

# PELVIPERINEOLOGY

A multidisciplinary pelvic floor journal

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## Contents

- 5 Editorial. Structuring reconstruction surgery in pelvic organ prolapse surgery. ANDRI NIEUWOUTD
- 6 Pelvic Floor Digest
- 7 What is the correlation between Pelvic Organ Prolapse and Quality of Life? Clinical validation of the Pelvic Organ Prolapse Quantification Index (POP-Q-I).  
NUCÉLIO LUIZ DE BARROS MOREIRA LEMOS, ANA LUIZA ANTUNES FARIA, JACQUELINE LEME LUNARDELLI, SILVIA DA SILVA CARRAMÃO, GIL KAMERGORODSKY, JEFFREY E. KORTE
- 11 Bilateral iliococcygeus fixation technique for enterocele and vaginal vault prolapse repair. HAIM KRISSE, STUART L STANTON
- 15 What's falling down. MARCO SOLIGO, ANTONELLO CORBO, CLAUDIO BEATI, SARAH MONTEFUSCO, MARIA CRISTINA CESANA, CARLA RAVIOLO
- 17 The presence and location of estrogen and progesterone receptors in the human pelvic cardinal ligaments.  
HAIM KRISSE, REUVIT HALPERIN, RUMELIA KOREN, YOAV PELED
- 20 Retropubic, transobturator and intraobturator tape procedures: how, when and why. FRANCESCO BERNASCONI
- 24 Reduction of external anal mucosal prolapse with circular stapler.  
CHRISTIAN RUSHFELDT, STIG NORDERVAL, BARTHOLD VONEN
- 27 PTQ™ bulking agent injection for the treatment of fecal incontinence: QoL and manometric evaluation.  
FRANCESCO GUERRA, FRANCESCO VELLUTI, DANIELE CROCETTI, FILIPPO LA TORRE
- 30 Aggressive angiomyxoma mimicking cervical polyp.  
ELISAVET PAPLOMATA, ASTERIOS FOTAS, DIMITRIOS BALAXIS, THEODOROS FILINDRIS, STAVROS CHARALAMBOUS, VASILEIOS ROMBIS



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# PELVIPERINEOLOGY

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Court FG, Whiston RJ, Wemyss-Holden SA, Dennison AR, Madern GJ. Bioartificial liver support devices: historical perspectives. *ANZ J Surg* 2003; 73: 793-501.

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The Standard Task Force, American Society of Colon and Rectal Surgeons: Practice parameters for the treatment of haemorrhoids. *Dis Colon Rectum* 1993; 36: 1118-20.

c) *Cited paper:*

Treitz W. Ueber einem neuen Muskel am Duodenum des Menschen, uber elastische Sehnen, und einige andere anatomische Verhaltnisse. *Viertel Jahrschrift Prar. Heilkunde (Prager)* 1853; 1: 113-114 (cited by Thomson WH. The nature of haemorrhoids. *Br J Surg* 1975; 62: 542-52. and by: Loder PB, Kamm MA, Nicholls RJ, et al. Haemorrhoids: pathology, pathophysiology and aetiology. *Br J Surg* 1994; 81: 946-54).

2) Chapter from a book:

Milson JW. Haemorrhoidal disease. In: Beck DE, Wexner S, eds. *Fundamentals of Anorectal Surgery*. 1<sup>st</sup> ed. New York: McGraw-Hill 1992; 192-214.

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# Structuring reconstruction surgery in pelvic organ prolapse surgery

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Declare the past, diagnose the present, foretell the future; practise these acts. As to diseases: make a habit of two things- to help, or at least do no harm.

Hippocrates; Epidemics, Bk I, sect XI

*The two groups of patients most neglected in prolapse surgery are the very young women with prolapse and the patient who had a suboptimal result after prolapse surgery. The reason why any gynecologist is not keen to operate on the young woman with symptomatic prolapse is the awareness that the repair gives not only poor long term results, but also results in tissue damage.*

*The patient who had had previous surgery, with a suboptimal result, creates a dilemma for the surgeon: the footprint of the previous surgery makes assessing difficult, and the re-do surgery is difficult due to tissue scarring and removal of tissue with the primary surgery. Success in addressing the prolapse is also less guaranteed with repetitive surgery. The use of synthetic materials in the vaginal wall of a young patient is for obvious reasons not an option, and in a patient with suboptimal result a challenge for repeat surgery.*

*A more structured approach to prolapse repair can be a viable option for these two groups of patients. If the primary surgery is done on a structured manner the harm done to the young patient is minimal. The re-do of failed previous repairs can also be done in a structured constructive manner- be it by repairing the underlying pathology (in a side and site specific manner) and bolstering it with a collagen graft, or by bridging the gap left by the undo process with a non-cross linked bio graft. In this re-do group of patients one obviously needs to motivate why one did not do the primary surgery in a structured constructive way in the first instance.*

*The yardstick of successes and failures of surgical results, though, is not only the claiming of successful correcting the damage or defect, but also the ability to deal with the complications. With a focus on the suboptimal results, be it failing to correct what had been set out to be done, or causing damage -even if the defect had been corrected-, one comes across what can be called the undo re-do factor of surgery. Before the surgical correction of the defect can be done with a secondary procedure (re-do) the after effects of the primary surgery must be undone (undo). This factor is what in the end will be the surgical legacy or footprint of the surgeon.*

*Prolapse surgery of yesteryear is based on getting rid of the bulging vaginal wall- it is seen as a central bulge of the underlying organ into the non supportive vaginal wall. The bulge is directly folded back to take the underlying organ away from the vaginal cavity. In the resultant surgery, tissue -be it vaginal skin or even perfectly normal organs like the uterus- is being removed. The formation of scar tissue can be experienced as an advantage. The first attempt at surgery is usually the best chance of success. In this type of surgery no reference is made to seek out and repair the underlying pathology that leads to the prolapse- the symptom of the disease is treated and not the cause. Secondary corrective surgery is to be done against the background of tissue damage and scarred tissue. The undo factor is hampered by scar tissue formation and at times depleted tissue. Especially the re-do aspect of surgery is challenging - shall one do the same procedure again or shall it be an alternative method?*

*No wonder that "innovative" avenues of pelvic floor surgery are being explored. In most of these pelvic organ support is being created by the introduction into the pelvis of different kinds of grafts and mesh implants. The basis of these surgical procedures in the anterior vaginal wall is to release the anterior vaginal support from its lateral sidewall attachments to the white line and the attachments to the central cervical ring. An indirect support system is created by bridging the gap from white line to white line, posterior aspect of the pubic rami to interspinous space with a xenograft or mesh of synthetic materials. The procedures are simplified to make incompetent surgeons more competent. Unfortunately do this lead to an increasing number of reports of complications- in most cases leading to corrective surgery and even removal of the placed materials. The undo re-do factor- especially the undo part- in these cases is high leaving the patients worse off compared to what they had been before the primary surgery. To re-do one needs to follow a new avenue of surgery.*

*Recognition of normal anatomical landmarks, understanding the integration of normal anatomy and normal function and how it is influenced by the damage that is present with pelvic organ prolapse provides the basis of successful reconstruction surgery. Suboptimal results in the standard treatment modalities available must be compared, with an emphasis on the undo/redo factors of each. This will show that an alternative could be to restore normal anatomy on a structured reconstructive way- especially if one realizes that it is never possible to reconstruct the vaginal supports in one operation only in all cases of prolapse. The primary surgery must allow for the laying down of building blocks that, if it does not result in full restoration of normal anatomy and function, at least can function as a foundation on which further surgery can be done. This will thus be an add-on rather than an undo/redo type of surgery in the patient with a suboptimal result.*

*This will set the stage for a more staged approach to reconstruction of the pelvic floor supports. An engineer will not build a bridge without laying the traffic still- we want to do that with still having the traffic present. With this approach it may be possible.*

*Could it be that our judgment is so clouded by industry and the input from them that we are blinded to see the obvious? It may be time to admit that the use of synthetic material- especially between the bladder and vagina- had been a surgical experiment that failed. We must look for better and fresher ideas.*

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This section presents a small sample of the Pelvic Floor Digest, an online publication ([www.pelvicfloordigest.org](http://www.pelvicfloordigest.org)) that reproduces titles and abstracts from over 200 journals. The goal is to increase interest in all the compartments of the pelvic floor and to develop an interdisciplinary culture in the reader.

## FORUM

**An introduction to genes, genomes and disease.** Hall PA, Reis-Filho JS, Tomlinson IP, Poulson R. *The Journal of Pathology* EPUBDATE: 2009-12-05. The human and other genome projects and subsequent resequencing programmes have provided new perspectives on the nature of the gene and how genes function. The complexity of the eukaryotic nucleus and the diversity of genetic regulatory mechanisms is central to understand how genes function, as well as the recognition of gene dosage issues. This introduction to the 2010 Annual Review Issue, Genes, Genomes and Disease, provides overviews of these areas and then considers their relevance to a range of human diseases.

**One example on how colloidal nano- and microparticles could contribute to medicine.**

Peteiro-Cartelle J, Rodríguez-Pedreira M, Zhang F et al. *Nanomedicine*. EPUBDATE: 2009-12-05

Nanomedicine is a popular keyword in the media, although everyone seems to associate it with different visions, hopes and even fears. This article from the point of view of a materials scientist, indicates what new materials will be possible, how they will be designed and which properties they could offer for diagnosis and treatment, from the point of view of a medical doctor it indicates which properties are actually desired and what materials are hoped for practical applications. Although sophisticated materials will be available in the future, they do not automatically match the requirements and demands of clinicians.

**Stem Cells: a review and implications for urology.** Yu RN, Estrada CR. *Urology*. EPUBDATE: 2009-12-08. The promise of stem cells is to provide a source of non-diseased material for the generation of patient-specific cells or tissue for replacement and reconstruction. The future of reconstructive surgery will surely incorporate a number of stem cell based technologies in revolutionary ways that may improve and extend lives. However, the ultimate clinical applicability of the different types of stem cells will depend on a complex synthesis of further basic research, future clinical trials, and ethical and regulatory reconciliation.

## 1 THE PELVIC FLOOR

**Effectiveness of EUS in drainage of pelvic abscesses in 25 consecutive patients (with video).** Varadarajulu S, Drelichman ER. *Gastrointestinal Endoscopy*. EPUBDATE: 2009-12-08. EUS is a minimally invasive, safe, and effective technique that affords long-term benefit for patients undergoing pelvic abscess drainage. In patients with an abscess that measured less than 8 cm in size, two 7F transrectal stents were deployed. In patients with an abscess that measured 8 cm or more in size, an additional 10F drainage catheter was deployed. Treatment was successful in 24 (96%) of 25 patients. The mean duration of the postprocedure hospital stay was 3.2 days. At a mean follow-up of 189 days (range 93-817), all 24 patients were doing well without abscess recurrence.

**Management of hemorrhage in severe pelvic injuries.** Jeske HC, Larndorfer R, Krappinger D et al. *The Journal of Trauma Injury, Infection, and Critical Care*. EPUBDATE: 2009-12-10. Major pelvic trauma results in high mortality. No standard technique to control pelvic hemorrhage has been identified. Of 1,476 pelvic fracture patients, 45 were included, 1 died, 2 underwent emergency laparotomy with pelvic packing, 42 underwent angiographic embolization before or after a TC scan. Application of a clinical algorithm focusing on basic radiologic diagnostics, external fixation, and early angiographic embolization was effective and safe to rapidly control hemorrhage in hemodynamically unstable trauma patients with pelvic fractures.

## 2 FUNCTIONAL ANATOMY

**Virtual pelvic anatomy simulator: a pilot study of usability and perceived effectiveness.**

Peyton Hassinger J, Dozois EJ et al. *Journal of Surgical Research*. EPUBDATE: 2009-12-05. A three-dimensional (3-D) pelvic anatomy teaching module derived from human magnetic resonance and computerized tomography images was used as a simulator for surgical education for medical students and surgery residents. Fifty percent of participants to the evaluation felt the module needed a higher level of anatomic detail.

**[Functional anatomy of the pelvic floor.]** Yiu R, Costa P, Haab F, Delmas V. *Progrès en Urologie*. EPUBDATE: 2009-12-09. The levator ani muscle is the major component of the pelvic floor, it is formed essentially by type I fibers with high oxidative capability and presence of slow myosin as in postural muscles. The aerobic metabolism makes it susceptible to injury caused by excentric contraction and mitochondrial dysfunction. The pelvic floor is innervated by the 2nd, 3rd, 4th anterior sacral roots. The perineum includes the musculofascial structures under the LA: ventrally the striated urethral sphincter and the ischio-cavernous and bulbospongious, caudally the fatty tissue filling the ischioanal fossa. Pelvic fascia covers the muscles; it presents reinforcements: the uterosacral and cardinal ligaments, the arcus tendineus fascia pelvis (ATFP) and the arcus tendineus levator ani (ATLA). The combined action of all these anatomical structures anteriorly form the perineal "hammock", medially the uterosacral and cardinal ligaments, posteriorly the rectovaginal fascia and the perineal body. The angles formed by the pelvic viscera with their evacuation ducts participate to the pelvic statics and during the pelvic dynamics these angles change due to the action of the musculofascial structures.

**HRT and mRNA expression of estrogen receptor coregulators following exercise in postmenopausal women.** Dieli-Conwright CM, Spektor TM, Rice JC, Schroeder ET. *Medicine & Science in Sports & Exercise*. EPUBDATE: 2009-12-03. The use of hormone replacement therapy (HRT) is a potential treatment to relieve symptoms of menopause in postmenopausal women, however, the effects on skeletal muscle are unclear. A single bout of maximal eccentric exercise enhances estrogen receptor transcriptional activity with a greater response.

## 3 DIAGNOSTICS

**[Evaluation of two classifications systems for pelvic prolapse on dynamic MRI.]** Novellas S, Mondot L, Bafghi A et al. *Journal de radiologie*. EPUBDATE: 2009-12-03. To determine the usefulness of two classification systems for pelvic prolapse detection and staging on MRI based on different anatomical landmarks, a prospective study of 30 patients with symptoms of pelvic prolapse was performed, the first using the pubococcygeal, the second the midpubic line. The classification system based on the pubococcygeal line appeared more reliable and simple for the evaluation of pelvic prolapse on MRI.

**X-ray microcomputed tomography as a tool for the investigation of the biodistribution of magnetic nanoparticles.** Rahn H, Odenbach S. *Nanomedicine*. EPUBDATE: 2009-12-05. Computed tomography studies the inner structure of opaque samples using the material-dependent attenuation of x-rays. Microcomputed tomography improves the spatial resolution to a few micrometers. An example for the application of x-ray microtomography is the study of the 3D biodistribution of magnetic nanoparticles in tumoral tissue after minimal invasive cancer therapy, which is one of the crucial factors for this kind of therapy.

The PFD continues on page 16

# What is the correlation between Pelvic Organ Prolapse and Quality of Life? Clinical validation of the Pelvic Organ Prolapse Quantification Index (POP-Q-I)

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**Abstract:** INTRODUCTION: This study sought to assess the correlation between the Pelvic Organ Prolapse Index (POP-Q-I)<sup>10</sup> and the Prolapse Quality of Life Questionnaire (P-QOL). SUBJECTS AND METHODS: Seventy-one consecutive patients were examined by a member of the urogynecology faculty blinded to P-QOL. Pearson's test was used to assess the correlation between the average POP-Q-I and P-QOL scores. Patients were then divided in four groups by prolapse intensity to assess the dose-response correlation. RESULTS: Significant, but low correlation was found for each point, the overall POP-Q-I and global POP-Q-I (table 2). After dividing the sample, we observed a significant dose-response correlation for both Overall (p=.005) and Global (p=.008) POPQ-I (table 4). CONCLUSION: These results clinically validate the POPQ-I and suggest that comparing anatomical outcomes alone is not enough when comparing different treatments, meaning assessment of clinical success should take into account patient expectations and post-intervention quality of life.

**Keywords:** Pelvic Organ Prolapse; Classification; POP-Q; POP-Q-I; Quality of Life.

## INTRODUCTION

Standardization of pelvic organ prolapse (POP) classification has been a major issue in the literature during recent decades<sup>1-9</sup>. Much of these efforts were based on the need for a uniform method to assess anatomical outcomes in POP research. Taking part on these efforts, we have proposed the Pelvic Organ Prolapse Quantification Index (POP-Q-I)<sup>2</sup>, which quantifies the prolapse as a standardized continuous variable, in which 0 means completely absent prolapse, while 1 reflects complete vaginal eversion. This standardized quantification makes anatomical outcomes variables statistically more powerful and optimizes research. The POP-Q-I was validated at our center in a blinded prospective randomized study, showing good inter-observer correlation<sup>9</sup>.

The clear utility of accurately measuring anatomic results, however, neglects a potentially critical element of clinical success: patient expectations and quality of life. The objective of this study was to assess the correlation between the POP-Q-I and quality of life (QOL), in order to clinically validate the former.

## SUBJECTS AND METHODS

The study was prospective, randomized and blinded. Seventy-one consecutive patients presenting to the outpatient urogynecology clinic of Santa Casa of São Paulo were included, after reading, agreeing and signing an informed consent, approved by the local ethics committee. Sample size was calculated on Minitab 15.1.1.1 (Minitab Inc.), considering an estimated correlation coefficient of .35, 80% power ( $\beta=.20$ ) and significance level of 5% ( $\alpha=.05$ ).

Patients with the following complaints were included: a sense of something coming or falling out of their vagina; the ability to feel a bulge coming out of their vagina; urinary incontinence; fecal or anal incontinence; pelvic fullness or pressure particularly when upright; having to push up on the perineum or digitate the vagina in order to urinate or defecate. All subjects that could not provide informed consent, subjects under age 18 years, pregnant or within 6 months post partum at the time of the exam, subjects who

could not tolerate a second pelvic exam at one clinic visit, and those who could not perform a Valsalva or deep cough were excluded.

Before the POP examination, a validated portuguese version of the "Prolapse Quality of Life" (P-QOL)<sup>10</sup> questionnaire was applied by a member of the Urogynecology staff. The questionnaire consists of 43 questions with responses ranging from "none/not at all", through "slightly/a little" and "moderately" to "a lot". Therefore, a four point (0-3) scoring system for each item was used for severity measurement of urogenital prolapse symptoms.

After answering the questionnaire, women were examined by a member of the urogynecology staff, blinded to the QOL result. All patients were examined in lithotomy, performing Valsalva or cough when the examiner considered the pressure achieved by Valsalva to be insufficient for a valid examination. POP-Q points Aa, Ab, C, Bp and Ap were measured. Point D was used only for the identification of patients with cervical hyperplasia. Genital hiatus (GH), perineal body (PB) and total vaginal length are not taken into account for the POP-Q-I, since it is not possible to estimate normal and maximum values for these measures. Measures were made with a wooden rule, following the directions of the POP-Q<sup>4</sup> and, for each point, two values were gathered (Fig. 1): Value1, the actual distance the point was from its original site; and Value2, an estimation of how far the point would go in case of total vaginal eversion.

Data were recorded on a form specially designed for this study and entered in Excel for Mac:2008 (Microsoft Corp.). We used Excel to calculate the POP-Q-I for both examiners at each point (Aa, Ba, C, Bp, and Ap) by dividing Value1/Value2; this score ranges from 0 (no prolapse) to 1 (total eversion of the given point). We calculated an overall score (maximum prolapse score for any point) and a global score (average of the five points).

In addition to P-QOL domain analysis, a standardized QOL index (QOL-I) ranging between 0 and 1 was calculated by dividing the observed score by the maximum possible overall score (including all dominions). Scores closer to 1 represent greater impairment of QOL.

POPQ-I results were first compared to the P-QOL results

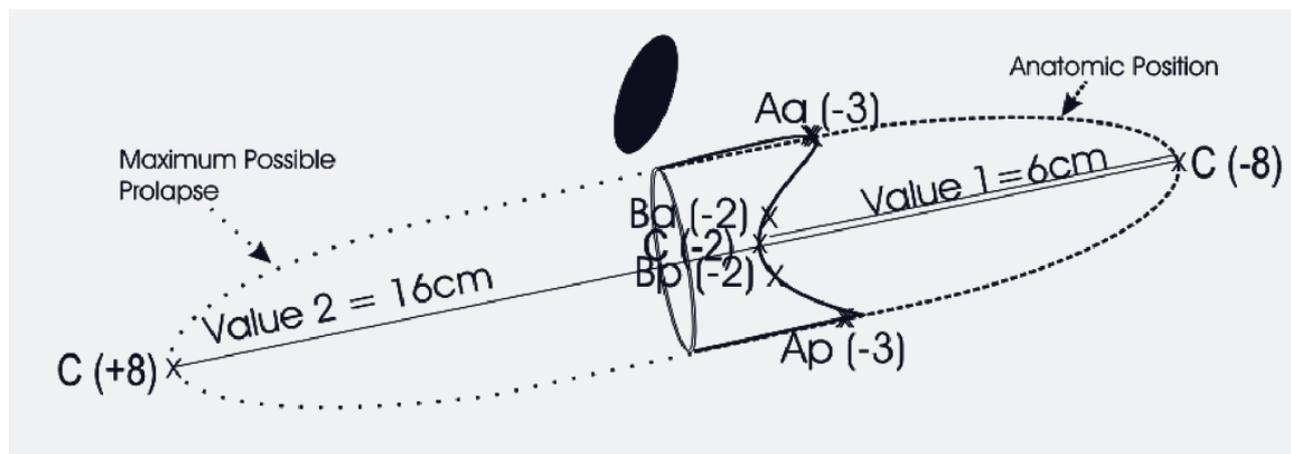


Fig. 1. – POP-Q-I is the result of the division of Value 1 (the actual distance the point was from it’s original site) by Value 2 (an estimation of how far the point would go in case of total vaginal eversion).

by Pearson’s correlation. In subsequent analyses, patients were grouped in an ordinal fashion according to Overall and Global POPQ-I (group I POPQ-I from 0 to .25; group II from .251 to .5; group III from .51 to .75; and group III >.75) in order to assess the dose-response relationship.

Data were analysed on SPSS for Macintosh version 16 (SPSS Inc.).

## RESULTS

Seventy-one women were included in the study. Their demographics, mean POPQ-I scores and mean standardized P-QOL scores are displayed in Table 1. Pearson’s correlation between QOL-I scores and the POP-Q-I for all points are displayed in Table 2. Significant, although weak correlation was observed for all points, except for point Ap.

“r” is the number of standard deviations that P-QOL score increases for every standard-deviation increase on POPQ-I. This means, for example, that for every 0.294 increase on POPQ-I, a 0.065 increase on P-QOL standardized score was observed (i.e.: for each POPQ-I SD increase, P-QOL increases R times P-QOL SD).

“r square” means the amount of the QOL-I score that is determined by the prolapse. In our example Overall POPQ-I prolapse is responsible for 10.7% of P-QOL score.

The correlation between the POP-Q-I and the domains of the P-QOL is shown on table 3. Note that although

TABLE 1. – Sample (n=71) demographics, mean POPQ-Index for each POP-Q point, mean Overall (maximum) and Global (mean) POPQ-I, mean P-QOL standardized score.

	Mean	Range	SD
Age	57.86	(34-82)	12.621
BMI	26.78	(20.08-33.6)	3.333
Parity	3.30	(0-14)	2.637
Aa	0.457	(0-1)	0.311
Ba	0.349	(0-1)	0.297
C	0.261	(0-1)	0.311
Bp	0.233	(0-1)	0.290
Ap	0.255	(0-1)	0.285
Global POPQ-I	0.311	(0-1)	0.259
Overall POPQ-I	0.479	(0-1)	0.294
QOL-I	0.303	(0-0.715)	0.200

TABLE 2. – Pearson’s Correlation: POP-Q-I vs. QOL-I

Point	R (95% Confidence Interval)	R square	P
Aa	0.266 (0.022-0.320)	0.071	0.025
Ba	0.249 (0.011-0.325)	0.062	0.036
C	0.258 (0.016-0.315)	0.066	0.030
Bp	0.283 (0.036-0.354)	0.080	0.017
Ap	0.201 (-0.024-0.306)	0.040	0.093
Overall	0.327 (0.068-0.377)	0.107	0.005
Global	0.290 (0.047-0.402)	0.084	0.014

most of the domains scores showed statistically significant correlation with both Overall and Global POP-Q-I, only the domains that relate to prolapse intensity (i.e Prolapse Impact and Severity) showed moderate correlation with the POP-Q-I, while more subjective domains correlated poorly (i.e.  $r < .40$ ) or did not correlate at all ( $p > .05$ ).

When grouping patients in an ordinal fashion (group I POPQ-I from 0 to .25; group II from .251 to .5; group III from .51 to .75; and group III >.75) a dose-response correlation between POPQ-I and QOL-I was observed. For each 0.25 increase on POPQ-I, there was a 0.06 increase on QOL-I, both for the overall ( $p=0.0059$ ) and for the global ( $p=0.008$ ) indexes (Table 3).

## DISCUSSION

The correlation between intensity of prolapse and quality of life is an active area of current research, as success of prolapse treatment has classically been considered anatomical cure and complication rates. In our results, we found an unexpectedly low correlation between prolapse intensity and QOL scores, suggesting that larger prolapses do not consistently correlate with a larger perceived problem. Elkadry et al.<sup>11</sup> have assessed patients’ goals for pelvic reconstructive surgery and observed that “Patient characteristics and the number of pelvic floor diagnoses do not seem to influence goal selection”. This means that it is not pelvic floor dysfunction itself that bothers the woman, but the lifestyle hindrances it causes. Those authors have also observed that objective cure of prolapse or incontinence does not predict satisfaction or goal achievement.<sup>11</sup> Ellerkmann et al.<sup>12</sup> found that “although there were weak to moderate correlations with respect to several symptoms that are typically thought to be compartment specific, it was not possible to deter-

TABLE 3. – Pearson’s Correlation: P-QOL domains scores vs. POP-Q-I

Domain	Global POP-Q-I			Overall POP-Q-I		
	r	r square	P	r	r square	P
General Health Perception	.082	.007	.495	.27	.001	.825
Prolapse Impact	.462	.213	<.001	.473	.224	<.001
Role Limitations	.25	.062	.036	.226	.051	.058
Physical Limitations	.365	.133	.002	.347	.120	.003
Social Limitations	.331	.110	.005	.312	.097	.008
Personal Relationships	.100	.010	.407	.058	.003	.632
Emotions	.290	.084	.011	.305	.093	.010
Sleep/Energy	.209	.044	.081	.232	.054	.052
Severity	.494	.244	<.001	.547	.299	<.001

mine a specific stage of prolapse at which these symptoms became more pronounced”. Other authors<sup>13-14</sup> have reached the same conclusion and failed to find a point at which vaginal descensus becomes clearly symptomatic. Those results also agree with Petros<sup>15</sup> pictorial algorithm for diagnosis and management of pelvic floor dysfunction, which bases surgical treatment mainly on the symptoms, instead of physical examination findings, as, according to this author, the intensity of symptom is individual and not related to the intensity of prolapse.

This study addresses the above issue by assessing the linear correlation between the amount of prolapse and the intensity of its impact on women’s QOL. Thus, there are two main differences between this and the above cited studies: the first is the continuous outcome variable, as stated; and the second is the fact that only symptomatic women were included, regardless of presenting or not any prolapse. These methodological differences grant a strict assessment of prolapse intensity and its impact on women’s QOL, instead of evaluating presence of symptoms on groups with and without prolapse. This may be the reason for the difference between ours and other studies results,<sup>10-15-16</sup> since these have addressed the mean symptom score difference between groups with and without pelvic organ prolapse. In our study, on the other hand, Pearson’s Correlation reflects the correlation between the QOL and POP-Q-I scores for each individual patient. This statistical difference highlights the actual impact of prolapse on QOL on each single patient and highlights its individually variable nature. This explains why the correlation is so low, although mean P-QOL and POP-Q-I are so close, as shown in Table 1.

On the other hand, when we split the sample in two groups, a significant difference appeared. The translation of these statistical findings is the following: groups with more advanced prolapse tend to show higher median P-QOL scores; but this is only a general, average, tendency which does not represent the truth when every single

woman is evaluated apart from her group. This evaluation was one the aims of our study. Moreover, the significant dose-response correlation observed here clinically validates the POP-Q-I, which had already demonstrated good inter-observer agreement.<sup>10</sup> Other authors have failed to identify this correlation with the traditional POP-Q stages, but found it when analyzing data in a more continuous fashion, based on the position of the leading prolapse edge.<sup>15</sup> These observations suggest that prolapse intensity should probably be better quantified by a continuous variable, instead of an ordinal categorical one, such as POP-Q stages, as we have stated elsewhere.<sup>2</sup>

In our analyses, we found POP intensity to be responsible for about 10% of the P-QOL score in symptomatic women. Statistically thinking, when it concerns a multifactorial outcome such as quality of life, a variable to which this amount of impact can be attributed is actually a very important one. On the other hand, clinically thinking, we can deduce that 90% of the impact on QOL is not correlated with the prolapse intensity. Even on domains designed to evaluate the direct prolapse impact on quality of life, the “r square” analysis never reached 30%.

The hindrances of this study include its cross-sectional design, which does not address the variability of symptoms as described by Sung et al.<sup>20</sup> This is due to the low educational level of the study population, which makes it very difficult to use diaries or self-administered questionnaires. Symptoms evaluation is then only possible by interviews at the time of consultation. Despite these limitations, our observations objectively demonstrate what other authors<sup>11,12,17-21</sup> have been stating: surgical outcomes must be based on patients expectations and symptomatic relief, and not only on anatomical outcomes. Based on the empirical observation that physician and patient surgical expectations are often mismatched, Brubaker & Shull<sup>19</sup> have proposed the “EGGS for patient-centered outcomes”, in which “E” stands for patients’ expectations, “G” stands for goal setting, another “G” for goal achievement, and “S” for satisfaction. This seems a reasonable proposition, since pelvic floor disorders are not life-threatening and the surgical objective should, thus be focused on patients’ symptoms and the resolution of lifestyle hindrances. Our results reinforce the above proposition, as well as the recommendation for validated questionnaires for symptomatic assessment in POP research.<sup>21</sup>

Summarizing, our results clinically validate the POP-Q-I by means of a dose response correlation that, to our knowledge, has not yet been demonstrated for traditional POP-Q stages. The data shown here also suggest that assessing anatomical outcomes is not enough as these are responsible for only

TABLE 4. – Dose-response analysis of “dummy variables” between grouped POPQ-I and QOL-I. For each 0.25 increase on POPQ-I, there was a 0.06 increase on P-QOL score, both for the overall and for the global indexes.

Reference	Quartile I to II (p**)	Quartile I to III (p**)	Quartile I to IV (p**)	p*
Overall	0.05 (.44)	0.096 (.15)	0.185 (.009)	.005
Global	0.11 (.04)	0.14 (.11)	0.17 (.03)	.008

\*Dose response analysis  
\*\*“Dummy variable” analysis

10% of patient satisfaction. Thus basing success and failure on anatomical outcomes alone may lead researchers and urogynecologists to neglect the main goal of treating pelvic floor dysfunction: to fulfill women's expectations and give back quality of life.

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# Bilateral iliococcygeus fixation technique for enterocele and vaginal vault prolapse repair

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**Abstract:** **OBJECTIVE:** To evaluate our surgical experience with iliococcygeus fixation for enterocele and vaginal vault prolapse repair. **DESIGN:** Prospective longitudinal study. **SETTING:** Tertiary care referral centre, St. George's Hospital, London. **METHOD:** Comprehensive questionnaire for pre- and postoperative prolapse, urinary, bowel, and sexual symptoms, a pre and postoperative site-specific vaginal examination following the standardized International Continence Society scoring for prolapse, preoperative urodynamic studies, analysis of surgical results. **POPULATION:** 32 consecutive women who underwent bilateral iliococcygeus fixation. **OUTCOME MEASURES:** Feasibility of the procedure, intra- and postoperative complications, short-term postoperative prolapse-associated symptoms and pelvic organ prolapse quantification. **RESULTS:** Three patients were lost for follow-up. The mean postoperative follow up for the remainder 29 patients (90.6%) was 11.5±6.25 months (range 6-25). Twenty-five patients (78.1%) had a previous hysterectomy. Concomitant surgery was performed in 30 patients (93.7%). The iliococcygeus fixation was completed successfully in all cases. The mean blood loss per surgical procedure was 224±104 ml (range 100-400). There were no intraoperative complications. Postoperatively, one patient needed a blood transfusion, one had transitory left leg pain, and four had temporary voiding difficulty. The mean hospitalization time was 4.5±1.9 days (range 3-9). There was a statistically significant improvement in all pelvic organs prolapse quantification measurements ( $p < 0.0001$ ). Three patients (10.3%) had recurrence of vault prolapse or enterocele. The mean total vaginal length was shorter postoperatively (7.2±0.8 cm versus 8.6±1.0 preoperatively,  $p < 0.001$ ). **CONCLUSIONS:** iliococcygeus fixation is a relatively safe vaginal surgery for the treatment of enterocele and vaginal vault prolapse.

**Key words:** Iliococcygeus fixation; Enterocele; Vaginal vault prolapse; POP; ICS

## INTRODUCTION

The exact incidence of post-hysterectomy vaginal vault prolapse is unknown, with rates ranging from 0.2% to 43%.<sup>1</sup> Many abdominal, vaginal and laparoscopic techniques have been described to correct this condition.<sup>2</sup> The vaginal approach has a swifter and less painful recovery. The most common vaginal techniques are sacrospinous fixation (SSF) and uterosacral suspension (USS). Iliococcygeus fixation (ICF) is an alternative vaginal technique for vault prolapse and enterocele repair first described by Inmon in 1963.<sup>3</sup>

The aim of this study was to describe our experience with iliococcygeus fixation (ICF) technique.

## METHODS AND PATIENTS

Between July 1998 and May 2001, 32 consecutive women underwent ICF at St. George's Hospital for the treatment of symptomatic vaginal vault prolapse or enterocele.

### Preoperative evaluation

Preoperatively, all patients underwent a standardized comprehensive urogynecologic review and complete physical, pelvic and site-specific vaginal examinations in the left lateral position using a Sim's speculum during a valsalva manoeuvre. The prolapse was graded using the standardized International Continence Society (ICS) scoring system for pelvic organ prolapse.<sup>7</sup> Each compartment (anterior, middle, and posterior) was evaluated and assessed for defects in pelvic support. All patients underwent preoperative multi-channel urodynamic evaluation with prolapse reduction to identify occult urinary stress incontinence or voiding difficulties. In case of combined vaginal defect and stress incontinence, additional surgery was performed as needed. All patients were fully informed and consented beforehand. All data were documented and registered on electronic datasheet.

### Operative technique

All patients received preoperative prophylactic antibiotics (metronidazole 500 mg and cephadrine 1 gr) and 5000 units

of fractionated heparin for deep vein thrombosis prophylaxis. Surgery was performed under general anesthesia with the patients in the dorsal lithotomy position. All patients were catheterised before the operation. In patients with uterine prolapse, a routine three-pedicle vaginal hysterectomy with or without bilateral salpingo-oophorectomy (BSO) was performed before the ICF. In patients with a previous hysterectomy, the posterior vaginal wall was opened via a midline longitudinal incision, and the recto-vaginal fascia was freed from the vagina by sharp dissection which was continued to the pelvic sidewall, where the ischial spine served as the landmark for identifying the iliococcygeus fascia (Figure 1). The surgeon then palpated the ischial spine and the right iliococcygeus fascia with his index finger. Using a regular needle holder with no. 0 polydioxanone (PDS) suture, a stitch was placed in the iliococcygeus

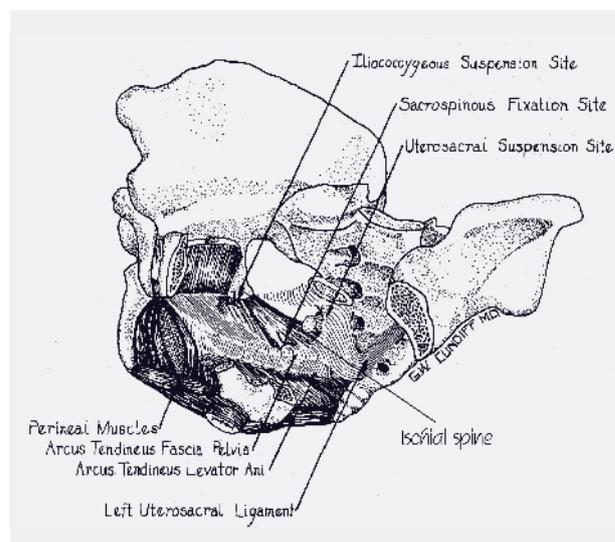


Fig. 1. - Sites for attachment during surgery for vaginal vault prolapse and enterocele repair including the iliococcygeus fascia (from Stanton & Monga, 2000, with permission).

fascia, about 1 cm medial and caudal to the ischial spine. Once the suture was secured, it was placed through the full thickness of the vaginal mucosa at the vault to anchor that side, later tied. This procedure was repeated on the other side. If a posterior or anterior repair was required it was then performed. After closure of the posterior vaginal wall, the iliococcygeus sutures were tied on either side to elevate the vault. In patients with stress incontinence, a Tension-Free Vaginal Tape (TVT) procedure was performed after the prolapse surgery. For secondary prolapse repair, we used prolene mesh (Johnson & Johnson, Brussels, Belgium) to reinforce the endo-pelvic fascia. All patients were advised to avoid strenuous activities and coitus for 6 weeks.

*Postoperative follow-up*

Patients were re-evaluated with a comprehensive urogynecological questionnaire and site-specific pelvic examination. Outcome measures included the feasibility of the procedure, intraoperative and postoperative complications, prolapse-associated symptoms and pelvic organ prolapse quantification (POP-Q).

*Statistical analysis*

A computerized database was created and all clinical data were collected prospectively and evaluated at the end of the study period. The results were analyzed by Stata 5.0 statistical software (Stata Corp., College Station, Texas). Statistical analysis was performed on the paired observation for each woman, before and after the operation. In addition, for a given symptom or physical finding, the proportion of women who improved was calculated. Improvement was defined as subjective symptoms and the objective physical findings before and after the operation. The Wilcoxon signed rank test was used to compare pre- and postoperative symptoms and POP-Q measurements. A p value of <0.05 was considered statistically significant.

**RESULTS**

Three other patients were lost to follow-up. The mean duration of follow-up in the remaining 29 patients (90.6%), was 11.5±6.3 months (range 6-25), mean age was 64.2±12.4 years (range 34-85), median parity was 2 (range 1-5), and mean body mass index was 22.8±3.7 kg/m<sup>2</sup> (range 20.8-31.1). Twenty-nine patients (90.0%) were menopausal, 14 (48.2%) used hormone replacement therapy, and only one

TABLE 1 - Preoperative and postoperative symptoms.

<i>Symptoms</i>	<i>Preop. (n=32)</i>	<i>%</i>	<i>Postop. (n=29)</i>	<i>%</i>	<i>P value<sup>a</sup></i>
Vaginal bulge	32	100	5	17.2	0.0001
Stress incontinence	5	15.6	1 <sup>b</sup>	3.4	NS
Voiding difficulty	5	15.6	0	0	NS (0.6)
Urgency, frequency and/or nocturia	8	25	5	17.2	NS
Incomplete bowel emptying	7	21.7	2	6.8	NS (0.7)
Constipation	7	21.7	4	13.7	NS
Decreased sexual activity <sup>c</sup>	9	64.2	3	37.5	0.02
Dyspareunia	2	14.2	2 <sup>d</sup>	25	NS

<sup>a</sup> Wilcoxon signed rank test

<sup>b</sup> Was not diagnosed before the operation.

<sup>c</sup> 14 patients were potentially sexually active preoperatively and 8 post operatively.

<sup>d</sup> One patient had dyspareunia preoperatively.

NS=none significant

was a smoker. Twenty-five patients (78.1%) had a previous hysterectomy (8 vaginal and 17 abdominal hysterectomy), 17 (53.1%), had previous prolapse surgery, and 11 (32.4%) had a previous continence surgery (Burch colposuspension in 10 and sling procedure in 1). Preoperative urodynamic evaluation showed stress incontinence in 9 patients, detrusor overactivity in 3, mixed incontinence in 1, and voiding difficulty in 2. Preoperatively all patients complained of a vaginal bulge. Postoperatively there was a decrease in prolapse sensation, voiding difficulty, urgency, frequency, incomplete bowel emptying, and constipation (Table 1). The findings on pre- and postoperative vaginal examination are shown in Table 2. There was a statistically significant improvement in all POP-Q measurements (p<0.0001). The ICF was completed in all cases. The mean blood loss per surgical procedure was 224±104 ml (range 100-420). Concomitant surgery was performed in 30 patients (93.7%) (Table 3). There were no intraoperative complications. Postoperatively, one patient had left leg pain that completely resolved after 6 weeks. This pain was attributed to the leg positioning during surgery. One patient had uncomplicated cystitis, 1 needed a blood transfusion for symptomatic anemia, and 4 patients had temporary voiding difficulty. Table 4 summarizes the operative data. Preoperatively, all patients had symptomatic apical prolapse (uterine, vaginal vault or enterocele) greater than grade 1. Postoperatively, only 3 patients (10.3%) had apical prolapse greater than grade 1, but 2 of them were symptomatic. However, on follow-up examination, other 6 patients (17.4%) had

TABLE 2 - Preoperative and postoperative vaginal examination findings.

<i>Site of prolapse</i>	<i>Preop. (n=32)</i>					<i>Postop. (n=29)</i>					<i>P value*</i>
	<i>Grade of prolapse</i>					<i>Grade of prolapse</i>					
	0	1	2	3	4	0	1	2	3	4	
Cystocele/ cystourethrocele	5	9	6	9	0	18	9	2	0	0	<0.0001
Rectocele	0	9	11	9	0	19	4	4	2	0	<0.0001
Enterocele	0	12	13	4	0	22	5	2	0	0	<0.0002
Uterus/ Vaginal vault	0	14	12	0	0	21	5	2	1	0	<0.0001
<i>Other vaginal parameters Mean±SD (range)</i>											
Total vaginal length (cm)	8.6±1.0 (7-10)					7.2±0.8 (6-8)					<0.0001
Vaginal introitus (cm)	4.6±0.9(4-7)					3.9±0.6 (3-6)					NS
Perineal body (cm)	3.4±1.1 (2-6)					3.3±0.6 (2-4)					NS

\* Wilcoxon signed rank test

NS=not significant

TABLE 3 - Concomitant surgery.

<i>Procedure *</i>	<i>No. of patients (n=32)</i>
Vaginal hysterectomy	6
Bilateral salpingo-oophorectomy	5
Anterior repair	16
Posterior repair+perineorrhaphy	22
TVT**	9
Mesh interposition	6

\* 29 patients had more than one surgical procedure

\*\* Tension-free vaginal tape

TABLE 4 - Surgery data.

Variables	No. patients/mean±SD
Feasibility	All patients
Estimated blood loss (cc)	224.6±104.8
Intraoperative complication	None
Postoperative complication	Blood transfusion for symptomatic anemia - 1 patient Left leg pain * - 1 patient Low urinary tract infection - 1 patient Voiding difficulty ** - 4 patients
Hospitalization (days)	4.6±0.9 (3-9)

\* Resolved after 3 months

\*\* One patient after TVT, all resolved in less than 2 months

TABLE 5 - Analysis of patients with postoperative prolapse greater than grade 1.

No. pts.	Postop. site and grade of prolapse	Symptoms	Preop. site and grade of prolapse	Operation for this compartment	Use of Mesh	Previous prolapse surgery
1	R2	Yes	R2	Yes	Yes	Yes
2	R3	No	R1	No	No	No
3	R3,E2,VP3	Yes	R2,E2,VP1	No	No	No
4	R2,E2,VP2	Yes	R3,E2	Yes	No	No
5	E2,VP2	No	E2	Yes	No	Yes
6	R2	No	R2	No	No	No
7	R2	Yes	R2	Yes	Yes	Yes
8	CU2	Yes	CU0	No	No	No
9	CU2	No	CU1	No	No	No

CU= cystoureterocele, R= rectocele, E= enterocele, VP= vault prolapse

TABLE 6 - Comparison between patients with poor and successful surgical results.

Variable	Successful group (n=20)	Failed group (N=9)	P value*
Follow-up (months)	11.1±3.3 (6-25)	12.2±3.8 (7-18)	NS
Age (years)	63.4±13.3 (42-85)	69.0±6.6 (66-79)	NS
Parity (median)	2 (1-5)	3 (1-4)	NS
Weight of the largest child (grams)	3284±185 (2990-3600)	3392±431 (2780-3800)	NS
BMI** (kg/m <sup>2</sup> )	23.4 (19.2-39.3)	24.1 (20.3-36.1)	NS
Previous hysterectomy	17/20 (85%)	6/9 (66.6%)	NS
Previous prolapse surgery	11/20 (55%)	3/9 (33.3%)	NS

No significant difference was found in: smoking, hormone replacement therapy, hospitalization time, estimated blood loss during surgery and intra- and postoperative complications.

\* Chi-square test

\*\* BMI- body mass index

prolapse (cystocele or rectocele) greater than grade 1 and 3 of them were symptomatic. The mean time to recurrent prolapse sensation was 6.2±1.9 months (range 4-9). Analysis of patients with postoperative prolapse greater than grade 1 is shown in Table 5. There was no difference in patient's characteristics between this group and the "success" group (Table 6). The mean total vaginal length was shorter postoperatively (7.2±0.8 cm versus 8.6±1.0 cm preoperatively, p<0.001), although there was no significant difference in vaginal hiatus width or perineal body lengths. Only one patient had a significantly short vagina of 4 cm. She was not sexually active and had had a previous vaginal hysterectomy combined with cystocele and rectocele repair.

## DISCUSSION

Surgery for vaginal vault prolapse has several goals: restore the normal anatomy, relieve symptoms, restore normal bowel and bladder function, and preserve satisfactory sexual function. Vaginal vault prolapse and enterocele may be a source of frustration to the surgeon because of the difficulty in satisfactory correcting of the defects for the long term, especially when preservation of a functional vaginal length is necessary. Benson et al<sup>5</sup> noted that 33% of patients who had previous vaginal surgery for prolapse required reoperation for recurrence. A variety of abdominal and vaginal surgical techniques have been suggested to correct the pelvic floor. The choice of procedure depends on the abdominal and pelvic anatomy, the patient's general health, previous pelvic surgery, the quality of the pelvic support tissues and the surgeon's skills. The more commonly used vaginal approaches for vault prolapse repair are sacrospinous fixation (SSF) and uterosacral suspension. However, the intraoperative complications of SSF are not infrequent and include damage to the neurovascular bundle that runs in the ligament. Moreover, the typical unilateral SSF results in vaginal deviation laterally and exposes the anterior vaginal wall to persistent or subsequent cystocele in up to 37% of the patients.<sup>6,7</sup> The main problematic complication of uterosacral suspension is ureteral obstruction reported in up to 11% of the patients<sup>8</sup>. Other disadvantages of both procedures are the need for a certain vaginal length and mobility in order to bring the vaginal vault to the sacrospinous or uterosacral ligaments without tension, and the need for a wide dissection to visualize the sacrospinous ligaments. Such dissection may increase the risk of bleeding and pelvic floor denervation.<sup>9</sup> By contrast, the iliococcygeus fascia does not have critical structures such as the pudendal vessels and nerve or the ureter immediately adjacent to it. Therefore, it is theoretically associated with a lower rate of pelvic pain from nerve entrapment, bleeding, and ureteral damage. Furthermore, because of the lateral position of the iliococcygeus fascia in relation to the other anchoring pelvic structures (sacrospinous ligament, uterosacral ligaments and the sacrum), surgery is technically easier to perform and the final surgical result is more closely mimics the normal anatomic position of the upper vagina. Another advantage of ICF is its feasibility in women with restricted vaginal mobility or a short vagina that cannot be attached to the sacrospinous or the uterosacral ligaments without tension. Our study group included 17 patients (53.1%) who had had previous surgery for prolapse. Yet, in none of them did we find significant difficulty in exposing the iliococcygeus fascia or accomplished the sutures placement. Patients weight, vaginal length, and previous pelvic surgery had no effect on the feasibility of the procedure. There were no intraoperative complications and the postoperative complications were left leg pain in one patient, which we attributed to surgical positioning resolved spontaneously

6 weeks later with no neurological deficiency. Another patient needed a blood transfusion for preoperative anemia that become symptomatic postoperatively. Shull et al<sup>10</sup> and Meeks et al<sup>11</sup> reported a success rate of more than 90% with ICF after a follow-up of 3-5 years. A recent study of Maher et al<sup>12</sup> compared sacrospinous fixation to ICF and found no significant difference in success or complication rates. Our results with ICF showed a good success rate of 89.7% for correcting apical prolapse (26/29 patients). However, critical analysis revealed that 6 out of the remaining 26 patients (23.0%) had rectocele or cystocele greater than grade 1 which was symptomatic in 3 of them. Five patients had no surgery for the failed compartment (preoperatively 2 had rectocele grade 2, 1 rectocele grade 1, and 2 cystourethrocele grade 0 and 1). In the 2 patients with rectocele grade 2, intraoperative re-assessment precluded surgery for these sites. Two other patients had deterioration of an existing prolapse, and only one patient had a denovo prolapse. The patient characteristics of the failed group were similar to those of the successful group.

We presume that the reasons for failure were as follows:

1. We did not perform a routine rectocele or cystocele repair in patients with multiple-site prolapse who had rectocele or cystocele grade 1 or less.
2. We did not use a routine mesh interposition in patients with previous surgery for prolapse.
3. We used polydgalactin 0 suture (absorbable material). Non-absorbable sutures or polydioxanone suture may be a better choice.
4. We altered the grade of prolapse during surgery.

A potential disadvantage of ICF is the position of ischial spines inferior to the normal position of the vaginal apex. This may result in shortening of the vagina, as shown in our study. We believe that in a not potentially sexually active patient, it is reasonable to judiciously shorten the vagina in order to decrease the risk of recurrence. However, in a potentially sexually active woman, attention should be directed leaving a functional vaginal length.

## CONCLUSIONS

The iliococcygeus fixation is a relatively safe and effective vaginal surgery for the treatment of vaginal vault prolapse and enterocele. Efforts should be made to correct all additional site of prolapse and to maintain an adequate vaginal length in sexually active women. The grade of prolapse should not be altered during surgery. In cases of secondary repair, a mesh interposition should be considered. Long-term follow-up is needed for further evaluation of this technique.

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# What's falling down?

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**Abstract:** BACKGROUND: vaginal prolapse beyond the hymenal ring is occasionally seen in emergency services and apart from patient's discomfort it doesn't represent a surgical emergency. There are very few exceptions to this general rule: vaginal bowel evisceration is one of these exceptional conditions. CASE: an 87 years old woman presented to our gynaecologic emergency service complaining of sudden lumping within her legs. A portion of viable small bowel was observed beyond the hymenal ring. An emergency abdominal approach was performed to reduce the bowel and reconstruct the vaginal cuff. The lady recovered uneventfully. CONCLUSION: women complaining of lumping discomfort have to be quickly examined to rule-out rare, but serious clinical conditions. No standard surgical approach is available, depending both on patient's clinical local and general conditions and on surgeon skills with different techniques.

## INTRODUCTION

Vaginal evisceration is a rare condition, mainly reported after previous hysterectomy in postmenopausal women<sup>1</sup> even though it is sporadically reported in women without previous pelvic surgery<sup>2</sup>. It is commonly considered that the cornerstone in the management of this rare and potentially life threatening condition is a quick diagnosis and prompt surgical intervention.<sup>1-4</sup> Some debate can be reserved for the most appropriate surgical approach.<sup>5</sup>

## CASE

We report a case of an 87 years old woman that was carried by the emergency service to our Obstetrics and Gynecologic emergency unit complaining of a sudden sensation of something falling down vaginally between her legs while doing her housework. Symptom onset was less than one hour at the time of presentation to our Casualty service.

At physical examination as clearly shown in Figure 1, the lady had a consistent portion of her small bowel extruded from her vaginal cuff, coming completely out of the hymenal ring. No bleeding was present and the extruded bowel had a healthy aspect without signs of vascular injury, nor dehydration.

On history taken the lady was primiparous and underwent an abdominal hysterectomy and bilateral adnexectomy for a benign adnexal cyst three years before. The lady also referred a gynaecological examination within the last year: a no better specified vaginal prolapse was observed but no surgery was considered.

After cautious vaginal exploration the possibility to reduce the bowel manually in the emergency room was considered unsafe due to the small size of the vaginal hole and the risk of a vascular iatrogenic injury. A General Surgeon was

consulted and an abdominal surgical exploration was decided in order to reposition the bowel under direct vision.

The extruded bowel was then covered with a saline wet gauze and kept into a plastic bag with 500 ml saline solution. Blood samples and ECG were taken and within 40 minutes the lady underwent a general anaesthesia. A longitudinal umbilico-pubic incision was performed starting preoperatively a double regimen antibiotic therapy (Cephalosporin 1 gr x 3/die and Metronidazole 500 mg x 2/die). At abdominal exploration the remaining intra-abdominal portion of the bowel was normal. The extruded small bowel was then gently pushed through the opened vaginal cuff into the abdomen under direct vision and its vascular tree carefully examined confirming that no vascular sufferance was present. Then the vaginal cuff was examined observing a 2 cm transverse hole.

The edges of the vaginal cuff were resected. Histology documented a picture of chronic inflammatory condition. The cuff was then sutured and suspended to the remnant of the uterosacral ligament identified on the patient right side.

The lady recovered uneventfully, she opened her bowel spontaneously on the fourth and was discharged on the fifth postoperative day.

At follow-up one month later she was well with a well suspended vaginal apex and normally functioning bowel.

## COMMENT

In his 2002 literature review Ramirez et al. reported a total of 59 cases of vaginal exenteration, mainly after vaginal surgery (63%), some after abdominal (32%) and very few after laparoscopic surgery (5%). The surgical management can be debatable. In fact we discussed within our team the possibility of approaching this case laparoscopically. We believe that a laparoscopic diagnostic step could have been considered. Nevertheless both the gynaecologist (AC) and the general surgeon (CB) involved in this case felt themselves more confident with a more traditional manual visceral handling because of the unpredictable strength to be applied to the bowel and its vascular tree in the effort of reducing it. We are of the opinion that the possibility of approaching the case in a less invasive manner (i.e. laparoscopically) relies entirely on the surgeon's feeling; the quick and uneventful recover of this 87 years old lady is in favour of the adopted strategy.

What is out of debate, in this case, is that when a lady comes to the emergency complaining of some lumping within her legs it is wise to get a quick eye to check "what's falling down?".



Fig. 1 - Viable small bowel protruding through the vagina.

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## Pelvic Floor Digest

continued from page 6

**[Alternatives to colonoscopy and their limitations.]** *Chaput U, Oudjit A, Prat F, Chaussade S. Presse Médicale* EPUBDATE: 2009-12-08. Conventional optical colonoscopy's morbidity and poor acceptability have led to the development of alternative techniques. Colo-TC has the best recognized performance (sensitivity 85% and specificity 97% for the detection of polyps >9 mm), but because of its irradiating nature MRI would be preferable: work on the topic is less abundant at the moment. Capsule endoscopy (the Pill-cam) for the colon is promising (sensitivity 64%, specificity 84%, positive predictive value 60%, negative predictive value 86% for detecting polyps >6mm). Improvements for standard colonoscopy (Aer-O-Scope, Invendoscope, CathCam colonoscopy) are in their infancy.

### 4 PROLAPSES

**[Risk factors and prevention of genitourinary prolapse.]** *Ragni E, Lousquy R, Costa P et al. Progrès en Urologie.* EPUBDATE: 2009-12-09. Vaginal delivery increases the risk of prolapse (proof level 1), though the Caesarian section cannot be considered a completely effective preventative method (proof level 2). The pregnancy itself is a risk factor for prolapse (proof level 2). Certain obstetrical conditions contribute to the alterations of the perineal floor muscle: a foetus weighing more than 4 kilos, the use of instruments at birth (proof level 3). If the risk of prolapse increases with age, intrication with hormonal factors is important (proof level 2). The role of hormonal replacement therapy remains controversial. Antecedent pelvic surgery has also been identified as a risk factor (proof level 2). Acquired factors as obesity, intense physical activity, constipation, increase the risk (proof level 3).

**[Update on the epidemiology of genital prolapse].** *Lousquy R, Costa P, Delmas V, Haab F. Progrès en Urologie.* EPUBDATE: 2009-12-09. The prevalence of pelvic organ prolapse (POP) varies between 2.9 and 11.4% in questionnaire-based studies. Aging is significantly associated with the prevalence and severity of POP. Pelvic disorders are a health economic challenge for the future due to the longer life expectancy of women and to an increasing demand for a better quality of life.

**[Urodynamics and prolapse.]** *Hermieu JF. Progrès en Urologie.* EPUBDATE: 2009-12-09. With urogenital prolapses bladder outlet obstruction and stress urinary incontinence are common findings. The diagnosis of stress urinary incontinence is made by physical examination, urodynamic tests are crucial to decide the most appropriate treatment for each individual patient. Despite some technical limitations, we recommend that a proper urodynamic investigation should be performed before any surgical intervention for urogenital prolapse.

**[The role of ultrasound in the exploration of pelvic floor disorders.]** *Lapray JF, Costa P, Delmas V, Haab F. Progrès en Urologie.* EPUBDATE: 2009-12-09. Pelvic and endovaginal ultrasounds should be systematic. Perineal and introital dynamic ultrasound allows the appreciation of the bladder neck and urethral mobility, certain complications with suburethral tape and pelvic mesh, post-mictional residual. Endoanal ultrasound is the first line morphological examination of the anal sphincter.

**[Non surgical treatment of prolapse.]** *Conquy S, Costa P, Haab F, Delmas V. Progrès en Urologie.* EPUBDATE: 2009-12-09. In case of stage 1 prolapses or surgical contra-indication, some non surgical treatment can be proposed: there is no proof of efficacy of hormonal treatment. Pessaries give 58 to 80% satisfaction, vaginal discomfort being improved by local estrogenotherapy. Pelvic floor training in moderate prolapse can be useful. Prevention includes careful delivery management, struggle against overweight, carriage of weight, chronic cough, etc.

**Risk factors for mesh erosion 3 months following vaginal reconstructive surgery using commercial kits vs. fashioned mesh-augmented vaginal repairs.** *Finamore PS, Echols KT, Hunter K et al. International urogynecology journal and pelvic floor dysfunction.* EPUBDATE: 2009-12-05. To establish retrospectively the overall graft erosion (exposure of any mesh upon visual inspection of the entire vagina) rate in a synthetic graft-augmented repair 3 months postoperatively, 124 grafts were evaluated. The overall erosion rate was 11.3%. There was a significantly lower erosion rate when using "commercial kits" vs. traditional repairs (1.4% vs. 23.6%).

**Effects of colpocleisis on bowel symptoms among women with severe pelvic organ prolapse.** *Gutman RE, Bradley CS, Ye W. International urogynecology journal and pelvic floor dysfunction.* EPUBDATE: 2009-12-05. Most bothersome bowel symptoms resolve after colpocleisis, especially obstructive and incontinence symptoms, with low rates of de novo symptoms. This was demonstrated in 152 women evaluated with the Colorectal-Anal Distress Inventory (CRADI) and the Colorectal-Anal Impact Questionnaire (CRAIQ).

**[Should a hysterectomy be carried at the same time as surgery for a prolapse by vaginal route?]** *Debodinance P, Fatton B, Lucot JP. Progrès en Urologie.* EPUBDATE: 2009-12-09. Hysterectomy during vaginal surgery for prolapse is indicated for major hysterocele or in case of concomitant uterine pathology. The anatomical and physiopathological facts are in favour of uterus or cervix preservation that does not modify the anatomical results of prolapse surgery. If a mesh is used, uterine or cervix preservation reduce the chance for a vaginal erosion. The sexual consequences, aside the narrow vaginal tube, are more psychological than objectively proved. The wish of pregnancy in young patient must leads to conservative procedures with sacrofixation (Richter or Richardson) better than cervix ablation (Manchester procedure).

The PFD continues on page 19

# The presence and location of estrogen and progesterone receptors in the human pelvic cardinal ligaments

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**Abstract:** **OBJECTIVE:** To determine the presence, location and intensity of estrogen and progesterone receptors in the cardinal ligaments. **PATIENTS AND METHODS:** A prospective study was conducted by sampling the cardinal ligaments of 29 consecutive women undergoing hysterectomy. The presence and location of estrogen and progesterone receptors were assessed by an immunohistochemical staining technique. **RESULTS:** Estrogen receptors were detected in 25 samples (86.2%), while progesterone receptors were detected in all of them. The estrogen receptors staining intensity index (SII) was significantly higher in premenopausal than postmenopausal women ( $1.5 \pm 0.7$  vs.  $0.9 \pm 0.7$ ,  $p < 0.02$ ). The percentage of progesterone receptors was significantly higher in the premenopausal group ( $88.1 \pm 15.5$  vs.  $60.0 \pm 31.1$ ,  $p < 0.002$ ). There was no association between the presence of both receptors with parity, body mass index, or smoking. All receptors were located in the nuclei of the smooth muscle cells and the blood vessel. **CONCLUSIONS:** Our data suggest that the cardinal ligaments serve as a target for the effect of estrogen and progesterone.

**Key words:** Cardinal ligaments; Estrogen; Menopause; Progesterone; Receptor.

## INTRODUCTION

Pelvic organ prolapse and urinary stress incontinence are major problems affecting quality of life in a vast number of women. The etiology is most probably multifactorial, with a major contribution of muscular denervation during vaginal delivery, genetic factors, and the aging process.<sup>1-4</sup> The higher prevalence of pelvic organ prolapse and urine incontinence in the postmenopausal period suggests that the hypo-estrogenic state might play an important role in their appearance.

To prove a role for sex hormones in pelvic support, one of the first steps would be to find evidence of sex hormone receptors in these tissues. The presence of estrogen and progesterone receptors has been already established in the sacrouterine ligaments and levator-ani muscles.<sup>6-9</sup> However, a thorough search of the English literature yielded no such studies about the cardinal ligaments, which are the most important ligaments that support the uterus.

The aim of this study was to assess the presence and location of estrogen and progesterone receptors in the cardinal ligaments.

## PATIENTS AND METHODS

All women undergoing abdominal or vaginal hysterectomy for fibroid uterus or uterine prolapse at the Assaf Harofé Medical Center Between June and September 2000 were enrolled in the study. All the women were consented before surgery. The exclusion criteria were: hormonal replacement therapy users (current or past users), patients who had a known or suspected malignant disease, cardinal ligaments distortion due to disease or adhesions, (endometriosis, pelvic inflammatory disease etc.) or patients who had previous pelvic surgery. A small piece of tissue from the cardinal ligaments was biopsied from the discarded hysterectomy specimen. No changes were done in the original operation for taking the biopsies. To ensure consistency, all biopsies were performed under the supervision of the main author (HK). All surgical specimens were sent as a routine for histological evaluation.

Tissue samples were fixed in 10% formaldehyde solution, processed by routine histological techniques, and embedded in paraffin. A five-micron section from each sample was stained with Hematoxylin & Eosin, and with monoclonal antibodies for immunohistochemistry for estrogen receptors (Zymed

Laboratories Inc., San Francisco, CA) and progesterone receptors (Zymed Laboratories Inc., San Francisco, CA).<sup>10</sup> After antigen retrieval with 10 mmol citrate buffer (pH-7.6), the monoclonal antibodies were diluted 1:100. Indirect immuno-peroxidase staining was performed using the Avidin-Biotin peroxidase technique.<sup>11, 12</sup> Counterstaining with Hematoxylin was performed to improve identification of cellular elements. Breast carcinoma, known to be positive for estrogen and progesterone receptors, was used as a positive control.

Histological evaluation of estrogen and progesterone receptors was done on all samples at the same time with Olympus BX light microscope (Olympus, Tokyo, Japan) under high power magnification x 40-eye piece by an experienced pathologist (RK) blind to the patient's characteristics. Estrogen receptors were calculated for each sample with the staining Intensity Index (SII) as follows<sup>10</sup>: (% weakly positive cells X 1) + (% moderately positive cells X 2) + (% strongly positive cells X 3) and the result was divided by 100. Progesterone receptor expression was calculated as the percent of stained cells.

All pertinent clinical and laboratory data including patients characteristics (age, parity, BMI, smoking, medical history) and estrogen and progesterone receptors evaluation were collected prospectively, recorded into a computerized database and was evaluated at the end of the study period. Menopause was defined as the absence of menstruation more than one year in women over the age of 45 years.

Statistical analysis was performed using the SPSS statistical software (Release 6.0, SPSS Inc.; Chicago, IL). Categorical variables were analyzed using chi-square test, and continuous variables were analyzed using Student's t-test.  $P < 0.05$  was considered statistically significant. The mean  $\pm$  standard deviation (SD) was computed for continuous variables.

## RESULTS

Twenty-nine patients were enrolled in the study. The mean age was  $51.4 \pm 10.0$  years (range 35-74). Thirteen patients (44.8%) were postmenopausal with an average time from menopause of  $13.8 \pm 9.3$  years (range 2-24). Only one patient was a smoker. Patient's characteristics are shown in Table I.

On histological examination, all specimens were consistent with the cardinal ligaments and were therefore

TABLE I – Patient's characteristics (n = 29).

Variables	Value	
Age* (yr)	51.4±10.0	(35-74)
Parity*	3.1±1.1	(1-5)
BMI (kg/ m <sup>2</sup> )*	24.3±4.3	(18.2-32.6)
Menopausal status**		
Premenopausal	16	(55.2%)
Menopausal	13	(44.8%)
Time from menopause (years)*	14.7±8.5	(2-24)
Indication for operation**		
Fibroid uterus	16	(55.1%)
Uterine prolapse	13	(44.9%)

\* Mean ± standard deviation with the range in parentheses.

\*\* Number of patients with the percentage in parentheses

suitable for the study. All the samples contained connective tissue, blood vessels, and smooth muscle fibers. Seven of 29 samples (24.1%) contained nerve fibers (5/16 in the premenopausal group and 2/13 in the post menopausal group. The difference was not statistically significant. The estrogen and progesterone receptors were located in the nuclei of smooth muscle cells and the blood vessels muscular wall, but not in the connective or neural tissue.

Estrogen receptors with variable intensities were found in 26 (89.6%) samples (Table II). Of the three negative samples, two were of premenopausal women with fibroid uterus and the other was of postmenopausal women with uterine prolapse. The mean SII of the all group was  $1.3 \pm 0.7$ . Dividing the study group to pre and postmenopausal women yielded a higher estrogen SII in the former ( $1.5 \pm 0.7$  vs.  $0.9 \pm 0.7$ ,  $p < 0.02$ ). All samples contained progesterone receptors. Premenopausal women had a significantly higher mean percentage of progesterone receptors compared with postmenopausal women ( $88.1 \pm 15.6$  vs.  $60.0 \pm 31.1$ ,  $p < 0.002$ ). There was not a statistically significant difference in estrogen or progesterone receptors in women with fibroid uterus compared with normal uterus (confirmed histologically).

## DISCUSSION

The cardinal ligaments form a wide fibro-elastic tissue extending from each side of the cervix and upper vagina to the pelvic sidewalls. They are composed of various types of collagen, elastin, smooth muscle, autonomic nerves, fibroblasts and vascular structures.<sup>13</sup> Along with the sacrouterine ligaments, endopelvic fascia, and levator ani muscles they play a major role in pelvic support and the prevention of uterine prolapse mainly presented in postmenopausal women. The mechanism of pelvic floor support, which is based on the anatomical and physiological qualities of the support tissues, needs to be elucidated before effective strategies can be formulated for the prevention and treatment of pelvic prolapse and urine incontinence. Some studies have suggested that the decreased estrogen level in this period, particularly in those who do not use hormonal replacement therapy plays a major role in these conditions.<sup>2, 14</sup> A large randomized placebo controlled study<sup>15</sup> found that treatment with raloxifene, a selective estrogen receptors modulator for the prevention of osteoporosis was associated with 50% reduction in the risk of pelvic floor surgery.

The existence of estrogen and progesterone receptors in the tissue is a major prerequisite for a hormonal effect on it. This has been previously proved in a variety of female genital tract structures, including the vagina, cervix, uterus, fallopian tubes, round ligaments, sacrouterine ligaments, levator ani muscles, and urethra.<sup>5-9</sup> This study establishes the presence of estrogen and progesterone receptors in

TABLE II - Estrogen and progesterone receptors intensity according to the menopausal state.

Variables	Premenopausal N=16	Postmenopausal N=13	P Value*
Mean age (yr)	47.0 ± 5.0 (35-55)	65.4 ± 9.2 (52-74)	<0.002
Mean BMI (kg/ m <sup>2</sup> )	26.0 ± 4.2 (18.2-33.8)	22.9 ± 4.2 (19.5-29.1)	NS
Estrogen receptors (SII)	1.5 ± 0.7 (0-2.4)	0.9 ± 0.7 (0-2.1)	P<0.02
Estrogen receptors (%)	68.1±32.7 (0-100)	38.1±29.7 (0-75)	P<0.001
Progesterone receptors (%)	88.7 ± 14.0 (20-100)	68.0 ± 32.7 (20-100)	P<0.002

All data is given in mean ± standard deviation with the range in parentheses.

SII = Staining Intensity Index

NS= Not significant

\* = Student's t-test

the cardinal ligaments a main pelvic ligament that hold the uterus and upper vagina at their normal position. We specifically located these receptors to the nuclei of smooth muscle cells and blood vessel. These findings are consistent with the known embryonic origin of the ligaments from the mullerian ducts, and supported by the lack of effect of parity, BMI on there presence. The intensity of estrogen and progesterone receptors was significantly higher in premenopausal compared with postmenopausal women. However, a significant overlap exists between the intensity of these hormones receptors in premenopausal and postmenopausal women. We assume that the quantity of estrogen and progesterone receptors may be dependent on the presence of these hormones in the tissue. A hypo-estrogenic state may lead to a down regulation of these receptors in the estrogen and progesterone depended tissues in the body including in the support tissues in the pelvis. It may raise the question about the possible influence of early hormonal replacement therapy on pelvic organ prolapse and urine incontinence later in life. A large randomized study<sup>16</sup> found that estrogen replacement therapy reduces the total vaginal collagen by increasing breakdown. The intermediate collagen was increased and the mature collagen was decreased. The type 1/3 collagen ratio was unchanged. The vaginal biopsies were taken after 6 months. Potentially, the replacement of mature old collagen by new immature collagen may be the transitional phase for increase in the collagen content. But we cannot exclude a paradoxical detrimental effect of exogenous estrogen on the pelvic floor.

Further studies are needed to evaluate the progesterone and estrogen receptors including estrogen receptors subtypes, which are of possible clinical importance in women with pelvic floor dysfunction, as well as the modulation of these receptors expression by endogenous and exogenous hormones.

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**Pelvic Floor Digest** *continued from page 16*

**5 RETENTIONS**

**Efficacy of traditional Chinese medicine for the management of constipation: a systematic review.** *Lin LW, Fu YT, Dunning T et al. Journal of alternative and complementary medicine. EPUBDATE: 2009-12-05.* In this Cochrane review of 137 controlled studies, traditional Chinese medicine interventions (Chinese herbal medicine, acupuncture) appear to be useful to manage constipation. Significant positive results were found in 15 high-quality studies. However there was heterogeneity in diagnostic procedures and interventions, hence the results should be interpreted cautiously.

**Sexual abuse: a strong predictor of outcomes after colectomy for slow-transit constipation.** *O'Brien S, Hyman N, Osler T, Rabinowitz T. Diseases of the Colon & Rectum. EPUBDATE: 2009-12-08.* Patients undergone subtotal colectomy and ileorectal anastomosis for slow-transit constipation at a university hospital from 1991 to 2006 were questioned about a history of anal and vaginal sexual abuse and 13 out of 15, all women, highly satisfied with the results of their surgery, came for assessment; 8 (62%) reported a history of sexual abuse, 7 (88%) both anal and vaginal. The history of sexual abuse resulted a strong predictor of more functional diagnoses, more pre-colectomy operations, and more post-colectomy medical care for abdominal complaints.

**Botox treatment for vaginismus.** *Pacik PT. Plastic and Reconstructive Surgery. EPUBDATE: 2009-12-03*

**Stapled transanal rectal resection for obstructed defecation: a cautionary tale.** *Titu LV, Riyad K, Carter H, Dixon AR. Diseases of the Colon & Rectum. EPUBDATE: 2009-12-08.* Stapled transanal rectal resection can be performed on a day-case basis with 77% of patient satisfaction. However major complications were seen in 7%; fecal urgency, reported by 46%, persisted at six months in 11%; 5% patients reported severe postoperative pain.

**6 INCONTINENCES**

**Defects on endoanal ultrasound and anal incontinence after primary repair of fourth-degree anal sphincter rupture: a study of the anal sphincter complex and puborectal muscle.** *Sakse A, Secher NJ, Ottesen M, Starck M. Ultrasound in obstetrics & gynecology. EPUBDATE: 2009-12-03.* In a 1-9-year follow-up period after primary suture of fourth-degree anal sphincter rupture, the frequency of anal incontinence was 67%. No clear association was seen between incontinence and sphincter defects detected on ultrasonography. There was an association between the angle of the puborectalis muscle and the extent of ultrasound defects.

**Retention test in sacral nerve stimulation for fecal incontinence.** *Michelsen HB, Maeda Y, Lundby L et al. Diseases of the Colon & Rectum. EPUBDATE: 2009-12-08.* Though sacral nerve stimulation is an established treatment for fecal incontinence, the mechanism of its action remains obscure. It does not alter the ability to retain rectal content and further studies are needed to investigate the reasons why it may be successful.

**Randomized controlled trial shows biofeedback to be superior to pelvic floor exercises for fecal incontinence.** *Heymen S, Scarlett Y, Jones K, Ringel Y, Drossman D, Whitehead WE. Diseases of the Colon & Rectum. EPUBDATE: 2009-12-08.* Biofeedback was more effective than pelvic floor exercises alone in producing adequate relief of fecal incontinence symptoms in patients for whom conservative medical management had failed.

**Factors associated with percutaneous nerve evaluation and permanent sacral nerve modulation outcome in patients with fecal incontinence.** *Govaert B, Melenhorst J, Nieman FH, Bols EM, van Gemert WG, Baeten CG. Diseases of the Colon & Rectum. EPUBDATE: 2009-12-08.* Older age, repeated procedures, and a defect in the external anal sphincter are factors that may indicate lower chances of success for test stimulation but do not exclude patients from sacral nerve modulation treatment. Although assessed in a selected patient group, no factors were predictive of the outcome of permanent stimulation.

*The PFD continues on page 29*

# Retropubic, transobturator and intraobturator tape procedures: how, when and why

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**Abstract:** The tension-free vaginal tape (TVT) procedure for treatment of female stress incontinence is the first modern minimally invasive midurethra sling operation and the only one thus far with reports on cure rates with follow-up periods of 5 years or more. The TVT is a safe and effective treatment for stress urinary incontinence (SUI), offering the benefits of a minimally invasive technique with good longterm results . Reported complications of the procedure include bladder and vascular injuries and to lesser extent bowel perforations and mesh erosion.

The transobturator approach (TOT) was developed as an alternative technique to minimise the risk of bladder and vascular injuries during the retro-pubic passage of the needle.

Reported cure rates of incontinence with the transobturator approach were similar to those observed with TVT; comparing retropubic and transobturator tapes, bladder perforations, pelvic haematoma and storage LUTS were significantly less common in the patients treated by transobturator tapes. Viceversa, the performances of retropubic and transobturator tapes were similar for all the other evaluable parameters (vaginal erosions, urinary tract infections, reoperation rates).

New minimally invasive procedures , like the novel TVT-SECUR (TVTs), were designed and introduced to overcome the peri-operative complications reported with use of TVT and TOT/TVT-O (bladder perforation, bowel, vessel and nerve injury, infection, thigh pain and bladder outlet obstruction) but their use needs again further evaluation with respect to efficacy and morbidity.

**Key words:** Urinary incontinence; TOT; Transobturator procedures; TVT; Complications.

Stress urinary incontinence (SUI) is a highly prevalent symptom that has been estimated to be among the top ten medical problems of adult women.<sup>1</sup> Worldwide about 200 millions women suffer of urinary incontinence (UI) (2-3 millions in England, 10-12 in the USA and 3 millions in Italy). In Thelma Thomas' epidemiological survey, one of the most frequently cited article in literature, prevalence of UI varies, based on population age, from 4.5% to 37%, with an average of 18%.<sup>2</sup> These data are confirmed in subsequent epidemiological studies also at a national level.<sup>3-4</sup> Although not life-threatening, SUI may seriously impair the physical, psychological, and social wellbeing of the affected patients<sup>5</sup>. Several procedures have been proposed for the surgical treatment of SUI, both in the hypermobility associated kind (type I-II) and in the Intrinsic Sphincteric Deficiency kind (ISD type III), as described by Blaivas and Olsson in 1988.<sup>6</sup>

This dicotomous view of SUI pathophysiology has been discussed so far, though it still plays a relevant clinical and prognostic role in the decision process on what kind of surgery to perform for each single patient. Since the first half of 90's almost 150 different surgical procedures have been described, among those the Burch colposuspension has been the gold standard in the treatment of type I and II SUI for the last 20 years, showing long term results of 80-90% success rate.<sup>7-8</sup>

The TVT procedure was developed during the early 1990s and introduced as a minimally invasive operation in 1996.<sup>9</sup> Many reports since then have shown that the TVT procedure is effective in many different groups of patients, with cure rates between 80% and 90% during follow-up periods of more than 3 years<sup>10-11-12-13</sup> (Tab 1 e 2).

The tension-free vaginal tape (TVT) procedure for treatment of female stress incontinence is the first modern minimally invasive midurethra sling operation and the only one thus far with reports on cure rates with follow-up periods of 5 years or more.<sup>14-15</sup> In one Nilsson's study the mean follow-up time was 91.1 months (range 78-100) which is 7.6 years. According to the women's own opinion, 81.3 % (65/80) were cured, 16.3 % (13/80) were improved and 1.3 % (1/80) was a failure,<sup>14</sup> and in his last published study the median time of follow-up was 141 months (range, 127-160), which is an average of 11 1/2 years: the cough

TABLE 1. – TVT results.

	Wang 1998	Ulmsten 1999	Olsson 1999	Meschia 2001	Jeffry 2001	Nilsson 2001
Patient number	70	50	53	404	112	85
Primary/ secondary	primary	primary	both	both	both	primary
Anaesthetic	epi	LA	LA/epi	LA/epi	LA/epi	LA
Follow-up (mo.)	12	36	36	21	25	60
Subjective cure	87%	86%	90%	92%	66%	85%
Objective cure	83%	86%	90%	90%	89%	85%

stress test was negative in 95.3 % (61/64) of the women, and 90.2 % had a negative pad test (55/61). Of these women, 90.2 % had both a negative stress test and a negative pad test and thus regarded objectively cured. By PGI, 77 % (53/69) regarded themselves as cured, 20% (14/69) as improved, and 3% (2/69) thought the treatment had failed. Asked if experiencing leakage on straining 93% (64/69) claimed they were dry; 97% were prepared to recommend the TVT operation to a friend.<sup>15</sup>

To date it is estimated that more than 1 million cases have been performed worldwide.<sup>16</sup>

After the success of TVT, several retropubic devices,

TABLE 2. – TVT results.

author	condition	n°	follow-up	results
Nilsson 2001	Primary SUI	85	5 years	85% cured 11% improved
Rezapour 2001	Recurrent SUI	34	4 years	82% cured 9% improved
Rezapour 2001	ISD	49	4 years	74% cured 12% improved
Rezapour 2001	Mixed incontinence	80	4 years	85% cured 4% improved
Meschia 2001	SUI and prolapse	86	2 years	88% cured 6% improved

including suprapubic arc (SPARC) sling, intravaginal slingplasty (IVS) sling, were introduced on the market to make the midurethral sling procedures even less invasive and to reduce the complications.<sup>17</sup> Many studies and also one recently published meta-analysis<sup>9</sup> showed that TVT outperformed both Burch colposuspension and other retropubic tension-free midurethral slings in terms of continence rates.<sup>18-19-20-21-22-23</sup> Complication rates following placement of TVT are usually considered low.

With regards to the intraoperative complications, bladder perforations have been reported to occur in 2.5–11.7% of cases, whereas significant bleedings are less common (0.5–2.5%). Postoperative complications included urinary tract infections (0.4–31.5%), de novo urgency (3.1–29%), transient or persistent voiding dysfunction (2.8–38%), vaginal and/or bladder erosions (0.6–5.4%), and so on.<sup>24</sup> Despite those encouraging figures, some cases of major complications have been reported, including bowel, vascular, and nerve injuries, sepsis, and patient deaths.

For these reasons, the transobturator approach (TOT) was developed as an alternative technique to minimise the risk of bladder and vascular injuries during the retro-pubic passage of the needle.

Although in the original TOT procedure,<sup>25</sup> the tape was inserted through the obturator foramen from the outside-to-inside direction, later, the inside-to-outside approach (TVT-O) with the passage of the tape from the vaginal incision to the obturator foramen has also been described.<sup>26</sup> Reported cure rates of incontinence with the transobturator approach are similar to those observed with TVT.<sup>27-28-29</sup> One recent Italian randomised prospective study that compared TVT and TVT-O with regard to peri-operative morbidity and short-term surgical outcome in women undergoing primary surgery for stress urinary incontinence showed that subjective and objective cure rates were 92% and 92% in the TVT group and 87% and 89% in the TVT-O group and that both procedures were equally effective in the short-term for the treatment of stress urinary incontinence with a highly significant improvement in incontinence-related QoL.<sup>29</sup>

Also the last French multi-centre experience reported similar results: with regard to efficacy, the surgeon assessed 886 (90%) patients as completely dry, 86 (8.7%) as improved and 12 (1.2%) as similar with a re-intervention only in 9 cases (0.9%). The post-operative complications in a series of 984 women were: residual pain in 2.7% of cases, urinary retention in 0.8%, vaginal erosion in 0.6% and paravescical hematoma in 0.1%.<sup>30</sup>

One meta-analysis of six trials that compared TVT and TVT-O (a macroporous polypropylene mesh, to be inserted inside-to-out through the obturator foramen), three RCTs comparing TVT with transobturator outside-to-in tape and a further study compared TVT with Monarc (a knitted macroporous polypropylene mesh to be placed outside-to-in through the transobturator route) concluded that comparing retropubic and transobturator tapes, bladder perforations (OR, 2.33; 95% CI OR, 1.26–4.32;  $p = 0.007$ ), pelvic haematoma (OR, 4.83; 95% CI OR, 1.22–19.15;  $p = 0.03$ ) and storage LUTS (OR, 1.81; 95% CI OR, 1.13–2.91;  $p = 0.01$ ) were significantly less common in the patients treated by transobturator tapes. Viceversa, the performances of retropubic and transobturator tapes were similar for all the other evaluable parameters (vaginal erosions, urinary tract infections, reoperation rates). The observed success rates were similar in both groups of TVT and transobturator approaches.<sup>32</sup>

In order to obtain the less invasive surgical approach, to reduce the risk of intra-operative complications, to use a mid-urethral sling in safe conditions with local anaesthesia and in a day surgery ward due to the minimal post-operative

TABLE 3. – TVT Secur results

	Neuman 2008	Oliveira 2009	Debodinance 2009	Meschia 2009
Patient number	100	107	154	95
Primary/secondary	primary	primary	primary	primary
Type	IUS	IUS/ IUM	IUS/ IUM	IUS
Follow-up (mo.)	12	12	12	12
Objective cure	88/93%	85%	81%	81%

pain, in 2006 the first mid-urethral mini-sling requiring a single vaginal incision was introduced. The novel TVT-SECUR (TVTs) is designed to overcome the peri-operative complications reported with use of TVT and TVT-O: bladder perforation, bowel, vessel and nerve injury, infection, thigh pain and bladder outlet obstruction.<sup>33</sup> This new device is composed of an 8 cm long laser cut polypropylene mesh and is introduced to the internal obturator muscle (Hammock position) by a metallic inserter, while no exit skin cuts are needed. This approach imitates the sub-mid-urethral support provided with the TVT-obturator (TVTs-O), yet imitating the TVT is possible as well, by introducing the TVT-SECUR arms retropubically rather than to the obturator area (TVTs-U). This “U” position approach requires urethral catheterization as well as diagnostic cystoscopy for recognition of possible bladder penetration. The initial pull-out force of the tape and further tissue ingrowth were studied in the sheep model, revealing satisfactory figures.<sup>33</sup> At the moment there is no prospective randomised trial comparing TVT and traditional transobturator slings, therefore no evidence can prove the clinical effectiveness of this new surgical approach. Nevertheless data from published studies seem promising. Success rates reported in literature range widely from 60 to 90%. Between the years 2007-2009 over 4000 implants have been performed and described in numerous international abstracts. Four prospective observational studies with a minimum follow-up of 12 months show satisfactory results (tab. 3).

Study populations are not comparable among the different articles but overall success rates range between 81 and 93%. Results are strongly dependent on surgical learning curve for each surgeon as shown by Neumann et al. In his article he compared the first consecutive 50 and the last consecutive 50 procedures, drawing some interesting conclusions regarding the number of intraoperative complications and success rate.<sup>34</sup> Similar results were reported by a recent observational multicentric prospective study on the use of TVT Secur system in urodynamic and/or

TABLE 4. – Perioperative complications

Intra-operative complications	2 sling re-positioning 1 LVP with implant of another sling 3 PE $\geq$ 200	
Post-operative complications	1 haematoma (spontaneous recovery) 1 temporary pain recovered within 7 days 8 urinary difficulties (RV > 100 ml):	4 recovered during 2 <sup>nd</sup> day 2 recovered during 3 <sup>rd</sup> day* 2 recovered during 8 <sup>th</sup> day* * 5 patients underwent associated surgery

TABLE 5. – Follow-up at 3.6 months and Centre characteristics. \* n° 5 re-operated recurring SUI; 1 TVT-s, 1 TOT, 1 BURCH, 2 infiltrating. No significant differences among groups found.

	TOTAL PATIENTS		TVT-s-O		TVT-s-U	
N° patients	136		110		26	
Total failures (n°-%)	17*	12.50%	14	12.73%	3	11.54%
Urodynamic SUI (n° patients)	95		81		14	
Total failures (n°- %)	14	14.74%	12	14.81%	2	14.29%
Potential SUI (n° patients)	41		29		12	
Total failure (n°- %)	4	9.76%	3	10.34%	1	8.33%
<b>Centre characteristics</b>						
Learning curve	TOTAL PATIENTS		Urodynamic SUI		Potential SUI	
Centres with < 10 implants	13		10		3	
Total failures (n°-%)	3	23.08%	2	20.00%	1	33.33%
Centres with 10-20 implants	33		25		8	
Total failures (n°-%)	5	15.15%	4	16.00%	1	12.50%
Centres with > 20 implants	90		60		30	
Total failures (n°-%)	10	11.11%	8	13.30%	2	6.67%

occult SUI associated to pelvic prolapsed pathologies. The study involved nine national urogynecological centres and a total of 147 patients, of which 136 (92.5%) took part to the 6-month-follow up and 69 to the 12 month-follow up. For each single case, operators were free to adopt the two different TVT-Secur system approaches, transobturator and/or retro-pubic.

Intra and post-operative morbidity is reported in Table 4.

No intra-operative bladder, urethral, vascular or nervous damage was observed; the total analysed population (136/147) at 6 months follow-up did not show sling urethral-vaginal erosion or signs of infection in the intervention site.

At the short-medium term, technique's percentage of failure (improved + failed) in the whole population was of 12.5% (Tab.5). The percentage of failures in the 95 patients with Urodynamic SUI (Group A) was of 14.74 (14/95), whereas in patients with potential SUI (Group B), the ratio was 9.76% (4/41). Of the 17 patients that were not cured, 9 (6.6%) resulted improved (resulting in a lower class with Ferrari's stress-test, VAS of lower degree and PGI-I  $\leq$  2) and 8 (5.9%) were unchanged; for 5 failures a further surgery intervention was required during the first 6 months of follow-up for serious recurring SUI (1 TVTs, 1 TOT, 1 Burch, 2 peri-urethral infiltrations) that resulted in complete recovery. Although no comparison has been made between two populations having similar general features, differences observed in percentages of success for the two sling applications (transobturator and retro-pubic approach) were not statistically significant.

Among centres with different level of experience and different number of patients, indeed there is a significant difference in the percentage of success according to the chosen approach (Tab. 6).

In the whole population, these percentages drop from 23.08% of failure observed in centres with less than 10 implants carried out, to 11.1% of those with more than 20 treated patients and the trend is the same both for Urodynamic SUI and Occult SUI (Table 5).

The analysis of study results show how, though applied in many urogynecological centres having a quite different learning-curve for this technique, TVT Secur System is a surgical method of treating Urodynamic and Occult SUI resulting to be safe (with low and minimal peri-operative

morbidity), versatile (with the possibility of applying sling through different techniques according to each operator's choice), effective (with high percentages of success similar to traditional mid-urethral slings, both for retro-pubic and transobturator approaches).

Observed short-mid term percentages of success seem to be maintained also on long-term.

More than with other mid-urethral slings, results of this study underline the importance of the learning curve for each single centre, and the need of adopting a new and original way of positioning and put under tension the sling.

The need of re-intervention for recurrent SUI already at mid-term follow-up observed in the population of treated patients (5/136) has to be highlighted as significantly higher than percentages reported in literature with traditional mid-urethral slings, and also at long-term (3-11 years) is slightly higher than 1% both for retro-pubic and transobturator approach.<sup>14-15-30</sup>

This study demonstrate feasibility, reliability and effectiveness of the used single incision mini-sling (TVT Secur System); the analysis of collected data shows how TVTs resulted in being an innovative therapeutic method for patients suffering from Urodynamic and/or Occult SUI: it is simpler, safer and its efficacy is similar to that of mid-urethral, retro-pubic and/or transobturator "traditional" slings. The data available in the international literature do not allow yet an evaluation on the real possibilities of this technique to be a safe alternative to mid-urethral traditional slings, and additional extensive randomised prospective comparative studies are needed.<sup>35</sup>

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# Reduction of external anal mucosal prolapse with circular stapler

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**Abstract:** A circular resection and stapling technique was introduced by Pescatori in 1997 for the treatment of rectal mucosal prolapse. This technique has also been applied in the treatment of external anal mucosal prolapse (EAMP). The aim of this study was to retrospectively assess the outcome of this technique used in our department for the treatment of EAMP.

From May 2003 to April 2007, 27 patients were operated with this technique. We were able to contact 23 of these patients who were invited to a follow up study. Eighteen (78%) were consulted and physically examined in the outpatient clinic while 5 (22%) were interviewed by phone.

At follow up median 14 (range 1.5 – 43) months after the operation, complications were seen in 13 patients (57%). Nine patients (39%) presented recurrences, five patients (22%) experienced fecal urgency and two patients (9%) described persistent post-operative pain. Three (13%) patients stated that they were not satisfied with the operation.

We report a high frequency of complications after circular resection and stapling of EAMP. Surprisingly, most patients were satisfied with the result of the operation, possibly because the symptoms from recurrences and complications were less bothersome than the ones from the primary EAMP. The technique may play a future role in carefully selected patients as a supplement to conventional techniques.

**Key words:** External anal mucosal prolapse; Haemorrhoidal prolapse; Circumferential mucosectomy; Stapled mucosal prolapsectomy; Longo procedure.

## INTRODUCTION

External anal mucosal prolapse (EAMP) is characterized by protrusion of the anal mucosa distal to the anal verge. The external component of the prolapse may be present only during defecation or straining, spontaneously or as a permanent, non-reducible condition. Common symptoms are bleeding, pain, itching, a feeling of obstructive defecation and secretion of mucus. A common treatment is rubber band ligations, but the Milligan-Morgan haemorrhoidectomy technique for excision of the redundant mucosa is by most considered the gold standard. Band ligation is associated with recurrences, pain and bleeding<sup>1</sup> and Milligan-Morgans technique with significant postoperative pain, anal incontinence and other complications<sup>2,3</sup>. Excision of rectal mucosal prolapse with a circular stapler device was first published by Pescatori in 1997<sup>4</sup> and a similar technique for the treatment of prolapsing haemorrhoids was published by Longo in 1998<sup>5</sup>. So far only a few studies focusing on the use of a circular stapler in the treatment of the EAMP have been published<sup>6,7,8</sup>. We report from our experiences with this method for the treatment of EAMP.

## MATERIAL AND METHODS

All 27 patients operated for EAMP with a circular stapler from May 2003 to April 2007 were invited by mail to a follow up investigation in the outpatient clinic. Two patients were dead and we were unable to reach another two. Twenty three patients (ten males; mean age, 50; range 25-83) accepted by written consent to participate in the study. Eighteen (78%) of the patients were seen in the outpatient clinic while five (22%) declined physical examination and were interviewed by phone.

The diagnosis was based on anamnestic and clinical findings. Some prolapses were only external following defecation and could not be reproduced by straining in a lithotomy position, whereas others could be demonstrated by straining or were permanently externalised. However, before the operation, with the patient anaesthetised and muscle-relaxed in the lithotomy position, all prolapses became visible outside the anal verge. Eight (35%) patients had a defecography in order to exclude a rectal full-thickness prolapse as a differential diagnosis.

The operative technique was performed essentially as described<sup>5</sup>. In brief, the operation was carried out in a day care

unit in general anesthesia and with the patient in a lithotomy position. Intravenous muscle relaxation was used to allow introduction of a wide anoscope without overstretching the anal sphincter. A single purse-string suture was then placed circumferentially in the mucosa 4-5 cm above the dentate line. A circular stapler (PPH 03, Ethicon Endo- Surgery, Inc., Cincinnati, USA) was introduced and the purse-string was tied around the stapler shaft before resection and stapling of the anal mucosa. Local anesthesia (Marcaine 0.5%) with adrenaline was injected circumferentially in the submucosa of the anastomosis in order to reduce bleeding and pain. If a residual prolapse was still present, a second procedure was performed immediately in some of these cases by placing the new purse-string suture in the anastomosis. Prophylactic antibiotics were not given. The width of the mucosal rings resected, was approximately 2 cm. The specimens were visually inspected for muscular tissue, but not histologically examined.

At follow up patients were questioned about symptoms before and after the operation and physically examined for residual prolapse and strictures. The distance from the anastomosis to the dentate line was measured by anoscope.

## RESULTS

All 23 patients presented a circumferential prolapse except from two (9%) with a semi-circumferential (180 degree) prolapse. Seven patients (30%) had external haemorrhoids in combination with the prolapse. None of the patients were previously operated with excision or circular resection and stapling for their prolapse. Two patients (9%) were previously operated with excision of haemorrhoids (Milligan-Morgans technique) and five (22%) had been treated with rubber band ligations for either prolapse or haemorrhoids.

The duration of the symptoms before the operation was mean 7 years (range 1 – 28 years). The main pre-operative complaints from the EAMP are listed in Table 1.

Twenty patients (87%) were operated by one surgeon and three patients by another two surgeons. At 30 days after the operation, 16 patients (70%) had reported symptoms.

Thirteen patients (57%) reported pain that lasted median 1 day (range 0-30 days), seven patients (30%) complained of fecal urgency, three (13%) patients noticed bleedings, two (9%) patients were constipated and one patient (4%) developed a thrombosed haemorrhoid that was incised.

TABLE 1 – Complaints before operation for EAMP

Bleeding	70 %
Hygienic problem	57 %
Pain	52 %
Difficult reduction of prolapse	48 %
Feeling of obstructed defecation	43 %
Pruritus ani	39 %
Fecal incontinence/secretion	22 %
Cosmetic problem	9 %

At follow up at median 14 (range 1.5 – 43) months after the operation 13 patients (57 %) reported one or two of the following complications: Recurrences in 9 patients (39 %) (included two patients who were reoperated for recurrences before follow-up), fecal urgency in five patients (22 %) persistent pain in two patients (9 %) and pruritus ani in one patient (4 %). The nine recurrences occurred median 6 (range 0 – 12) months after the operation. Two of the five patients with fecal urgency reported a gradual improvement in the follow up period. Two patients reported long lasting pain. In one patient the pain was caused by an anal fissure which healed in 4.5 months. The other one reported continuous post-defecational pain with no sign of improvement at follow up. Five patients complained of fecal incontinence before the operation. For two of these the condition was unchanged after the operation while two reported an improvement and one patient was cured. No patients developed anal incontinence following the procedure.

Five patients were reoperated before follow up. One was operated for a missed internal rectal prolapse with laparoscopic anterior rectopexy. Two were reoperated for their recurrent EAMP with either an additional circular resection or a Milligan-Morgan excision combined with a rubber band ligation. One of these still had a small recurrent prolapse at follow up. Two patients were operated for haemorrhoids with either band ligations or Milligan's excision.

Eleven patients (48 %) stated that they were "very satisfied", nine patients (39 %) were just "satisfied" whereas three patients (13 %) were "not satisfied" with the results at follow up.

A physical examination with digital exploration and proctoscopy was performed in 18 patients (78 %). No strictures were revealed. The anastomosis was identified in all patients. All anastomosis were well healed except from one that appeared inflamed, bleeding after touched by the anoscope. Four patients (22 %) presented haemorrhoids. Six of the nine anamnestic recurrences were physically examined. One of these patients presented a 360 degree circumferential prolapse, four presented a 30-50 degrees sectorial prolapse whereas one patient was not able to present the prolapse by straining. The mean distance from the linea dentata to the anastomosis was 3.8 cm (range 1.5 -5.5 cm).

## DISCUSSION

We here report a retrospective study on the treatment of EAMP with a circular resection and stapling device. The long pre-operative duration of the disease, in our study 7.1 years, reflects probably a lack of general knowledge about this disease and its treatment. Studies on the treatment of external haemorrhoids by circular resection and stapling of the proximal mucosa are comprehensive<sup>2,5,9,10,11,12,13</sup>, whereas studies focusing on operations of EAMP with the same technique, are few with a small number of patients<sup>6,7,8</sup>.

TABLE 2 – A functional classification of EAMP.

Grade	Anamnestic presentation of EAMP
A	The prolapse is external only at defecation
B	The prolapse is external at defecation and spontaneously in between defecations
C	Permanent external prolapse, not reducible

The classification and terminology of ano-rectal prolapses may be confusing. It is important to differentiate between the full thickness and the mucosal prolapses since these two conditions are treated in different ways. Mucosal prolapses may be internal and are then named rectal internal mucosal prolapses (RIMP)<sup>14</sup>. The RIMP may be graded<sup>15</sup> and the third degree RIMP describes a prolapse where the mucosa reaches as far as the anal verge by straining. This condition should be kept distinct from the term EAMP<sup>6</sup> which is also named haemorrhoidal prolapse. The differentiation between internal and external prolapses may also be of importance for evaluating the cause of a possible, associated obstruction<sup>4</sup>. Pescatori has made a classification system for RIMP<sup>15</sup>. Accordingly we have proposed a clinical grading of the EAMP based on the degree of presentation of the prolapse external of the anus according to anamnestic information (table 2).

Nine (39%) of our patients reported recurrences. In the most comparable study, Altomare reported no recurrences but two patients required one rubber band ligation each for persistent minimal mucosal prolapse<sup>6</sup>. Smaller recurrent prolapses occupying only a part of the circumference may in fact represent a residual prolapse not detected after the primary resection. We propose that a follow up with an anamnestic and physical examination after 6 months should be an integrated part of the treatment in order to be able to perform a supplementary procedure if necessary.

A relatively high proportion (22%) of our patients complained of lasting fecal urgency after the operation although the condition was improving for two of the five patients. None of the 18 patients in Altomare's study was reported to suffer from fecal urgency after the operation while Pescatori reports fecal urgency in 23% of the patients operated with stapled mucosectomy for either haemorrhoids or rectal internal mucosal prolapse<sup>9</sup>. Since the technique for circular stapling of both haemorrhoids and EAMP is the same, some side effects and complications may be comparable in these two groups. However, in a large multicentric review of patients stapled for haemorrhoids, the rate of fecal urgency was only 0.2%<sup>11</sup>. Surprisingly, four of five of the patients in our study with fecal urgency were satisfied with the result of the operation, indicating that this complication was less important than the symptoms from the prolapse. A similar finding of high patient satisfaction despite frequent postoperative symptoms is also reported after circular stapling for haemorrhoids<sup>13</sup>.

One of our patients reported chronic post-defecational pain that continued beyond the time frame of this study. She also suffered from a non-relaxing puborectalis syndrome before the operation. Pescatori found that non-relaxing puborectalis syndrome is a negative predictive factor for the outcome after excision of rectal internal mucosal prolapse, and we do agree with him when he recommends non-operative treatment if there is evidence of this condition<sup>14</sup>. Furthermore, chronic anal pain after stapled mucosectomy for hemorrhoids has been reported in 1.6-16% of the cases<sup>10,11,12</sup>, and new-onset post-defaecation pain syndrome developed in 4% of the patients<sup>16</sup>.

Our measured distance from the dentate line to the

anastomosis was mean 3.8 cm whereas this distance in Altomare's study was mean 1.5 cm. Longo states that the resultant staple line should be at least 2 cm proximal to the dentate line<sup>17</sup>. The excision of a more distal part of the EAMP may explain the lower number of recurrences in Altomare's study compared to our more proximal stapler line. Although our level of the staple line is more correct than in Altomare's study according to Longo's statement, it may still be too high in order to remove the most protruding part of the mucosal prolapse that may be more distal than our level of resection.

We conclude that the circular resection and stapling of EAMP is an alternative treatment to rubber band ligation and Milligan-Morgans excision of mucosa. However, the number of operations complicated with fecal urgency and the recurrence rate is very high in this study and represents a contra-indication for patients with only moderate symptoms. Future studies should be carried out prospectively in order to compare circular stapling with conventional techniques. Until then, our attitude to this technique in the treatment of EAMP is restrictive despite little post-operative pain and mainly satisfied patients.

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# PTQ™ bulking agent injection for the treatment of fecal incontinence: QoL and manometric evaluation

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**Summary:** Fecal incontinence is a debilitating symptom that limits the social and working activities of the patient. Prevalence is probably underestimated, and it is higher in geriatric population and in elderly people with psychiatric disorders. First-line treatment consists of medical and rehabilitative therapy. Use of bulking agents has been proposed in the last years for the treatment of anal incontinence after failure of conservative therapy.

Sixteen patients suffering from mild to moderate fecal incontinence were treated with PTQ™ bulking agent endoanal injection from April 2004 to June 2007. Clinical and manometric evaluations were performed. Quality of Life questionnaires were administered. Good results were reported in almost all cases. CCF-FI score improved from a median of 10,4 before to 5,6 2 years after procedure. Manometry showed a marked increase in median resting and squeeze anal pressures. A limited improvement was observed in Quality of Life scores. No adverse events were registered.

Anal bulking agents should be considered for all patients suffering from fecal incontinence after failure of the conservative therapy being the procedure minimally invasive, repeatable, effective and safe.

**Key words:** Fecal incontinence; Bulking agents; Anorectal manometry.

## INTRODUCTION

Fecal incontinence (FI) is a distressing and socially debilitating symptom which causes the patient to gradually abandon all forms of social, family and working relationships.<sup>1</sup> FI exists along a wide spectrum of variable complaints going from soiling of underclothes or flatus incontinence to complete loss of control of bowel emptying. In many cases, patients feel so inhibited and are so afflicted by this condition that they are reluctant to discuss the problem with a physician and FI is probably therefore an underestimated disease. The calculated prevalence of FI is between 0.5% and 18.4% in non-institutionalized adults, 32% in the geriatric population and 56% in elderly people with psychiatric disorders.<sup>2,3,4,5</sup> Medical treatment should be offered in all cases. Conservative treatment, such as dietary changes and pelvic rehabilitation is reported to be effective in 65-70% of cases.<sup>6</sup> In those patients who do not benefit from conservative treatment, a surgical approach must be proposed. Injection of bulking agents, already used in the treatment of urinary incontinence,<sup>7</sup> has been proposed recently as a substitute for surgical treatment of anal incontinence.<sup>8</sup>

## MATERIALS AND METHODS

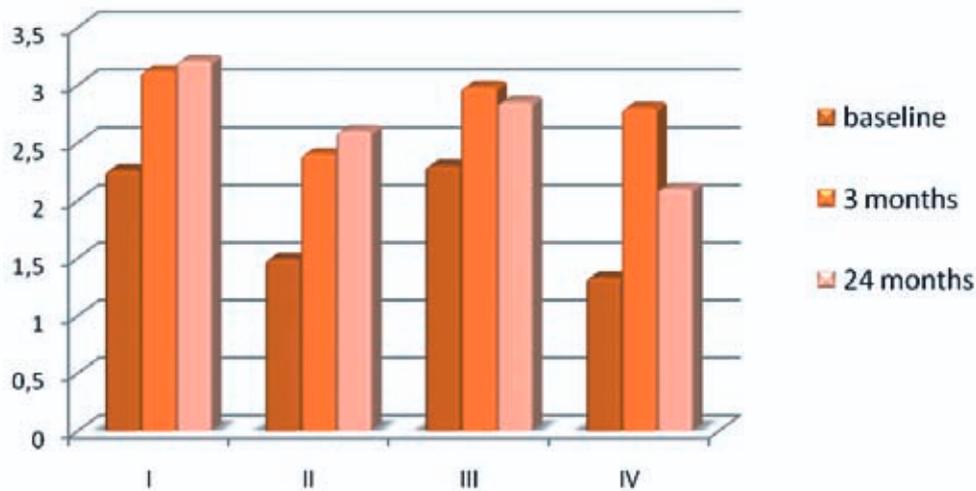
Between April 2004 and June 2007 sixteen patients suffering from mild to moderate fecal incontinence (CCF-FI score < 15) were selected and treated with transanal injection of PTQ™ bulking agents. All patients had undergone conservative therapy, including dietary changes and pelvic rehabilitative treatment with electrostimulation and biofeedback protocols with no satisfactory improvement of symptoms. Each patient was evaluated with clinical assessment including anoscopy at baseline and at 7, 30 and 90 days and 24 months after treatment. To evaluate social and psychological impact for each patient, a Fecal Incontinence Quality of Life Scale (FIQL) was examined before and 3 and 24 months after treatment.<sup>9</sup> An anorectal manometric study was also performed at baseline and at 3 and 24 months after treatment. Anoscopic exam was performed to identify patients with ongoing anorectal and/or non-anorectal diseases which may modify evaluations following the procedure. Patients with rectal prolapse, fecal impaction, symptomatic haemorrhoids, perianal and anal scarring,

perianal sepsis, congenital anal sphincter defect, uncontrolled diabetes, immunodeficiency, acute inflammation, infection or malignancy, pregnancy or within one year postpartum and patients who had undergone proctological surgery in the 12 months preceding enrollment were excluded. All patient completed a consent form. Subsequent clinic evaluations, including anoscopic exam, were performed 7, 30 and 90 days and 24 months after the injection to verify the correct positioning and possible dislocation of the prosthetic material. CCF-FI score calculation was needed at baseline to find the correct indication to treatment with bulking agent, which was proposed to patients with mild to moderate fecal incontinence (CCF-FI score < 15). Subsequent evaluations at 3 and 24 months after treatment were used to assess clinical trend. Anorectal manometry was performed pretreatment, and at 3 and 24 months, using a manometric system (Dyno Compact, Menfis Biomedica – Bologna, Italy) and anorectal manometry PVC catheter with balloon, 5 way, 12 Fr. For each exam, maximum resting pressure and maximum squeeze pressures were registered. Each patient was treated under local anesthesia as an outpatient procedure, placed in Sims position after surgical cleaning of the area. Prophylactic broad-spectrum antibiotics were administered to each patient a few minutes before the implant. A 18-gauge rigid needle, loaded onto the PTQ™ implants syringe, was used to inject PTQ™ in the internal sphincter-submucosal interface, entering the skin about 25 mm from the anal margin. By placing a digit through anal canal, attention was paid not to damage endoanal mucosa during the procedure.<sup>10</sup> Three equidistant (circumferentially about 90, 210 and 330 degrees) boles of 2,5 ml of PTQ™ were injected for each patient. PTQ™ implants (PTQ™ Implants – Uroplasty BV, The Netherlands) are solid, irregularly textured, medical grade polydimethylsiloxane elastomer implants suspended in a hydrogel carrier of polyvinylpyrrolidone (PVP or povidone). PTQ™ implants are held in place at the implantation site when the hydrogel carrier is replaced by body fluids and host fibroblast subsequently deposit collagen around the implants.

## RESULTS

Sixteen patients with moderate fecal incontinence (CCFIS < 15) were selected for treatment with PTQ injectable anal

TABLE 1. – FIQL score variations.



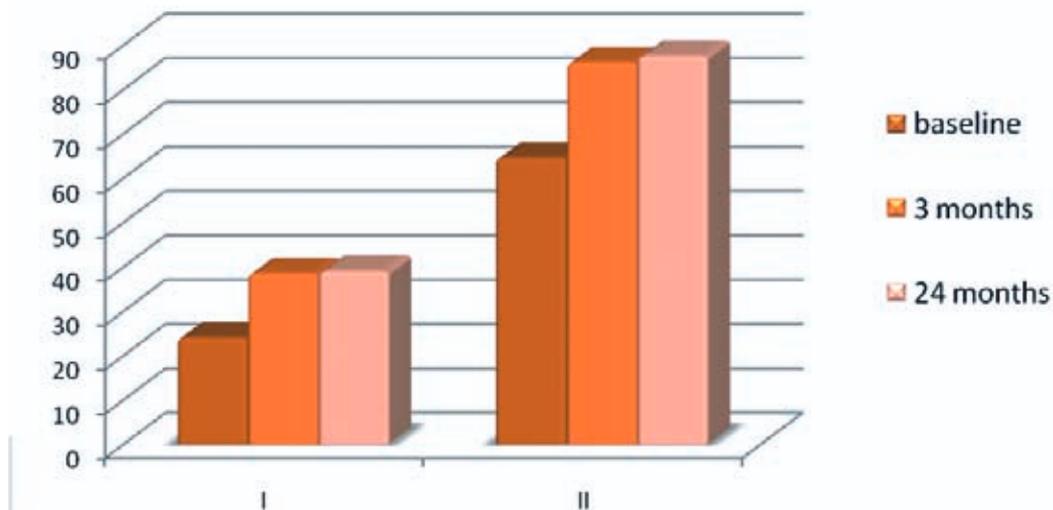
bulking agents. No serious adverse event was reported during or after the injection. No adverse events were reported such as infection or dislocation of the prosthetic material in subsequent visits. In a patient, because of the lack of improvement at 3 months control, two additional boles of PTQ were injected with the same procedure and the patient showed a modest improvement of symptoms at 2 years.

Improvement in CCFIS was from a median of 10,4 (range 6-14) at baseline to 5,5 at 3 months and to 5,6 at 24 months after treatment. An improvement in patients quality of life was demonstrated by FIQL median score variation from baseline to 3 and 24 months follow-up with encouraging results as shown in table n.1. Median scores are calculated for each FIQL's domain: lifestyle (I), coping/behavior (II), depression/self perception (III), embarrassment (IV). Global improvement was also reported by manometric findings. As shown in table n.2 median anal resting pressure (I) was of 24 mmHg at baseline (range 10 – 35) and improved to 38,5 (range 20 – 50) at 3 months and to 39 (range 25 – 50) at 24 months control. Similar results were given by maximal squeeze pressure (II) that increased from a median of 64,5 mmHg at baseline (range 25 – 140) to 86 (range 65 – 145) at 3 months and to 87,5 (65 – 135) at 24 months after the procedure.

DISCUSSION

Use of bulking agents already registered good results for the treatment of urinary incontinence. Endoanal injection of prosthetic bulking agents for the treatment of anal incontinence is reported to be safe and effective in a high number of short- and medium-term studies.<sup>11,12</sup> In our experience PTQ™ implants have shown no complications with good results on clinical and manometric evaluation with an encouraging keeping of improvement at 2-years follow up.<sup>13</sup> The procedure has proved to be safe and easy to perform by expert operators and well-tolerated by the patient.<sup>14</sup> According to literature bulking agents should always be taken into consideration in cases in which conservative medical therapy has not proved effective.<sup>15</sup> To date, the large number of conservative therapeutic solutions in the treatment of fecal incontinence should be considered for all degrees of incontinence.<sup>16</sup> It is demonstrated that mild to moderate anal incontinence is healed in a good percentage of patients and improved in almost all cases.<sup>17</sup> However, non-surgical treatment of severe fecal incontinence can be taken into consideration with non-curative purposes, but in preparation for a possible restorative or substitutive intervention with improved outcomes.<sup>18</sup>

TABLE 2. – Median manometric findings variations.



Encouraging results obtained, in agreement with most recent literature, show that endoanal injection of bulking agents is effective in treating mild to moderate fecal incontinence. This procedure is minimally invasive, repeatable, not associated with major complications and is feasible in an outpatient regime. Moreover the good patient compliance associated with favorable cost-benefit analysis requires further studies with a longer term follow-up to assess bulking agents as the first line treatment for mild to moderate fecal incontinence non-responsive to medical therapy.

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## Pelvic Floor Digest

continued from page 19

**Anterior sphincteroplasty for fecal incontinence: a single center experience in the era of sacral neuromodulation.** *Oom DM, Gosselink MP, Schouten WR. Diseases of the Colon & Rectum. EPUBDATE: 2009-12-08.* It has been reported that patients with external anal sphincter defect may also benefit from sacral neuromodulation. The success of this technique raises the question whether anterior overlapping sphincteroplasty still deserves a place in the surgical treatment of fecal incontinence. This study investigated the outcome of anterior sphincteroplasty in a series of 172 patients after a median follow-up of 111 months. Results were acceptable to excellent in 60% of patients, especially in those under the age of 50 years at surgery.

**Myoblasts differentiated from adipose-derived stem cells to treat stress urinary incontinence.** *Fu Q, Song XF, Liao GL, Deng CL, Cui L. Urology. EPUBDATE: 2009-12-09.* Adipose-derived stem cells have the ability of differentiating into multiple lineages, including myoblasts. This ability to induce myoblasts can be used to treat stress incontinence, with the advantages of minimal invasion and faster recovery as proved in 20 female incontinent rats.

### 7 PAIN

**Efficacy of montelukast, a leukotriene receptor antagonist, for the treatment of dysmenorrhea: A prospective, double-blind, randomized, placebo-controlled study.** *Fujiwara H, Konno R, Netsu S et al. European Journal of Obstetrics & Gynecology and Reproductive Biology. EPUBDATE: 2009-12-01.* Montelukast is a clinically reasonable management option to consider before prescribing an hormonal agent, it may be effective in alleviating pain associated with dysmenorrhea in some women. It is safe and does not influence hormonal levels.

**Increased cold-pain thresholds in major depression.** *Schwier C, Kliem A, Boettger MK, Bär KJ. Journal of Pain. EPUBDATE: 2009-12-01.* Patients suffering from major depressive disorder show a decreased sensitivity for external or skin surface pain, eg, for heat or electrical stimuli, as compared to healthy controls.

**Effect of meal ingestion on ileocolonic and colonic transit in health and irritable bowel syndrome.** *Deiteren A, Camilleri M, Burton D et al Digestive Diseases and Sciences. EPUBDATE: 2009-12-02.* Postprandial symptoms in irritable bowel syndrome (IBS) have been associated with increased bowel contractility. This study shows that ileocolonic transit immediately after eating is higher in IBS diarrhea predominant (IBS-D) patients than in the healthy controls, whereas colonic transit is blunted in IBS-C (constipation predominant).

The PFD continues on page 32

# Aggressive angiomyxoma mimicking cervical polyp

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**Abstract:** PURPOSE: The purpose of this paper is the presentation of a case of an aggressive angiomyxoma of the uterine cervix in a 29-year-old woman. METHOD: The patient was presented with dysuria, and mild suprapubic pain. The preoperative diagnosis after the physical examination was uterine cervical polyp. RESULTS: Histological examination performed after surgical excision however, showed a densely vascular, poorly circumscribed neoplasm, composed of spindle-shaped cells widely spaced from each other in myxoid stroma. These findings were compatible with the diagnosis of an aggressive angiomyxoma. CONCLUSION: Aggressive angiomyxoma is a rare soft tissue tumor of the pelvis and perineum. Pathologic and clinical characteristics of the tumor are discussed.

**Keywords:** Dysuria; Aggressive angiomyxoma; Cervical polyp.

## INTRODUCTION

Aggressive angiomyxoma is a mesenchymal tumor initially first described in 1983.<sup>1</sup> It typically appears as a soft tissue mass of the pelvis and perineum in women of reproductive age.<sup>2</sup> Its differential diagnosis includes myxoma, myxoid liposarcoma, sarcoma botryoides, and other soft tissue tumors with secondary myxoid changes.<sup>1</sup> We present a rare case of aggressive angiomyxoma of the uterine cervix, clinically simulating a pedunculated cervical polyp.

## CASE REPORT

The patient, 29 years old, presented to the outpatient department for a routine health care visit. She was nulliparous, reported to be sexually active. She complained of mild suprapubic pain and dysuria. Upon the speculum examination, the presence of a large, polypoid, pedunculated mass originating from the uterine cervix was noticed. The presumptive diagnosis was cervical polyp and the treatment recommended was elective surgical excision.

The tumor was removed with an electrocautery blade electrode under general anesthesia. It originated from the external cervical os and its base of about 1cm in diameter was fulgurated. The patient was discharged the next day.

The surgical specimen measured 5 x 4 x 2 cm. It was glistening white, soft and solid (Fig. 1). Histologically, the lesion was poorly circumscribed, partially covered by mature squamous epithelium (Fig. 2) and contained rare endocervical glands. The intermediate stroma composed of mesenchymal spindle-shaped cells widely separated

by myxoid stroma which also contained many small- and medium-sized thick-walled vessels. Rare bundles of smooth muscle cells and few mast cells were also identified. Immunohistochemical examination showed positive reaction of the spindle cells to desmin and smooth muscle actin (SMA), while they were negative to S-100 protein and CD34 antigen. The latest revealed the rich vascular network of the neoplasm. Proliferation index antigen Ki67 was practically negative. These findings were consistent with aggressive angiomyxoma.

Two years after surgery the patient remains in good general condition with no signs of relapse.

## DISCUSSION

The term dysuria refers to a condition during which a patient has difficulty in voiding. It is described as painful or uncomfortable urination and it is an extremely common symptom regarding urinary tract pathological cases. The most common cause of dysuria in women is urinary tract infections. It can be observed in any age and in both sexes. Urinary tract infections are one of the most common infections in women. However when a female patient is presented with dysuria a detailed medical and lifestyle history is obligatory. Bicycle riding, horse riding, depression or use of specific drugs such as anticholinergics for Parkinson's disease can be causes of dysuria. Physical examination including speculation of the vagina and the urethra may reveal causes of dysuria that are not related to urinary tract infections such as urethral



Fig. 1 - Glistening white, polypoid cervical mass, of soft and solid texture.

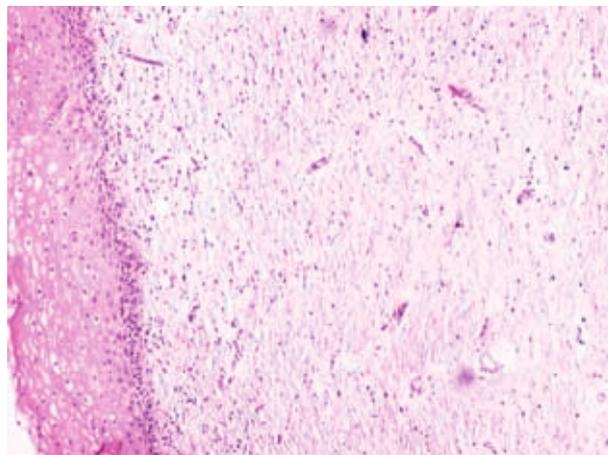


Fig. 2 - Poorly circumscribed bulky mass, partially covered by cervical epithelium. Histochemical stain H&E, X200.

damage during sexual intercourse, vaginitis, vulvovaginitis or tumors.

Aggressive angiomyxoma is an uncommon, slow growing mesenchymal tumor that usually affects the pelvis and perineum of adult women. It may be clinically misdiagnosed as an inguinal hernia or a Bartholin cyst, while polypoid configuration has not so far been reported.

Its pathogenesis is not completely understood. Recent cytogenetic studies revealed chromosomal translocations in specimens of aggressive angiomyxoma. These include HMGA2 protein rearrangement at chromosome 12,<sup>3,4</sup> and a t(5;8)(p15;q22) translocation.<sup>5</sup>

The tumor is poorly circumscribed; it consists of spindle and stellate cells separated by myxoid stroma, focally rich in collagen fibrils and prominent vessels. Vascular spaces vary in size and include large thick-walled vessels without an arborizing pattern. Stromal fibrils and spindle cells immunohistochemically exhibit myofibroblastic differentiation (smooth muscle and fibrous tissue),<sup>1-6</sup> a fact that histologically differentiates the mass from common cervical polyps. Mitotic activity is usually exceedingly low.

The term "aggressive angiomyxoma" was designated to this neoplasm to emphasize the neoplastic nature of the blood vessels and its tendency to be locally aggressive and recur after treatment. Recurrence rates up to 70 % have been reported, thus long term follow-up of the patient is necessary.<sup>1-7</sup>

It is typically a benign, non-metastasizing neoplasm, in two cases however<sup>8,9</sup> multiple metastases have been reported, including pulmonary involvement, and both women died.

Surgical excision with free margins is the treatment of choice in most of the times. In several cases, removal of the tumor may be difficult due to local infiltration and adjuvant therapy may be used. Treatment options include use of hormonal manipulation, such as tamoxifen, raloxifen or GnRH analogs, radiotherapy and arterial embolisation.<sup>10-11-12</sup> Nevertheless, their role in the definite treatment or treatment of recurrences of aggressive angiomyxoma needs further investigation.

## CONCLUSION

Although symptoms as dysuria or suprapubic pain refer to common situations as urinary tract infections each patient which is presented with these symptoms should be carefully evaluated. Medical history and physical examination can help in the diagnosis of rare conditions that may require special treatment or any invasive therapy. Usually dysuria is treated with the use of antibiotics. But in cases in which the administration of antibiotics is not helpful and the symptoms persist, the presence of situations other than urinary tract infections should be considered and the patient should be closely reevaluated.

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**Electrodermal measures of Jing-Well points and their clinical relevance in endometriosis-related chronic pelvic pain.** *Ahn AC, Schmyer R, Conboy L et al. Journal of alternative and complementary medicine. EPUBDATE: 2009-12-05.* Electrodermal measures at Jing-Well acupuncture points, "indicator" points located at the tips of fingers and toes, are significantly associated with clinical outcome in 14 adolescent women (ages 14-22) with laparoscopically diagnosed endometriosis and chronic pelvic pain.

## 8 FISTULAE

**Do we need new surgical techniques to repair vesico-vaginal fistulas?** *Zambon JP, Batezini NS, Pinto ER et al. International urogynecology journal and pelvic floor dysfunction. EPUBDATE: 2009-12-02.* The urogenital fistula continues to be a devastating distressful problem. Hysterectomy is the major etiology. Complex vesicovaginal fistulae repair may need tissue interposition by vaginal or abdominal approach and depends on the surgeon's experience and local factors like size, location, and previous radiotherapy. Using traditional approaches is possible and reasonable to treat any sort of vesicovaginal fistula.

**Endoscopic repair of post-traumatic fistulae of posterior urethra using hyaluronic acid dextranomer.** *Appignani A, Bertozzi M, Prestipino M. Urology. EPUBDATE: 2009-12-08.* A prostatic urethral fistula, developed from an abscess after an intervention to correct a pubic symphysis fracture was repaired with a minimally invasive endourologic procedure, using the hyaluronic acid dextranomer, commonly used in vesicoureteral reflux treatment.

**Assessment of the efficacy of the rectovaginal button fistula plug for the treatment of ileal pouch-vaginal and rectovaginal fistulas.** *Gonsalves S, Sagar P, Lengyel J et al. Diseases of the Colon & Rectum. EPUBDATE: 2009-12-08.* The Surgisis Biodesign rectovaginal button fistula plug with a total of 20 plug insertions was used in 5 patients with rectovaginal fistulas and 7 ileal pouch-vaginal fistulas. At a median follow-up of 15 weeks, 58% had been treated successfully. All plug failures were the result of dislodgement of the plug. There was no morbidity.

## 9 BEHAVIOUR, PSYCHOLOGY, SEXOLOGY

**Female sexual dysfunction.** *Clayton AH, Hamilton DV. Obstetrics and Gynecology Clinics of North America. EPUBDATE: 2009-12-01.* Sexual dysfunction is influenced by a variety of factors: medical, psychiatric, cultural, and stage of life. A variety of treatment modalities exist, though current research has not yet provided Food and Drug Administration approved therapies for sexual disorders in women.

**Intimate partner violence.** *Zolotor AJ, Denham AC, Weil A. Obstetrics and Gynecology Clinics of North America. EPUBDATE: 2009-12-01.* A knowledge of patients' intimate partner violence victimization may help physicians develop a better understanding of patients' presenting symptoms and health risks associated with this common problem that takes on many forms, including psychological/emotional, physical, and sexual abuse, and affects many women.

**When depression complicates childbearing: guidelines for screening and treatment during antenatal and postpartum obstetric care.** *Muzik M, Marcus SM, Heringhausen JE et al. Obstetrics and gynecology clinics of North America. EPUBDATE: 2009-12-01.* One in 5 women experience an episode of major depression during their lifetime. Management of depressed peripartum women includes care of a growing fetus or breastfeeding infant. The treatment is complex and requires input from a multidisciplinary team (obstetrician, psychiatrist, and paediatrician)

**[Prevalence of erectile dysfunction in patients consulting urological clinics: the ENJEU survey (one day national survey on prevalence of male sexual dysfunction among men consulting urologists).]** *Droupy S, Giuliano F, Cuzin B. Progrès en Urologie. EPUBDATE: 2009-12-01.* This first survey in French urologists' community emphasizes the high prevalence male sexual dysfunctions including erectile dysfunction for inpatients visiting their urologists. Despite declared urologists' interest for male sexual dysfunction, the discrepancy between the high prevalence of erectile dysfunction and the low rate of patients consulting for this condition probably explains the low rate of patients using treatments.

**Laparoscopic radical cystectomy. The new gold standard for bladder carcinoma?** *Castillo OA, Vitagliano G, Vidal-Mora I. Archivos Espanoles de Urologia. EPUBDATE: 2009-12-04.* Laparoscopic radical cystectomy is associated with diminished operative bleeding, time to oral intake and hospital stay. It is a reproducible technique but it demands a very long learning curve.

**Penile foreign bodies.** *Pastor Navarro H, Donáte Moreno MJ, Segura Martín P et al. Archivos Espanoles de Urologia. EPUBDATE: 2009-12-05.* Penile foreign bodies are placed for a wide variety of reasons, but primarily for erotic or self-arousal purposes, rarely this is due to an accident. The consequences can be mild or very severe, resulting in penile amputation.

**Does vaginal size impact sexual activity and function?** *Schimpf MO, Harvie HS, Omotosho TB et al. International urogynecology journal and pelvic floor dysfunction. EPUBDATE: 2009-12-05.* Vaginal size does not affect sexual activity or function. Total vaginal length and genital hiatus were assessed using the POPQ exam and the Female Sexual Function Index (FSFI) in 505 women. They did not differ between women with normal FSFI scores and those with sexual dysfunction.

## 10 MISCELLANEOUS

**Sustained efficacy and immunogenicity of the human papillomavirus (HPV)-16/18 AS04-adjuvanted vaccine: analysis of a randomised placebo-controlled trial up to 6.4 years.** *Lancet. EPUBDATE: 2009-12-08.* 560 women were included in the vaccine group and 553 in the placebo group. Vaccine efficacy against incident infection with HPV 16/18 was 95.3% (95% CI 87.4-98.7) and against 12-month persistent infection was 100% (81.8-100). Vaccine efficacy against CIN2+ was 100% (51.3-100) for lesions associated with HPV-16/18 and 71.9% (20.6-91.9) for lesions independent of HPV DNA. Up to 6.4 years an excellent long-term efficacy, high and sustained immunogenicity, and favourable safety was demonstrated.

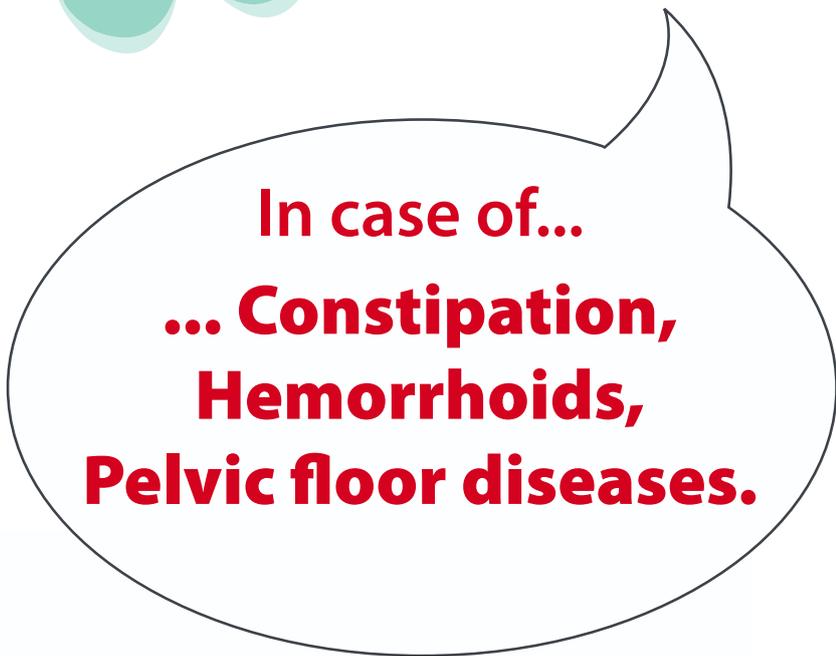
**Pregnancy and inflammatory bowel disease.** *Mahadevan U. Medical Clinics of North America*

*EPUBDATE: 2009-12-01.* The article covers important questions that arise for physicians caring for women with inflammatory bowel disease. Fertility, pregnancy outcomes and the safety of medications in pregnancy and lactation are discussed.

**Page disease of the vulva: a study of 56 cases.** *Shaco-Levy R, Bean SM, Vollmer RT et al. European Journal of Obstetrics & Gynecology and Reproductive Biology. EPUBDATE: 2009-12-09.* The records of 56 patients with vulvar Page disease, a rather controversial issue, were reviewed. Only rarely it results in a patient's death, but recurrences are common and can be noted many years after the initial treatment. In general stromal invasion is not associated with worse prognosis. Intra-operative frozen section analysis of the margins as well as initial radical surgery does not reduce recurrence rate. Radiation therapy given to five patients who either had multiple positive surgical margins or experienced disease recurrence and refused additional surgery resulted in complete response with no further recurrences.



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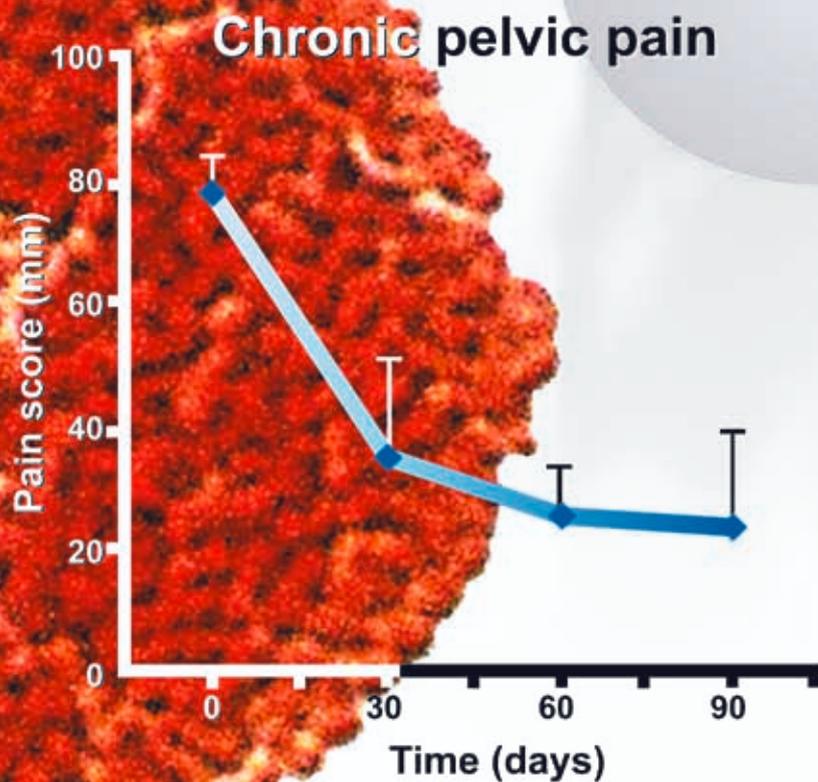
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