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PELVIPERINEOLOGY

A multidisciplinary pelvic floor journal

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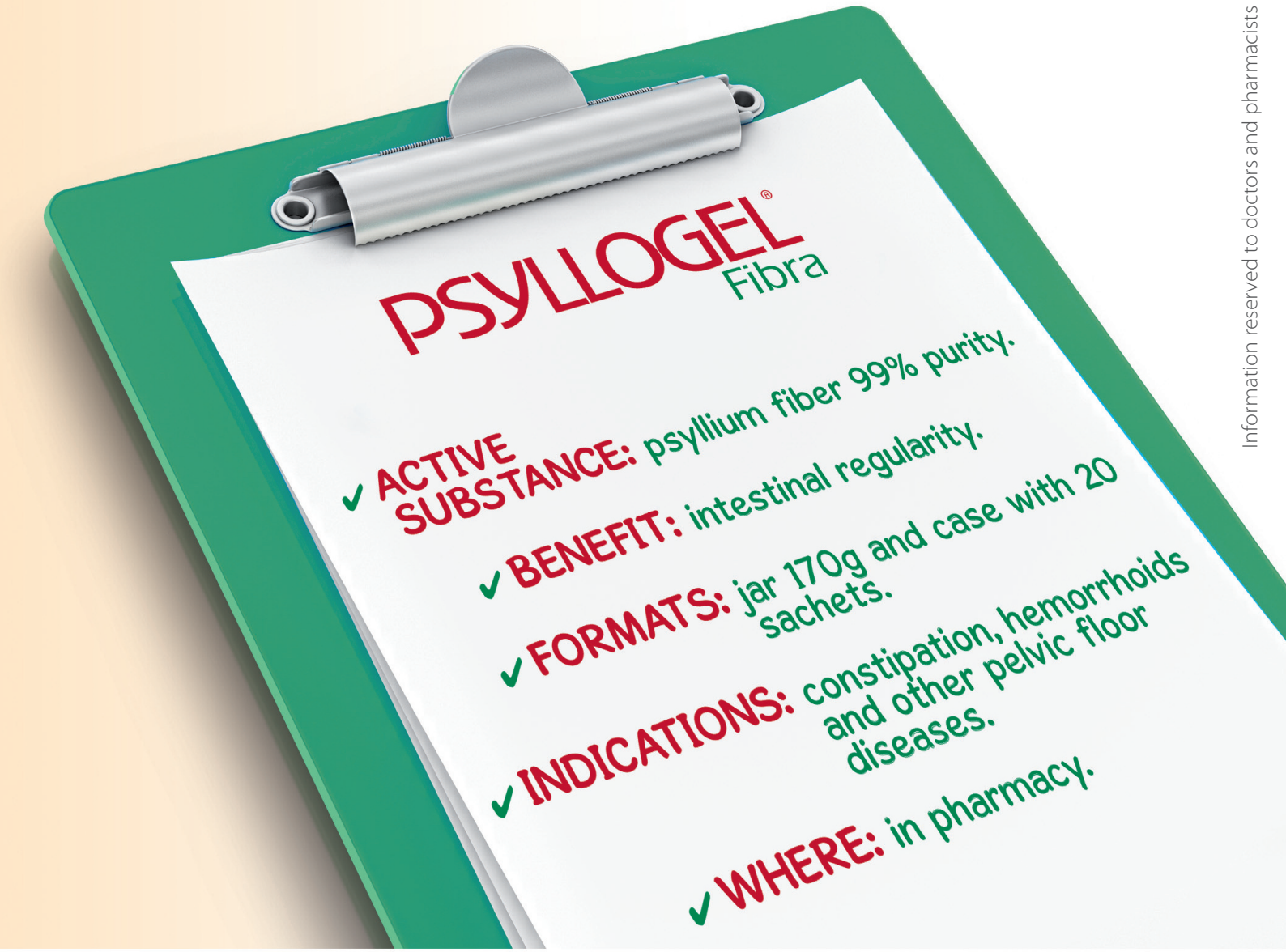

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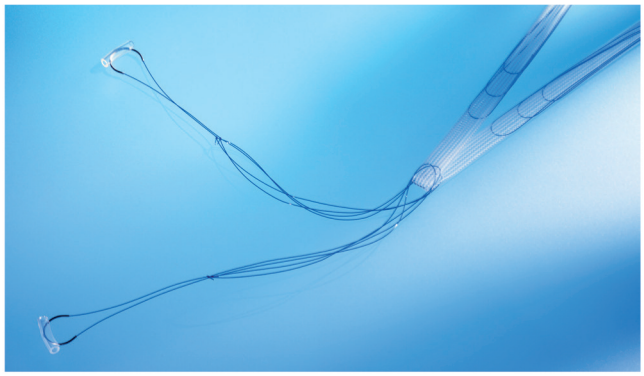

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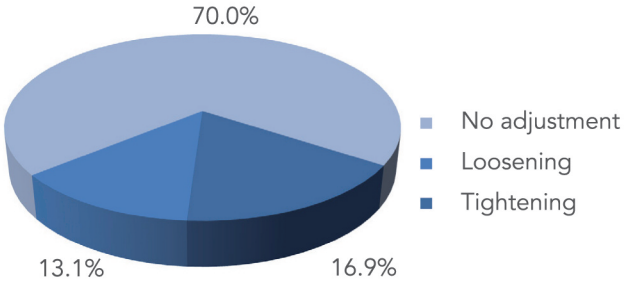

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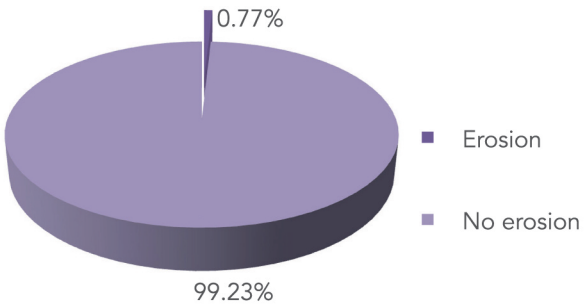

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Original article

Collagen contents variations between different stages of anterior vaginal wall prolapse

ANDRÉS MARAMBIO[1], CÉSAR SANDOVAL[1], RAÚL VALDEVENITO[1], MICHEL NASER[1], VALENTÍN MANRÍQUEZ[1], RODRIGO GUZMÁN[1], JORGE LECANNELIER[1], JAIME JANS[1], AMALIA AGUILERA[1], GUILLERMO DÍAZ[2]

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Abstract: Objective: Vaginal prolapse is a common disease, whose etiology is not well understood. Many studies have focused on alterations in the levels of collagen would present these patients, yielding conflicting results. Aim of the study: To measure the amount of types I and III collagen found in the connective tissue lining the vagina among patients with anterior vaginal wall prolapse and compare it with patients without prolapse and between different clinical stages of prolapse. *Materials and Methods:* Cross-sectional study. Statistical analysis was carried out considering a statistical power of 80% and an alpha level of 5%. Results: A total of 84 patients in different stages as per natural distribution were recruited. The mean patient age was 53,9 ± 11 years (32-78). We didn´t find significant differences in the levels of type I and type III collagen, between the various stages of prolapse or when comparing with the control group. *Conclusion:* Our histological findings in the endopelvic fascia reveal that there would be no changes in the levels of type I and type III collagen between the different stages of genital prolapse, so it would not meet an etiological role in the development of this pathology.

Key words: Pelvic Organ Prolapse; Vaginal Prolapse; Pelvic Floor; Type I and III Collagen.

INTRODUCTION

To date, although risk factors are well known, the reason why some women suffer vaginal wall prolapse remains unclear. Several research lines have emerged as an attempt to unveil the susceptibility of some patients to suffer this. Research has focused on connective tissue findings and comparison with those women without prolapse. Research work has studied alteration in collagen amount and structure, measuring various collagen subtypes, mainly types I and III collagen.[1-12] Moreover, variations in a series of other molecules participating of collagen metabolism such as metalloproteinases[1,7,10,13,14] and their inhibitors[10,14] and cathepsin,[1] as well as the metabolism of elastin,[1,6,8,11] smooth muscle[15,16] and extracellular matrix glycoproteins[4,11] have been studied in patients with and without the pathology. Unfortunately, results have been contradictory impeding the unscrambling of the proposed objectives. This might be the result of a lack of uniformity seen in published work regarding patient selection, prolapse type (many times not even specified), staging methods, use of small sample size, different biopsy sites and standardization of this, indirect measurement of collagen, etc. Nevertheless, it's possible to note that most of the results point towards a decrease in collagen amounts in the vaginal support structures of such patients, controlling by other variables that also have an effect on this such as age and hormonal status.

The aim of this study is to perform a cross-sectional study, measuring the amounts of types I and III collagen in the connective tissue that surrounds the vaginal wall in patients with different stages of anterior vaginal wall prolapse and without such condition. Although the vast majority of studies have been carried out on uterine prolapse with analysis of level I suspension, the present study has been designed to be carried out on patients with anterior wall prolapse and analysis of level II, since it`s the most common site[17] and thus the mostly addressed for treatment. Based on the literature, the proposed work hypothesis is that in patients with anterior vaginal wall prolapse the contents of types I and III collagen in the connective tissue that overlays the vagina are decreased, and such decrease would be proportional to the prolapse stage clinically diagnosed as per POP-Q.

PATIENTS AND METHODS

A cross-sectional and analytic study was carried out. Patients with anterior vaginal wall defects with indication for surgery were included. Patients admitted to surgery for other benign gynecological pathologies were included as the control group (stage 0). All the patients were informed of the nature of the study and provided their authorization for admission with an informed consent. The study was previously approved by the hospital Ethics Committee (dated January 10th, 2008; certificate of approval No. 5). Design consists of an initial assessment including medical history, physical examination, and documentation of age, occupation, symptoms, history other pathological conditions, obstetric formula, type of delivery (vaginal, cesarean or forceps delivery), history of macrosomy (defined as birthweight > 4.000 gr.), presence of menopause, smoking habit, family history, weight, height, body mass index, POP-Q and associated urinary incontinence. Exclusion criteria were: prior history of pelvic surgery, cancer of any origin, radiation therapy, neuromuscular o connective tissue disorders, pelvic inflammatory process, endometriosis, current pregnancy or presence of adhesion or scar at the biopsy site.

A sample was obtained during surgery from the connective tissue adjacent to the anterior vaginal wall at the Ba point, because it`s the zone where cystocele usually recur[18]. For this reason prolapse staging classification was based on the maximum extension according to that point. Efforts were made to obtain sufficient tissue for the analysis required (at least 2 x 2 cm.) and dissecting the sample to obtain only single fascia tissue, separating the vaginal wall (epithelium and muscular wall) or any other structure which does not correspond to connective tissue. Once obtained, samples were immediately stored in liquid nitrogen at –80 °c until completion the adequate number of patients per group. Then, were analyzed with an immunowestern

blot technique, which consists roughly of: a) initial homogenization of samples with a tissue lysis buffer solution in the presence of enzymatic inhibitors (RIPA buffer), in a dounce glass homogenizer, with subsequent sonication of the specimen during 7 minutes, and re-homogenization to ensure a total distribution and finally centrifugation at 10.000 rpm at 4 ºc during 10 minutes to extract the supernatant containing the protein of interest; b) quantification of extracted proteins with the Lowry method; c) electrophoretic separation of proteins (as per molecular weight), on a acrylamide/polyacrylamide gel (8%); d) electrotransference of the proteins to a nitrocellulose membrane; e) incubating with a specific antibody targeted to the protein of interest (an antibody recognizing human type I collagen, CN: AB758 and an antibody recognizing human type III collagen, CN: MAB3392, Chemicon, Millipore, US), and subsequently with a second horseradish peroxidase conjugated antibody and finally, chemiluminiscense immunodetection and subsequent detection with autoradiography films; f) quantification of such final product (the bands on the film) with the appropriate software that shows the results as total pixels per band to be quantified. Thus we obtained a quantitative variable and comparable between different samples, since the method standardized by the unit of tissue, regardless of the initial size of the biopsy. Samples were analyzed, interpreted and reported by professionals blind to the different analysis groups.

To carry out this study we decided not to consider stage IV prolapse because its low frequency of presentation, so that the sample size was composed of 96 patients distributed in 72 patients with prolapse (stages I, II and III) and 24 patients in stage 0 (control group). Calculation of sample size was estimated considering a prevalence of prolapse of 30% in the general population[19,20] on a universe of 2.000 patients attending at our Female Pelvic Floor Unit per year, an estimation error of 9%, a statistical power of 80% and an alpha level of 5%. All data concerning the preoperative record and the measured collagen values were concomitantly entered into an Excel database. Statistical analysis was carried out with the Stata 8.1 software (Stata Corp., Lakeway Drive, TX, USA). The following statistical tests were used: Mann Whitney, Student´s T, Kruskal Wallis, chi-square, ANOVA and multiple regression analysis. A $p \leq 0,05$ was considered as statistically significant.

TABLE 1. – Mean age of patients per prolapse stage.

Stage	Patients Mean Age
0	49.2±9
I	48±8
II	55.1±1
III	61±9

TABLE 2. – Association between different variables and the presence of prolapse.

Variable	**Number**	**P**
Gestations	357	0.19
Deliveries	296	0.11
Vaginal	226	0.007
Cesarean	49	0.02
Forceps	22	0.06
Miscarriage	61	0.84
Child > 4000 gr.	21	0.07
Menopause	43	0.45
HRT[a]	14	0.53
Smoking	21	0.61
Constipation	26	0.49
Family history	14	0.7
Obesity	34	0.09

[a:] Hormone Replacement Therapy

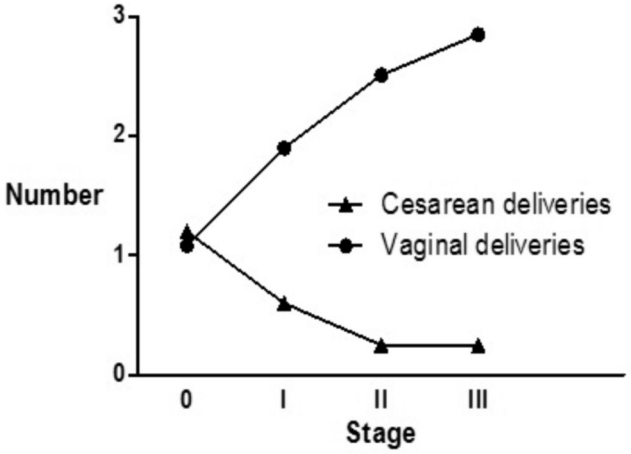

Figure 1. – Distribution of vaginal / cesarean deliveries per prolapse stage.

RESULTS

The study was conducted between September 2007 and March 2010. A total of 84 patients were recruited, without attaining the estimated study sample for stage 0 (12 patients), by the refusal of this patients to be exposed to a vaginal biopsy. Mean age was 53,9±11 (32 - 78). Patient age increased significantly ($p<0,001$) as they had a higher prolapsed stage (Table 1). The vast majority of patients were housewives (49,4%), followed by administrative (15,1%) and commerce activities (11,1%). Occupation of the rest of patients included various activities. Main clinical onset form was stress urinary incontinence (SUI), observed in 37 patients. In the total group, 67,8% of the patients had SUI, and it`s presence was significantly associated to the presence of prolapse ($p=0,007$) and increased significantly ($p=0,024$) with higher prolapse stages. Upon analysis of the various pre-operative variables, there were statistically significant differences between the different groups in terms of vaginal ($p=0,006$) and cesarean deliveries ($p=0,02$), while the rest of the analyzed variables did not relate to the presence of prolapse and did not differ between the various study groups (Figure 1 and Table 2).

At the molecular analysis, there were no significant differences in type I collagen levels neither between patients with and without prolapse ($p=0,82$) nor between the different prolapse stages ($p=0,68$). However, there was a tendency towards an increase in type I collagen levels as the prolapse stage increased (Figure 2). As for type III collagen, again there were neither significant differences between patients with and without prolapse ($p=0,41$) nor between the different prolapse stages ($p=0,47$), however, there was a tendency towards a decrease in such levels as the degree of prolapse increased (Figure 3). When carrying out the multiple regression analysis, with age and type of delivery being used as control variables (only variables statistically different between groups), there were no statistically significant differences in type I collagen levels between patients with and without prolapse ($F^{3,89}=1,08$; $p=0,36$) and between different prolapse stages ($F^{5,87}=1,26$; $p=0,28$). The same findings were evidenced for type III collagen levels when comparing patients with and without prolapse ($F^{3,91}=0,68$; $p=0,56$) and different prolapse stages ($F^{5,89}=0,65$; $p=0,66$). As for the type I collagen / type III collagen ratio

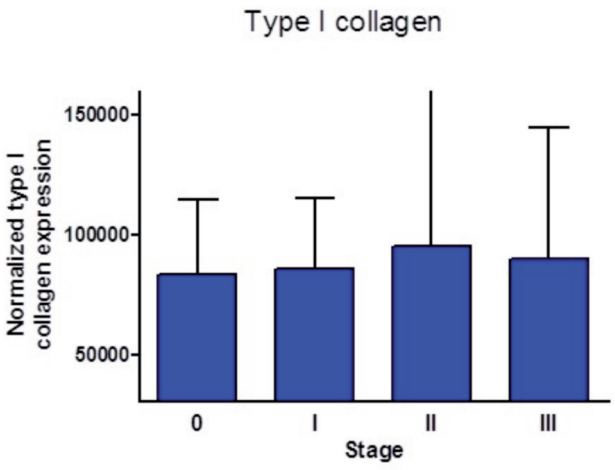

Figure 2. – Type I collagen levels per prolapse stage.

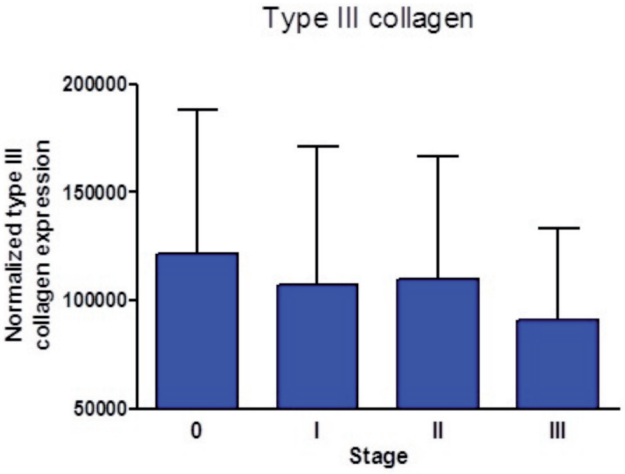

Figure 3. – Type III collagen levels per prolapse stage.

there were no significant differences between patients with and without prolapse (p=0,56) nor between the different prolapse stages (p=0,75), however, there was a tendency towards an increase in the ratio as the degree of prolapse was higher (Figure 4). When analyzing collagen levels in patients with SUI, they evidenced a significantly higher content of type I collagen than patients without SUI (p=0,03), and there were no differences in type III collagen levels (p=0,4). Finally, upon analyzing the various patient variables available (Table 2), including age, there were no statistically significant differences neither in type I and III collagen levels nor in type I collagen / type III collagen ratio.

DISCUSSION

In view of the discordant published literature on the field, the aim of the present work has been to shed light into what`s really happening with collagen in pelvic connective tissue of patients with prolapse. Although the study group includes patients of different ages, it has been shown that prolapse affects mainly woman in the fifth, sixth and seventh decades of life, with highest incidence between fifty and sixty years. This is the reason why most of our patients are already housewives without a current labor occupation. Prolapse onset includes classically a sensation of heaviness or vaginal bulging, however here has evidenced that presence of SUI is significantly associated to this condition, with an increase in it`s incidence as the prolapse stage progresses. Because SUI is a more disabling disease, it has become the main onset form or concern upon consultation. Both, patient age and type of delivery (vaginal or cesarean) are two prolapse risk factors that have been widely documented. In the present study there were the only two factors associated to the presence of prolapse, and have directly correlated to stage.

Several studies have addressed genital prolapse in search for anomalies in collagen and other extracellular matrix structures metabolism, trying to find the cause or the first physiopathologic changes involved in such disease, to explain the pathology and therefore enable the early identification of susceptible patients. Literature reports concerning types I and III collagen have been diverse and contradictory. Most of these works indicate that physiopathology of prolapse would involve a decrease in total collagen and types I, III and VI collagen at least, in the connective tissue surrounding the vagina.[1-5,10,11] Moreover, there would be an increased activity of certain metalloproteinases at the vaginal epithelium of patients with prolapsed.[1] It's from this information that the main hypothesis has emerged and has prevailed to date, indicating that the decrease of types I and III collagen specifically, in support tissues, would represent a key event in the subsequent development of pelvic organ prolapse, an event that doubtlessly will be associated to various other factors that would facilitate such process. On the other hand, various studies point to an increase at least in types III and V collagen levels, in association to a tissue-remodeling environment resulting from a greater metalloproteinase activity.[6-9] These works refer to the fact that a greater amount of a more lax collagen, such as type III, would favor the development of prolapse. The results of the present work do not support such theories, because it can be seen that in this series, the largest presented so far in the study of this matter, neither of both types of collagen present significant variations in the different groups to be compared, both for patients without prolapse when compared with the rest of the patients, as well as between the different stages of prolapse. Likewise, upon carrying out the multiple regression analysis, with the confounding variables (age and vaginal deliveries) present as control variables, statistical significance was not attained between patients with and without prolapse or between the various stages. When observing the numbers, it was possible to see that there are certain tendencies as the disease worsens. For example, type I collagen has a tendency to increase in higher prolapse stages and inversely, type III collagen tends towards a decrease, thus reflecting accurately a progressive increase of the type I / type III collagen ratio. This could be related to a post-trauma cicatricial tissue, in which a firm scar is progressively generated over time, as collagen III is decreasing and finally replaced for type I collagen, all once injury and descent have occurred.[21] Some of these changes have already been reported and previously described in connective tissue as secondary to injury and repair processes.[22] In this sense, it is worth noting that patients with SUI presented a significantly greater amount of type I collagen than patients without SUI, something that could represent a greater initial injury with a larger associated tissue response, the latter being in accordance with clinical reports of one of the aforementioned works.[3]

However, all of these trends can't be interpreted and the final analysis show no differences between the levels of type I and III collagen in the connective tissue surrounding the vagina in woman with and without prolapse or the different stages. Limitation of this study was the lack of sample size of our control group which can be a source of bias, nevertheless, the others groups were complete and showed no changes related to our initial hypothesis.

In conclusion, patients with pelvic organ prolapse do not

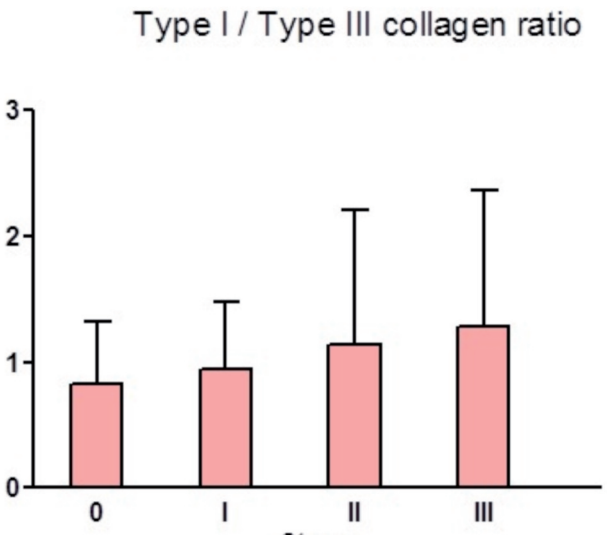

Figure 4. – Type I / type III collagen ratio per prolapse stage.

differ in levels of type I and type III collagen measured in the fascia surrounding the vagina, when compared with control patients or between different stages of prolapse. Based on this finding, levels of type I and type III collagen are not important in the study of the pathogenesis of this disease, so future histological studies should be focused on other types of molecules or tissues looking for changes that explain the development of this disorder.

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This investigation was conducted in the Female Pelvic Floor Unit of the University of Chile Clinical Hospital. We want to thank to all the people that works there and especially to Pamela Contreras for the laboratory work at the Chemistry and Pharmacy Faculty and Alvaro Reyes (M.Biostat.) for the statistical analysis at the Bureau for Clinical Research Support of the University of Chile Clinical Hospital.

CONFLICTS OF INTEREST STATEMENT

None of the researchers has conflicts of interest to declare. The present study was financed by funding granted by the “2007 Clinical and Basic Clinical Research Contest” of the Bureau for Clinical Research Support from the University of Chile Clinical Hospital.

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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** and **Proctologists/Colo Rectal Surgeons** 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… Marambio et al. investigate in their study 84 patients with different stages of prolapse and compare the collagen I and III content in the connective tissue lining the vagina. In their study they were not able to find significant correlations of collagen contents and prolapse degree. There is still discordant evidence in the literature regarding this matter. Possible reasons could be: 1. The sampling sites are heterogenous or inadequate. 2. The parameters measuring connective tissue metabolism are inadequate. 3. The etiology is truly different.

In response to 1. Marambio took care to sample a defined anatomical mark in the vagina. Nevertheless heterogeneity is still a matter as it cannot be ruled out. In response to 2. The authors investigated collagen I and III by quantitative, molecular analysis. This is certainly an advantage, however many other parameters and molecules could still influence connective tissue quality. In response to 3. This cannot be answered by this study, as other etiological factors were not investigated. There is however a large evidence that connective tissue (lax ligaments) play a major role in pelvic floor disorders (Petros P, Integral theory).

From the urological, clinical point of view, the etiology is certainly important, as different therapeutical approaches have been developed over the years, including tissue substitution by alloplastic material. Evidence from surgical studies using connective tissue substitutions support also the fact, that deficient connective tissue serves as a major causative factor.

In conclusion, although in their study Marambio et al. could not identify significant differences between vaginal collagen I and III content comparing patients with and without prolapse, the etiology that lax vaginal ligaments are causative for pelvic floor disorders is not ruled out, due to multiple complicating and confounding factors possibly present.

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Gyne… I congratulate the authors on an excellent and important study. The findings of this article, no significant changes in collagen I&III in patients with pelvic organ prolapse (POP), are consistent with the statement of the Integral Theory[1] that it is the laxity of ligaments caused by altered collagen/ elastin which is the major cause of POP, bladder and bowel dysfunctions. Altered collagen/elastin does not necessarily mean diminished collagen content. It is possible to look at the pathogenesis of vaginal or ligament laxity as follows:

connective tissue in the area of the urogenital organs is sensitive to hormones. During pregnancy, collagen is depolymerized by placental hormones, and the ratios of the glycosaminoglycans change. The vagina and ligaments weaken. This explains the uterovaginal prolapse so often seen during pregnancy. Laxity in the hammock may remove the elastic closure force, causing urine loss on effort. This condition is described as stress incontinence. Loss of membranous support may cause gravity to stimulate the nerve endings (N) at the bladder base, so causing premature activation of the micturition reflex, expressed as symptoms of 'bladder instability'. This condition is perceived by the pregnant patient as frequency, urgency and nocturia. Laxity may also cause pelvic pain, due to loss of structural support for the unmyelinated nerve fibres contained in the posterior ligaments. The action of gravity on these nerves causes a 'dragging' pain. Immediately prior to delivery, the collagen fibrils of the cervix depolymerize further, losing 95% of their strength.[2] This allows the massive stretching of tissues required for delivery. Removal of the placenta restores connective tissue integrity and the symptoms rapidly disappear in a large percentage of patients. However, if the collagen fibres have been stretched extensively at delivery re-polymerize in an extended position, the vagina and ligaments may now be much looser than previously, causing POP, bladder and bowel dysfunction. The collagen content may remain the same. It is ligament laxity which diminishes the strength of the directional muscle forces controlling the musculoelastic elastic functions of the pelvic floor, not collagen content.

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Procto… In the pathogenesis of genital prolapse the role of type I-III collagen is debated and in Marambio's study it does not appear to be consistent. In the proctologic literature, focusing on the rectal prolapse, a similar approach is lacking without relevant studies on the para-rectal tissues support. There are many theories describing different causes of the rectal prolapse but none of them seems to settle the matter once and for all.[1] The anatomical basis for rectal prolapse is a deficient pelvic floor allowing the rectum falling out of the anus. An interesting hypothesis argues that there is a significant difference in joint mobility between patients undergone to surgery for rectal prolapse and a control group, suggesting a role of the connective tissue disorder in the development of the prolapse.[2] Moschcowitz in 1912[3] described a redundant sigmoid colon within a deep pelvic cul de sac, the patient's excessive straining exiting in the prolapse. Other authors proposed that the complete rectal prolapse is the evolution of a rectal intussusception. This theory does not consider the extremely low percentage of patients in which the internal prolapse becomes external, as confirmed by defecography studies. Injuries to the pudendal nerves, due to stretching of the pelvic floor, may also play a role.[4] A laxity of the lateral ligaments of the rectum, or a loose sacral fixation to the sacrum combined with a supposed underlying connective tissue disorder (still hypothesis) and a colonic dysmotility have been also considered responsible of the rectal prolapse, a condition whose ethiology still needs a lot of attention and research.[1]

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Original article

Cardinal ligament: a live anatomical study

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Abstract: Background: The cardinal ligaments insert onto the anterior surface of cervix and pubocervical fascia. They support the bladder base, preventing cystocele, and are a key support for the uterus, helping to prevent prolapse. Many cadaveric studies doubt the existence of the cardinal ligament. *Objective:* To define the live anatomy of the cardinal ligament (CL). *Patients and Methods:* A live anatomical study during routine surgical dissection involving 3 groups of patients. Group1: 61 women with cystocoele and/or uterine/apical prolapse. Group 2: 30 women with uterine pathology undergoing vaginal hysterectomy. Group 3: 3 women undergoing abdominal hysterectomy. The course of the CLs was assessed during surgery using the Tissue Fixation System (TFS), by rectal palpation under traction, by approximating them medially using Allis forceps to monitor the effect on the cystocoele and uterine prolapse. *Results:* The CLs attach onto the anterior surface of the cervix and are laterally displaced in patients with high cystocoele. The cardinal ligament is attached to a point 2cm above the ischial spine. Approximation of the laterally displaced CLs ("simulated operation") in the operation room prior to commencing surgery restored a high cystocoele, anteverted the uterus, and partially restored a 3rd or 4th degree uterine prolapse. *Conclusions:* As well as inserting into the lateral part of the cervix, the cardinal ligaments also insert into the anterior part of the cervix. This insertion plays a major role in retaining the uterus in an anteverted position, in preventing a high cystocele, and to assist in uterine/apical support.

Key words: Cardinal Ligament; Retroverted Uterus; Uterine Prolapse; High Cystocoele; Cervical Ring; Tissue Fixation System.

INTRODUCTION

According to Robert Zacharin, the first usage of the name "cardinal ligaments" was by Kocks in 1880, while its alternative description, "Ligament of Mackenrodt", followed Mackenrodt's 1885 anatomical dissections in the newborn.1 Mackenrodt described transverse ligaments from the lateral part of the cervix to the pelvic sidewalls. Based on cadaveric and histological studies, the very existence of the cardinal ligament has been questioned. This debate, initiated by Winter in 1896,[1] has continued to the present day.[2] In line with previous investigators, Kato et al.[2] demonstrated a structure which corresponded to the cardinal ligament by gross dissection of the paravesical and pararectal spaces. In their histological examination, however, they described the superolateral part of the ligament as a "vague area".

Irrespective of such histological studies, Mengert in 1936[3] demonstrated the importance of the parametrial tissues in uterine support by attaching a 1 kg weight to the cervix, and measuring the descent on severing the following ligaments in turn, round, ovarian, uterosacral, upper and lower thirds of the broad ligament.

General and specialized anatomy textbooks invariably show the cardinal ligaments inserting into the lateral part of the cervix. Almost all these anatomical studies have been in fresh or treated cadavers.

Our early experience with the TFS (Tissue Fixation System) minisling operation for correction of high cystocoeles and uterine prolapse[4,5] indicated that the cardinal ligaments are attached to the anterior part of the cervix. Furthermore, whatever the histological evidence for non-existence of these ligaments, we found that antero-lateral suspension was an essential element in the anatomical support of the uterus and bladder.

Our aim was to identify and define the cervical attachments and function of the cardinal ligaments in 3 groups of patients undergoing cystocoele repair, vaginal or abdominal hysterectomy.

As this was part of a clinical audit, Ethics Committee approval was not sought. The principles outlined in the Declaration of Helsinki were followed. Written informed consent was obtained from all the study participants.

PATIENTS AND METHODS

The cardinal ligament anatomy was examined in three groups of patients using the Baden Walker classification.

Group 1. Sixty-one patients, underwent cardinal ligament repair using the Tissue Fixation System (TFS) either for 3rd degree cystocoele alone (n=10), or as part of a uterine/vaginal prolapse operation (n=51). The cardinal ligament was repaired first, and the change in prolapse noted; following this, the uterosacral ligament was repaired as indicated.[4,5]

Group 2. Thirty patients with uterine prolapse of varying degrees (1st &2nd n=27; 3rd &4th n=3) who had vaginal hysterectomy for uterine pathology. The insertion of the cardinal ligament (CL) onto the anterior part of cervix was examined following separation of the vaginal mucosa.

Group 3. The course of the cardinal ligament to the side wall of the pelvis and the ureter were assessed in 3 patients, who had no prolapse, and who had abdominal hysterectomy for uterine pathology.

Assessment of medial insertions of CL Groups 1 and 2 were assessed for cardinal ligament dislocation from the anterior cervical ring by inspection, contralateral traction on the cervix/vaginal apex during rectal examination, by "simulated operations" whereby the dislocated ends of the cardinal ligaments were approximated, figures 1 and 2, and by surgical dissection.

Assessment of sidewall insertions of CL Rectal examination to assess the lateral insertions of the CL. The cervix was stretched contralaterally. The index finger located the ischial spine, and was then directed 2cm upwards to locate the lateral insertion of the ligament.

"Simulated"* (or "virtual") operation A high cystocoele (cervical ring/cardinal ligament defect) was differentiated

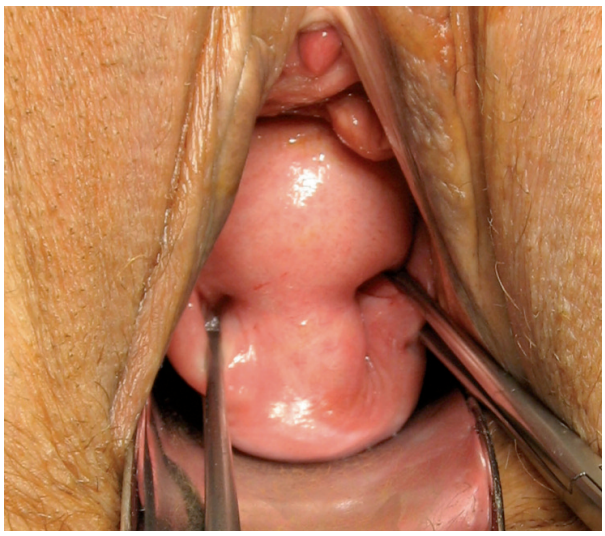

Figure 1. – Diagnosing a cardinal ligament/cervical ring defect. The vaginal tissues prolapsed along the sides of the cervix are grasped approximately 2cm lateral to the cervix, and approximated medially.

from a central or paravaginal cystocoele defect using a 'simulated' operation in the operation room. The vaginal tissue was grasped laterally in the position of the dislocated cardinal ligaments (usually 2cm lateral to the cervix) and approximated medially, figures 1&2. This maneouvre will not restore a central cystocoele or paravaginal defect, which continues to bulge.

A model of the pelvis with elastic "ligaments" attached to the cervix, figure 3, was used to model how the uterine prolapse altered the insertion angle of the cardinal ligament, an important detail as regards the surgical technique for prolapse.

Surgical technique

During cystocoele repair, an inverted "T" incision was made extending from 1cm above the anterior lip of cervix (or hysterectomy scar) to 1cm short of bladder neck. The vagina was dissected off the bladder, and the bladder off the cervix (or anterior vaginal wall in patients with previous hysterectomy). Using Allis forceps, firm tissue was identified laterally, grasped and stretched so as to define its course towards the pelvic sidewall.

In patients undergoing vaginal hysterectomy, the anterior vaginal wall was reflected off the anterior wall of the uterine cervix, and the bladder was dissected off the vagina and uterine cervix so that the attachments of the cardinal ligament to cervix could be inspected and defined.

In the 3 patients undergoing abdominal hysterectomy, the broad ligament was opened out between the round and broad ligaments to identify the ureter, uterine vessels and vein, the cardinal and uterosacral ligaments.

RESULTS

The mean age of the patients was 61 years (33–85); median age was 59 years; mean weight was 63kg (49–102 kg); mean parity was 3 (0-7). The anterior attachment of the cardinal ligaments was most evident in patients undergoing vaginal hysterectomy. In patients with 3rd or 4th degree uterine prolapse, and no cystocoele, the cardinal ligament was often intact, but extended (Figure 4).

Group 1. Sixty-one patients underwent cardinal ligament repair using the Tissue Fixation System (TFS) either for 3rd degree cystocoele alone (n=10), or as part of repair of uterine prolapse (n=51), 24 of which were 3rd or 4th degree. In patients with cystocoele (n=32), the anterior insertion of the cardinal ligaments was not recognizable, and the ligaments were displaced laterally.

In almost all cases, it was possible to identify and grasp a firm band of tissue, 2cm lateral to the cervix. When this tissue was stretched, it could be felt proceeding 30 degrees inferolaterally in a direction above and forward of the ischial spine, as described by Curtis. In those patients with prolapse and no significant cystocoele, (n=29), the prolongation of the cardinal ligament anteriorly was more evident (Figure 3).

Group 2. In the 30 patients who had vaginal hysterectomy for uterine pathology, a clearly fibromuscular structure, the cardinal ligament, was seen ascending onto the anterior part of the cervix, with the uterine artery pedicles below, figure 4. More laterally, the cardinal ligament merged with the uterosacral attachment to the posterior part of the cervix.

Group 3. Three patients had abdominal hysterectomy for uterine pathology. The ureter was situated between 1cm and 2cm lateral to the cervix, passing below the uterine artery, then proceeding in a forwards and upwards direction, well away from the insertion of the cardinal ligament which was directed 30 degrees downwards. When the uterus was stretched contralaterally, a firm structure could be felt below the uterine arteries, proceeding in the direction of the spine. Because of the complexity of structures in the broad ligament, we could not visually identify the lateral insertions of cardinal ligament.

Differentiation of cystocoele by inspection. Prolapse of the vaginal epithelium laterally around the cervix is characteristic of a cardinal ligament/cervical ring defect, and reflects the lateral displacement of the ligament, figure 5. A central cystocoele, being caused by rupture or thinning of the pubocervical fascia (PCF), has a shiny appearance on examination. A'high cystocoele', like a pure lateral defect, frequently has transverse rugae.

"Simulated operation". We found the "simulated operation", figures 1 and 2, was an accurate predictor of cardinal ligament defect as a cause of cystocoele in the 32 patients with cystocoele. The cystocoele almost completely disap-

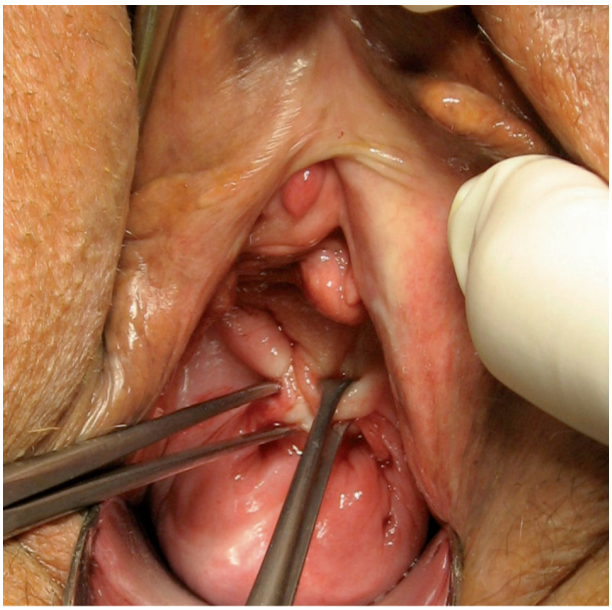

Figure 2. – "Simulated" operation. Disappearance of the cystocoele following approximation of the forceps confirms cardinal ligament/cervical ring defect as the cause of the cystocoele.

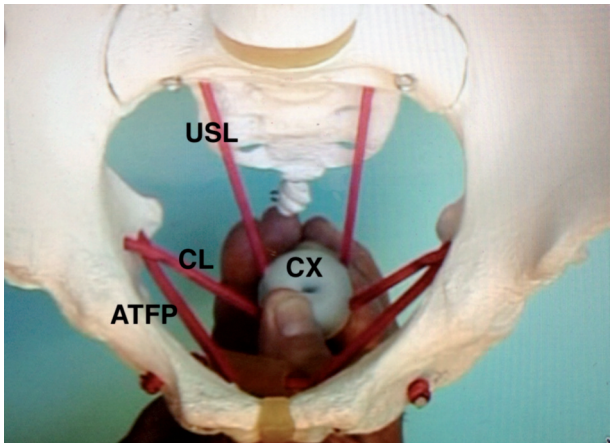

Figure 3. – Modelling uterine prolapse The "Cervix" (CX) has been stretched downwards. Note how both cardinal (CL) and uterosacral ligaments (USL) are stretched downwards. ATFP= arcus tendineus fascia pelvis. A :"simulated operation" brings together the medial parts of the CL, effectively shortening them, bringing CX back into the vagina.

peared on approximation of the cardinal ligaments with Allis forceps in 23 patients. The other 9 patients also had a central/lateral defect, as diagnosed by a persistent anterior bulge.

Rectal examination to assess lateral insertion of the cardinal ligament. When the cervix was stretched contralaterally, the index finger located the ischial spine, and was then directed 2cm upwards. A tense firm structure could be followed towards the bony side wall and cervix.

Pelvic Model. Stretching the model of the cervix downwards beyond the level of the ischial tuberosities elongated

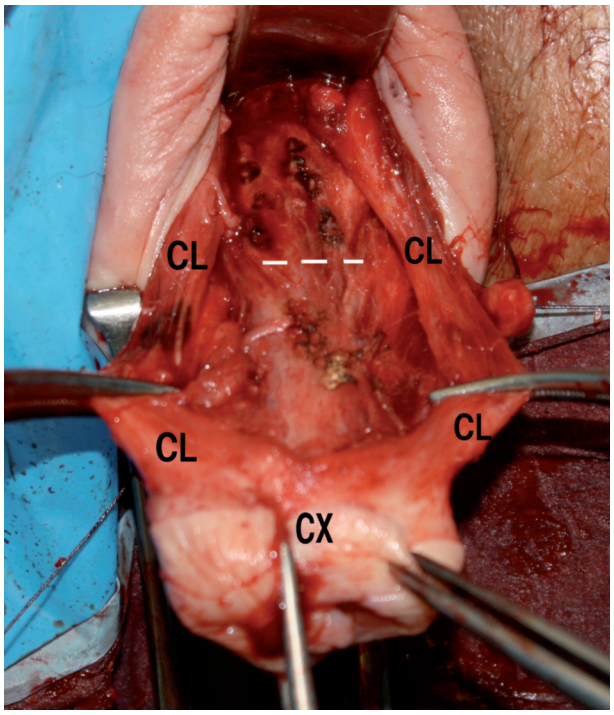

Figure 4. – Pathologically stretched Cardinal Ligaments (CL) attaching to the anterior part of cervix (CX) in a patient with 4th degree uterine prolapse. The vagina has been dissected away from the anterior part of an elongated cervix. The level of the endocervix is indicated by white broken lines. The cardinal ligament has been stretched laterally with forceps.

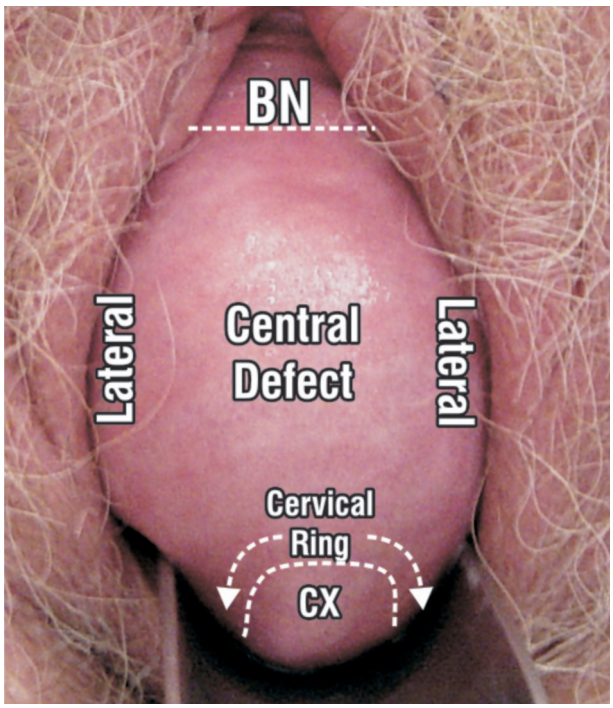

Figure 5. – Prolapse, 3rd degree, of bladder and uterus. A large central defect extends laterally. Prolapse of bladder around cervix (CX) (curved arrows) is characteristic of CL/cervical ring defect. The central defect remained after the Allis forceps test (see figures 1&2). BN=bladder neck.

both cardinal and uterosacral ligaments, indicating that both are important elements for uterine support, figure 3. On pressing down on an inflated balloon, the cardinal and ATFP ligaments became distorted, indicating that both are important supporting structures of the pubocervical fascia, and therefore, bladder base.

The simulated surgical operations performed using the model indicated how shortening and strengthening the elongated ligaments, anteverted the uterus, strengthened the pubocervical fascial supports, and restored the cervix to its correct anatomical position.

DISCUSSION

Our study, carried out in live patients as part of normal surgical dissection, demonstrated that the cardinal ligaments were attached to the cervix anteriorly, but not in all patients, in particular, those presenting with cystocoele.

The key to deeply understanding the structure and function of the cardinal ligaments was the "simulated operation" technique, which reduced a high cystocoele, and uterine prolapse. Per rectum palpation of the cardinal ligament while stretching of the tissues, and direct identification during surgery provided further insights. (see earlier website references).

We found that a torn or displaced cardinal ligament was a significant cause of high cystocoele, uterine retroversion, and uterine prolapse, as detailed in figure 6. Essential to this pathogenesis is the anterior insertion of both cardinal ligaments. Standard anatomical textbooks invariably show attachment of the cardinal ligaments to the lateral side of the cervix, rather than its anterior part. Based on cadaveric histology, Buller et al,[6] described fibres spreading anteriorly in their study of the uterosacral ligaments, but do not mention insertion of cardinal ligaments onto the anterior part of the cervix. In his drawings, Curtis[7] (1942) clearly shows a fascial envelope attaching anteriorly and posteriorly into what

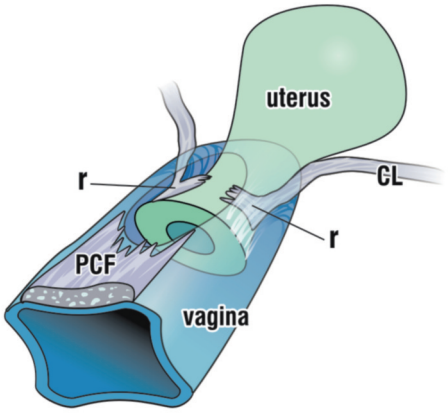

Figure 6. – Dislocation of the cardinal ligaments from their insertion into the anterior part of the cervical ring allows the uterine body to retrovert. At the same time, the insertion of the musculoelastic fascial layer of the vagina tears, allowing prolapse of the bladder (high cystocele).

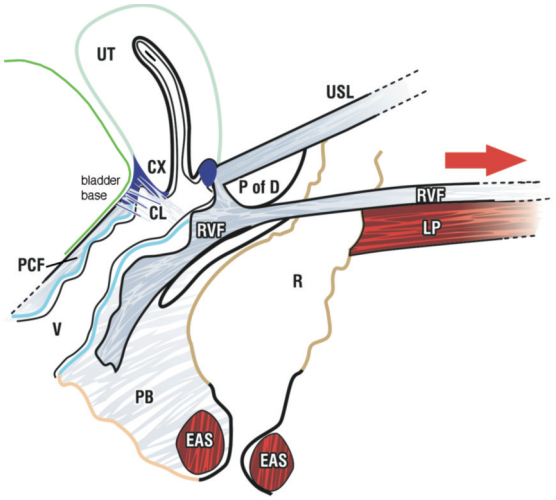

Figure 7. – The principal supporting elements of the uterus are the uteroscral ligaments (USL) rectovaginal fascia (RVF) which attaches to the levator plate muscle (LP), a posterior vector which tensions the rectum (R) and uterus backwards. Clearly the cardinal ligament (CL) has only a subsidiary role. It is also clear that dislocation of CL and pubocervical fascia (PCF) from cervix (CX) will result in rotation downwards of bladder base into vagina (high cystocele).

appears to be a circular cervical ring attached to the vagina. However, no special function was assigned by Curtis to this anatomical relationship. Curtis considered that the endopelvic fascia is defined as a ridge which sweeps forward from the region of the spine of the ischium and obturator muscle dividing into an inferior fascial arch, the white line, and the somewhat superiorly placed slightly curved arcuate (cardinal) ligament. He stated that there was a double layer of fascia between adjacent organs. Each fascial envelope is in intimate relationship with the musculature of the corresponding viscus, receiving muscle fibres from it.

Mengert's serial transections of adjacent structures underlined their importance in maintaining the position of the uterus. Yet, on histology, there is a well-established paucity of a definitive cardinal ligament structure. Zacharin,[1] Curtis,[7] Kato,[2] and others, discuss the importance of the connective tissue surrounding blood vessels as an important structural component.

Perhaps the answer to this anatomical dilemma lies in the physical characteristics of Collagen 1. In bundles, Collagen I has a breaking strength of 18,000 lbs /square inch or 1300 Kg/q cm.[8] Therefore very little collagen is required to support a uterus weighing a few hundred grams.

From a structural perspective, the debate on whether or not a cardinal ligament really exists is not really relevant. From a practical reconstructive surgical perspective, we have found that a broken or stretched insertion of cardinal ligament to the cardinal/cervical ring complex, figure 6, may result in bladder base descent (high cystocele), uterine retroversion, and a varying degree of uterine descent. It is evident on examination of figure 4 that a tensioned tape will shorten the cardinal ligaments, "reglue" the pubocervical fascia and cardinal ligaments to the anterior cervical ring, restore the uterine axis to an anteverted position, and partially restore uterine prolapse. These surgical principles are similar to those described in 1907 by Fothergill in his "Manchester Repair" operation.[10] The main difference is that Fothergill was attaching weakened ligaments to weakened ligaments, whereas use of the tape creates a permanent collagenous neoligament.

It is clear from figures 3 and 7, however, that the major supports for the uterus are the uterosacral ligaments. The cardinal ligament does, however, have an important subsidiary supporting role.

CONCLUSIONS

Contrary to accepted thought, the cardinal ligament inserts into the anterior part of the cervix. It plays a major role in retaining the uterus in an anteverted position, a major role in retaining the bladder and preventing cystocele, and a variable, but important role in uterine support.

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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** and **Proctologists/Colo Rectal Surgeons** 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… In this study the Authors identified and defined the cervical attachment and function of the cardinal ligaments in three groups of patients undergoing cystocele repair, vaginal or abdominal hysterectomy respectively. In particular they conclude, contrary to what was previously thought, that the cardinal ligament inserts into the anterior part of cervix and plays the major role in retaining both the uterus in an antiverted position and the bladder, and finally in preventing cystocele. The information obtained from this paper is absolutely important for the surgical correction of cystocele and the correction of uterine prolapse as well. In this context, the Authors' experience with TFS minisling operation in the correction of high cystocele and uterine prolapse is to substantiate the above.[1,2] The results reported in this manuscript could be the starting point for a new philosophy of approach using this type of minimally invasive surgery even though the role of the cardinal ligament remains controversial and at the same time fascinating both for its function as morphological support of pelvic viscera and for the neurofunctional aspect as reported in the past.[3] A study with MRI performed before and after the TFS minisling operation would be extremely interesting to confirm from an anatomical point of view the topographic displacement of the cardinal ligament.

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Gyne… The paper of Wagenlehner at al. is a brilliant anatomical research on the existence and the physiopathological role of the cardinal ligament. They performed a live on site anatomical study, which oversteps the bounds of both cadaveric studies and live imaging studies. They give us an anatomical picture of pelvic supports in women with and without genital prolapse. In brief, authors compared women undergoing vaginal surgery for uterine/bladder prolapse (group I) and women undergoing vaginal (group II) or abdominal (group III) hysterectomy for uterine pathology, the II group either with or without prolapse. They confirm the role of cardinal ligaments in supporting the uterus – in antiverted position – and bladder. This was elicited by the clearest evidence of the fibromuscular structure in patients without prolapse. Conversely, the ligaments were intact but extended in patients with high grades of prolapse and not recognizable in those with cystocoele. These findings foster the open debate on cystocoele as a consequence of uterine descent. Authors' analysis goes deeper on a biochemical level: the properties of collagen ultra-structure seem to be the cause of the anatomical finding. The link between the two levels could be a biomechanical study of pelvic support.

In conclusion this work gives a contribution not only in the anatomical debate, but open the doors to further discussions about a defect-tailored surgery for prolapse. In fact, once known the anatomical pattern, the surgical aspect should be analyzed in order to assess the best management of our patients.

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Procto… The article by Wagenlehner et al. is interesting and intriguing for proctologists. The Authors have shown that the cardinal ligaments as well as inserting into the lateral part of the cervix, also insert into its anterior part. They suggest that a torn or displaced cardinal ligament may be a significant cause of high cystocoele, uterine retroversion and uterine prolapse, whereas surgical correction of the ligaments restores the cervix to its correct anatomic position. Cardinal ligaments therefore are anatomical cornerstones to the prevention of pelvic organ prolapse.

The importance of uterine prolapse is well known to proctologists. Rectoanal intussusception is present in 40.3% of women affected by uterine prolapse and concurrent descending perineum syndrome. These women have a positive correlation between the severity of fecal incontinence (Jorge score) and the degree of genital relaxation, and this is most probably indicative of a link between pelvic organ prolapse and anorectal dysfunction. 1 Finally, both pelvic organ prolapse and anorectal dysfunction are influenced by the damage of the connective tissue and this can be proven by the evidence that repair of damaged ligaments cures idiopathic fecal incontinence.2 Therefore knowledge of the role of cardinal ligaments in assisting uterine/apical support becomes determinant in understanding how the loss of the integrity of the pelvic fascia may interfere with anorectal dysfunction. Useful suggestions might be provided for the performance of laparoscopic ventral rectocolpopexy.

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Original article

Polynucleotides and terpinenol: an effective aid in preventing mesh exposure in pelvic floor surgery

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Abstract: Objective: Pelvic surgery with mesh has proven to be more effective than conventional reconstructive surgery but cases of complications connected with these prostheses occurred. *Aim of the study:* We aimed to study the effectiveness of Polynucleotides and Terpinenol in preventing these complications. *Patients and methods:* Between January 2010 and December 2011, 166 female patients separated into two series were evaluated: the first treated with vaginal douches with an 0.05% solution of sodium hypochlorite; the second with ovules containing Polynucleotides and Terpinenol (PT). Parameters of success were the absence of signs and symptoms of exposure of the mesh and the trophism and appearance of the mucous membrane of the vagina as assessed by the surgeon, patient satisfaction, discomfort, itching or a burning sensation and signs of a Candida infection. *Results:* Overall, the number of mesh exposures was 6, of which 5 in Group, 1 in Group 2 (p = 0.043). Trophism improved significantly both at three months and at six months in the PT treated group: even more they complained less of discomfort, itching and/or a burning sensation (p = 0.001). No cases of clinical evidence of Candida albicans infection were found in Group 2 at the follow-up examination one month after surgery, compared with 21.5% in Group 1 (p=0.001). *Discussion:* This study demonstrated the effectiveness of PT ovules both in preventing complications such as mesh exposure following pelvic floor surgery and in enabling rapid and lasting healing, minimising local symptoms such as discomfort, itching and a burning sensation. Their effectiveness in respect of Candida albicans infection was also demonstrated.

Key words: Pelvic Surgery; Mesh Erosion Prevention; Polynucleotides; Terpinenol; Quality of Life.

INTRODUCTION

Pelvic reconstruction surgery with mesh has proven to be more effective than conventional reconstructive surgery.[1,2,3]

However, the first cases of complications connected with these prostheses, such as mesh exposure and/or erosion, occurred.[4]

There is still very little international literature on this topic, limited to a few case reports and assessments of their incidence, suggesting possible surgical solutions.[5] Studies aimed at preventing mesh-related complications are extremely rare.[6,7]

Similarly, there are only a few studies on the trophism of the pelvic organs and tissues and, specifically, of the mucous membrane of the vagina. The basis for initiating our study was our experience in the use of Polynucleotides as wound-healing adjuvants[8] in fields other than urogynecology.

An observational and experimental study on the role of Polynucleotides in tissue regeneration and trophism[8] prompted us to consider a possible role for them in pelvic surgery.

Moreover, an earlier experience regarding their use in the treatment of benign lesions of the vaginal portion of the uterus, the vagina, the vulva and the perineum[9] confirmed and increased our interest in Polynucleotides, particularly when combined with Terpinenol.

PATIENTS AND METHODS

Between January 2010 and December 2011, a total of 166 female patients, separated into two consecutive series, underwent surgical procedures using polypropylene meshes for treating pelvic perineal disease.

The first series (Group 1) consisted of 68 women, average age 59, who were instructed to use vaginal douches with an 0.05% solution of sodium hypochlorite.

The second series (Group 2) consisted of 98 women, average age 62. Following surgery, they were instructed to use ovules containing a combination of Polynucleotides and Terpinenol (PT) as an adjuvant treatment to improve tissue trophism and wound-healing and also to limit the occurrence of post-operative Candida albicans infections.

Vaginal ovules based on Polynucleotides and Terpinenol are a class III medical device (CE0373) (Mastelli S.r.l. - Sanremo).

Both groups followed the same prophylactic pattern calling for one application/day for 30 days after surgery. In accordance with the customary and widely accepted guidelines, all the patients also received perioperative prophylaxis in the form of an antibiotic and an anticoagulant.

All the patients were followed up with examinations 1 week, 1 month, 3 months and 6 months after surgery. The parameters for evaluating success of the treatment were first and foremost the absence of signs and symptoms of exposure of the mesh and, as secondary objectives, the trophism and appearance of the mucous membrane of the vagina as assessed by the surgeon (according to the following scale: 1 = poor trophism of the tissues, 2 = minimum trophism of the tissues, 3 = trophic tissues), patient satisfaction (VAS – Visual Analogue Scale – from 1 to 5 as follows: 1 = patient dissatisfied, 2 = patient not very satisfied, 3 = patient sufficiently satisfied, 4 patient satisfied, 5 = patient highly satisfied), the onset of discomfort, itching or a burning sensation, signs of a Candida infection and, lastly, safety of the product (assessed by monitoring adverse events, if any) an its tolerability.

Patients with complications such as mesh exposure underwent revision surgery, following which they were excluded from the follow-up and monitored as a separate group.

No patients aged under 18, patients with malignant tumours or already being treated with wound-healing substances were included in the study. The written informed consent of each patient was obtained before enrolling them in the study. The study was conducted in accordance with the World Medical Association Declaration of Helsinki.

STATISTICAL ANALYSIS

The continuous variables are shown as mean values ± SD, while the categorical variables are shown as absolute and percentage occurrences. The comparison between the

normal variables in the two independent samples was made using Student's t-test, while in case of non-normal distribution the Mann-Whitney test was used. The data was collected in a database created in a prospective manner using Microsoft Excel and SPSS 16.0 (SPSS Inc., Chicago, IL, USA) was used for the statistical analysis. Statistical significance was calculated applying two-tailed tests with a p value of <0.05.

RESULTS

The patients underwent the following surgical procedures: "TVT-O" (Transvaginal Tension-Free Vaginal Tape - Obturator)," TVMA" (Transvaginal Mesh - Anterior), Transvaginal Uterine Sling Suspension (Sling Hysteropexy), "T " plasty (T shaped prosthesis made of biological and polipropylen tissues combination) for treatment of rectocele, either as single procedures or combined and associated with one another in case of defects affecting several organs. All the patients completed the 6-month follow-up and nothing abnormal was reported with regard to the data collection. Comparable in terms of age and distribution of the surgical procedures. Overall, the number of complications (Table1) such as mesh exposure was 6, of which 5 in Group 1 (that is to say 7.4% of the cases, 1 in Group 2 (that is to say 1 %) (p = 0.043). A total of 6 cases of erosion were recorded, of which 5 in Group 1 (7.4%) and 1 in Group 2 (1%) (p=0.043). In Group 1, one case of dehiscence of the suture and very slight exposure of the sling (TVT-O) (aged 81), one case of exposure of the part made of synthetic material of a "mixed-T prosthesis" on the vaginal side following correction of a rectocele (aged 37), one case of a vaginal abscess following correction of a rectocele with a "mixed T prosthesis" leading to exposure of the portion of the prosthesis made of synthetic material (aged 77) and, lastly, two cases of patients (aged 58 and 72) with exposure in way of the anterior vaginal wall secondary to TVMA occurred. In Group 2, the only case that occurred was that of a patient (aged 68) who complained of exposure in way of the anterior vaginal wall secondary to TVMA. The 6 cases of mesh exposure underwent revision surgery with removal of any excess portions of the prosthesis. They were excluded from the follow-up at the time of corrective surgery and followed up as a separate group. All 6 patients were found to heal effectively and completely within one month in 5 cases out of 6 and within 3 months in the last case, who was also the youngest patient (aged 37). None of the patients had functional complications and none required further surgery. Trophism of the mucous membrane, an aspect considered essential for avoiding complications such as mesh exposure, was found to have improved both at three months (p=0.011) and at six months (p=0.005) in those patients who had been treated with PT. Table 2 shows secondary endpoints evaluation. At all the follow-up examinations the patients treated with PT complained less of discomfort, itching and/or a burning sensation (p=0.001). Patient satisfaction, measured on a VAS scale from 0 to 5, took the overall experience of each patient into consideration. The statistical analysis did not highlight any significant differences between the two groups.

TABLE 1. – Mesh exposure between Group 1 (vaginal douches) and Group 2 (vaginal ovules containing Polynucleotides and Terpinenol).

	GROUP 1 68 patients	GROUP 2 98 patients	P value
Exposure	5 (7.4%)	1 (1%)	0.043

No cases of clinical evidence of Candida albicans infection were found in Group 2 at the follow-up examination one month after surgery, compared with 21.5% in Group 1 (p=0.001). This difference was not found to be significant three months after surgery, probably due to the fact the patients who had tested positive at the previous examination had started to receive treatment for the infection. Lastly, six months after surgery the difference between the two groups was again found to be significant (p=0.007). It is essential to stress that the absence of side effects secondary to the administration of PT ovules confirmed the safety of the product study, since its tolerability proved excellent.

DISCUSSION

Nowadays, quality of life is one of the main objectives of medicine, and in particular of surgery for treating functional complaints. Specifically, pelvic-floor surgery involves a vast number of patients requiring prompt and effective action. The continuous quest for excellence includes the investigation of new products able to produce a tangible impact on the quality of life of patients.

It has been shown that PT ovules restore the physiological environment of the vagina thanks to their viscosity and buffering capacity (pH 4/4.5), leading to the formation of a protective film that adheres to the mucous membrane and is able to re-create the best conditions for rapid healing.[9] The Polynucleotides provide a further stimulus for cell regeneration in the tissues being repaired.[10,11]

Thus, trophism of the mucous membrane was found to be statistically better in the cases treated with PT ovules. This was also associated with a lower impact of collateral symptoms such as discomfort, itching and a burning sensation. This further supports the effectiveness of PT ovules as a wound-healing adjuvant able to control effects secondary to surgical procedures on the vaginal mucosa. As far as concerns the VAS scale, although no statistically significant differences were highlighted, a small difference one month after surgery should be pointed out. It appeared that this difference could be attributed to the higher incidence of mesh exposure as a complication in Group 1, which was found at about one month after surgery. It led to more severe symptoms in these patients and the need for revision surgery. On the other hand, the absence of significant differences at the time of the various follow-up examinations can be related to the good functional results of the functional surgery on the patients in the study. Terpinenol also enabled effective control of Candida albicans, as already demonstrated in other studies.[12] The clinical studies illustrated in the literature confirmed earlier laboratory experience, and were the starting point for our study.

CONCLUSION

This study demonstrated the effectiveness of PT ovules both in preventing complications such as mesh exposure following pelvic floor surgery and in enabling rapid and lasting healing, minimising local symptoms such as discomfort, itching and a burning sensation. Their effectiveness in respect of Candida albicans infection was also demonstrated.

PT ovules associated with excellent knowledge of the anatomy of the pelvic floor, a correct surgical technique and careful selection of the patients are effective tools in preventing complications of pelvic perineal prosthetic surgery.

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TABLE 1. – Secondary endpoints evaluation in the 2 groups.

	GROUP 1 68 patients					**GROUP 2 98 patients**					**P value**
TROPHISM OF MUCOSA		**T1**	**T2**	**T3**	**T4**		**T1**	**T2**	**T3**	**T4**	
	1	38.5%	33.8%	31.3%	28.6%	**1**	30.8%	22.0%	22.0%	23.0%	T1 p=0.478
	2	38.5%	41.6%	46.8%	49.2%	**2**	38.4%	29.7%	30.8%	38.5%	T2 p=0.011
	3	23.0%	24.6%	21.9%	22.2%	**3**	30.8%	48.3%	47.2%	38.5%	T3 p=0.005
											T4 p=0.104
DEGREE OF SATISFACTION VAS 1-5	**1**	0%	3.1%	4.7%	1.6%	**1**	0%	0%	1.1%	0%	
	2	4.6%	9.2%	6.3%	6.3%	**2**	0%	2.2%	1.1%	1.1%	
	3	24.6%	21.5%	18.8%	19.0%	**3**	24.2%	20.9%	19.8%	26.4%	
	4	53.8%	47.7%	50.0%	52.5%	**4**	58.2%	61.5%	56.0%	50.5%	
	5	17.0%	18.5%	20.2%	20.6%	**5**	17.6%	15.4%	22.0%	22.0%	
	Average	3.83	3.69	3.75	3.84		3.93	3.90	3.97	3.93	T1 p=0.363
	± sd	±0.76	±0.98	±1.01	±0.88		±0.65	±0.67	±0.75	±0.73	T2 p=0.140
											T3 p=0.147
											T4 p=0.477
DISCOMFORT ITCHING BURNING	**Yes**	53.8%	60%	31.3%	31.7%	**Yes**	22%	11%	1.1%	2.2%	T1 p=0.001
	No	46.2%	40%	68.8%	68.3%	**No**	78%	89%	98.9%	97.8%	T2 p=0.001
											T3 p=0.001
											T4 p=0.001
CANDIDA ALBICANS	**Yes**	10.8%	21.5%	7.8%	17.5%	**Yes**	4.4%	0%	1.1%	3.3%	T1 p=0.224
	No	89.2%	78.5%	92.2%	82.5%	**No**	95.6%	100%	98.9%	96.7%	T2 p=0.001
											T3 p=0.087
											T4 p=0.007

T1 = 1 week, T2 = 1 month, T3 = 3 months, T4 = 6 months
TROPHISM 1 = Tissue not very trophic, 2 = tissue slightly trophic, 3 = tissue trophic
DEGREE OF SATISFACTION: 1 = dissatisfied, 2 = of very satisfied, 3 = fairly satisfied, 4 = satisfied, 5 = Highly satisfied

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Original article

Dissecting study of subperitoneal tissue of the female pelvis

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Abstract: Many studies supported the existence of a real fascial pelvic retroperitoneal system closely related to the endopelvic fascia. To better understand the organisation of the retroperitoneal fibroadipose tissue, dissections of 25 un-embalmed female pelvis were performed. Proper fibrous ligaments connecting the viscera with the pelvic walls were not identified, but connective condensation where the vessels were numerous and larger were recognised. Thin connective laminae surround the vessels adventitia and are connected with the septa between the adipose lobules. The 3D arrangement of the fibroadipose tissue corresponds to a mesh of thin connective laminae that borders the small adipose lobule and are connected with the visceral adventitiae, the vasculonervous sheath and the parietal pelvic lamina, constituting an anatomical device, which, passing the functional limits of any individual ligament, has elastic supporting properties. In absence of real ligament, the fibroadipose pelvic tissue could have not only the passive role of filling the spaces, but also an active role with supporting function coming from the intrinsic tissue proprieties and from the muscular tension of the pelvic floor.

Key words: Pelvis; Woman; Prolapse; Fibroadipose tissue; Anatomy.

INTRODUCTION

The space between the pelvic peritoneum and the pelvic fascia is filled with fibroadipose tissue (FAT) that surrounds the viscera, the vessels and the nerves of the pelvic cavity. A system of fibrous connective bundles with antero-posterior direction (sacro-pubic laminae of Farabeuf) and with transversal direction (cardinal ligaments of Mackenrodt) is described. These ligaments are considered to allow intrapelvic organs relative mobility while maintaining their position.[1] Histological studies on FAT of different pelvic regions have demonstrated that the pelvic ligaments don't correspond to a classic ligament (dense, regular connective tissue with fibres regularly oriented to form thick bundles).[2] Dissecting studies on cadavers demonstrated the absence of true ligament in the female pelvis.[3] To better understand the organisation of FAT, dissections of the un-embalmed female pelvis were performed.

MATERIALS, METODS AND RESULTS

Anatomical dissection was undertaken in 25 female unembalmed cadavers (range: 35-72 years old), without a history of pelvic diseases. The pelvic peritoneum was dissected at the level of the anterior lamina of the broad ligament with a sagittal direction towards the pubis body, midway between the viscera and the lateral pelvic walls. After the section of the round ligament, at the level of the medial third, the two peritoneal flaps were dissected with lateral and medial direction.

With a moderate traction of the uterus, a gradual removal of the FAT of the bladder pelvic space was performed. The obliterated umbilical artery and the obturator vessels and nerves were identified, closed to the lateral pelvic walls. The uterine artery, surrounded by the venous vessels of the uterovaginal plexus showed a lateromedial course, with an anterior obliquity. The pelvic part of the ureter was found medially to the uterine vessels and run in proximity of the superior portion of the lateral vaginal wall. The removal of the adipose lobules showed thin translucent, very fragile laminae. Between the ureter and the vaginal walls, the FAT was thicker and the removal of the lipidic part of it was performed, with visualisation of the small whitish nervous bundles. Connective thickening ascribable to ligaments were not found. At the level of the bladder a fibroadipose lobular lamina (3-4 mm thick) was easily isolated, placed on its anterior surface. In the pararectal space the pararectal nervous bundles with sagittal course were easily identified, corresponding to the hypogastric plexus (Figure 1).

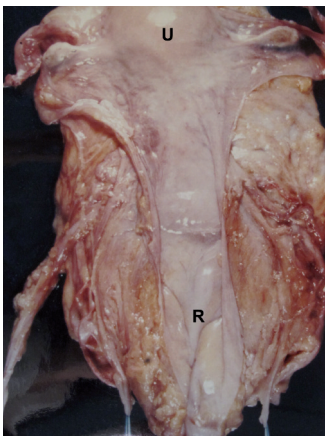

Figure 1. – Schematic representation of the topography of the inferior hypogastric plexus (dotted lines) and the nerves for the pelvic viscera, uterus (U) and rectum (R).

DISCUSSION

Many studies supported the existence of a real fascial pelvic retroperitoneal system closely related to the endopelvic fascia.[4-6] During our dissections, proper fibrous ligaments connecting the viscera with the pelvic walls were not identified, but connective condensation where the vessels were numerous and larger was recognised. In the parametrium a rich mesh of venous vessels close to the uterine artery and terminal part of the ureter was documented. Thin connective laminae surround the vessels adventitia and are connected with the septa between the adipose lobules. The dissection of the FAT at the level of the sacrouterine folds demonstrated the presence of nervous bundles, corresponding to the inferior hypogastric plexus, surrounded by the areolar connective laminae. The 3D arrangement of the FAT corresponds to a mesh of thin connective laminae that borders the small adipose lobule and are connected with the visceral adventitiae, the vasculonervous sheath and the parietal pelvic lamina, constituting an anatomical device, which has elastic supporting properties. In absence of real ligament, the FAT could have not only the passive role of filling the spaces, but also an active role with supporting function coming from the intrinsic tissue proprieties and from the muscular tension of the pelvic floor.[2] In conclusion, the FAT is the key element of the topographic anatomy of the female pelvis. In fact, in analogy with the mediastinic tissue, it linked the viscera and the pelvic walls, filling the interposed spaces and giving support to the vasculonervous structures.

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Medical Practice

The "Italian Society of Urodynamics' (SIUD) delivery & pelvic dysfunctions card": an Italian language screening tool

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Abstract: Urinary and anal incontinence, pelvic organ prolapse, perineal pain and reduction in pelvic floor muscle strength and function can occur after delivery as a result of damage to the pelvic structures. Debate is open on risk factors, prevalence and management of pelvic postpartum dysfunctions. In Italy few centers offer a specific management of obstetric pelvic injuries and often the treatment of these dysfunctions relies on the willingness of single professionals. Moreover there is often inadequate communication between the birth center and professionals who take care of the woman during the puerperal phase and most women are poorly, or not at all, informed about postpartum pelvic dysfunctions, their evolution and treatment opportunities. To face these problems the Italian Society of Urodynamics, continence neurourology and pelvic floor (SIUD) has established a specific committee. Starting from existing experiences, the group has created a recording tool aiming at standardizing women pelviperineal assessment in the postpartum period and selecting women who need to be addressed to conservative treatment. This tool has been named "SIUD delivery & pelvic dysfunctions card" and is presented here.

Key words: Pelvic Floor Dysfunctions; Incontinence; Postpartum; Delivery; POP.

INTRODUCTION

Pregnancy and delivery are well known factors of damage to pelvic floor structure and function.

Urinary incontinence can follow a vaginal delivery because of injury to connective tissue support, to pelvic nerves or muscles and also directly to urinary tract.[1] Damage of the pelvic structures can also give onset to anal incontinence, pelvic organ prolapse (POP), perineal pain, dyspareunia and impairment of voluntary pelvic floor muscle function.[2]

Pelvic floor muscle treatment (PFMT) has shown to be effective in the treatment of urinary incontinence (Grade of recommendation A), and a rehabilitative approach is also proposed for treatment of POP, anal incontinence, pain and dyspareunia. Literature other than on urinary incontinence is scant; nevertheless there are evidences that PFMT can improve POP symptoms and severity (Grade of recommendation A) and it is recommended also in the treatment of fecal incontinence as a part of a conservative management (grade B).[3]

Strategies to deliver PFMT to women during pregnancy and in the postpartum period can vary widely: from providing PFMT to all women, either symptomatic or not (preventive approach) to providing it exclusively to symptomatic women as a specific treatment measure.

The first hypothesis is clearly not feasible while considering cost-benefit and sustainability of PFMT. In fact even the 5th International Consultation on Incontinence states: "*it should be considered the cost benefit of population based approaches to health professional taught postpartum PFMT to all postpartum women regardless of their status*".[3]

The identification of selection criteria for PFMT during pregnancy and after delivery is therefore a key point.

To deal with this topic the Italian Society of Urodynamics, continence, neurourology and pelvic floor (SIUD) has established a specific committee. The first commitment of the group, starting from Italian and international existing experiences, has been to propose a recording tool named "*SIUD delivery & pelvic dysfunctions card*" with the double aim to provide a standardized evaluation system for epidemiological studies and to select women who might need conservative treatment in the postpartum period.

BACKGROUND

Two different approaches in selecting women to refer to PFMT after delivery can be considered:

– a *risk factors approach,* selecting at hospital discharge women considered at risk of developing pelvic dysfunctions;

– *a signs of damage approach,* selecting women who still have symptoms or signs of pelvic dysfunction at follow up in the postpartum period.

The *risk factor approach* has been adopted in more than one birth center. Of interest is the experience from the Obstetrics and Gynecological Clinic of Brescia where a standardized tool (called "Perineal card") was developed, consisting of a check list of risk factors resulting in a final risk score. On the basis of that score, women were addressed or not to a PFMT.[4]

The main advantage of this approach is to provide to the birth center a simple tool to select women who need more attention, due to an increased risk of developing pelvic floor dysfunctions. A similar approach was proposed in a previous study by Chiarelli, even if this work took in account only 2 risk factors, forceps delivery or a vaginal delivery of a large baby > 4000 g.[5]

A lot of risk factors have been identified as significantly associated with the occurrence of pelvic floor trauma. Unfortunately at present no agreement exists about which factor or combination of factors can influence the outcome in terms of urinary incontinence, prolapse, anal inconti-

nence, pain and dyspareunia. For these reasons the risk factors approach doesn't represent the best way of selecting the group of women that most need a PFMT.

On the opposite side, *the signs of damage approach* has been adopted in the "Mamme senza incontinenza (Mothers without incontinence)" Project, sponsored in 2003 by the Piemonte Regional Health Authority.

In that case the selection criteria were based on the presence at two month postpartum consultation of at least one amongst 5 symptoms or signs: urinary incontinence (if still persistent 30 days after delivery), anal incontinence (if still persistent 1 week after delivery); more than mild pain or dyspareunia still reported at the time of consultation; POP > 2nd degree according to the Halfway system and perineal testing at digital palpations < 2 in a 0-4 scale (AIPDA testing).[6]

The *signs of damage approach* has the advantage of selecting women who actually "have" pelvic floor dysfunction, narrowing patients number in order to better address specific treatment resources.

Data from a selection of 124 primiparous women within the "Mamme senza incontinenza" Project showed at 2 months after delivery, a 12 % incidence of one or more positive criteria. Those women were addressed to conservative treatment. More in detail, urinary incontinence was present in 9,6% of cases, fecal incontinence in 0,8%, perineal testing <2 (AIPDA score) in 4% and perineal pain/dyspareunia in 4,8% of women.[7]

It's worth to notice that in Italy it's quite common that women have their first postpartum consultation by a gynecologist who is not related to the delivery center. In this case, due to a lack of information about pregnancy and delivery risk factors a "signs of damage approach" represents the only way to deal with the problem.

THE SIUD PROJECT

The project aims at improving care of postpartum pelvic floor dysfunctions. Promoting knowledge and awareness of postpartum pelvic floor dysfunctions amongst health care professionals as well as amongst women via a standardized approach, is part of this aim.

The first step of the project has been to define a standard instrument to collect data for both kinds of approach: the *Risk Factor* and the *Signs of damage approach*. While the first one simply needs to collect data concerning pregnancy and delivery, the second approach is a little bit more complex, dealing with different anatomical compartments and functions. The effort through simplicity and adoption of already validated instruments, whenever possible, has been considered while designing this tool.

The result is a "**SIUD delivery & pelvic dysfunctions card**" composed of two different sections:

A "**Delivery Card**" collecting obstetrical data and potential risk factors and a "**Post partum screening card**" collecting the *signs of damage*.

Delivery Card (appendix 1)

As clearly shown in *appendix 1* the *Delivery Card* includes the most significant obstetrical data and potential risk factors beside mother demographical data. It also takes into consideration urinary retention (if persistent 24 hour after delivery) and preexisting or during pregnancy pelvic functional disorders. This tool is intended to be completed by the clinical staff at the time of discharge from the birth center. Therefore it should be available for the first puerperal consultation.

Post partum screening card (appendix 2)

The "post partum screening card" is intended to record the presence of pelvic dysfunctions after delivery. As shown in *appendix 2* the card is composed of five sections: urinary incontinence, anal incontinence, pelvic organ prolapse, pain and dyspareunia and pelvic floor muscle dysfunction. Based on validated existing instruments every section includes a quantification system to provide an outcome measure for observational or interventional approaches. For each considered dysfunction an assessment tool is included in the card as follows:

1. Urinary incontinence: an Italian validated translation of the ICI q SF.[8]
2. Anal incontinence: the so called Wexner incontinence score.[9]
3. Pelvic organ prolapsed: POP-q simplified staging system.[10]
4. Pain and dyspareunia: visual analogic system (VAS).
5. Pelvic floor muscle dysfunction: the Oxford modified grading system.[11]

We then arbitrarily established a cut-off for every section (see appendix 2) as a selection criteria for management (counseling, lifestyle interventions or rehabilitation according to the condition) when at least in one section the cutoff is exceeded, so a population that is worthwhile of attention can be selected.

This tool is intended to be completed by the clinical staff at postpartum consultation.

Further step of the SIUD committee on Pregnancy & Pelvic dysfunctions will be to standardize a management protocol for women selected via the *Post partum screening card*. In that protocol data collected through the Delivery Card will be compared with those emerging from the Screening card and management outcomes.

DISCUSSION

Epidemiological studies show that up to 33% among primiparous are affected by urinary incontinence during the first 3 months postpartum and that within the first year postpartum small changes in prevalence occur.[1]

The prevalence of anal incontinence after childbirth is reported as up to 26-38% between 6 weeks-6 months postpartum and recent studies suggest to extend postpartum follow-up visits beyond the typical 6-8 weeks to provide surveillance for potential anal incontinence.[12]

Very few studies investigated pelvic organ prolapse (POP) prevalence shortly after delivery, although POP is commonly considered a frequent consequence of delivery. A recent study reports that POP Q stage > 2 was present at 6 months postpartum in 18, 1% of women who delivered by spontaneous vaginal delivery and in 29% of cases after instrumental vaginal delivery.[13]

Perineal pain and dyspareunia during the first trimester postpartum are reported by many women after vaginal delivery, and spontaneous recovery is reported in the great majority of them. Nevertheless perineal pain is still reported by 3-6 % of women at one year after delivery[14] and dyspareunia by 24% at 6 months and 8% at 12 months.[15]

A recent review on pregnancy and postpartum related pelvic floor disorders states that there is some evidence that PFMT can be used to reduce urinary incontinence during pregnancy and up to 1 year after birth.[16] Moreover PFMT could have a long-term effect, as reported by Dumoulin, who showed benefits of physiotherapy for post partum urinary incontinence still present 7 years after treatment.[17] On the contrary evidence of PFMT efficacy in the postpartum period in case of fecal incontinence is insufficient.[16]

As a population based approach it is clearly not feasible, we need to establish selection criteria for PFMT in postpar-

tum period. The selection criteria can range from the simple identification of risk factors for pelvic floor dysfunctions to a more complex symptoms-based approach or, even more selectively, to restrict PFMT to women with documented pelvic floor damage after delivery.

Currently in our country there are at least 3 problems when dealing with post partum pelvic floor dysfunction: 1. *Availability:* few centers provide specialized management and in many cases the possibility of being treated depends on the willingness of single professionals; consequently the approach to postpartum pelvic dysfunctions is poorly standardized and not commonly available. *2. Communication:* in many cases no communication exists between birth centers and professionals who take care of women in the postpartum period. 3. *Awareness:* many women are not enough, or not at all, informed about postpartum pelvic dysfunctions, their evolution and treatment opportunities.

Therefore postpartum pelvic dysfunctions should be better addressed from healthcare providers. This comes from epidemiological evidence compared with the availability of effective treatments. The SIUD committee has worked to provide a standardized assessment tool that combines obstetrical data with signs and symptoms of pelvic floor dysfunction in the postpartum period. We think that providing a standardized evaluation and establishing criteria for selecting women who need care might improve the management of women affected by postpartum pelvic dysfunction.

CONCLUSIONS

Delivery is the most stressful event for the pelvic floor occurring during a woman's lifespan. Nevertheless, at present, management of potential obstetric injury to the pelvic floor is extremely controversial. Moreover from a clinical point of view it is currently a neglected topic, and this is particularly true in Italy. The Italian Society of Urodynamics has defined an Italian language standardized system, the "*SIUD delivery & pelvic dysfunctions card*" to collect data about delivery, to evaluate mothers in postpartum and to select women who most need PFMT. This will help in the future both for research and clinical purposes.

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Appendix 1 and Appendix 2 can be downloaded from www.pelviperineology.org with regular size characters

APPENDIX 1

DELIVERY CARD

Surname……..Name……(mother)
Delivery date ……/……/……

	NUMBER/ TEXT	YES	NO
Age (mother)			
Previous vaginal delivery (number)			
BMI (at delivery)			
Dystocic labour (type)		**yes**	**no**
Second stage of labour (minutes)			
Precipitous labour		**yes**	**no**
Induced labor (if "yes", specify the method: oxytocine, prostaglandines, amniotomy/other)		**yes**	**no**
If induced labor specify the clinical indication: hypertensive disorders/gestational diabetes/post-term prolonged pregnancy/premature membrane rupture/other			
Emergency caesarean section		**yes**	**no**
Elective caesarean section		**yes**	**no**
Episiotomy (if "yes", specify if midline or mediolateral)		**yes**	**no**
Vaginal-perineal tear (0-4 scale as reported below)*		**yes**	**no**
Episiotomy complications (infection, haematoma, tear, other)			
Vacuum extraction delivery		**yes**	**no**
Forceps delivery		**yes**	**no**
Kristeller maneuver		**yes**	**no**
Epidural analgesia		**yes**	**no**
Cefalic circumference (cm)			
Fetal weight (grams)			
Twin birth (number)		**yes**	**no**
Labour position (recumbent, squat, on all fours, on the side, into water, other)			

Urinary retention after delivery (if persistent after 24 hours)	**yes**	**no**

Dysfunctions before delivery	Before pregnancy		During pregnancy	
Stress urinary incontinence	**yes**	**no**	**yes**	**no**
Urge urinary incontinence	**yes**	**no**	**yes**	**no**
Anal incontinence (flatus)	**yes**	**no**	**yes**	**no**
Anal incontinence (stool)	**yes**	**no**	**yes**	**no**
Dyspareunia	**yes**	**no**	**yes**	**no**

**Perineal-vaginal tear grading*

Intact No tissue separation at any site

First degree	Injury to the skin only (i.e. involving the fourchette, perineal skin and vaginal mucous membrane)	
Second degree	Injury to the perineum involving perineal muscles but not the anal sphincter	
Third degree	Injury to perineum involving the anal sphincter complex	• 3a: Less than 50% of external anal sphincter thickness torn • 3b: More than 50% of external anal sphincter thickness torn • 3c: Both internal and external anal sphincter torn
Fourth degree	Injury to perineum involving the anal sphincter complex (external and internal anal sphincter) and anal epithelium and /or rectal mucosa)	

APPENDIX 2

POSTPARTUM SCREENING CARD

1) URINARY INCONTINENCE

☐ YES ☐ NO

Type: ☐ stress ☐ urge ☐ mixed ☐ other

ICIQ-SF

(INTERNATIONAL CONSULTATION ON INCONTINENCE QUESTIONNAIRE SHORT FORM)

Thinking about how you have been, on average, over the past four weeks:

1. How often do you leak urine?*
   - ☐ 0
   - ☐ 1 **about once a week or less often**
   - ☐ 2 **two or three times a week**
   - ☐ 3 **about once a day**
   - ☐ 4 **several times a day**
   - ☐ 5 **all the time**
2. We would like to know how much urine you think leaks.
   How much urine do you usually leak (whether you wear protection or not)?
   - ☐ 0 **None**
   - ☐ 2 **A small amount**
   - ☐ 4 **A moderate amount**
   - ☐ 6 **A large amount**
3. Overall, how much does leaking urine interfere with your everyday life?
   Please ring a number between 0 (not at all) and 10 (a great deal)

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

☐ *tick the box if you leak urine more than once a month, less than once a week

CUT OFF
SCORE >=1

2) ANAL INCONTINENCE

Fecal incontinence	☐ yes	☐ no
Flatus incontinence	☐ yes	☐ no
Soiling	☐ yes	☐ no

WEXNER SCORE

Incontinence	Never	Rarely Less than 1/month	Sometimes More than 1/month Less than 1/week	Usually More than 1/week Less than 1/day	Always More than 1/day
Solid	0	1	2	3	4
Liquid	0	1	2	3	4
Gas	0	1	2	3	4
Wear pad	0	1	2	3	4
Lyfestyle altered	0	1	2	3	4

Total score ☐

CUT OFF
At least of the following

- **SCORE > 0 *(almost 1)*if solid or liquid incontinence**
- **SCORE > 1 *(almost 2)* if flatus incontinence**

3) PELVIC ORGAN PROLAPSE

Simplified POP-Q STAGING

STAGE 0	No prolapse demonstrated
STAGE 1	Most distal portion of the prolapse is more than 1 cm above the level of the hymen
STAGE 2	Most distal portion of the prolapse is 1 cm or less proximal to or distal to the plane of the hymen
STAGE 3	The most distal portion of the prolapse is more than 1 cm below the plane of the hymen.
STAGE 4	Complete eversion of the total length of the lower genital tract is demonstrated

Most distal portion is:
☐ anterior ☐ central ☐ posterior

CUT OFF
SCORE >=2

4) PERINEAL PAIN AND DYSPAREUNIA

	YES	NO
1-Perineal pain		
2- If "yes", do you think it is a problem for you?		
3-Dyspareunia		
4- If "yes", do you think it is a problem for you?		
5- Resumption of sexual acitivity		
6- If "yes", how many weeks after delivery?		

PERINEAL PAIN
VISUAL ANALOGIC SCALE (0-10) ☐

DYSPAREUNIA
VISUAL ANALOGIC SCALE (0-10) ☐

MARINOFF dyspareunia scale ☐

0- No dyspareunia
1- Intercourse is painful but the degree of discomfort does not prevent penetration
2- The pain prevents intercourse from taking place on most occasions
3- Pain results in total apareunia

REDUCED VAGINAL SENSITIVITY AT INTERCOURSE
(compared to pre-pregnancy sensitivity)

VISUAL ANALOGIC SCALE (0-10) ☐

CUT OFF
If perineal pain or dyspareunia are a problem
(if answered "yes" to questions 2 or 4)

5) PELVIC FLOOR MUSCLE DYSFUNCTION

MODIFIED OXFORD GRADING

0 = nil (no discernibile muscle contraction)
1 = flicker (a flicker or pulsation is felt under the examiner's finger)
2 = weak (an increase in tension is detected without any discernible lift)
3 = moderate (muscle tension is further enhanced and characterized by lifting of the muscle belly and also elevation of the posterior vaginal wall; a grade 3 or stronger can be observed as an in-drawing of the perineum and anus)
4 = good (increased tension and a good contraction are present which are capable of elevating the posterior vaginal wall against resistence)
5 = strong (strong resistance can be applied to the elevation of the posterior vaginal wall; the examining finger is squeezed and drawn into the vagina)

Grade
left ☐
right ☐

CUT OFF
Grade <=2
(even if one side only)

SELECTION CRITERIA FOR MANAGEMENT

Dysfunction	Evaluation tool	Cut off
UI	ICI q SF	≥1
AI	Wexner score	≥1 if solid or liquid and/or ≥ 2 if gas
POP	Simplified POP q staging	≥2
Pain/ dyspareunia	VAS	If it is a problem for the woman
Pelvic floor	Oxford Score	≤2

Original article

Apical pelvic floor prolapse surgical repair: comparison of anterior and posterior pelvic floor compartments vaginal mesh implants

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Abstract: Objectives: Urogynecologists are constantly looking for simple, safe and durable methods to cure apical pelvic floor prolapse (A-PFP). We used a well-known surgical technique utilizing either anterior or posterior pelvic floor compartment synthetic mesh (Prolift®, Gynecare, Somerville, NJ, USA) to reinforce the pelvic floor in cases of A-PFP with high risk of recurrence. The aim of this study was to analyze and compare cure rates as well as peri and post-operative related complications. *Patients and methods:* Patients with advanced A-PFP and being at risk for recurrence were enrolled into the study and underwent either anterior or posterior mesh implantation, according with the surgeon's decision. Previous Pelvic Organ Prolapse (POP) surgical reconstruction, first degree relative with significant pelvic floor fascial defect and poor pelvic supportive tissue were regarded as risk factors for A-PFP recurrence. Pre-operative demographic data, operative details immediate and long term postoperative follow-up data were prospectively collected for patients at the first post-operative month and year. Tele-interview was held at study conclusion by un-biased researchers who collected also the data from patient's charts and analyzed it. *Results:* A total of 57 A-PFP patients were subjected to the mesh operation in an overnight setting, at a university or privat hospitals, between October 2006 and May 2008. Twenty seven had an anterior compartment mesh and 30 patients had a posterior compartment mesh. Colporrhaphies and anti-incontinence mid-urethral synthetic sling operations (TVT-SECUR or TVT-Obturator®, Gynecare, Somerville, NJ, USA) were added upon indications. Peri and early post-operative complications included one event of bladder outlet obstruction which was conservatively treated. The operation failed and repeated surgery was needed with 3 patients, two of them had an anterior and one posterior mesh implant One patient of each group presented with an opposite side pelvic floor prolapse and 3 had recurrent USI. *Conclusions:* The mesh A-PFP reconstruction anterior and posterior mesh operation carries a low complication rate and high cure rate. The current study supports the previously reported favourable therapeutic outcome of this procedure and shows that the anterior and posterior meshes are similar regarding out-come. Thus, is the surgeon who allows to choose the mesh to be used as he finds anatomically and surgically appropriate.

Key words: Apical Pelvic Floor Prolapse; Surgical Reconstruction; Mesh Implant.

INTRODUCTION

It is evident that pelvic organ prolapse (POP) occurs when the supporting pelvic floor becomes weakened or stretched, usually caused by childbirth, leading to descent of the pelvic organs to the vagina and beyond. POP might affect each of the 3 pelvic floor compartments or any combination of them. This contributes to the impairment of pelvic organ function and a deterioration of patient quality of life. POP is estimated to severely affect approximately 11% of the female population. A-PFP, referring to the centro-apical prolapse of the pelvic floor, occurs in up to 20% of parous women. It might be related to a variety of urinary, bowel and sexual symptoms. A-PFP is estimated to be surgically treated in 5% of the total female population. Furthermore, up to 30% of those who undergo traditional non-mesh surgery might eventually go through repeat prolapse surgery, some of them following hysterectomy.[1-4]

Operation for A-PFP cure, such as vaginal hysterectomy, colporrhaphy, with or without plication of the utero-sacral ligaments, as well as sacro-spineous and sacral colposuspentions, are also associated with up to 30% recurrence rate, as determined by objective POP scoring and prolapse-related subjective symptoms. Previous POP surgical reconstruction, first degree relative with significant pelvic floor fascial defect and poor pelvic supportive tissue were regarded as risk factors for A-PFP recurrence.[5-12]

Experience with abdominal wall herniorrhaphy showed that the mesh implant concept had a low recurrence rate, and it was therefore subsequently implemented for pelvic floor herniation repair.

However, unlike abdominal wall hernia vertical mesh repair, the vaginally implanted horizontal meshes are subjected to relatively high levels of physical pressure, including sexual intercourse, thus should be well secured to solid pelvic structures such as the sacro-spineous ligaments (SSL), the pre-sacral fascia, the arcus tendinous fascia pelvis (ATFP) or the utero-sacral ligaments. The preferred anchoring method involves passing the mesh arms through the ligaments, since that probably results in longer lasting support than suture methods of mesh fixation.

Furthermore, just a thin and fragile mucosa layer covers the vaginal mesh, compared to the thick abdominal wall coverage of the abdominal hernia mesh; hence, mucosal erosion and vaginal mesh exposure are possible post-operative complications in the former. Steps should be taken to minimize mucosal erosion and the hazards of vaginal mesh protrusion.

The first innovative procedure for the correction of the apical vaginal support defect using a vaginal approach was replacement of the utero-sacral ligament by a synthetic sling positioned at the levator plate level, the Posterior Intra-Vaginal Sling (PIVS). Restoration of the utero-sacral ligament support and resuspension of the uterine isthmus, make the addition of vaginal hysterectomy unnecessary.[13-18] By not removing the uterus, the cervical ring, a solid central pelvic anchoring point is preserved. This provides extra stability for the pelvic floor by recruitment of the related ligamentary architecture for the pelvic reconstruction and avoids potential iatrogenic weakening of the pelvic floor due to surgical impairment

of innervation and blood supply. In contrary, adding hysterectomy to mesh pelvic floor reconstruction significantly increases (O.R. = 15 odd confidence intervals) the risk of post-operative vaginal mesh exposure. Other occasional adverse outcomes of hysterectomy are vaginal shortening and psychological effects in terms of the woman's body image and self-esteem.[19-28]

This study goal is to evaluate and compare the anterior and posterior meshes for A-PFP reconstruction, in terms of cure and failure rates as well as related complications rates, safety and durability of cure.

PATIENTS AND METHODS

The study was designed as a two patient's cohort study, comparing two surgical procedures for the treatment of A-PFP. The primary outcome measures were A-PFP mesh reconstruction safety, adverse effects and durability of cure at long term follow-up. Patients experiencing stage 3 or 4 vaginal apical supportive defects, diagnosed clinically in accordance with the International Continence Society (ICS) Pelvic Organ Prolapse Quantification (POPQ) standard scoring system, and who were at increased risk for recurrence of the POP, were referred for mesh implantation operation. Risk factors for recurrence included previous POP reconstruction surgery, first degree relative with a significant POP or poor pelvic floor tissue as assessed clinically.[29-32] Patients with mild POP and not at risk for recurrence were referred to conventional native tissue operations, Patients who had undergone previous pelvic irradiation, or with immune-depression, active infection, systemic steroid use or poorly controlled diabetes were excluded.

Thorough informed consent was obtained. All patients were given one gram Monocef (Cefonicid, Beecham Healthcare) intravenously prior to surgery. All patients were prepared by an iodine antiseptic vaginal wash prior to the commencement of surgery. Spinal or general anesthesia was elected upon patient's request.

Patients with an anterior vaginal wall defect, with or without an apical vaginal support defect had an anterior mesh implantation through a longitudinal median anterior wall incision and para-vesical lateral dissection. The mesh was spread from one pelvic side wall to the other, from the bladder neck to the uterine cervix or vaginal apex, so as to replace the whole anterior compartment endo-pelvic fascia. Proper mesh placement required a rather large para-vesical dissection, along the bony pelvis up to the iliac spines laterally and posteriorly and to the pubic bone anteriorly. The mesh arms were passed through the ATFP ligament to prevent weakening. The mesh was also secured to the fascial ring of the uterine cervix or to the vaginal apex at the insertion point of the former sacro-uterine ligaments so as to recruit the endo-pelvic ligaments for improved support. Mesh fixation to the para-urethral tissue was also done to ensure better stabilization of the construction.

For patients with posterior vaginal wall defect (recto-enterocele), with or without apical prolapse, a posterior mesh was implanted. This was carried out through a longitudinal median posterior wall incision, then freeing the vaginal wall from the rectum and the herniated peritoneal sac of the enterocele. A para-rectal dissection was then performed to the level of the SS ligaments. The mesh was spread from one pelvic side wall to the other, from the vaginal apex to the perineal body, to replace the whole posterior compartment endo-pelvic fascia. The mesh was also secured to the fascial ring of the uterine cervix or to the vaginal apex at the insertion point of the former sacro-uterine ligaments so as to recruit the endo-pelvic ligaments for improved support. The mesh was fixed to the perineal body to ensure better stabilization of the construction. Special surgical steps to prevent mesh exposure were undertaken. This included implying meticulous tension free technique with both, vaginal wall and mesh, refraining from excessive vaginal mucosa trimming and dissecting below the sub-mucosal fascia, so as to preserve blood supply and nerve endings. This avoids ischemia, poor healing and tissue necrosis, which might potentially lead to vaginal mesh erosion. It is important to replace sufficient portions of the endo-pelvic fascia, beyond the borders of the herniating endo-pelvic fascia and pelvic floor herniation, with the mesh. This is best achieved by spreading the mesh from one pelvic side-wall to the other, from the urethra and bladder neck to the vaginal apex, through the posterior compartment all the way down to the perineal body.

Patients presenting with additional significant features of pelvic floor relaxation underwent anterior or posterior colporrhaphy, as well as anti-incontinence surgery when indicated, at the same time as the mesh operation.

Pre-operative demographic data, operative details and immediate postoperative follow-up data were prospectively collected for all patients. Intra-operative and post-operative complications of all patients were recorded prospectively. The patients were interviewed at the first postoperative month and 1 year after. Subjective data recording included symptoms as urgency, frequency, stress and urge incontinence of urine or feces, sexual function impairment, voiding habits and pelvic pain and bulging. The file data collection was carried out by non-involved researchers. Patients were tele-interviewed by these researchers at study conclusion, September 2011. The study was approved by the review board (Helsinki committee). The study patients were provided with detailed relevant information prior to their signing the consent form. All patients were given 1 gr Monocef® (Cefonicid, Beecham Healthcare) intravenously one hour prior to surgery. They all underwent an iodine antiseptic vaginal wash before the surgery. The mode of anesthesia depended on the patient's request. Urinary bladder catheterization or diagnostic cystoscopy was not routinely carried out. Patients presenting with opposite compartment prolapse and urinary stress incontinence had anterior and/or posterior colporrhaphies and anti-incontinence mid urethral sling operations respectively, concomitant with the mesh reconstructive surgery. All operations were carried out by a single surgeon (MN) at a university hospital and a private hospital. These study patients were reported earlier with a longitudinal large scale publication.[33]

All statistical analyses were performed using SPSS 18 (IBM Corporation, Somers, NY). The student T test was used for comparison of quantitative variables between groups, while the Chi-square test or Fisher's exact test were used to compare categorical variables between groups. The Mc-Nemar test was used for longitudinal data comparison. All statistical tests were evaluated at the P=0.05 level of significance.

RESULTS

Between October 2006 and May 2008, 58 A-PFP mesh operations were performed (Prolift®, Gynecare, Somerville, NJ, USA). Of these 27 included anterior mesh implants and 30 had posterior mesh implants. Patients with USI had additive sub mid urethral sling (SMUS) anti-incontinence surgery (TVT SECUR® or TVT-Obturator®, Gynecare, Summerville, NJ, USA) and patients with opposite pelvic floor relaxation had additive native tissue colporrhaphy. No significant intra-operative injuries were reported. One pa-

tient had an early post-operative bladder outlet obstruction, treated conservatively. Dyspareunia occurred with 2 patients, one of each group. No tape exposures were recorded.

Three patients (2 of the anterior and 1 of the posterior group) presented with operative failure and had to be re-operated. Two patients, 1 of each group, had opposite side pelvic floor compartment prolapse. In 52 patients (91%) were the results satisfying, being both – free of complications and cured, as defined by the POPQ criteria. This includes patient's satisfaction with the anatomical results and cure of the debilitating introital lump related to the prolapse as well as proper function of the pelvic organs: the vagina, the bladder and the ano-rectum.

The patients' personal characteristics pre-operatively showed no statistical differences between the two groups. Age, parity, menopause, bladder over-activity, previous anti-incontinence surgery and the presence of chronic illnesses were similar for the two patient groups. There was no difference between the groups with regard to the operative details, including the length of the procedure and the need for concomitant colporrhaphy and SMUS operations. Operative injuries and cure rates as well as post-operative complication rates were similar in the two groups. Fifty percent of both groups presented for 1 year follow-up meeting, all were tele-interviewed at study conclusion.

DISCUSSION

Pelvic floor reconstructive surgeons, being aware to many hazards with pelvic mesh implants,[29-40] are often facing the need to decide whether to implant an anterior or posterior mesh for assuring A-PFP long durability cure. Frequently the decision is made according with the anatomical situation, namely – by verifying which of the pelvic floor compartments is prolapsed more – the anterior or the posterior. The surgeon has no data to predict if this decision entails the best reinforcement for the apico-central pelvic floor compartment. This rather small two armed cohort study looked at this particular issue. The two comparable patient's groups, who were operated each with an anterior or posterior mesh and followed-up for 3-5 years, shows no difference regarding the A-PFP correction. The mesh A-PFP reconstruction, anterior and posterior mesh operation carries a low complication rate and high cure rate. The current study supports the previously reported favourable therapeutic outcome of this procedure and shows that the anterior and posterior meshes are similar regarding out-come. Thus, is the surgeon allowed to choose the mesh to be used as he finds anatomically and surgically appropriate.

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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** and **Proctologists/Colo Rectal Surgeons** with their critical opinion and a teaching purpose. Differences, similarities and possible relationships between the data presented and what is known in the three fields of competence are stressed, or the absence of any analogy is indicated. The discussion is not a peer review, it concerns concepts, ideas, theories, not the methodology of the presentation.

Procto… Following Petros Integral Theory about the pelvic floor organs suspension system and DeLancey's studies on urogenital suspension systems, the Authors have considered the patients with apical pelvic organ prolapse in order to select those for mesh or autologous tissue suspension. The aim was to find differences after positioning the meshes posteriorly or anteriorly to the vaginal walls. Evaluating the results, the conclusion is interesting and seems rather important, as no differences have been found after placing the prostheses either between vagina and bladder or between vagina and rectum.

Any defect of one compartment of the pelvic floor has often negative consequences on the other compartments, and the repair of one of them may have positive effects on the others. Indeed, corrections of posterior and central compartments, as in case of ventral rectocolpopexy, have been demonstrated to result in an improvement of the bladder activity as well.[1]

Looking for a more complete interdisciplinary interpretation, in Neuman's work a coloproctologist would appreciate to be informed about the preoperative ano-rectal work up and some scored symptoms related to the posterior compartment, knowing also how they were eventually modified in the post-operative evaluation.1 Dealing with POP, it is worth to remember that the transabdominal use of meshes in colorectal surgery began many decades ago, and for several reasons this has never caused those concerns regarding the use of prosthetic material (mainly by transperineal / transvaginal approach) that nowadays are creating a lot of discussion in the field of urology and gynecology.

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Original article

The rhabdosphincter has a role in pressure generation but not continence

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Abstract: Background: The rhabdosphincter is a thin horseshoe shaped layer of striated muscle which sits outside the smooth muscle layer of the mid urethral zone. Though evidence has been presented for the role of a musculoelastic mechanism involving forward contraction of the suburethral vaginal hammock, this tiny structure , the "rhabdosphincter" is still considered to be the main continence mechanism by many authors. *Aim:* To assess the contribution of the rhabdosphincter to urethral pressure and continence. *Patients and methods:* Four women, mean age 61 years (range 51-71 yrs), parity 0-4 (mean 2.6) with urodynamically demonstrated genuine stress incontinence and no detrusor overactivity (DO). The pressure exerte d by the "rhabdosphincter" was measured during coughing by single Gaeltec microtip transducers before and after surgical dislocation of the suburethral vaginal hammock during a "tension free" midurethral sling operation performed under local anesthesia. The transducer catheter was oriented ventrally at 12 o'clock to maximize the pressure recorded during rhabdosphincter contraction. Five pressure readings were taken from each patient during coughing, taking care to ensure a valid reading at the high pressure zone.
Results: Intraoperatively, urine loss occurred for the first time, or greatly worsened when the suburethral vagina was disconnected from the urethra. Maximum intraurethral pressure increase recorded on four patients at midurethra was 78, 94,112, and 170% of the preoperative reading. *Conclusions:* The pressure "P" readings are potentially misleading in that they measure only the formula, P=force/area, in this case force from the rhabdosphincter, a weak muscle less important in the closures mechanism of the urethral tube. We hypothesize the rhabdosphincter acts as an adjunctive sealing mechanism.

Key words: Rhabdosphincter; Urethral pressure; Continence mechanisms; Stress incontinence; Urethral closure.

INTRODUCTION

The rhabdosphincter (Figure 1), was described by Gosling[1] as composed of striated muscle shaped in a horse-shoe and located outside the smooth muscle layer of the urethra. It is most prominent in the midurethral area. The posterior portion is relatively thin. The muscle cells are all of the slow twitch variety. These cells were unusually small with diameters of only 15 to 20 μm. DeLancey,[2] studied the anatomical relationships of the urethra to its surrounding structures in the series of dissections and microscopic examinations. He summarized these in terms of their occurrence as a percentage of total urethral length. Zero was taken at the bladder neck. He defined the *intramural urethra* as that length of the urethra traversing the bladder wall and it occupied zero to twentieth percentile. The *midurethra* was that length occupying the twentieth to sixtieth percentile. It was occupied mainly by the striated urethral sphincter muscle. In an extensive anatomical study, Huisman[3] considered that these structures were far too small to constitute an effective sphincter. He demonstrated that in older women, the striated muscle fibres degenerated with time, sometimes consisting only as a few atrophied fibres infiltrated with fatty tissue. Perrucini et al.[4] also demonstrated muscle atrophy with time. Yet, in spite of ultrasound evidence of urethral closure from behind during coughing or straining[5, 6] this tiny structure is frequently considered as constituting the main continence mechanism.

The aim of this study was to assess the contribution of the rhabdosphincter to urethral pressure and continence under stress (coughing) by isolating it from the musculoelastic closure mechanism.

PATIENTS, MATERIALS AND METHODS

Ethics

The operation was approved by local IRB and all patients signed informed consent.

Pre-operative investigations

Initially five patients were tested. All patients attended for testing with a comfortably full bladder, and were urodynamically tested on an Ormed 5000 system using the methods described by Asmussen and Ulmsten.[7] Instability (including a handwashing test), urethral pressure profile, cough, strain, and "cut-off"(squeeze) pressure transmission ratios, peak urine flow rate, emptying time, and residual urine were routinely assessed. Cough, strain, and "cut-off" pressure transmisssion ratios were repeated a few seconds later in all patients.

Operation

A "tension-free" midurethral sling operation was performed under local anaesthesia in 5 patients, using bilateral paraurethral incisions to dislocate the suburethral vaginal hammock from both pubococcygeus muscles as per the classic Goebell –Stoeckl-Frangenheim operation. The patient was sedated with an opiate analgesic pre-operatively, but received no muscle relaxant. An intravenous line was inserted, and the patient kept sedated, but co-operative with appropriate doses of midazolam (dosage 5-12mgs), administered by an anaesthesist. Prilocaine 1% diluted 1 in 3 (80-100 mls) was used to infiltrate the suprapubic skin, rectus muscles, periurethral and subpubic tissues, bilaterally. In the first part of this operation, bilateral incisions were made in the lateral sulci. A specially designed rigid tunneller with an external cross-sectional diameter of 6mm was inserted through the incisions and entered the Cave of Retzius, before emerging directly above the pubic bone through a prior 1.5 cm horizontal incision. Two plastic inserts were left in situ. After the measurements were completed, a tape was inserted by means of the tunneller in order to create an artificial pubourethral ligament.

Intra-operative pressure transmission testing

This was performed during the operation with a) intact vagina, b) after the two full depth lateral incisions had been made and opened out, with insertion of two plastic inserts

of the IVS tunneller, but prior to completion of the operation. Prior to testing each patient, the bladder was filled with 240 ml of saline. A single Gaeltec transducer was calibrated for accuracy using a water column between 10 and 100 cm H2O high before each operation. The transducer was introduced with the pressure sensor ventrally oriented at 12 o'clock to maximize the pressure recorded during rhabdosphincter contraction. The purpose of orienting the transducer ventrally at 12 o'clock was to render the measurement of the closure force from the rhabdosphincter as relevant as possible.

Pressure recording began within the bladder at a starting distance of between 7cm and 9cm from the external meatus with the patient coughing at each stage. Because the functional urethral length varied considerably between patients, in all patients care was taken to acquire readings in the zone of maximal urethral pressure. A minimum of 5 pressure readings were taken from each patient during coughing, taking care to ensure a valid reading at the high pressure zone.

RESULTS

The mean age was 61 years (range 51-71 yrs), parity 0-4 (mean 2.6). All 5 patients had urodynamic genuine stress incontinence (GSI), with no detrusor overactivity (DO) on urodynamic testing.

Vagina intact

Taking maximum readings only within each patient, mean pressure measured during coughing at the high pressure zone in the 5 patients was 41 cm H2O (range 20-73 cm H2O).

After bilateral incisions in the sulcus, plastic inserts in situ

In two patients the maximum cough pressure within the urethral pressure zone was below 100% of that measured with intact vagina (78% and 94%); in two patients results were in excess of 100% (170% and 112%). No recording was obtained in the 5th patient because of an unforeseen anaesthetic problem at that point of the procedure. Therefore this patient was excluded from the study.

Urine leakage

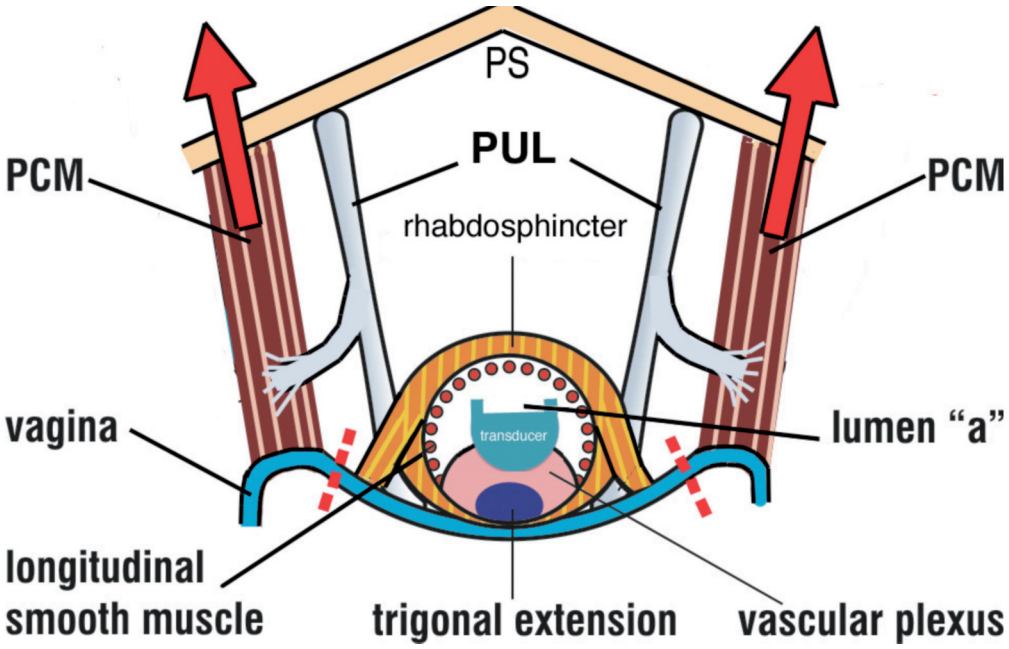
With the vagina intact, slight urine leakage was noted on stress (straining and coughing) in two patients after the bladder had been filled to 240 ml, but no urine leakage in the other two. After the bilateral incisions were made in the sulci, plastic inserts in situ, all four patients lost profuse amounts of urine on coughing. On completion of the operation, urine leakage ceased immediately in all 4 patients.

DISCUSSION

This study raises three important questions:

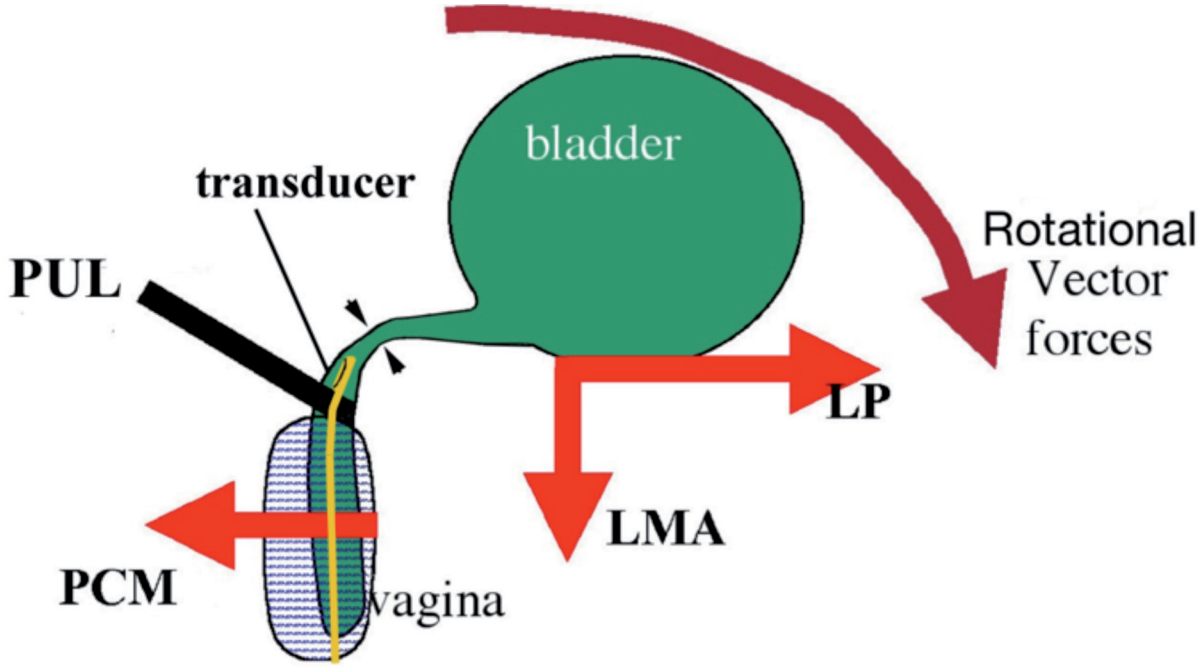
1. *What generates the pressure measured during MUP and during coughing?*
2. *What is the role of intraurethral pressure in continence?*
3. *What is the role of the rhabdosphincter in urethral closure and continence?*

With reference to question 1, "what generates intraurethral urethral pressure", in this study, all pressure measurements were carried out with a vagina dislocated from its lateral attachments to the closure muscle m.pubococcygeus, so that the transducer had to be measuring only the pressure exerted in the space 'a' directly above the transducer (Figure 1), a consequence of rhabdosphincter contraction and urethral stretching by the posterior vectors LP/LMA (Figure 2) which would narrow space "a" (Figure 1), small arrows (Figure 2). As pressure is Force/Area, pressure measured in the four patients was force rhabdosphincter /area 'a'.



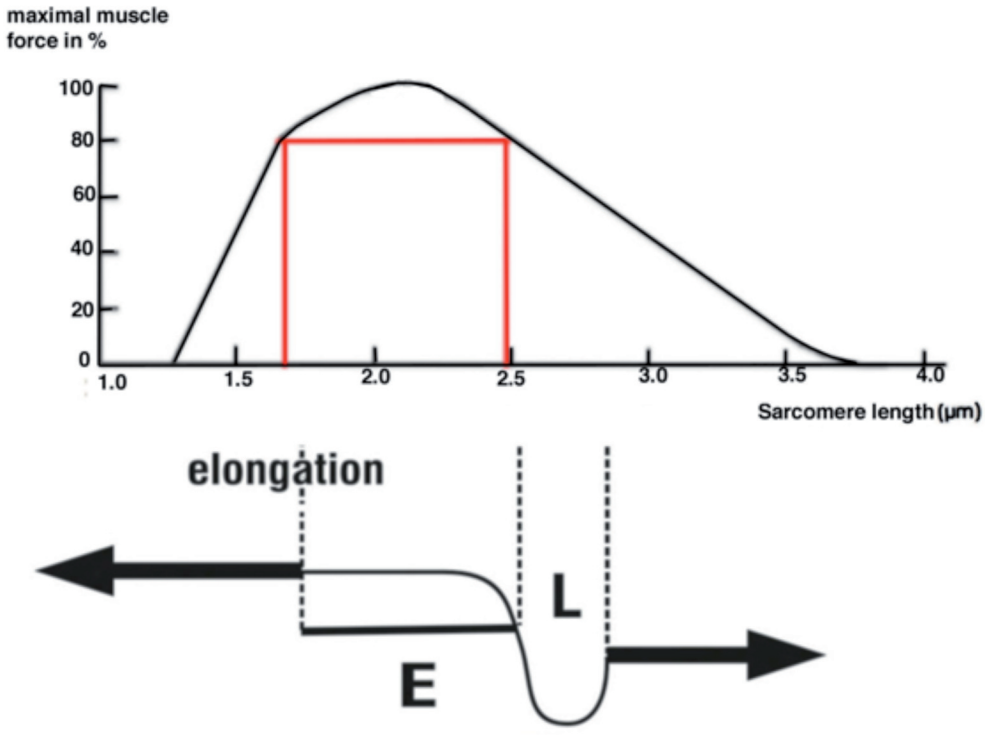
Hypothesized components of urethral closure. Perspective: coronal section of vagina at midurethra. The trigonal extension and vascular plexus are known as the "Cresta Urethralis"; arrows = vector closure forces (fast and slow twitch) from contraction of the anterior pubococcygeus muscle (PCM) which stretches the vagina upwards to close the urethral lumen'a'. Contraction of the rhabdosphincter over the "Cresta Urethralis" provides a water-tight mucosal seal, and is recorded as a pressure rise on effort. The vagina was dislocated from PCM surgically by a full thickness incision between vagina and PCM (broken lines). Note narrowing of space "a" by the transducer.

Figure 1. – Rhabdosphincter ("horse-shoe" striated muscle).



M. pubococcygeus (PCM) pulls the vagina forwards against the pubourethral ligament, "PUL" to close the distal urethra; LP/LMA stretch the proximal urethra against PUL to narrow it (small arrows; LP=levator plate; LMA=conjoint longitudinal muscle of the anus. This action occurs around the tip of the transducer which is effectively pushed forwards to further narrow the space "a" in Figure 1.

Figure 2. – Distal and proximal closure mechanisms of the urethra.[5]



Any laxity "L" in the muscle insertion points, whether rhabdosphincter or the three vectors in Figure 2, will effectively lengthen the striated muscles and result in a lower contractile force.

Figure 3. – Gordon's Law, a striated muscle contracts only over a fixed distance "E".

With reference to question 2, "role of intraurethral pressure in continence". With age especially, the collagenous attachments of vagina to PCM, PUL to urethra, rhabdosphincter to urethra and trigone, even the collagenous components of the vascular plexus,

Figure 1, all weaken; the lumen "a" expands and pressure falls, as Pressure=Force/Area. The rhabdosphincter also atrophies with age[3, 4] so that Force applied to "a" also weakens, causing a further pressure drop when measured. This hypothesis explains the onset of ISD, especially in the older age group. Though this hypothesis explains fall in urethral pressure with age, fall in urethral pressure is not per se causative of USI, as demonstrated by Kapoor et al.[8] It has been demonstrated that a high rate of cure can be achieved in patients with ISD with a midurethral sling.[9, 10] In two studies,[11, 12] a subgroup of patients with ISD (MUPs <20cm H2O) became 100% continent, *yet their post-operative MUPs remained <20cm H2O*. These data further support Kapoor et al.'s findings[11] that pressure per se is not an indicator of continence. Pressure, whether low, as in intrinsic sphincter deficiency (ISD), or high, as in our study, influences neither leakage nor continence. In contrast, it has been demonstrated by upward pressure at midurethra with a hemostat under transperineal ultrasound control that *an intact pubourethral ligament* (PUL) is the key factor for control of urinary stress incontinence and restoration of urethrovesical geometry.[6] (See video at www.integraltheory.org). Further validation comes from > 1,500,000 midurethral sling operations since 1995[13] for cure of USI. A lax PUL will result in effective lengthening of PCM (Figure 1). According to Gordon's Law,[14] this will weaken all three muscle closure forces (arrows Figure 3).

With reference to question 3, "role of the rhabdosphincter in closure and continence", it has been discussed in the answer to the question 2, that pressure per se is not an indicator of continence. Pressure merely measures force relative to the area over which it is measured. The role of the rhabdosphincter in continence control was examined thoroughly by Huisman[3] from a biomechanical/anatomical perspective. Huisman described how the rhabdosphincter (Figure 1) inserted inferiorly into the prolongation of the superficial trigone. He also described a cavernous type plexus submucosally in the cresta urethralis which was analogous to that in the corpora cavernosa of the male. In a series of histological studies extending from the new-born to old age, he was able to demonstrate that severe atrophy occurred in this muscle with time. He concluded that this was a weak muscle, and was not a major factor in continence control.

How to explain urine leakage with cough pressure increases of 112% and 170%?. Clearly, these measurements are misleading, as it is known that in urinary stress incontinence (USI), intraurethral pressure falls in relative terms to zero.

It has been demonstrated[5, 6] that on effort, backward/downward vectors stretch and rotate the proximal urethra around PUL (Figure 2). This action occurs around the tip of the transducer which in certain circumstances may "splint" the midurethra, effectively pushing the anteriorly oriented tip closely towards the anterior urethral wall to create a false reading, measuring the force transmitted by the rhabdosphincter over a greatly constricted area. The dislocated hammock could not stretch the vagina upwards to close the space lateral and posterior to the transducer. The urine ran out from around the three sides of the transducer.

We conclude:

1. The pressure readings in this and other studies can be potentially misleading in that they only measure the formula, Pressure=Force/Area.

2. The muscle force, in this instance, can only derive from the rhabdosphincter, which we have shown is a weak muscle incapable of closing the urethral tube.

3. Closure (continence) is different from pressure recorded, as demonstrated recently by Kapoor et al.[8]

4. We hypothesize the rhabdosphincter acts principally as an adjunctive sealing mechanism.

5. The musculofascial mechanism is the most important mechanism for urethral closure.

Limitations of the study. Only 4 patients were tested. However, according to Popper[15], this was sufficient to invalidate the "pressure hypothesis", one validated exception being sufficient to invalidate a hypothesis.

Note: Despite pressure rises >100% when the suburethral vagina was detached during midurethral sling surgery, 2/4 patients lost large amounts of urine. This indicates that musculoelastic closure is a most important mechanism for continence.

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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** and **Proctologists/Colo Rectal Surgeons** 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… In our continued quest for understanding the pathopysiology of female stress incontinence and how our operations may work, these authors, using the Integral theory, try to explain the relative contribution of the two most important factors in the female continence mechanism, namely the rhabdosphincter and anterior vaginal support. This paper in a way challenges the traditional belief of the understanding of ISD (intrinsic Sphincter Deficiency) which is defined by a low leak point of <60 cm H2O or MUCP of <20cmH20. They have shown, although in only a small patient cohort, that by restoring pubourethral ligament (PUL) function via a mid urethral sling (MUS), urethral closure and hence continence, can be obtained regardless of the leak point pressure or MUCP at which leakage takes place. This is reflected, and may explain, in clinical practice why the MUS can be so effective in restoring continence in most patients with either hypermobility-, or ISD-predominate incontinence. So far, literature is scarce on the anatomical explanations of these observations, other than that recent data do show the MUCP and LPP can be useful in selection of the surgical approach as the retropubic route maybe more effective than transobturator for lower LPP or MUCP.

This paper may also explain in those pts where the MUS fails (ie. after effective restoration of the PUL), that possibly the rhabdosphincter was more important IN THAT patient than the PUL, and hence a compressive procedure like bulking agent, pubovaginal sling, or artifical urinary sphincter would be more effective than a mid urethral sling.

Although the subject number is small and the results yet to be validated by others, this paper is an interesting read and certainly offers some food for thought with respect to the pathophysiology of female stress incontinence. It is by constant careful observation and critical thinking "outside the box" that science continue to advance.

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Gyne… Urinary continence is just one aspect within the vast complexity of human being functions. Nevertheless, even considering only female urinary continence, a full understanding is lacking. The article from Wagenlehner et al. clearly highlights the uncertainty of our knowledge. Quite surprisingly the smaller the field of observation, the greater the complexity we discover. In this light has the urinary continence mechanism to be considered, as a complex phenomena where many different factors interact. Urologist and colorectal surgeons have real sphinteric structures to take care of, gynaecologists may hardly consider the bulbocavernous (otherwise *constrictor vaginae*), or at a higher level the pubococcigeal muscles as sphincteric structures; but this is not the case, at least from a functional point of view, for both structures and for different reasons.

Therefore strictly from the gynecological corner of a multidisciplinary perspective I don't have much to comment on in the present paper. My only concern is on the static of the distal anterior vagina after "bilateral paraurethral incisions to dislocate the suburethral vaginal hammock from both pubococcygeus muscles". Further numbers and a long follow-up would be necessary to address this topic.

Incidentally I notice that the terminology adopted throughout the paper sometimes is adherent to the most recent ICS standardization (*Detrusor Overactivity*), sometimes not (*Genuine Stress Incontinence, Instability*); in a multidisciplinary perspective adherence to a standardized language is a major concern. That's why one can only partially agree with statement 5 in the conclusions: structural integrity of the musculofascial mechanism is just one mechanism of urethral closure, not necessarily the most important one. Throughout the paper, as well as commonly in debates around this subject, various biological components are considered: muscles, connective tissue, bones, vascularisation. No words about neurological components, but neuromuscular junction integrity plays for sure a role in urinary continence mechanism. Surprisingly this aspect is completely ignored in the clinical assessment of urinary stress incontinence. On the contrary anorectal function testing also include the assessment of *rectoanal inhibitory reflex* and *cough reflex*. Should one learn from the other? Anyway the paper mainly addresses the concept of urethral pressure measurements. The Authors criticize its role, and this is absolutely acceptable. But it has to be emphasized that "*measurements*" are the problem, not the pressure per se: at present methods of pressure measurements are misleading. The pressure generated within the urethra conceptually remains the synthesis of all the forces cooperating in continence. At present a non interference instrument to measure it is not available, but further research in this direction is welcome.

1. F Azpiroz, P Enck, WE Whitehead. Anorectal functional testing: review of collective experience. *Am J Gastroenterol*, 2002; 97: 232-240.

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Procto… This interesting article by Wagenlehner et al along with other published evidence lends further weight to the proposed Integral Theory by Petros, that tension in the pubourethral ligaments and their close relationship to the pubococcygeus muscle is the main mechanism by which urinary continence is achieved, and that the rhabdosphincter plays only a supportive role. Is it possible to take this further and make further hypotheses as to how faecal continence is maintained.

There is good evidence from manometric studies that continence is not directly related to external sphincter pressures. Perhaps the external sphincter is the rhabdosphincter of the anus, augmenting continence but not primarily responsible. The interrelationship of the puborectalis/pubococcygeus, levator plate and longitudinal muscle of the anus are a much more likely explanation. Simultaneous contraction of the levator plate pulling backwards; the puborectalis/pubococcygeus pulling forwards; and longitudinal muscle of the anus pulling downwards, acts to increase the anorectal angle and close the anorectal opening, deferring defecation and at the same time, as suggested in this paper inhibiting micturition. Anyone who has ever suppressed their flow of urine mid-micturition will be well aware of the simultaneous sensation of contraction and closure of their anus. The converse is also true. Perhaps time has come for colorectal surgeons to stop focussing on the external sphincter as the cause of incontinence and play closer attention to the integrated actions of the other muscles as outlined above. We should try to understand their anatomy, the possible role of loss of tension, and the various mechanisms that may contribute to such a loss. We might as a consequence, investigate the effect on faecal incontinence of repairing their respective ligamentous supports.

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Book review

As announced in the Editorial by Bruce Farnsworth (Pelviperineology 2011; 30:5) this is the seventh of a series of articles highlighting the different sections of the book "Pelvic Floor Disorders, Imaging and a Multidisciplinary Approach to Management" edited by G.A. Santoro, P. Wieczorek, C. Bartram, Springer Ed, 2010 .

Pelvic pain

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The *seventh section* of "Pelvic floor disorders - Imaging and Multidisciplinary Approach to Management" is focused on chronic pelvic pain, a common, disabling problem among women, frequently overlooked and under-diagnosed, resulting in inappropriate referral and inadequate treatment. Considering the prevalence of chronic pelvic pain on the level of 15% in women between the ages of 18 and 50 years, it has a substantial economic impact as 15% of women with chronic pelvic pain miss an average 12.8 hours of work per month in the United States, which accounts for $14 billion of lost productivity per year. As the sources of pelvic pain are multifactorial, and their causes are difficult to determine the clinicians must be familiar with the clinical, pathologic, and radiologic characteristics of the underlying causes in order to be able to make an accurate diagnosis in most cases and facilitate referral for appropriate therapy.

The first chapter is focused on painful bladder syndrome/interstitial cystitis (PBS/IC), also known as bladder pain syndrome (BPS/IC). It is a chronic, multifactorial disorder with symptoms of urinary frequency, urgency, and pelvic pain, often associated with other painful diseases, which profoundly affects patients' quality of life due to its disabling aspects. Although its etiology is not known and clinical characteristics vary among patients, early recognition of BPS/IC is crucial. Physical evaluation is a critical component of diagnosis, together with questionnaires and local cystoscopy, which is not mandatory but a good preliminary investigation to rule out other conditions. The therapeutic strategy aims to reduce or eliminate the symptoms, so improving quality of life and interfering with the potential disease mechanism. Therapies include conservative, medical (oral, subcutaneous, and intravesical), or interventional procedures.

In *the second chapter* of this section entitled *"Pelvic Pain Associated with a Gynecologic Etiology"*, Sondra L. Summers and Elizabeth R. Mueller outline that chronic pelvic pain is a difficult clinical dilemma, which requires the services of a multidisciplinary approach and team. A thorough history that includes a patient questionnaire, review of records, and interview by a trained clinician are important first steps. A detailed physical exam which incorporates techniques of pain mapping is also key to developing a protocol that will assist each patient with individualized therapy. There is also a role for vulvar biopsy if the patient's presentation does not provide immediate diagnosis. Cultures or other testing for infections is paramount, so that treatable sources of pain are not overlooked. Likewise, cytology and biopsies of the cervix can be important in a patient with a friable cervix. Empiric treatment with antibiotics analgesics, or suppression of the hormonal cycle with oral contraceptives, progestational agents, or GnRH agonists can be an effective first line of therapy and can be initiated during completion of the workup. Failure to respond to first-line treatments should be followed up with a discussion regarding other parallel protocols such as a change in medication or more invasive therapies such as trigger point injections or surgical evaluation and treatment. Psychotherapists should assist the patients in dealing with the stress and possible concomitant depression that can accompany chronic pain syndromes. Moreover, the relationship between a woman with chronic pelvic pain and her healthcare provider is crucial, especially in those scenarios where the treatment modalities are not improving the quality of life with pain relief. These women will require more therapy and care even if the ultimate outcome does not result in complete pain relief.

The *third chapter* is describing *"Pelvic Pain with Coloproctologic Etiology"*. There are many possible causes of anorectal pain such as inflammatory or functional disease, pelvic tumors, postoperative complications. Patients with active ulcerative colitis experience visceral pain secondary to hyperalgesia and allodynia, while in those with quiescent or mild ulcerative colitis and Crohn's disease hypoalgesia is more common. PID such as prostatitis or interstitial cystitis can cause recto-anal pain, also. "Functional" disorders such as levator ani syndrome, proctalgia fugax, coccygodynia and Alcock's canal syndrome cause severe anal pain affecting the QoL. Patients with IBD complain of pelvic pain, although there are no structural lesions underlying this symptom. Anorectal tumours commonly cause pain. Radiotherapy has been demonstrated to be an useful mean to improve pelvic pain. Sexually transmitted infections can cause proctitis. Bowel endometriosis causes a wide variety of symptoms, from rectal bleeding to pelvic pain on defecation. Haemorrhoids, anal fissures and anal absceses are the most common proctological diseases associated with anal pain. Chronic proctalgia has been also described after many surgical procedures. Accuracy in collecting medical information and in physical examination is mandatory. The multidisciplinary workup should be focused to demonstrate or exclude a disease in each individual patient, although in some it fails to reach the correct diagnosis and cure.

In *the fourth chapter "Surface Electromyography and Myofascial Therapy in the Management of Pelvic Pain"* M. Jantos reviews current research in relation to the pain syndromes such as bladder pain syndrome, levator ani syndrome and vulvodynia, identifying the muscle dysfunctions for each disorder and providing guidelines for functional normalization. The anatomical and functional complexity of pelvic floor muscles increases the risk of pelvic floor

disorders. Idiopathic bladder, vulvar and rectal pains represent three common pain syndromes that affect the anterior, middle, and posterior pelvic compartments. Evidence suggests that these disorders are of somatic and muscular origin and are associated with hypertonic pelvic muscle states. Two potential mechanisms by which muscle overactivation gives rise to sensitization and pain include ischemia and myofascial trigger points found in muscle tissue, ligaments and fascia. Clinical modalities essential to the management of these pain disorders include surface electromyography and myofascial therapy. Surface electromyography provides an objective means of evaluating and normalizing pelvic muscle function, while myofascial therapy provides the means of resolving trigger point related pain.

In the *fifth chapter "Chronic Pelvic Pain: A Different Perspective"* P. Petros presents chronic lower abdominal pelvic pain, collision dyspareunia, and vulvodynia as related to laxity in the uterosacral ligaments. Unexplained chronic pelvic pain comprises up to 10% of outpatient gynecology referrals and may be an indication for laparoscopy in up to 35% of laparoscopies and 10% of hysterectomies. The syndrome is quite characteristic: low abdominal 'dragging' pain, usually unilateral, often right-sided, low sacral pain, deep dyspareunia, and postcoital ache, tiredness and irritability. The pain has been demonstrated to be a referred pain. With injection of local anesthesia in the posterior vaginal fornix the pain disappears temporarily. An initial cure rate of up to 80% has been reported following tensioning and reinforcement of the uterosacral ligaments, most recently with the tissue fixation system (TFS). Pelvic pain is rarely psychological and it can be cured or improved both surgically and non-surgically.

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