 0.20 and 7.03 ± 0.22, in the suspension group (Group 2), respectively (Table 3). The comparison between preoperative C value and the C value at the 6 month follow up in this group did not show statistically significant difference ($p = 0.1433$). However, the comparison between preoperative TVL and the TVL at the 6th month follow up showed statistically significant difference in this group ($p < 0.0001$).

TABLE 1. The demographic parameters of patients.

	Group 1	Group 2	p value
Age (years)	48.2 (min. 35 - max. 69)	46.9 (min.36 - max.65)	0.4720
Parity	2.46	2.33	0.6928
Body mass index (kg/m^2	23.87 ± 1.7	24.47 ± 2.4	0.7683

TABLE 2. The preoperative POP-Q scoring of the groups.

Variable	Group 1	Group 2	p value
C point	-4.56 ± 0.25	-4.63 ± 0.20	0.84
TVL	8.56 ± 0.23	8.,73 ± 0.22	0.63

TABLE 3. The comparisons between C point and TVL values between groups.

	Suspension group	plication (Group 1)	Suspension (Group 2)	group
Preoperative	-4.56 ± 0.25	8.56 ± 0.23	-4.63 ± 0.20	8.73 ± 0.22
6th month follow up	-5.30 ± 0.25	8.76 ± 0.23	-4.46 ± 0.20	7.03 ± 0.22
P value (preop vs.6th month)	0.0002	0.4539	0.1433	< 0.0001

No complication has been seen in the patients at the intraoperative or late postoperative period.

DISCUSSION

There are some studies indicating that the uterosacral suspension which is being performed concomitant to hysterectomy would not only be used for the prophylaxis of vaginal vault prolapse but also can cure the already existing apical prolapse.[6, 7] In accordance with this; our study has showed that when the vault was suspended to the USLs and the USLs were plicated to each other as well as to the vaginal vault the C point moves upwards (cephalad) and this seems to be prophylactic against cuff prolapse. When the data regarding TVL measurements are evaluated, it will be seen that the length of the vagina has decreased (preoperatively 8.73 to 7.03 at the 6th month follow up) in group 2 and the difference was statistically significant ($p = < 0.0001$). This may be a heralding sign for the potential of vault prolapse because this type of shortening of vaginal length could not be due to surgery. We should also stress that all the surgeries have been performed by the same surgeons (AAS, EKM) by using the same technique, therefore, if the shortening of vagina in group 2 was the result of surgery, more or less a shortening of vaginal length would have been seen in group 1 as well. The decrease in TVL measurement and not observing any significant change in C point upwards in group 2 can be regarded as a forthcoming cuff desensus in the long term.

Lowenstein, *et al*.[7] found that the suture erosion was the most common complication (9%) of uterosacral plication technique and they argued that suture erosion was associated with concomitant surgery (such as colporraphy posterior) and older patient. In our study we have not noticed any erosion during the follow up. However, it should be on mind that erosion is a timely phenomenon.

Uterosacral plication and ureteral kinking are a well known association. Therefore, application of intraoperative cystoscopy in order to determine this complication has been advocated.[6] In our study, we did not perform intraoperative cystoscopy and have not seen any complication related to the ureters. We believe that the sutures that had been placed were not at a risky level for trapping ureters. We would not advocate cystoscopy to be applied intraoperatively due to the ease and low riskof our technique. Also, by not performing cystoscopy, we saved our patients the cost and complications of an invasive procedure.

Abdominal uterosacral suspension + plication is a fairly simple procedure. It does not necessitate special surgical training and can be performed with the same equipment used for hysterectomy.

CONCLUSION

To our knowledge, this is the first study comparing two techniques in order to prevent vault prolapse and we observed that uterosacral suspension + plication concomitant to abdominal hysterectomy has sustained statistically significant effect favouring its application. This simple procedure would be a preventive measure against vault prolapse. However, further studies with longer follow ups and larger sample size are required to clarify the net effect of this technique on vaginal vault prolapse.

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Original Article

The efficacy of the anorectal functional examinations and the correlation with the symptoms of evacuation difficulty

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Abstract: Aim. The aim of this study was to assess the efficacy of anorectal functional examinations. M*ethod:* Forty-three patients who fulfilled the Rome III diagnostic criteria for functional constipation were enrolled in this study from March 2013 to May 2014. Balloon expulsion test (BET), anorectal manometry (ARM) during attempted defecation, and defecography were performed. The correlation between BET, ARM, defecography and symptoms of evacuation difficulty was assessed. *Results:* There was a significant correlation in the difference between the balloon expulsion volume and recto-anal pressure, the recto-anal pressure and evacuation of paste, and the anal relaxation rate and evacuation of paste. Moreover, there was a significant correlation between the balloon expulsion volume and evacuation of paste in the symptom represented by the item, "Minutes in lavatory per attempt" and between the recto-anal pressure and evacuation difficulty. *Conclusion:* The findings for each of the anorectal functional examinations revealed that there was not much of a correlation between the symptoms of defecatory disorders and patient complaints. However, a combination of examinations can probably benefit the characterization of the functional defect and the precise diagnosis of functional defecation disorders (FDD).

Keywords: Anal manometry; Balloon expulsion test; Defecography; Evacuation difficulty.

INTRODUCTION

Anorectal disorders are becoming the number one cause of evacuation difficulty. Constipation, in particular, is a relatively common complaint but may be the result of complicated causes. In general, the causes are functionally separated into the following subgroups: slow colonic transit, normal colonic transit, and defecatory or rectal evacuation abnormalities.[1] Smooth defecation involves the complex physiological interaction of the rectum, the effective motility of the gastrointestinal tract, the coordination of the pelvic floor muscles, and the relaxation of the external anal sphincter.[2] Anorectal dysfunction is detected by a series of physiological examinations which include the balloon expulsion test (BET), anorectal manometry (ARM), X-ray, MR defecography and electromyogram. These examinations provide a lot of information about anorectal function and shows just how complex this system is. The Rome III criteria recommends the above mentioned anorectal examinations but does not provide any guidelines on the status and the analytical procedure of the combined application.[3] However, due to the complicated nature of the symptoms, a thorough examination is performed to learn as much as possible about the patient's anorectal dysfunction.

The aim of this study was to assess the efficacy of the anorectal functional examinations to make the evaluation system more simple and effective.

PATIENTS AND METHODS

Subjects

Forty-three consecutive patients who fulfilled the Rome III diagnostic criteria for functional constipation and who completed the anorectal function evaluation questionnaire were enrolled in this study from March 2013 to May 2014 at Takano Hospital after informed consent was obtained. We assessed the correlation between BET, ARM and defecography. In addition, we assessed the correlation between each examination and the symptoms identified using the constipation scoring system (CSS)[4] and the information given by the patients themselves. Patients were excluded from the study if they had significant cardiovascular, respiratory, neurologic, psychiatric illnesses, severe psychological problems and/or endocrine and metabolic diseases.[5] The patients were interviewed before the examinations and after they completed the constipation scoring system (CSS) and indicated whether or not they experienced evacuation difficulty (Yes or No). Once institutional review board (IRB) approval was obtained a prospective non-randomized study was launched. The risks of additional x-ray exposure were disclosed to the patients in the process of getting informed consent.

Methods

Balloon expulsion test (Balloon expulsion volume) Patients were administered a phosphate enema (left lateral decubitus position with flexion of the knees and hips) at least 30 minutes prior to the procedure. An empty well lubricated rubber balloon was gently inserted into the rectum. The other side of the balloon was attached to a plastic tube and a catheter with an air-filled syringe to inflate the balloon. Patients were then asked to move into a sitting position and try to expel the balloon. After each successful attempt, the volume of air was gradually increased by 10ml increments and continued over a period of two minutes until the patient was unable to expel the balloon. The volume of air residue in the last successfully expelled balloon was measured and recorded as the "balloon expulsion volume (BEV)". A BEV reading equal to or greater than 30ml was considered normal (max. 50ml).

Manometry during attempted defecation (recto-anal pressure difference & anal relaxation rate). Patients were administered a phosphate enema at least 30 minutes prior to the procedure. ARM was performed using a solid-state manometric assembly with 2 lateral sensors spaced at 6.5cm intervals (Star Medical, Japan). After the 2-channal pressure assembly was gently inserted into the rectum (left lateral decubitus position), by placing the proximal sensor in the anal canal and the distal sensor in the rectum, the patients was asked to push. The pressure in the rectum and anal canal during attempted defecation were measured simultaneously. The difference in the recto-anal pressure (RAPD) was calculated by subtracting the minimum anal residual pressure during attempted defecation from the maximum rectal pressure during attempted defecation. The anal relaxation rate (ARR) was calculated as follows; max-

imum anal rest pressure - residual pressure during attempted defecation)/maximum anal rest pressure.[6] The patients were then divided into three subtypes based on the RAPD results and in accordance with the Rome III diagnostic criteria for functional defecation disorders (FDD).

Defecography (evacuation of paste & anal-rectal angle difference). Patients were administered a phosphate enema (left lateral decubitus position) of approximately 100 ml of barium paste 30 minutes prior to the procedure. The barium paste was mixed with oatmeal to create a consistency of stool similar to Bristol type 4. The patient was then asked to sit on a commode. Lateral photos of the pelvis were taken during the pushing phase and while the patient was in a sitting position. The results of the "evacuation of paste" were classified as either "none", "partial" or "complete". The anal-rectal angle was the angle between the anal canal and the tangential line drawn along the posterior rectal wall behind the impression just proximal to the upper anal canal. The normal anal-rectal angle (ARA) during rest and defecation was increased. The results of the anal-rectal angle difference were classified as either "normal" or "abnormal".[7]

Statistical analysis

The statistical analysis was performed using the statistical package for social science (SPSS) software version 19.0. Spearman's correlation coefficient was used to determine correlations and the chi square (x^2) test was used for group comparisons of dichotomous variables. Statistical significance was preset at $P < 0.05$.

RESULTS

Patient characteristics and examination results

The mean age of the 43 patients (27 male; 16 female) enrolled in this study was 69 years (range 19 - 87 years). The balloon expulsion volume and number of patients are as follows; 0 ml (6 patients), 10 ml (11 patients), 20 ml (11 patients), 30 ml (7 patients), 40 ml (3 patients), and 50 ml (5 patients). The mean RAPD was -23.2 ± 48.63 cmH20 (range -146.2 - 87.7 cmH20) and the mean ARR was -50.0 ± 90.6% (range 226.1 – 100). The X-ray defecography revealed that 11 patients had complete evacuation, 13 patients had partial evacuation and 19 patients were unable to evacuate the paste. Twelve patients were able to increase the anal-rectal angle during the push phase compared to the rest phase, and the remaining 31 patients were unable to change the anal-rectal angle and in some cases it even decreased. The pre-examination interview results revealed that 35 patients complained of evacuation difficulty and the CSS score ranged from 2 to 20 with a mean of 10.1 ± 5.0 (Table 1).

Correlation between examinations

The correlative evaluation was performed based on the recorded data. The statistical analysis revealed that there was a significant relationship in four matches of the examinations. Correlative analysis revealed that the balloon expulsion volume was positively correlated with the recto-anal pressure difference($R = 0.565$, $P < 0.01$) and evacuation of paste ($R = 0.451$, $P < 0.01$), but did not correlate with the anal relaxation rate (R=-0.293, P=0.056) and ARA difference ($R = -0.08$, $P = 0.602$). There was a significant correlation between the recto-anal pressure difference and evacuation of paste ($R = 0.488$, $P < 0.01$), but there was no correlation with the ARA difference ($R = -0.05$, $P = 0.748$). There was a positive correlation between the anal relaxation rate and evacuation of paste ($R = 0.482$, $P < 0.01$), but there was no significant correlation with ARA difference ($R = -0.1$, $P = 0.53$). These findings are available for inspection in Table 2 and Figure 1.

Table 1. Basic characteristics and examination results.

Characteristics	
Age (yr/[mean/range])	69/19～87
Gender (male/female)	27/16
Balloon Expulsion Volume(n)	
0/10/20/30/40/50ml	6/10/11/7/3/6
RAPD(cmH20[mean/range])	-23.2±48.63[-146.2～87.7]
ARR(%[mean/range])	-50.0±90.6[-226.1～100]
Evacuation of paste(n)	
None/ Partial/ Complete	19/13/11
Anal-rectal angle difference(n)	
Increase	12
No change or decrease	31
Complaint of "evacuation difficulty" (n)	
Yes	35
No	8
CSS(mean score/range)	10.1±5.0/2～20
FDD according to Rome III (n/total)	31/43

Table 2. Correlational analysis of results of the examinations.

Exam 1	**Exam 2**	**Correlation coefficient**	**P value**
BEV	RAPD	R = 0.565	P < 0.01
BEV	ARR	R = -0.293	P = 0.056
BEV	Evacuation of paste	R = 0.451	P < 0.01
BEV	ARA difference	R = -0.08	P = 0.602
RAPD	Evacuation of paste	R = 0.488	P < 0.01
RAPD	ARA difference	R = -0.05	P = 0.748
ARR	Evacuation of paste	R = 0.482	P < 0.01
ARR	ARA difference	R = -0.1	P = 0.53

Correlation between each examination and symptom

The CSS was applied to evaluate the symptoms of constipation. We performed a correlation analysis between the examinations and the CSS results. We identified a single symptom for evacuation difficulty and discovered that there was a correlation with the results of the examinations. Also, we evaluated the efficacy of the results to the complaint of evacuation difficulty and found that there was no significant correlation between the CSS and each examination result ($P = 0.64$, $P = 0.96$, $P = 0.79$, $P = 0.58$, $P = 0.07$). There was a significant correlation between the symptom represented by the item "Minutes in lavatory per attempt" and the balloon expulsion volume ($R = -0.419$; $P < 0.01$) and evacuation of paste ($R = -0.300$; $P = 0.04$). The evacuation difficulty complaint significantly correlated with the recto-anal pressure difference ($R = -0.304$, $P = 0.04$). See Table 3.

Correlation between the FDD diagnosis and the patients' complaint according to the Rome III criteria of FDD.[8]

Thirty-one patients were diagnosed as having FDD but only three did not complain about evacuation difficulty. However, of the 12 patients excluded by the criteria, 7 patients did complain about evacuation difficulty. The statistical analysis revealed a significant difference between the complaint of evacuation difficulty and the diagnosis of functional disorders ($x^2 = 5.846$, $P = 0.016$). Four patients were complicated with abnormal rectal sensation and one patient was complicated with abnormal anal sensation. Two patients experienced anal pain and three patients experienced fecal incontinence (Figure 2).

DISCUSSION

Defecatory disorders are common in the community affecting 10-15% of the population.[9, 10] The anorectum is a

TABLE 3. Correlational analysis of results of the examinations and the CSS, examinations and symptoms, and examinations and patient complaints.

	CSS (〜30)	**Frequency of bowel movements (0〜4)**	**Painful evacuation (0〜4)**	**Feeling incomplete evacuation (0〜4)**	**Minutes in lavatory per attempt (0〜4)**	**Evacuation difficulty (No or Yes)**
Balloon expulsion volume	R = -0.073 (P = 0.64)	R = -0.071 (P = 0.65)	R = -0.053 (P = 0.74)	R = 0.107 (P = 0.50)	**R = -0.419 (P < 0.01)**	R = -0.204 (P = 0.19)
Recto-anal Pressure difference	R = -0.007 (P = 0.96)	R = 0.179 (P = 0.25)	R = -0.060 (P = 0.71)	R = 0.114 (P = 0.47)	R = -0.218 (P = 0.16)	**R = -0.304 (P = 0.04)**
Anal relaxation rate	R = 0.041 (P = 0.79)	R = 0.095 (P = 0.55)	R = 0.053 (P = 0.74)	R = -0.138 (P = 0.38)	R = 0.174 (P = 0.26)	R = 0.275 (P = 0.07)
Evacuation of paste	R = -0.086 (P = 0.58)	R = 0.083 (P = 0.60)	R = -0.020 (P = 0.90)	R = 0.026 (P = 0.87)	**R = -0.300 (P = 0.04)**	R = -0.109 (P = 0.48)
ARA difference	R = 0.271 (P = 0.58)	R = -0.043 (P = 0.78)	R = 0.274 (P = 0.07)	R = 0.217 (P = 0.16)	R = 0.184 (P = 0.24)	R = -0.026 (P = 0.87)

complex functional unit that collaborates with the pelvic floor muscles and nerves. Despite the advances in the examinations for the diagnosis of FDD, the characteristics of functional disorders are still difficult to distinguish. Therefore, a comprehensive clinical assessment is extremely important for the accurate diagnosis and management of FDD. The balloon expulsion test, defecography and ARM are frequently used for diagnosis and effective evaluation. However, many examination results overlap in the evaluation of defecatory disorders. Therefore, it is necessary to assess the correlation of each anorectal functional examination and the corresponding symptoms.

The balloon expulsion test is well known as a simple and inexpensive examination for screening defecatory dysfunction. Previous studies have shown that the balloon expulsion test has relatively high specificity and negative predictive values.[11] Inability to expel a 50-ml water/air-filled balloon from the rectum within 120 seconds of attempted defecation is defined as dyssynergic defecation by BET. However, some studies found contradictory results for BET.[11-13] Different diagnostic criteria for pelvic floor dyssynergia in these studies may be the cause of these contradictory results. The aim of this study was to assess the correlation between the results of ARM, defecography and complaint of evacuation difficulty and therefore the balloon expulsion volume (BEV) test was adopted. The findings in this study revealed that there was a significant positive correlation between BEV and the results of RAPD (R = 0.565, P < 0.01) and evacuation of paste (R = 0.451, P<0.01), but there was no significant correlation with the results of the

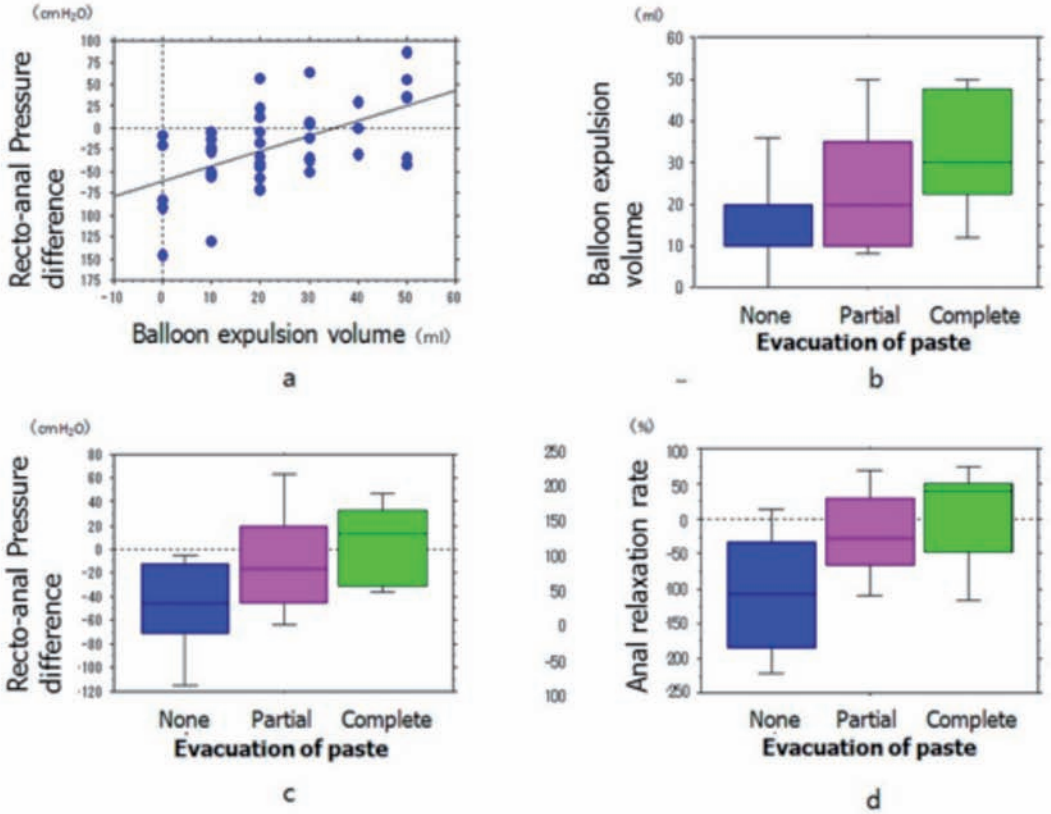

Figure 1. – Significant correlation between examinations. a, Significant correlation between recto-anal pressure difference and balloon expulsion volume; b, Significant correlation between balloon expulsion volume and evacuation of paste; c, Significant correlation between recto-anal pressure difference and evacuation of paste; d, Significant correlation between anal relaxation rate and evacuation of paste.

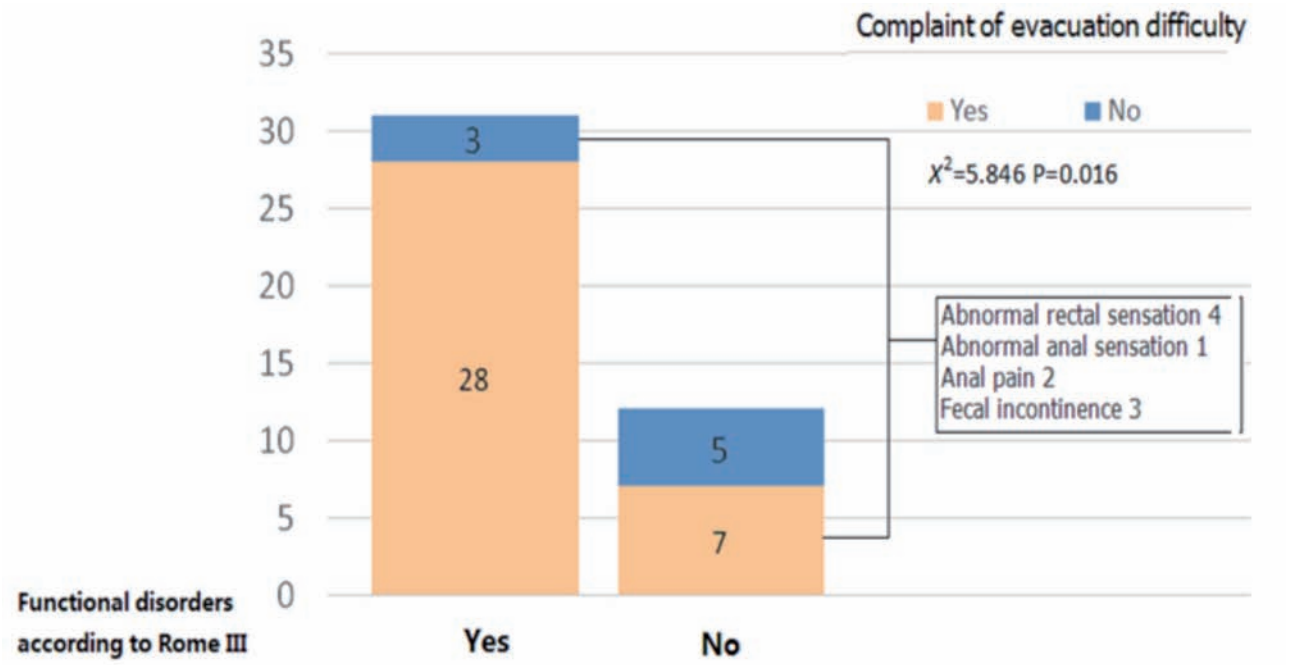

Figure 2. – Significant difference between patient complaint of evacuation difficulty and the FDD diagnosis according to the Rome III criteria.

ARR and ARA difference. Anorectal manometry is the most well established and widely available tool for investigating anorectal function. The ARR and RAPD are the most widely used tests for the detection of anorectal functional disorders.[14] Normal ARR and RAPD suggest an adequate increase in rectal pressure and relaxation of the external anal sphincter (EAS). Failure to perform this coordinated maneuver confirms the diagnosis of dyssynergic or obstructive defecation.[15] Compared to the other tests measured during the resting state, ARR and RAPD measured during an attempt to defecate can exhibit more valuable information about the characteristics of functional defects. In our study, the results revealed that there were significant positive correlations between RAPD and BEV ($R = 0.565$, $P < 0.01$), RAPD and evacuation of paste ($R = 0.488$, $P < 0.01$), and ARR and evacuation of paste ($R = 0.482$, $P < 0.01$). Therefore, based on the above mentioned results, ARR and RAPD are effective examinations.

Defecography is another widely used examination for patients with evacuation difficulty, especially when the clinical symptoms are inconsistent or when there are anatomic causes resulting in obstruction (i.e. internal intussusception, solitary rectal ulcers, rectoceles, and rectal prolapse).[7, 16, 17] The most significant findings related to defecatory disorders include inadequate widening of the anorectal angle and/or the decent of pelvic organs and tissues (i.e., internal intussusception, rectoceles, and rectal prolapse).[18] The anorectal angle has been well defined but the correlation between the extent of the decent and the obstructive defecation has not yet been established. However, the residue of paste after attempting to defecate suggests that there may be a functional defect. In our study, the results revealed that there was a significant positive correlation between the evacuation of paste and BEV ($R = 0.451$, $P < 0.01$), RAPD ($R = 0.488$, $P < 0.01$) and ARR ($R = 0.482$, $P < 0.01$). However, the ARA difference poorly correlated with the other examinations. Up until now, no studies have been done to investigate the clinical significance of ARA.

Interviews with patients are important in the diagnosis and assessment of anorectal functional disorders. The CSS was established based on patients' subjective symptomatic complaints and physiologic findings.4 We evaluated the correlation between the examinations and CSS results. The results showed that none of the single examinations had a significant correlation to the CSS score and RAPD was negatively correlated with the patient self-assessment of evacuation difficulty ($R = -0.304$, $P = 0.04$). Further investigation revealed that there were significant negative correlations between BEV and the item "Minutes in lavatory per attempt" ($R = -0.419$, $P < 0.01$), and evacuation of paste and the item "Minutes in lavatory per attempt" ($R = -0.300$, $P = 0.04$). The symptoms of evacuation difficulty were the result of a series of causes (i.e., anismus, insensitive anorectum, rectocele) and therefore a single examination cannot pinpoint the exact cause of evacuation disorders.

CONCLUSION

There was a significant correlation between each examination. ARA was the only exception and should therefore not be included in routine examinations. However, there was no significant correlation between each result of the anorectal functional examinations and the symptoms of defecatory disorders and patient complaints. A combination of tests would probably be more beneficial in characterizing the functional defects and in determining the precise diagnosis of FDD.

DISCLOSURE STATEMENTS

We declare no conflict of interest.

Authorship: All autors were involved with initial research design, data collection and analysis, manuscript drafting, and final approval.

Conflict of interest: None

Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent: Informed consent was obtained from all individual participants included in the study.

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Multidisciplinary Uro-Gyne-Procto Editorial Comment

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

Uro-gynecologist... This article emphasizes, yet again, that there is no correlation between anal manometry and anorectal symptoms. As such it is a valuable addition to the literature. My perspective is to correlate the findings of this paper with the 2008 Musculoelastic Theory of Anorectal Function and Dysfunction in the Female.[1]

The Theory has no place for manometry as it has been demonstrated that it is the Internal Resistance to fecal flow and the external opening mechanism thereof (not pressure) which are the key factors in anorectal opening and closure and therefore, obstructive defecation and fecal incontinence.[2, 3]

The theory does, however, have a place for the anorectal angle, as this is opened out by external muscle forces, figure 1 With a weak uterosacral ligament (USL) insertion point, the opening and closure forces may weaken[4] to cause both fecal incontinence or obstructive defecation symptoms.[1-3]

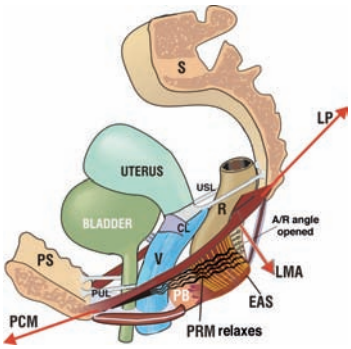

Figure 1. – **Anorectal closure and defecation** standing, sagittal view.
Anorectal closure m. puborectalis (PRM) contracts; LP stretches the posterior rectal wall backwards; LMA rotates the rectal wall around the contracted PRM to create the anorectal angle and closure.
Defecation m. puborectalis (PRM) relaxes (broken lines). This allows the posterior vectors LP/LMA to stretch open the posterior wall of the anorectum, opening out the anorectal angle. The PCM stabilizes the anterior rectal wall, preventing it from prolapsing inwards. Active opening exponentially decreases the internal frictional resistance, inversely by the 3rd power of radius change. The rectum contracts and empties.

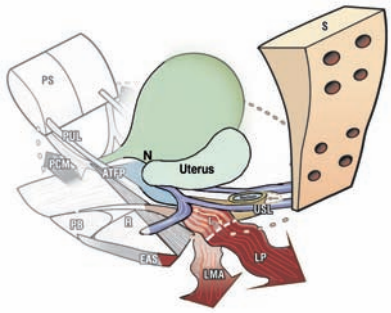

Figure 2. – **Potential consequences of loose uterosacral ligaments as interpreted by Gordon's Law** View from above.
The uterus has prolapsed to 1st degree. The USLs have elongated by 'L', as have LP and LMA. The rectum also has descended, by virtue of its attachments laterally to the elongated USL. The contractile strength of LP/LMA has diminished. The external mechanism for opening out the posterior wall of the rectum has weakened according to Gordon's Law;[4] the anal canal remains partly closed; the patient interprets this as 'obstructive defecation".

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