

PELVIPERINEOLOGY

A multidisciplinary pelvic floor journal

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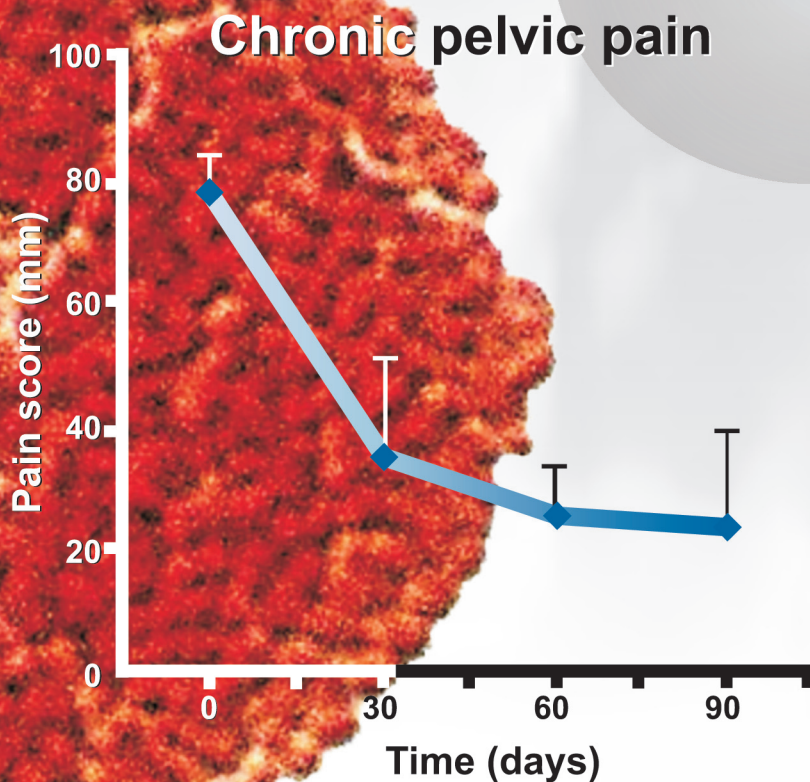
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AAVIS Editorial

AAVIS was established in 1997 by a small group of Australian gynaecologists with an interest in the new field of Ambulatory vaginal surgery pioneered by Petros and Ulmsten. In recent years AAVIS has developed into a multidisciplinary society which brings together like-minded individuals from a variety of disciplines, in particular gynaecologists, urologists and colorectal surgeons, all of whom share an interest in the complex problems relating to the female pelvic floor. Change occurs in everything we do, usually by necessity. The executive committee of AAVIS has recognised the importance of adapting to change - not only to engage more with its current members and to attract new members, but also to provide a more comprehensive knowledge base.

One of the most significant changes that has occurred is the way that we now use the internet. The internet is an excellent source of information - but it is information that we have to seek out for ourselves. The success of social networking forums such as Facebook and Twitter is a testament to the way we would like the internet to be - the information should find us. These facilities are encompassed in the concepts of Web2.0.

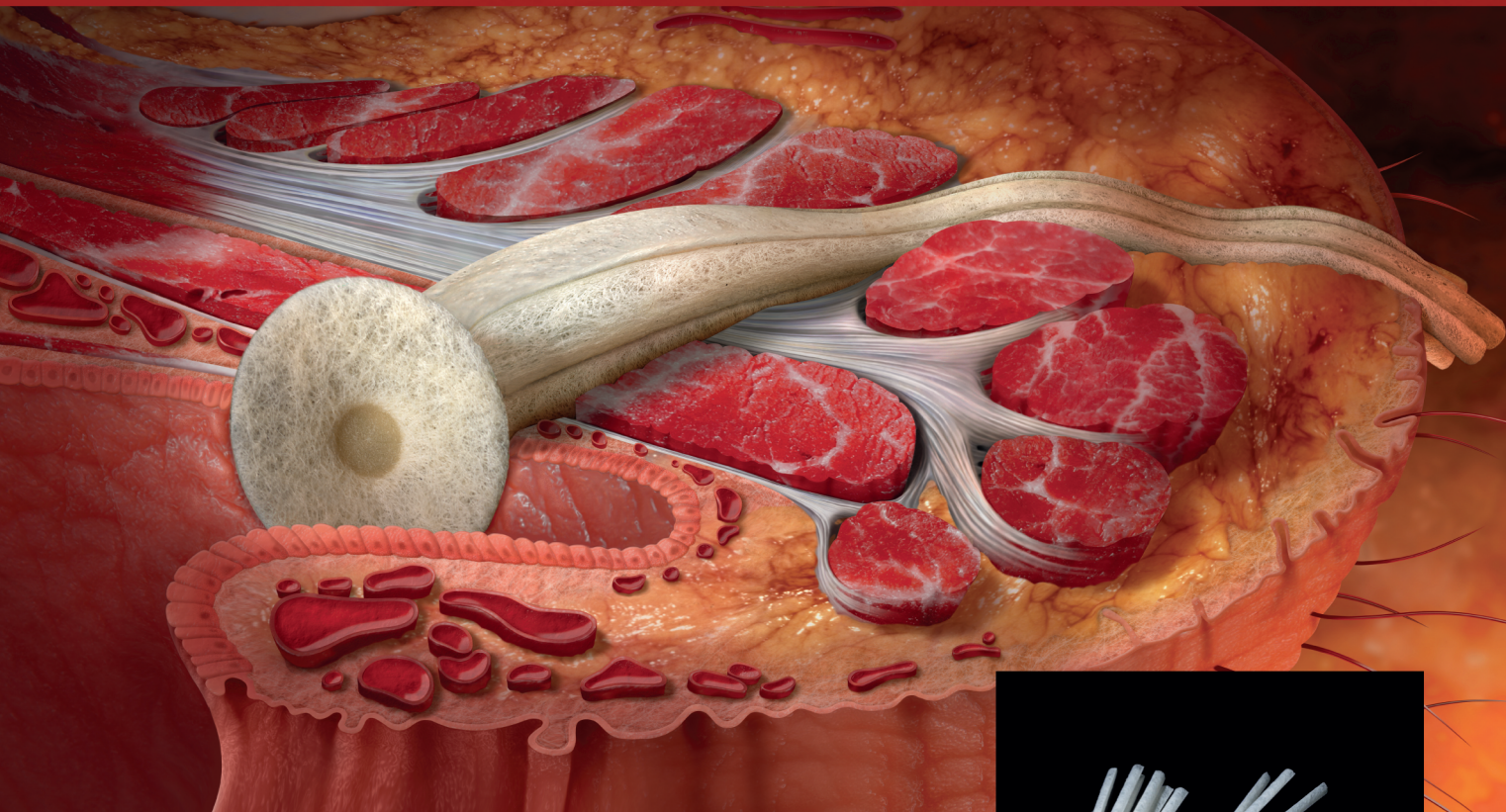
Because of the multi-disciplinary background of the specialists involved with AAVIS, Web2.0 features lend themselves spectacularly well to providing individual members with the facilities that allow them to share their knowledge. The Executive is very pleased to announce that the Society in general, but in particular the website, is about to undergo a dramatic transformation that will allow a whole host of exciting activities for members such as creating their own profiles and uploading their own media content, in particular videos. Members can then invite other members to share this content. There will also be discussion forums initiated by experts in their own field but allowing individual members to have their say. And there will also be blogs that permit a more informal discussion. Members will be able to sign up to a particular feature which means that they will be notified of new postings automatically. There will also be the usual features such as e-news letters about the latest research results and training news.

As with last year's annual meeting in Noosa, the presentations at this year's meeting will be webcast and will be available for on-demand viewing via the new website. In line with this exciting new development the Society will be undergoing a renaming and rebranding exercise to reflect its multidisciplinary stance. The Executive has decided to introduce a membership fee and is extremely confident that you will quickly appreciate the benefits of belonging to the Society. Content is king and because you will have access to an ever-expanding library of content it is also very confident that the membership database will grow exponentially. The aim is to continue to hold a conference every year, probably alternating between Australia and Europe, and one of the many benefits of membership will be a reduced conference fee.

The Executive looks forward to meeting all current and new members at the annual conference in Vienna and for the opportunity to informally discuss your ideas relating to the new online facilities.

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FISTULA PLUG

Intestinal endometriosis: the gynaecologist, the radiologist and the colo-rectal surgeon as a multidisciplinary team

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Abstract: Deep infiltrating endometriosis (DIE) is defined as infiltration by endometriotic tissue into anatomical structures and organs. Endometriotic tissue is composed of endometrial glands and stroma. DIE is a particular form of endometriosis and it occurs in 30–40 % of women. Of all forms of intestinal endometriosis, 90% of cases, present with colorectal involvement with a significant impact on the quality of life of these patients. Although the deep infiltrative form of the disease is the most serious, generally being accompanied by severe symptoms at the site of infiltration of the endometriotic foci, no clear guidelines exist for the evaluation of patients with suspected bowel endometriosis. On the basis of recent evidence in literature, intestinal endometriosis is neither diagnosed nor managed in a standardized or appropriate manner. A very high number of patients receive “hit and miss” treatments, often resulting in surgery that does not eradicate the problem. A complete assessment and pre-surgical diagnosis of DIE is crucial. In this work we propose an operative model specifically designed to identify, treat and follow patients affected by intestinal endometriosis. The diagnostic-therapeutic run has to be standardized following a precise sequence of consultations: the gynaecologist must screen patients for DIE and refer them to a dedicated radiologist; the radiologist should both localize intestinal nodules and estimate the relationship between the depth of lesions and the percentage of the circumference of the bowel segment affected by the disease. In our opinion, at this point the patient benefits from a consultation with the colo-rectal surgeon specialized in treating low intestinal pathologies such as cancer or endometriosis. With this work philosophy, different specialists constitute part of an overall solution and treatment plan for each patient to manage their individual symptomatic profile.

Key Words: Intestinal endometriosis, Deep infiltrating endometriosis, Colorectal resection

INTRODUCTION

Endometriosis is the presence of endometrial-like tissue outside the uterus that induces a chronic inflammatory reaction. This is predominantly found in women of reproductive age of all ethnic and social groups and generally associated with pelvic pain and infertility. Infertility problems can impact on the physical, mental and social well being of a woman and can have a profound effect on her life, including the ability to finish an education, maintain a career, or to create a family. For these reasons the European Union Written Declaration has recognized endometriosis as a disease with an important economic impact on the community demonstrating a significant association with health costs related to diagnostic delays and therapeutic expenses including surgery, drugs, and assisted reproductive technologies (ART).¹ Defining endometriosis as a ‘disease’, ‘illness’ and/or a ‘physiological phenomenon’ with a known cause or known triggers/mechanisms remains so far misunderstood by many scientists. Consequently, endometriosis remains a considerable challenge for those who attempt to identify and recognise the symptoms and signs of a disease that varies according to the location and severity of the implants, as well as the impact on the woman.

Pelvic pain is an important issue in the health care of women contributing to 10% of all outpatient gynaecological visits, 40% of laparoscopies and is the indication for 10% - 15% of hysterectomies.² The existence of a relationship between chronic pelvic pain symptoms and endometriosis is widely accepted, but various other painful pelvic symptoms are also normally present in the general population.³

Since there is no definitive criteria to determine whether the pain is actually caused by endometriosis both the American and the Royal Colleges of Obstetricians and Gynaecologists have recommended the empirical use of medical therapy before confirming a diagnosis of endometriosis.⁴ However, endometriosis may be a progressive disease and laparoscopic diagnosis in patients suffering from this potentially serious condition could be appropriate.

Leaders in the field continue to support the need of a reliable non-invasive test to distinguish the pain between endometriosis and other causes since there is an approximate 10 year delay in the diagnosis of this pathology. This is generally because both women and family doctors tend to consider this type of pain as normal and neglect the need for treatment.⁵

Endometriosis therefore has to be considered a complex pathologic condition with unknown pathogenesis and various clinical manifestations. Women affected by the disease can have nil, mild or severe symptoms and these can be unrelated to the severity of the clinical syndrome (minimal, moderate or severe). At present, superficial endometriosis is considered a normal phenomenon in women in the childbearing years, whereas ovarian cysts and deep infiltrative endometriosis (DIE) are the more severe and generally painful manifestations of the condition. DIE is a particular form of endometriosis and occurs in up to 30%-40% of patients with endometriosis and has a characteristic penetration > 5 mm under the peritoneal surface.⁶ These lesions are considered very active and are strongly symptomatic since DIE implants are found in specific locations, such as uterosacral ligaments, torus uterinus (retrocervical area of the uterus where the uterosacral ligaments join together), the posterior vaginal wall and the anterior rectal wall.⁷ Endometriotic implants of the gastrointestinal (GI) tract occur in an estimated 5-37.5 % of patients with endometriosis. The most commonly affected areas, in decreasing order of frequency, are the rectosigmoid colon, small intestine, cecum and appendix. The implants are usually serosal but can eventually erode through the subserosal layers and cause marked thickening and fibrosis of the muscularis propria. An intact overlying mucosa is almost always present, because the implanted tissue only rarely invades the mucosa. Inflammatory response to cyclic haemorrhage can lead to adhesions, bowel stricture even to gastrointestinal obstruction.⁸

Although the deep infiltrative form of the disease is the most serious, generally accompanied by severe symptoms

at the site of infiltration of the endometriotic foci, no clear guidelines exist for the evaluation of patients with suspected bowel endometriosis. This topic has been a source of great debate in recent literature concerning 2 issues: preoperative diagnosis and the optimal form of treatment. In this work we propose an operative model specifically designed to identify, treat and follow patients affected by intestinal endometriosis. With persistent and/or chronic diseases, continuity of care becomes the only stabilizing factor for the patient who needs ongoing treatment; our solution to this complex pathology is a centrally co-ordinated care for patients with endometriosis within a multi-disciplinary centre or network of accredited practitioners. The first step is therefore to assign a central gynaecologist to the woman seeking help for her endometriosis symptoms. This gynaecologist screens patients with pelvic pain, selects the suspect DIE cases and refers them to a dedicated radiologist. Our unit uses very sensitive diagnostic methods, enabling us to detect the presence and localization of intestinal endometriosis.⁹ With the advances in diagnostic imaging methods that permit identification of the deepest layer and provide information such as the number of bowel lesions and the percentage of the circumference affected, it is possible that the decision regarding which type of procedure should be performed may be defined before surgery.¹⁰

In our opinion, it is only at this point that the patient benefits from a consultation with the colo-rectal surgeon specialized in treating low intestinal pathologies such as cancer or endometriosis. Surgical treatment of bowel endometriosis is associated with a significant rate of complications and any woman undergoing this type of surgery must be fully informed of the possible risks and complications by an appropriately trained and experienced surgeon.

With this work philosophy, different specialists constitute part of an overall solution in the treatment plan for each patient to manage their individual symptomatic profile.

THE GYNECOLOGIST

The central gynaecologist must have continuously updated knowledge on all diagnostic and management options for symptomatic women with endometriosis. They are the one who works with the woman to co-ordinate and tailor-make her long-term treatment plan, depending on which symptoms need to be managed at any given time.

The first consultation of a patient referred for suspected endometriosis is crucial and lasts about 45 minutes. Great attention is paid to familial anamnesis, personal medical history, characterization of pain and quality of life beyond the current reason for the visit. The gynaecological examination has to reveal and localize the possible endometriotic lesions. A traditional speculum examination is done for full visual inspection of possible implants and a cotton-tipped swab should be used to evaluate both the cervical os and the paracervical/cervical tissues for tenderness. The manual portion of the pelvic examination should always be initiated with a single index finger, first noting any introital tenderness or spasm suggesting vaginismus. Next the levator ani muscles are palpated for tone and tenderness. Normally this palpation causes only a pressure sensation, but in patients with pelvic floor pain it may cause pain consistent with at least part of the patient's clinical pain symptoms.

The retrocervical area and the uterosacral ligaments should be palpated with great care in patients with suggestive endometriosis, because this is the most important location for endometriosis and is frequently associated with palpable nodules and indurations.¹¹ An easier evaluation can be made through a rectal examination rather than a vaginal examination. The cervix, paracervical areas and vaginal fornices should be transvaginally or transrectally palpated

with a single digit for tenderness or selective trigger points in order to identify endometriosis and to differentiate it from other problems such as repeated cervical trauma (usually from intercourse), pelvic infection and ureteral pain.¹² Unfortunately, it has been demonstrated by practitioners expert in managing this pathology that 50% of cases of laparoscopy-proven endometriosis had normal findings on preoperative pelvic examination.¹³ This evidence and the need of an intranet solution allowing the radiologist and colo-rectal surgeon to work together forced us to develop a software to manage our cases of endometriosis. Different practitioners with their different sets of skills, play an important role in providing a holistic solution to an individual's needs; if all the specialists are connected and can communicate easily, the likelihood of positive, long-term results becomes greater. While the central gynaecologist may be situated in one place, it is unlikely that it is possible to gather the entire network's expertise underneath one roof. A viable solution has been to create a 'multi-disciplinary network of excellence' – a virtual centre – where specialists work in different locations but where (a) a central, shared electronic file for each patient is maintained and updated at every consultation carried out within the centre/network to ensure that every practitioner is kept continuously up to date and (b) where regular and formal interdisciplinary discussions regarding patient management are conducted.¹⁴ Since 2006 our Unit has been using a dedicated software (IE-RING(c), Mediasoft Srl, Genoa, Italy)¹⁵ to clinically manage cases of suspected and confirmed endometriosis (video-clip demonstration: <http://www.galliera.it/endometriosi/promoie.html>). The software's real-time calculation of the entered data provides a final score, defined as endometriosis index (EI) that quantifies the pathological status at the time of each consultation. This way all the data from each patient consultation or surgery is saved and accessible via hospital intranet.

The structure of the panels have been specifically designed for the integrated approach of different specialists according to recent data published in order to standardize entry criteria and outcome measures for clinical trials in endometriosis-related pain.¹⁶ In particular, to screen women for the intestinal form of endometriosis, a panel of the electronic system is dedicated to comorbidities such as dyschezia and bowel function (figure1). Our preliminary data shows significantly

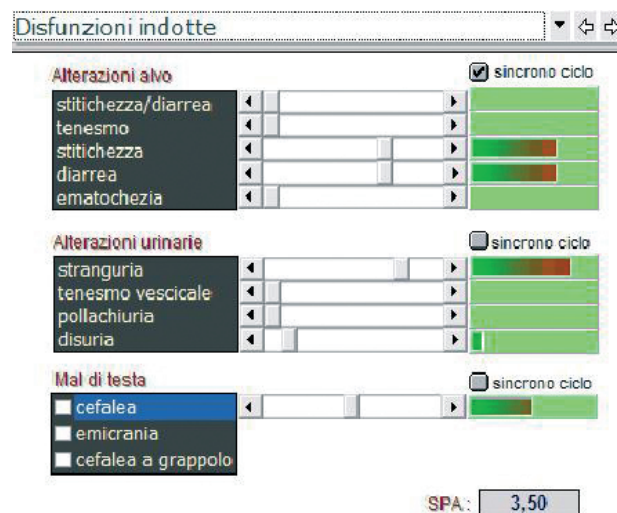


Fig. 1 – Panel 3 of IE-Ring Software. Induced dysfunction and physical alteration (SPA) is the result of the following subitems: intestinal symptoms (*Alternating constipation and diarrhoea + Rectal tenesmus + constipation + diarrhoea + Rectal pain*). Urinary symptoms and headache characterization follow.

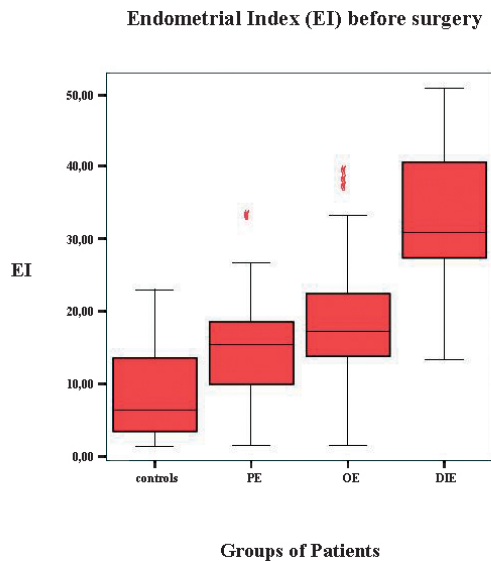


Fig. 2 – Endometrial Index (EI) before surgery. EI = Endometriosis Index. PE = peritoneal endometriosis. OE = ovarian endometriosis. DIE = Deep infiltrating endometriosis. The pre surgery EI calculated by our software in patients with proven DIE resulted in significantly higher values than those of women with no adhesions nor endometriosis. Kruskal Wallis test was used for the calculation of P; data are expressed as mean \pm standard deviation. P for trend < 0.001 for each score.

higher EI values in patients affected by DIE compared to healthy women or with minor forms of endometriosis (figure 2, Table 1). This work methodology has allowed us to pre-operatively screen 29 cases of deep infiltrating endometriosis (22 were with intestinal localizations) out of 120 patients studied.

Each woman referred to the radiologist with suspect DIE needs to be informed in detail of the nature of this form of endometriosis. This step has to be considered as crucial by the primary gynaecologist in managing these cases because this is the starting point of the diagnostic run for DIE. Patients need to be psychologically ready to face the possible diagnosis during different examinations being aware both of the clinical implications and of the potential benefits. Once intestinal endometriosis has been confirmed by the radiologist (figures 3A-B) important discussion needs to take place with patients on topics such as that endometriosis is a benign condition and that after surgery the woman can expect a dramatic improvement in their quality of life. It is the duty of the primary gynaecologist to convey this, since each case is evaluated on the basis of the impact of the disease on the physical, mental and social well being of the patient. Only when the woman is fully informed and strongly motivated to perform multidisciplinary surgery will she be referred to the dedicated colorectal surgeon.

The surgical act is the starting point of the therapeutic run for DIE and can only be fully successful if the diagnostic run has optimally prepared both patient and practitioners.

THE RADIOLOGIST

The imaging diagnosis of intestinal endometriosis

The diagnosis of intestinal endometriosis is a controversial subject: surgery is the only available gold standard and imaging techniques are not considered as diagnostic methods for intestinal endometriosis. When DIE is suspected, it becomes essential to know in advance if an intestinal involvement exists, in order to plan preoperatively if an intestinal resection or an easy nodulectomy will be needed¹⁷ and to obtain patient consent before surgery. Ultrasonography and MRI are the most diffuse and well

TABLE 1 – Clinical characteristics of patients. VAS = visual analogue scale; EI = endometriosis index; ASRM = American Society of Reproductive Medicine endometriosis score; data are expressed as mean \pm standard deviation for continuous variables or as number (%) for categorical variables; Mann-Whitney test for continuous variables, Fisher exact test for categorical variables; † Independent sample t-test was used to test difference in mean age between groups.

	Deeply Infiltrating Endometriosis (n = 29)	No diagnosis of DIE (n = 91)	p†
Age (years)	35 \pm 5	37 \pm 6	0.1
Familiarity of endometriosis	2 (7)	2 (2)	0.2
Current infertility	15 (52)	31 (34)	0.1
Missed school/work (days/month)	8.3 \pm 8.1	2.6 \pm 4.6	< 0.001
Sleep impairment (nights/month)	1.2 \pm 2.3	0.4 \pm 1.8	0.006
VAS for daily activity restriction	5.3 \pm 2.3	2.5 \pm 2.4	< 0.001
VAS for dysmenorrhea	7.7 \pm 1.8	5.1 \pm 3.2	< 0.001
VAS for non menstrual pelvic pain	4.2 \pm 3.0	2.0 \pm 2.6	< 0.001
VAS for dyspareunia	4.8 \pm 3.2	2.2 \pm 2.8	< 0.001
ASRM score	51.5 \pm 31.5	19.0 \pm 24.9	< 0.001
EI scores before surgery	33.0 \pm 10.1	14.9 \pm 9.2	< 0.001
EI scores after surgery	5.4 \pm 3.1	3.9 \pm 2.9	0.01

*VAS = visual analogue scale; EI = endometriosis index; ASRM = American Society of Reproductive Medicine endometriosis score; data are expressed as mean \pm standard deviation for continuous variables or as number (%) for categorical variables; Mann-Whitney test for continuous variables, Fisher exact test for categorical variables; † Independent sample t-test was used to test difference in mean age between groups.

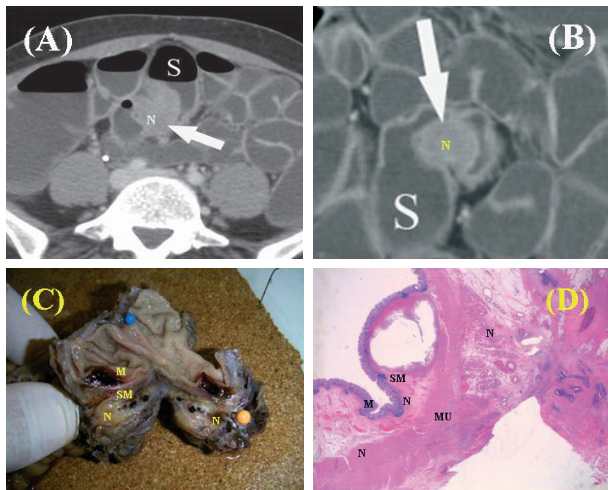


Fig. 3 – Intestinal endometriotic nodule. S = Sigmoid colon. N = endometriotic Nodule. M = Mucosal layer of intestine. SM = Sub-mucosal layer of intestine. MU = Muscular layer of intestine. (A) Axial scan of multislice CT: the arrow shows the nodule of infiltrating endometriosis. The homogenous margin of the nodule suggests that the mucosal layer is not infiltrated. (B) Coronal multislice CT reconstruction: the nodule involves the sub-mucosal layer and the regular profile bulges the mucosa, not infiltrated. (C) Photograph of the resected tract of sigmoid colon affected by endometriosis. (D) Hematoxylin-Eosin section of the tract of sigmoid colon massively infiltrated by endometriosis.

known imaging techniques in DIE detection.¹⁸ These two techniques are both non invasive and have the advantage of being radiation free.

The double contrast barium enema

The double contrast barium enema is the classic radiological technique used in colon evaluation and scientific literature has long reported on the use of this technique in intestinal endometriosis detection.¹⁹

However, there are well known limitations to this imaging and diagnostic approach. The double contrast enema is a radiological technique targeted towards mucosal layer evaluation: its main limitation is the inability to investigate the anatomy around the colon. It is possible to visualize defects to the mucosal layer (tumours, polyps, diverticula and other endoluminal lesions) but pathologies outside the colon wall (abscesses, expansive masses, parapsychological impressions from other extraintestinal organs) are only indirectly detectable. Endometriosis involves the intestine from outside the wall, it is a pathology deriving from the peritoneum or from a sub-peritoneal space. Radiographic findings are constituted to and described as masses extrinsic to the colon wall, with irregular and speculated limits, determining thin defects of the parietal profile.^{20,19} Because of this, more than one type of test must be carried out in order to distinguish endometriotic nodules from other wall anomalies (diverticula, neoplastic lesions, extraintestinal metastatic lesions with peritoneal diffusion), which can imitate the endometriotic pattern of the lesion.

The Magnetic Resonance Imaging (MRI)

Endometriotic lesions have a typical signal in MRI: high intensity in T1 weighted images and in T2 weighted images. This hyperintensity persists in the T1 weighted sequences after the fat suppression (fat sat techniques) giving diagnostic value to MR.²¹ The haemorrhagic content of the nodules and the histologic structures (glands and epithelium) determine the signal pattern in MR sequences. Particularly in MRI the fat saturation technique is mandatory to complete the differential diagnosis between endometriotic lesions and

a teratoma.²² When we use MRI criteria based on signal differences between T1 and T2 as above described, the sensibility and specificity referred to in literature to diagnose endometriosis are 90 and 98% respectively.²³ These principles can also be used to diagnose other endometriotic implants in the abdomen or pelvis. However, the structural components of the endometriotic nodule are variable and not always visible. The fibrotic component of the nodules is frequently high and they can be poorly vascularized, with a minimal content in gland and epithelium. These differences give a low nodule signal and a poor signal rising after i.v. paramagnetic contrast medium.

To detect an intestinal endometriotic lesion a careful study of the intestinal wall is needed: peristalsis and colonic content reduce image quality and limit its sensitivity. The challenge is to measure the depth of wall penetration to distinguish the adventitial lesion from nodules infiltrating the muscularis propria.

The MSCT-enteroclysis

Recently the MSCT-enteroclysis has been proposed as a method to detect and characterize such intestinal wall lesions of endometriotic origin. The intestine must be properly prepared before the study, in order to give an accurate and complete evaluation of the intestinal wall. The more frequently used intestinal cleansing protocol is similar to the pre-colonoscopy protocol. It is very important to clean the intestine without irritating the mucosa and to avoid using drugs that cause intensive mucosal irritation after cleansing. Just before the volumetric scan starts, the patient undergoes intestinal distension with a transparent enteroclysis, using water at physiological temperature (37°C) to limit patient discomfort. Around 2000-2200cc of water is used to obtain an homogeneous distension of the whole colon. Hypotonisation with Joscine bromide (Buscopan, Boehringer, Florence, Italy) injected i.v. or diluted in 30 cc of saline solution can also reduce patient discomfort and intestinal peristalsis. Using this method, parietal defects are detectable at the mucosal surface as well as around the intestinal wall. The contrast value windows between the intestinal lumen (hypodense because of the water inside), the intestinal wall (enhanced after the intravenous injection of the iodinated contrast medium) and the pericolic structures (fat, vessels, peritoneum, viscera), give an ideal visualization of the solid endometriotic nodules. The pharmacological hypotonisation reduces the risks due to peristalsis artifacts. Endometriotic nodules appear solid and poorly vascularized after the iodinated contrast medium injection (figures 3A-B). Intestinal involvement of endometriosis is different to other intestinal lesions, since it infiltrates the intestine from outside normally leaving the mucosa intact and not causing damage to the anatomy of the wall. This allows us to differentiate diagnosis with other pathologies of the intestinal wall, such as lymphoma or adenocarcinoma, deriving respectively from the submucosa and from the mucosal layer. The MSCT-enteroclysis technique has several advantages, it is a very quick method and provides us with a high temporal resolution: modern scanners can cover the whole abdomen in few seconds with a single volumetric acquisition. The radiation dose is greatly reduced and thanks to the variability of technical parameters it is possible to optimize x-ray techniques, especially since patients are normally of reproductive age.

However, MSCT findings of solid intestinal nodules always require the differential diagnosis between endometriotic nodules and other solid lesions involving the colon wall from the outside, for example ovarian cancer or peritoneal lesions. The main characteristic of MSCT-enteroclysis is that it could become a “one-stop-shop” technique in the preoperative management of intestinal endometriosis.

MSCT information is important for the gynecologist and his team in preoperative planning. By knowing if intestinal endometriosis is present and establishing whether other professionals, such as an urologist, are needed to be involved, all can guarantee a good surgical result.

THE COLORECTAL SURGEON

The colorectal surgeon (CRS) carries out both a diagnostic and therapeutic role in patients affected by intestinal endometriosis. In DIE, 22.7% of the nodules are located in the intestine and two thirds of these are found distally from the rectosigmoid junction.²⁴ The symptoms indicating intestinal involvement are constipation, tenesmus, perineal or rectal pain during defecation and more rarely rectal bleeding. They are often worse in correspondence with the time of menstruation and can sometimes be of such intensity that they can disable the patient.

During the diagnostic phase the CRS makes an appropriate anamnesis and a subsequent clinical examination including a proctoscopy. Two types of information can be deduced: the first is a confirmation of the DIE diagnosis, since its symptoms could also be attributed to other colo-proctological (CP) pathologies. The second is to give a presumable level of intestinal involvement, especially when the rectum is affected, as in the majority of cases.

Pelvic nodules are detected either through direct palpating or by causing pelvic pain through the anterior rectum wall. Bimanual digital exploration allows to completely evaluate the level of involvement of the rectovaginal septum. The preservation and functioning of the anal sphincters are also checked during the examination: this is extremely important should a lower rectal resection be necessary. The clinical exam is completed by a rigid proctoscopy. A vision of the mucosa allows us to evaluate its and possible cause for rectal bleeding. Rectal distention by air insufflation may trigger pelvic pain, while palpation of the anterior rectal wall with the proctoscope helps to localize the height of involvement by measuring its distance from the anus. An accurate diagnosis can therefore be made and the CRS is able to properly inform the patient about the extent of resection, its possible complications and the eventual need of a protective stoma in the case of a low colorectal or coloanal anastomosis.

Familiarity with this type of patient can also lead the CRS to recognize other possible DIE patients referred to him for constipation or pelvic pain. Moreover, the CRS could reach this type of diagnosis after investigating the duration of symptoms and the eventual association with dyspareunia and dysuria and refer them to the gynecologist. During surgery the CRS mobilizes the rectosigmoid tract starting on the left side allowing for an identification of the ureter which must be isolated up to its distal portion. During posterior bowel isolation it is important to both protect the superior hemorrhoidal artery and spare the hypogastric nerves until a sigmoid or rectal resection is decided. Access to mobilize the rectum is ideally gained through the avascular 'holy plane'. When the recto vaginal septum is involved a posterior isolation of the rectum below the nodule is advised, to better see the intestinal wall and the compromised area. This way, once the nodule is freed from the genital sides, the rectum is nearly completely distally isolated and ready for "en block" resection. The experience of the CRS is highly evident in the cases where an evaluation of how appropriate a local removal of a nodule infiltrating the intestinal wall at a superficial level must be made. This can be done using the peeling technique of the rectal wall or nodulectomy with partial resection or disk resection.²⁵

The peeling technique has the advantage of preventing bowel opening but carries a greater risk of incomplete

excision, reported in literature as more than 67% [26-36]. Another risk is to miss a possible micro-perforation, which can be the cause of pelvic peritonitis in the post operative period. The hydropneumatic test (visualization of bubbles in the pelvis filled with water after air insufflation of the rectum) is a way to highlight their presence. It is often preferred to carry out segmental bowel resection with subsequent high or low colorectal anastomosis. Guidelines do not currently exist to help decide between nodulectomy or resection. The decision is still made on a case to case basis for the majority of patients, since different factors such as depth of infiltration, multicentricity of the nodules, involvement of the lymph nodes and their meaning can play a role in the decision making. Abrao et al. state that in 45 cases of endometriosis of the rectum, 42.2% of the cases had multiple lesions and 64% had mucosa and sub-mucosa involvement and of these 89% had more than 40% of the bowel involved. 94% of the cases also had the internal muscle layers involved.¹⁰ This data supports the need for segmental resection in cases of recto sigmoid nodules. The frequency of multi focal lesions is also considered by Kavallaris and Remorgida as an indication of segmental resection.^{35,36} In a study of 26 DIE consecutive cases of rectosigmoid resection 42.3% of the cases showed lymph nodal foci of endometriosis.³⁷

Surgical experience is of paramount importance. This pathology, benign and affecting young patients, often shows very complex case situations of infiltration, involving the distal rectum and various extra intestinal structures (annexes, ureters, bladder, muscles and nerves). The procedure requires surgeons who can guarantee not only a low level of CR complications but also able to perform resections in laparoscopy. There are few abdominal pathologies like DIE, where video laparoscopy is best indicated. Video laparoscopy is considered the gold standard for DIE treatment, reducing post operative adhesions. It is well known how these may complicate possible further surgery and could cause post operative symptoms. Cosmetics reasons should not be underrated since patients are sometimes very young. In order to minimize alterations of the abdominal wall, the removal of the specimen, after rectal or colon resection, through the vagina has also been proposed:³⁸ in this study, conducted on 33 patients, dyspareunia was not found. The results of using video laparoscopy surgery to treat DIE show high rates of conversion. Generally, surgery complication levels are higher than those for cancer surgery. In the Emmenuel and Davis review³⁹ a generally accepted level varies between 10 and 30%, even if Jerby gives a reduced level of complications specific to resective surgery in video laparoscopy.⁴⁰ The incidence of anastomotic fistula varies between 0 and 17%, while the incidence of a recto vaginal fistula is higher than 10%. In more than 30% of cases changes in urinary and intestinal functions are found. As mentioned before, it is necessary to carry out a temporary stoma in a notable number of patients (between 2 and 10%) while this becomes definitive in 0 to 6% of patients. It is difficult to discriminate between the effect of resection from the other associated procedures when considering the remission of symptoms in resected patients. The little long term data in literature shows that patients submitted to intestinal resection have a complete remission of pelvic pain with follow up varying between 15 and 40.5 months.⁴¹⁻⁴⁵ Dubernard recently demonstrated how the QOL SF-36 can forecast the improvement in the quality of life after colon resection due to endometriosis through laparoscopy and how this improvement is highly significant in the majority of patients.⁴⁶ Few studies refer to the fertility outcome after intestinal resection due to DIE: data varies between 23 and 52%. Many of these patients have undergone associated procedures such as annessiectomies, removal of ovarian cysts and hysterectomies. It is therefore very difficult to evaluate the impact of intestinal resection on fertility and

further studies are needed. Much rests in the understanding and exploration of DIE and prospective multicentric studies on a high number of patients with adequate follow up are necessary to verify the impact of treatment. These studies necessitate a classification instrument of patients and their pathology, such as the one proposed in this paper. This would record cases consistently, provide a specific database and reference point for the various professionals involved, constituting an essential instrument for scientific progression in this subject.

CONCLUSIONS

As awareness increases towards endometriosis and the full effects of its impact on the quality of lives of the women affected come to light, the need to work on adding information on etiology, physiopathology and natural history of intestinal DIE becomes more urgent.

On the basis of recent evidence in literature, intestinal endometriosis is neither often diagnosed nor managed in a standardized or appropriate manner. A very high number of patients receive "hit and miss" treatments, often resulting in surgery that does not eradicate the real problem. This is the main reason that explains the difficulty of understanding if we have a real recurrence of endometriosis or a disease that has never been treated, despite previous operations. The MSCT-enteroclysis and MRI play complementary roles in DIE diagnosis. They are crucial in recognizing deep endometriosis and in detecting intestinal wall infiltration. These techniques need to have a more established position in the diagnostic approach of DIE. The future imaging of DIE probably will be, in the majority of cases, "x-ray free": our goal must be to improve the MR approach, which up to now has not always been used in intestinal infiltration detection. In order to detect DIE we must evaluate the recto-sigmoid colon wall during pelvic examination and a combined study named MR-enteroclysis of the colon must be further developed. A complete assessment and pre-surgical diagnosis of DIE is crucial. These steps have to be made by the Gynecologist, Radiologist and CRS in a multidisciplinary setting in order to be able to provide all the necessary information to the patient and obtain their consensus before surgery. The team should have a standardized and validated score to quantify both the aggressiveness of the disease on different organs and on the quality of life of these women. We propose software assistance in order to save and analyze all the clinical variables from patients before surgery; this instrumental support would allow to evaluate the real benefits of surgery on DIE in an objective way.

Once a correct diagnosis is made we consider it mandatory to decide with the patient, whether or not to perform intestinal surgery. It is presumed that a unique and radical operation gives the best chance for a long lasting full recovery and a better quality of life.

It is very important to identify the real indication for surgery and the wishes of the woman at this stage. The possible scenarios are essentially three: low quality of life, infertility and a low quality of life associated to infertility. Endometriosis is not a malign condition and radical surgery can have major complications (intestinal, urinary, vascular etc); in the diagnostic-therapeutic run we propose that the patient decides on their own 'customised' treatment.

Once intestinal surgery is accepted by the patient, the operation has to be radical and when possible performed laparoscopically. The endoscopic approach gives better cosmetic and functional results, and reduces risks connected to intestinal adhesions. The operative modalities have to be decided based on factors such as motivation, age, maternity desire and comorbidities of the patient. The surgery has to be multidisciplinary and performed by a dedicated and trained

team of a colo-rectal surgeon and gynaecologist who are also expert in laparoscopy. In our opinion gynaecologists, radiologists and colo-rectal surgeons have to coordinate their efforts in order to create centres dedicated to patients affected by intestinal DIE and to promote a flow of information both on the existence and the prevalence of this pathological condition and develop consensus statements on his treatment.

It is mandatory for the immediate future to stimulate clinical research with prospective multicentric studies enrolling patients who are then classified and treated in a standardized manner.

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Transperineal rectocele repair with porcine dermal collagen implant. A two-year clinical experience

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Abstract: Purpose: Symptomatic rectocele results in obstructed defecation and constipation. Surgical repair may provide symptomatic relief. A variety of both synthetic and nonsynthetic graft materials have been used in the rectocele repair to enhance anatomical and functional results, and to improve long-term outcomes. Methods: In this prospective study we treated a series of 10 women suffering from symptomatic rectocele with transperineal repair using porcine dermal acellular collagen matrix BioMesh (Pelvicol™). Results: Follow-up ranged from 2 to 20 months and all patients demonstrated good anatomical results; thus far there have been no difficulties with delayed healing. There were no major intraoperative or postoperative complications (infection, abscess, hematoma, either vaginal or rectum injury, transfusion). There have been no complaints related to bowel function, and those patients who were sexually active prior to surgery have not experienced problems with sexual function or dyspareunia. Conclusions: Rectocele repair with Permacol® by the transperineal approach seems an effective and safe procedure that avoids some of the complications associated with synthetic mesh use. Randomized prospective studies with long-term follow-up and documentation of both safety and efficacy using validated questionnaires and quality of life surveys are warranted to confirm these results.

Keywords: Rectocele, Obstructed defecation, Biofeedback, Biomesh.

INTRODUCTION

Rectocele is an herniation of the rectum through the rectovaginal fascia and posterior vaginal wall causing a protrusion into the vaginal lumen. It's a common disorder in women with history of multiple vaginal deliveries and it is asymptomatic in 80% of cases. Symptomatic rectocele is less common, usually affects postmenopausal females, and results in obstructed defecation and constipation.

Surgery should be considered when conservative therapy fails and a careful patient selection, based on an accurate morpho-functional assessment, is crucial to obtain a satisfactory outcome^{1,2}.

The purpose of surgical repair in the management of rectocele repair are essentially the restoration of normal vaginal anatomy and the restoration or maintenance of normal bladder, bowel, and sexual function^{1,2}.

Transperineal repair of the fascial defect may provide restoration of normal anatomy and symptomatic relief. A variety of both synthetic and nonsynthetic graft materials have been used in the rectocele repair to enhance anatomical and functional results and improve long-term outcomes.

Recent advances in pelvic reconstructive surgery are due in part to the availability of new graft materials that allow reinforcement and repair of large pelvic fascial defects minimizing adverse graft-related effects and infections. Porcine acellular collagen matrix (Permacol®) seems to relief symptoms minimizing postoperative complications¹⁻⁵.

This prospective study was designed to assess the short and medium-term outcomes and the safety of transperineal rectocele repair with an acellular porcine dermal collagen implant (Permacol®) in a cohort of 10 women with symptomatic rectocele after medical treatment failure.

MATERIALS AND METHODS

Between January 2008 and January 2010, 10 women presenting with symptomatic rectocele after medical treatment failure, were evaluated and surgically treated at the Division of General Surgery of the Department of Surgery, Tor Vergata University Hospital, Rome.

All the patients underwent a pre-treatment evaluation, which included anamnesis, concerning pregnancies, episiotomy, previous gynaecological, urological, or ano-rectal surgery and symptoms, clinical examination of the perineum, rectum and vagina, anorectal manometry, anoscopy and defecography.

Anorectal manometry was performed at rest, after voluntary contraction (ie, the maximal voluntary increase above the resting tone) and during straining. At defecography, resting state, voluntary and maximum contraction of the sphincter and pelvic floor muscles, and straining during defecation were recorded. Rectal emptying was also assessed. X-ray films were taken in each position and dynamic assessment of the defecation was also obtained.

All patients were operated on by the same senior surgeons (G.M.).

Written informed consent had been obtained from all the subjects after a full explanation of the procedure.

Regarding the surgical technique, a transverse perineal incision was made, and the plane between the external anal sphincter and the posterior vaginal wall was developed with diathermy to ensure meticulous hemostasis. The dissection was extended to the vaginal apex to expose the rectocele, the perirectal fascia and the levator arc. Following the site-specific repair, four to five absorbable sutures (2/0 Vicryl, Ethicon, Somerville, N.J., USA) were placed in the levator arc, beginning near the vaginal apex and continuing distally toward the perineal body. A Permacol® BioMesh was affixed to these sutures and laid in place in the rectovaginal space. Using the same type sutures, the graft was then sutured to the levator arc on the opposite side followed by closure of perineal incision.

A vaginal pack and urinary catheter were placed for the first 24 h. Prophylactic antibiotics and antimicrobial irrigation solution were used to decrease the risk of postoperative infection. In every patient metronidazole was given intravenously at the beginning of the operation and after surgery for 5 days (500 mg three times daily).

Patients were clinically assessed at the first follow up visit up to 7 days after the operation. Subsequently they were followed up every 15 days for the first 2 months and follow up controls were planned at 6, 12, 24 and 36 months.

Demographic data faecal continence and complications were recorded. Degree of continence was scored according to the Wexner continence score.

The scoring system of Watson⁶ was adopted for evaluating the clinical symptoms of perineal digitation, straining, incomplete evacuation, and vaginal bulging. Each symptom was graded from 0 to 3, and the maximum total score was 12.

For objective evaluation of anatomic repair, the patients were examined on the proctologic examination table by an

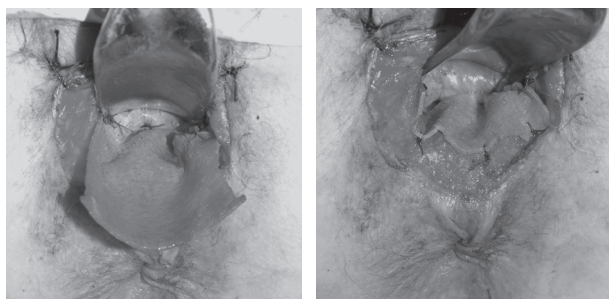


Fig. 1. a,b – Transperineal rectocele repair with biomesh. The mesh is placed in the recto-vaginal space and fixed with interrupted sutures to the levator ani plate on both sides.

independent observer with a finger inserted in the rectum to elevate the anterior rectal wall.

The quality of life was evaluated using SF-36 questionnaire. During follow up visits all patients were submitted to clinical examination of the perineum, rectum and vagina, digital exploration and anoscopy. Rx defecography was performed at 2 months follow up Rx defecography was planned at 12, 24 and 36 months.

All statistical elaborations were obtained by using Statistics for Windows (Statsoft; Tulsa, Okla, USA). The results were expressed as mean \pm standard deviation (\pm SD); Wilcoxon's signed-rank test was used for differences between preoperative and follow-up symptom scores. $P < 0.05$ was considered as significant.

RESULTS

Between January 2008 and January 2010, 10 women presenting with symptomatic rectocele after medical treatment failure, were evaluated and surgically treated at the Division of General Surgery of the Department of Surgery, Tor Vergata University Hospital, Rome.

The study was approved by the Institutional Committee of the Tor Vergata University of Rome.

Baseline characteristics of patients are showed in table 1. Follow-up ranged from 2 months to 20 months.

At 2 months, the mean total Watson score was significantly lower than the preoperative score ($P < 0.0001$) (table 2) and every patient has demonstrated good anatomical results.

There were no major intraoperative or postoperative complications (infection, abscess, hematoma, rectal or vaginal injury, blood loss, or transfusion).

One case of urinary infection solved with antibiotics was recorded. One patient had delayed wound healing of the perineal incision with completed wound healing 21 days after the intervention.

At two months follow up, there have been no complaints related to bowel function, and those patients who were sexually active prior to surgery have not experienced problems with sexual function postoperatively. The anterior rectocele was significantly reduced in size (< 2 cm) in all patients after surgery at defecography.

Improvements in the mental and physical component scores of the SF-36 were recorded but were not statistically significant ($p > 0.05$).

Five patients were followed up at 12 months. No patient experienced sexual function problems; two patients referred straining grade 2 and showed a rectal wall bulging of 2 cm at defecography.

DISCUSSION

The goal of surgery in the management of rectocele are the restoration of normal anatomy and the restitution or maintenance of normal bowel and sexual function¹⁻³.

Three different approaches have been reported for rectocele repair: transanal approach which consists of mucosal resection and anterior rectal wall plication; transvaginal approach which includes excision of part of the posterior vaginal wall and anterior levatorplasty; finally the transperineal approach which consists of extraluminal anterior access to the rectocele and biomesh placement in the rectovaginal space^{4,7-11}.

Both transanal and transvaginal repairs have shown several limitations: resting and squeeze pressure reduction after transanal repair; dyspareunia and obstructed defecation persistence after transvaginal repair⁷.

Rectocele repair with biomesh (Permacol®) by the transperineal approach seems an effective and safe procedure that avoids some of the complications associated with synthetic mesh use¹¹.

Permacol® is an acellular sheet of porcine dermal collagen in which the collagen fibers have been cross-linked using diisocyanate to avoid graft biodegradation. Permacol® is not cytotoxic, hemolytic, pyrogenic or allergenic and it has been helpful in inguinal, incisional and parastomal hernia repairs. Permacol® seems especially helpful in the perineal repairs that are at high risk of wound contamination that would contraindicate the use of synthetic meshes given the possibility of chronic infection and fistulation^{11,12}.

TABLE 1. – Baseline characteristics of patients.

Patient	Age	Mean Resting Pressure	Mean Squeeze Pressure	Asimmetry Index At Rest	Asimmetry Index At Squeeze	Defecographic pattern
1	58	36,5	48,2	43,5	35,1	Rectocele 3 cm; incompl emptying
2	37	37,6	67,3	35,6	36,5	Rectocele 3,5cm; incompl emptying
3	46	30,9	38,9	39	40,7	Rectocele 2.5 cm; incompl emptying
4	26	58,3	61,5	44,8	28,3	Rectocele 4 cm; incompl emptying
5	48	61,2	93,7	25,1	15,4	Rectocele 3cm; incompl emptying
6	55	55,9	98,8	28,7	22,4	Rectocele 5 cm; incompl emptying
7	25	14	31	30,7	25,2	Rectocele 3,5 cm; incompl emptying
8	70	36,7	56,8	27,8	19,8	Rectocele 5 cm; incompl emptying
9	65	39,2	49,5	48,2	42,5	Rectocele 3,5 cm; incompl emptying
10	47	36,5	48,2	43,5	35,1	Rectocele 4.5 cm; incompl emptying

TABLE 2. – Symptoms' score of the patients

Symptoms	Preoperative	Postoperative	P*
Perineal digitation	2.52 ± 0.53	0.67 ± 0.58	0.0001
Straining	2.61 ± 0.57	0.14 ± 0.41	0.0001
Incomplete evacuation	2.45 ± 0.75	0.53 ± 0.60	0.0001
Vaginal bulging	2.34 ± 0.62	0.26 ± 0.44	0.0001
Total	9.65 ± 1.83	1.61 ± 0.55	0.0001

Actually, given the immediate contact between vaginal, rectal wall and underlying host tissues through fenestrations in the mesh graft material, delayed healing and infective complications seem less frequent.

In a recent experimental study¹³ comparing intraperitoneal implantation of polypropylene versus dermal collagen in 16 rats, histological examination at 4 weeks showed intense inflammatory response with disorganized collagen in the polypropylene group and minimal inflammatory response with thin collagen in the collagen group.

Similarly this histological view showed vascular ingrowth stimulated by collagen mesh 14 days after dermal collagen implant in an experimental model.

If we overview the literature, although there are only few clinical studies, good results have been reported by all the authors in line with our experience⁹⁻¹⁶.

Smart and coworkers¹⁰ recently reported a series of 10 women treated with transperineal biomesh implant. Eighty percent of treated patients referred constipation improvement, 70% reported improvement of vaginal bulging. Two cases of perineal hematoma and one case of dyspareunia were recorded in absence of infections and relapse.

In a larger trial Leventoglu¹⁴ treated 84 women with symptomatic rectocele with transperineal collagen implant. Anatomic repair was assessed in 89% of patients and there was a significant improvement of constipation and vaginal bulging. Morbidity rate was 8%. Neither mesh infection nor mesh rejection nor sexual function worsening were detected.

Considering the results of transvaginal biomesh repair, Kohli and co-workers successfully treated 43 women with rectocele using transvaginal biomesh repair and reported no defecatory and vaginal symptoms in all patients 12 months after the operation.

Dell and co-workers⁹ recently reported a series of 35 patients successfully treated with porcine dermal collagen bioMesh in absence of major complications. Neither defecation disorder nor vaginal bulging were referred after the operation at an average follow up of 12 months.

Finally, Altman and coworkers^{12,17} reported a series of 29 patients treated with transvaginal implant of biomesh with defecation and vaginal bulging improvement. At 12 month follow up 14 women had no rectocele.

More recently, Novi¹⁶ studied sexual function after rectocele transvaginal biomesh repair in 100 women with questionnaires to evaluate quality of life and symptoms relief and found improvement of sexual function in absence of dyspareunia.

In summary, transperineal rectocele repair with biomesh seems an effective and safe procedure that avoids complications associated to synthetic mesh use avoiding rectal sutures and preserving both rectum and vagina^{18,19}. However, large randomized prospective studies are warranted

to confirm these results and to explore mid and long term effects regarding relapse, sexual and gastrointestinal function.

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Detrusor instability is a rare presentation of pelvic subserosal fibroma, seven years following a total abdominal hysterectomy and bilateral salpingo-oophorectomy: Case report

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Abstract: Solitary Fibrous Tumours (SFT) are uncommon, slow growing, well-circumscribed tumours arising from the mesenchyma. These tumours were first described in the thoracic cavity, originating from the pleura but have since been reported in various sites including the prostate, bladder, peritoneum, soft tissue, liver and kidney. This case report describes a 40 year old woman, presenting with symptoms of detrusor instability due to a midline solid, discrete pelvic mass, centred above the bladder, with displacement of the sigmoid colon evident on CT scan. Histology revealed a 'subserosal fibroma'. This article describes the current literature relating to pelvic solitary fibrous tumours.

Key words: Subserosal fibroma; Solitary fibrous tumours; Detrusor instability

INTRODUCTION

Solitary fibrous tumours (SFT) or commonly known as fibromas, were first documented at the turn of the 20th century, originating in the intrathoracic cavity, typically from the pleura. Fibromas are slow growing, well circumscribed, spindle cell neoplasms arising from the mesenchyma. Since the 1960s, there have been an increasing number of case reports describing fibromas in extrathoracic sites including the orbit, meninges, upper respiratory tract, thyroid, salivary gland and spinal cord. In the last 20 years, reports of fibromas have been documented in the peritoneum, retroperitoneum, urinary bladder, uterus, cervix, vulva, vagina, paravaginal space, ischioanal fossa and fallopian tube¹⁻⁸.

The presentation of pelvic solitary fibrous tumours remains highly variable and related to anatomical relationships and size⁴. SFT are commonly asymptomatic, but compression on adjacent structures has been associated with bowel obstruction and bilateral ureteral obstruction⁴, vaginal bleeding or dyspareunia¹⁰. There have been case reports of systemic features such as arthralgia and hypoglycaemia in cases of extrathoracic SFT^{1,5,8}. This case report describes a unique presentation of a pelvic fibroma with detrusor instability following a total abdominal hysterectomy and bilateral salpingo-oophorectomy.

The search strategy used in Medline included the key words; solitary fibrous tumour, pelvis and subserosal and the subject headings; neoplasms fibrous tissue and fibromas. Hand searching methods were also employed. There were 14 english articles pertaining to solitary fibrous tumours in the pelvis.

CASE REPORT

A 40 year old woman was referred by her general practitioner (GP) because of stress urinary incontinence, urgency and urge incontinence. She was seen in the urogynaecology clinic and stated that these symptoms started few years ago but have worsened recently. She passes urine up to 8 times during the day and once during the night. Seven years ago she had total abdominal hysterectomy and bilateral salpingo-oophorectomy for pelvic endometriosis, confirmed by histological examination. It was stated in the operative notes that no residual disease was left. She had been on annual oestradiol implants since her procedure. Recent testing of midstream urine sample arranged by her local doctor did not show any urinary tract infection. She had two children via normal vaginal delivery. There was no other past medical or surgical history of significance.

On examination, she was generally well with abdominal palpation normal. Pelvic examination revealed a normal vulva and vagina with no genital prolapse. Bimanual

pelvic examination revealed a large solid mass that was felt centred in her pelvis. The urodynamic assessment revealed no residual urine with normal uroflowmetry. Detrusor instability was demonstrated and associated with significant urgency but no urge incontinence. No urodynamic stress urinary incontinence was demonstrated. A pelvic ultrasound was arranged and a blood test to check for serum tumour markers (CA 125, CA 19.9 and CEA).

On her follow-up visit, all tumour markers were well within normal limits. The pelvic ultrasound showed a midline solid pelvic mass measuring 9.1 x 8.5 x 8.4 cm. There was no evidence of hydronephrosis in either kidneys and no ascites. Due to uncertainty of the origin of the mass, a CT scan of the pelvis and abdomen was arranged.

Portal venous and delayed phase multi-detector spiral CT scan showed a solid pelvic mass centred to the right of midline but occupying the greater part of the lesser pelvis. It measured 10.7 x 8.5 x 10.2 cm. It was centred above the bladder but separate from it. The mass displaced the sigmoid colon superiorly and was adjacent to the vaginal vault. No definite organ of origin could be identified. There was very small volume of ascites but no intra-abdominal lymph node enlargement. The kidneys, liver, spleen, pancreas and adrenal glands were normal. The CT images of from this case study are shown in Figure 1.

Due to the past history of the total abdominal hysterectomy and bilateral salpingo-oophorectomy along with the uncertainty of the origin of the mass she was referred to the surgical team. The findings from the laparotomy by the surgical team revealed a large pelvic mass, which was adhered to the sigmoid colon. The procedure was complicated by the presence of vascular adhesions. The bowel was separated from the mass uneventfully and the mass was completely removed. The histology of the mass was reported as a subserosal fibroma with no malignant changes seen.

The patient made a complete recovery. No postoperative urodynamic assessment was performed due to complete resolution of her urinary symptoms following her surgery. At the 2 year follow up appointment, she remained symptom free.

DISCUSSION

This case report outlines the significance of considering solitary fibrous tumours as a differential diagnosis for a pelvic mass resulting in common urogynaecological presentations. The differential diagnosis of a pelvic fibroma most commonly includes leiomyoma or leiomyosarcoma, hemangiopericytoma and fibrosarcoma³.

In 1997, Chan proposed diagnostic criteria for solitary fibrous tumours, with the essential diagnostic features

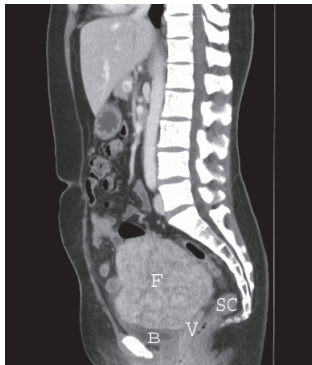


Fig. 1. – Is a sagittal section from the portal venous and delayed phase spiral computerised tomography of the patient in this case study. This figure illustrates clearly the subserosal solitary fibrous tumour in the paravaginal space, centered above and compressing the bladder along with displacing the sigmoid colon. The mass measures 10.7 cm anteroposteriorly x 8.5 cm wide x 10.2 cm craniocaudally (SC: sigmoid colon, B: bladder, V: vagina and F: fibroma).

including circumscription, hypercellular and hypocellular foci, short spindly with scanty and poorly defined cytoplasm, haphazard, storiform or fascicular arrangement of spindle cells, intertwining of thin or thick collagen and CD 34 positive. Immunohistochemical markers such as CD 34 are used to further differentiate solitary fibrous tumours from myofibromas, neurofibromas, nodular fasciitis, dermatofibroma and dermatofibrosarcoma protuberans¹⁰. The CD 34 antigen is a transmembrane glycoprotein on the cell surface that is widely used as a vascular marker¹². Positive markers for solitary fibrous tumours include bcl-2, CD 99 and CD 34.

The majority of extrathoracic solitary fibrous tumours follow a benign course. Chan and colleagues found that malignancy was documented in 13% of extrathoracic SFT, compared with the 23% of intrathoracic tumours. A review article examining the histological features and outcome of 7 cases of retroperitoneal solitary fibrous tumours found there was local recurrence in one case, associated with incomplete resection³. Chan believes this observed difference is due to the more recent recognition and reporting of the extrathoracic solitary fibrous tumours, rather than a lower malignant potential. Therefore, histopathology can not always predict the clinical behaviour, and follow up is essential¹².

The importance of imaging of palpable pelvic masses is essential in the diagnosis and planning for surgical management (see Figure 1 and 2). MR imaging of the pelvic region may be useful in further distinguishing the tissue of origin and has an important role in staging of pelvic tumours, although imaging modalities have not been specifically defined for solitary fibrous tumours¹³. Colour or Power Doppler ultrasound and MRI have been shown to further differentiate subserosal myomas from extrauterine tumours¹⁴. Interestingly, one case report describes central malignant degeneration of an extrathoracic SFT in the pelvis of a 61 year old man, which was detected on CT and MRI¹⁵.

In this case study, the significance of the previous total abdominal hysterectomy and bilateral salpingo-oophorectomy 7 years prior to this presentation is most probably unrelated to the subserosal fibroma but contributed to a more complicated surgical resection. There has been only one case report in the literature that described a benign solitary uterine leiomyoma on the pelvic peritoneum following a hysterectomy for subserosal fibroids 5 years previously¹⁶.

The ability to resect the extrathoracic solitary fibrous tumours is the major determinant of prognosis and ongoing surveillance is essential¹². While the recognition of extrathoracic solitary fibrous tumours has evolved in the last 20 years, the epidemiology, pathophysiology and long term prognosis of this mesenchymal tumour remains uncertain.

Most cases of detrusor instability are idiopathic in nature.

When a pelvic tumour compresses on the bladder and causes urinary symptoms, urodynamic assessment is more likely to reveal stress urinary incontinence rather than detrusor instability. Pelvic tumours can irritate the bladder and result in detrusor instability.

No postoperative urodynamic assessment was performed in this patient as she continued to be asymptomatic until she was last seen 2 years after her surgery.

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QOL audits of TVT surgery applied to small patient numbers are a worthwhile addition to clinical practice

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Abstract: This paper considers whether a validated quality of life (QoL) questionnaire would be a useful clinical audit tool for practitioners or units who operate for stress urinary incontinence, have a relatively small case-load and who may be interested in using these data for credentialing or reaccreditation. We prospectively evaluated changes in QoL domains using the King's Health Questionnaire (KHQ) in a series of 14 women undergoing a TVT procedure. All women had urodynamically proven stress incontinence and completed the KHQ preoperatively and again between 12-61 (mean 32.8) months after surgery. The women were also asked to complete non-validated analog scale responses to two questions regarding satisfaction with the procedure and the extent of residual incontinence and to indicate whether they would recommend their procedure to a friend. Five of the nine KHQ domains showed clinically and statistically significant improvements in QoL and three domains showed clinically significant improvements which did not reach statistical significance. Six (43%) women were completely dry following their procedure and these were the only women who were completely satisfied. Nine women would definitely recommend the procedure to a friend. Prospective collection of KHQ data provides an estimate of the degree of improvement resulting from treatment and provides a basis for benchmarking of the performance of an individual or group. However, current QoL questionnaires are deficient when it comes to the evaluation of common complications of surgery such as urinary retention.

Key words: Quality of life; Kings health questionnaire; Tension free vaginal tape

INTRODUCTION

Urinary incontinence has a significantly adverse affect on quality of life (QoL).¹ When surgery for stress urinary incontinence is contemplated, currently, the TVT procedure appears to be the operation of first choice. Large, multicentre studies have demonstrated significant improvement in QoL indices following a TVT procedure.^{2, 3, 4} Because of the substantially smaller caseload of individual practitioners there is uncertainty regarding the sensitivity of QoL questionnaires to detect changes in small series. It has not been established if an individual surgeon would be able to demonstrate clinically or statistically significant improvements in QoL parameters. Medical practitioners are increasingly required to produce evidence of satisfactory performance for credentialing and re-accreditation, with demands coming from employers, hospitals and professional colleges. Thus, it is useful to establish if prospective QoL audit has a place for small units and individual practitioners who perform continence procedures.

In this paper we explore the use of the Kings Health Questionnaire (KHQ) - a validated QoL questionnaire⁵ - in the prospective evaluation of a small series of women presenting with urinary incontinence and undergoing a TVT procedure. We determine whether the KHQ could be a useful addition to routine clinical assessment and follow up when continence surgery is planned.

METHODS

Fourteen women presenting for management of urinary incontinence to the Lyell McEwin Health Service in Adelaide Australia completed the Kings Health Questionnaire (KHQ),⁵ as a baseline evaluation at the time of their preoperative urodynamic study and again by postal follow up between 12-61 (mean 32.8) months after their TVT procedure. Preoperatively, nine women reported urge and stress incontinence and five women reported pure stress incontinence. Thirteen women had urodynamically proven stress incontinence and one woman urodynamically proven stress incontinence and idiopathic detrusor overactivity. The women's ages ranged from 37.6 – 82.3 (mean 56.8) years at the time of their procedure and parity ranged from 0-4 (mean

2.3). Two women had previous procedures for incontinence, three had previous prolapse surgery and eight had a previous hysterectomy.

The version of the KHQ that we employed is available in the reference cited⁵ and comprises 21 questions ordered in to 9 domains (table 1). The raw scores for each question, which are in the range of 0-5, are recalculated to a score of 0-100 for each domain where 0 indicates no problem and 100 indicates a very severe problem. A change in a domain score of plus or minus 5% is thought to represent the minimal clinically significant change.⁶ The most recent version of the KHQ is currently available to download from the website of the National Institute for Clinical Excellence (www.nice.org.uk/nicemedia/pdf/word/cg40implmentationadvickehq.doc).

The surgical procedures were predominantly undertaken by trainees under the supervision of a consultant gynaecologist. Four women had a vaginal repair and one woman vaginal hysterectomy and repair in addition to the TVT procedure. The remaining nine women had a TVT procedure only. Clinical records were used to determine demographic details and complications of the procedure.

Three additional non-validated questions were sent with a covering letter accompanying the follow up KHQ. Two questions were "Please choose a number between 1 and 10 to rate your overall satisfaction with your treatment, where 1 = completely unsatisfied and 10 = completely satisfied", and "Please choose a number between 1 and 10 to rate any residual wetness following your treatment where 1 = wet all the time and 10 = completely dry". Women were also asked whether they would recommend this treatment to a friend with the same condition. Possible answers were "Yes", "No" or "Don't know". These additional data were collected to undertake correlation analysis against the KHQ domains to help us to establish if a simplified questionnaire would suffice for routine clinical audit.

The results for the KHQ domains, which were not normally distributed, were analysed using the Wilcoxon Signed Rank test using SPSS for Windows 15. A power calculation for the Wilcoxon Signed Rank Test is not available in this software package. Descriptive statistics and the Spearman rho correlation test were run in SPSS 15.

TABLE 1. – A description of the domains of the Kings Health Questionnaire (Kelleher 1997).

Domain	Number and type of questions	Likert scale
General Health Perception	One question addressing general health not directly related to urinary incontinence	1-5 (very good – very poor)
Incontinence Impact	One question addressing effect of incontinence on quality of life	1-4 (Not at all-A lot)
Role Limitations	Two questions addressing effect of incontinence on ability to perform normal tasks of daily living	1-4 (Not at all-A lot)
Physical Limitations	Two questions addressing effect of incontinence on ability to perform physical exercise and travel	1-4 (Not at all-A lot)
Social Limitations	Two questions addressing effect of incontinence on ability to perform social activities	1-4 (Not at all-A lot)
Personal Relationships	Three questions addressing effect of incontinence on relationships and sex life	0-4 (Not applicable-A lot)
Emotions	Three questions addressing effect of incontinence on emotions and feelings	1-4 (Not at all-Very much)
Sleep/Energy	Two questions addressing effect of incontinence on sleep and energy	1-4 (Never-All the time)
Severity Measures	Five questions dealing with strategies used to manage incontinence, worry and embarrassment	1-4 (Never-All the time)

A repeat analysis of the dataset was undertaken using the statistical functions (paired t-test and correlation) available in Excel, which assume data are normally distributed. This was done because most practitioners do not have ready access to stand alone statistical software and to determine whether the conclusions would be significantly altered by assuming normality of distribution and running the readily available standard parametric tests.

Ethics approval for this study was given by the North Western Adelaide Health Service ethics committee.

RESULTS

Five of the nine KHQ domains showed clinically and statistically significant improvements in QoL (table 2) after the TVT procedures. Three domains showed clinically significant improvements which did not reach statistical significance. In one domain (General Health) there was

no change. These conclusions were not materially altered by re-running the analysis using the parametric statistical functions available in Excel.

Overall, the magnitude of change in QoL was large and in the direction of improvement. The median improvement in score was 50 points or more for five domains and between 16-45 points for three others. The domain General Health showed a deterioration of 12 points in its median value ($p=0.79$).

The postoperative satisfaction and dryness scores each ranged from 1-10 with 10 women recording scores above 5 for both variables. Only six (43%) women were completely dry following their procedure and these were the only women who were completely satisfied with their procedure. Satisfaction and dryness scores were very strongly correlated (Spearman's rho 0.98, $p < 0.001$). The correlations between postoperative KHQ data and satisfaction scores are shown in table 2.

TABLE 2. – Preoperative (before) and postoperative (after) Kings Health Questionnaire (KHQ) data in 14 women undergoing a TVT procedure for urodynamic stress incontinence (p values in column 6 calculated with the Wilcoxon signed rank test). Column 7 shows the Spearman's rho correlation coefficients between the KHQ domains and analog satisfaction scores as reported postoperatively only (* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$).

Domain	Median before	Median after	Interquartil range before	Interquartile range after	p-value	Correlation with satisfaction score
General health	25	37	25-50	0-50	0.79	-0.64*
Incontinence impact	67	16	67-100	0-67	0.01	-0.87***
Role limitations	58	0	29-83	0-54	0.02	-0.69**
Physical limitations	67	0	33-83	0-54	0.01	-0.68**
Social limitations	16	0	8-44	0-25	0.24	-0.62*
Personal relations	50	0	0-87	0-75	0.13	-0.87**
Emotions	56	11	30-81	0-70	0.07	-0.86***
Sleep/energy	50	33	33-83	17-54	0.02	-0.75**
Severity measures	67	17	38-93	0-62	0.02	-0.92***

Complications in this series included one case of bladder perforation (no sequelae), one case of de novo bladder instability, one case of urinary retention requiring postoperative catheterisation for less than 48 hours, one case of urinary retention requiring postoperative catheterisation for less than one week, and two cases of urinary retention requiring catheterisation of up to three weeks, giving an overall rate of urinary retention of 28%.

DISCUSSION

Our data demonstrate that it is possible to show clinically and statistically significant improvements in KHQ QoL domains following TVT procedures in only a small series of unselected cases. The first domain called "General Health" is not expected to be improved by a continence procedure but the remaining eight domains may be expected to show improvement postoperatively, depending on the effectiveness of the procedure and the sensitivity of the instrument. Although possibly due to small numbers in this series three of the KHQ domains did not show a statistically significant improvement, we have shown that the KHQ is sensitive enough to be used by those who wish to audit surgical outcomes in a small case series. The KHQ is simple to administer preoperatively and by mail for post-operative follow up. The main disadvantage of the KHQ and other QoL questionnaires is that data entry and manipulation are required to record the responses to the questionnaire and to recalculate the answers to each question to a percentage score for each domain. This is relatively simple and can be done in Excel, which is inexpensive and widely available.

An alternative to the individual practitioner approach would be for colleges such as the RANZCOG or organisations such as AAVIS to support their members by providing data entry and analytical facilities ideally through a secure web site. The problem of patient confidentiality could easily be resolved by only permitting data entry by de-identified ID number, which would require the practitioner to keep a record of the ID key to permit patient identification through his or her practice.

The question remains whether the KHQ or other QoL questionnaires are worth the effort compared with the simple, non-validated questions regarding satisfaction, dryness and recommendation to a friend. On this occasion, we have shown very strong negative correlations between a simple "1-10" satisfaction score and many of the postoperative KHQ domains. However, we did not find these strong correlations in another series from our unit which evaluated QoL in women treated non-surgically for mixed incontinence⁷ and others have concluded that simple analog scores are insufficient.⁸

Thus, there would be little prospect of having data accepted for publication if only non-validated methods were employed. There is also a real problem in determining a suitable "cut point" for the arbitrary values¹⁻¹⁰ defined in our non-validated questions if we want to explore more than just the extreme, inarguable case of a "10" or perfect result, which in this series was reported by only 43% of women. This 43% "completely dry" rate is consistent with published data on the TVT procedure.^{9,10} Conversely, pre- and post-operative KHQ data permit an estimate of the degree of improvement resulting from treatment using an instrument that has been validated against objective criteria such as pad

tests and urodynamic studies. It also forms a good basis for benchmarking one's performance against the performance of colleagues undertaking the same procedures, both in terms of baseline severity (case selection) and improvement following surgery.

In our opinion a very important deficiency of the version of the KHQ that we used and other QoL questionnaires is that they do not directly measure the commonest and arguably most problematic complication of continence surgery, which is urinary retention and associated problems including recurrent urinary tract infection (UTI) and symptoms of obstructive voiding. The latest version of the KHQ, which was not available when we set up our data base, contains a question related to symptoms of recurrent urinary tract infection (UTI). In our small series the rate of postoperative urinary retention was 28%, albeit that in all cases the retention had resolved within three weeks. There were no cases of recurrent UTI. For a meaningful audit, these and related data (e.g. requirement for tape division or excision; new and persisting obstructive voiding symptoms) must be reported.

In conclusion, we recommend the KHQ to practitioners wishing to engage in prospective audit of continence procedures provided the language of the questionnaire is appropriate to their population and provided additional data are collected particularly in relation to postoperative voiding difficulties.

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Filshie clip migration into wall of urinary bladder presenting with acute abdominal pain. Case report and review of English literature: from 1990 to April 2009

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Abstract: Female sterilization with Filshie clips is a commonly used contraceptive method around the world. Migration of the Filshie clip is a well recognized complication of this type of female sterilization and it is usually without subsequent serious morbidity. We report a case of a Filshie clip migration to the wall of the urinary bladder that resulted in presentation with acute abdominal pain 10 years following tubal occlusion. We have also reviewed all cases of migration of Filshie clip reported in the English language to date. The possibility of Filshie clip migration should be considered in the clinical presentation of unexplained abdominal pain, groin lump or perineal sepsis in women with past history of sterilization with Filshie clips.

Key words: Filshie clips; Migration; Urinary bladder; Acute abdominal pain.

INTRODUCTION

Tubal occlusion with Filshie clips is one of the preferred methods of female sterilization. It has a low failure rate when correctly applied. Complications of this method of sterilization can be divided mainly into two groups: early (peri-operative) and late complications. Early complications include mortality (1-2/100,000 procedures, mainly as a complication of general anaesthesia), visceral injury (bowel, urinary bladder and uterus), vascular injury and unintended laparotomy (1-2%). Procedure failure (occurrence of pregnancy including ectopic pregnancy) is the main late complication of this procedure. Migration of Filshie Clips is also a late complication; it is usually asymptomatic and does not result in serious morbidity. It should be kept in mind that in rare instances it can cause significant symptoms and morbidity.

CASE REPORT

A forty year old patient presented to one of the district hospitals with a one week history of right iliac fossa pain of increasing severity, requiring opiate analgesia. She also reported vaginal bleeding of one month duration after her periods had been absent for 18 months. She did not have nausea or vomiting, urinary or bowel symptoms. She had 3 children by normal vaginal delivery, followed by laparoscopic tubal occlusion using Filshie clips 10 years ago. Her past surgical history included an appendicectomy. When she was examined by the medical officer in the district hospital, he reported that she was haemodynamically stable and afebrile. Abdominal examination revealed right iliac fossa and supra-pubic tenderness. Pelvic examination revealed moderate tenderness on mobility of the cervix. Serum beta-HCG was negative and white cell count was normal. The patient continued to have worsening of her pain in the right iliac fossa. It was decided to refer her to the tertiary hospital. On arrival to the tertiary hospital, her pain was still worsening although her clinical picture did not change from what is described above. Pelvic and abdominal ultrasound examination did not show any significant abnormality to explain her ongoing pain. A laparoscopy was arranged to investigate her pain together with hysteroscopy, dilatation and curettage to investigate the prolonged uterine bleeding after cessation of periods for 18 months. Hysteroscopy revealed a normal uterine cavity and endometrium. An endometrial biopsy was obtained and was sent for histology. At laparoscopy the right-sided

Filshie clip was found migrated away from the fallopian tube. It was implanted deeply in the wall of urinary bladder where it reflects from the anterior upper cervical wall on the right side. It was covered with thick peritoneal adhesions. On the left ovarian fossa there was a small patch, grey in colour, consistent in appearance with endometriosis. The buried Filshie clip was removed laparoscopically without inflicting bladder perforation. The grey patch on the left ovarian fossa was also excised. The patient recovered well after the surgery with instant and complete resolution of the right iliac fossa pain. She was discharged home on the first postoperative day. When she was reviewed 6 weeks later, she was in good health and free of pain. The histopathology of uterine curetting showed excessive glandular and stromal breakdown, there was no hyperplasia or malignancy. The histology of the excised grey patch on the left ovarian fossa confirmed endometriosis.

DISCUSSION

The Filshie Clip system for mechanical tubal occlusion has been available since 1982¹ and is a common means of achieving sterilisation. Filshie clips, and other mechanical devices for tubal occlusion, are preferable to tubal electrocoagulation because electrocoagulation can result in accidental electrical burns and is associated with an increased risk of ectopic pregnancy, compared to mechanical methods.² In addition, they are associated with lesser tubal damage, thus increasing the chance of reversal by tubal anastomosis. Technical proficiency and correct placement is emphasised throughout the literature as key to optimum efficacy of all methods. Application of the Filshie clip to positively identified fallopian tubes leads to avascular necrosis at the site, followed by division and healing of the stumps.³ The clips are held in place following peritonealisation, although they may detach if this process is slow to occur.⁴ Symptomatic presentation secondary to migration of Filshie clips is rare but recognized complication of sterilisation by this method. It was estimated by Filshie that migration of one or more clips would occur in 25% of women.¹ It is likely that not all loose clips cause symptoms, hence a proportion go undetected. When the Filshie clip was assessed for approval by the United States FDA in 1996, only 6 cases of migration or expulsion were reported amongst 5454 women involved in trials; there were three cases of spontaneous expulsion and three cases of incidentally discovered asymptomatic migration observed.⁵

TABLE 1. – Articles published (1997 – April 2009) of Filshie clip migration to the urinary bladder detailing clinical presentation, surgical notes, duration after application and means of removal of Filshie clip.

Reference	Presentation	Pre-operative and operative conditions	Duration after tubal occlusion	Site of migration	Means of expulsion/extrusion/ removal
Kesby and Korda (1997)⁶	24 hour history persistent macroscopic haematuria	Uncomplicated procedure Nil post-op complications Nil pelvic pathology	7 years	Urinary bladder –deep bed of chronic mucosal ulceration on right side	Spontaneous expulsion per urethra
Miliauskas (2003)⁷	2 week history pelvic pain and haematuria	Uncomplicated procedure Nil pelvic pathology	2 years	Urinary bladder - local abscess formation	Surgical removal (partial cystectomy)
Connolly et al. (2005)⁸	4 month history vague suprapubic discomfort, worse with menses Irritative bladder symptoms: frequency, nocturia, urgency	Past history ovarian cystectomy Uncomplicated procedure Nil anatomic abnormalities	10 years ⁹	Urinary bladder – nodule of chronically inflamed tissue on dome of bladder	Spontaneous expulsion per urethra (6 weeks after initial presentation)
Palanivelu and Lynch (2007)¹⁰	1 year history of intermittent lower abdominal pain & painful micturition	Uncomplicated procedure	18 months	Urinary bladder	Spontaneous expulsion per urethra

Case reports documented migration of clips to the peritoneal cavity and specific organs, many with clinical presentations involving acute or chronic pain that mimicked common intra-abdominal pathologies (Table 1 and 2). Time to presentation varied greatly, from 6 weeks to approximately 20 years following sterilisation. In the majority of cases, where reported during the tubal occlusion, pelvic anatomy was observed to be normal with absence of pelvic pathology. The procedure was reported to have been uncomplicated in most cases. Presumably, these favourable conditions facilitated identification of anatomical structures and correct placement of clips. There was no apparent association between site of migration, history of gynaecological procedures or pelvic pathology and duration to presentation.

To date, migration to the urinary bladder has been reported in 4 other cases (Table 1). Additional sites of migration were the anterior abdominal wall (4), perianal/pararectal tissues (4), peritoneal cavity (3), groin (3), colon (2) and vagina (1) (Table 2). With the inclusion of this case, there were more reported cases of migration to the bladder than to other sites. Regarding migration to the bladder, the lack of urinary symptoms in this case may be because the migrated Filshie clip did not migrate through the full thickness of the bladder wall.

Abscess formation, ulceration, fistula formation, tissue induration and adhesion formation were commonly observed and suggest local tissue reaction to the Filshie clip. Resolution of symptoms following removal of migrated clips, regardless of the means by which this occurred, supports the assumption that the pain and associated symptoms were due to a local inflammatory response.

It is apparent that accurate documentation of anatomy, pelvic pathology and correct clip placement at the time of tubal occlusion can help in identifying long-term complications, but also preclude problems from a medico-legal perspective. It is reassuring that none of the reported cases of Filshie clip migration have resulted in mortality prior to their removal or chronic morbidity subsequent

to their removal. Nevertheless, the clinical presentations necessitated radiological interventions and invasive surgery in most to identify and retrieve the clip(s). As such, the authors recommend that clip migration and its possible sequelae should be carefully explained to patients to ensure they are aware of this potential complication, that it may occur from weeks to years after occlusion and has varied presentations.

CONCLUSION

This case adds to the body of literature concerned with migration of Filshie clips. Although rare, migration should be considered in the differential diagnosis of women experiencing abdomino-pelvic pain, without obvious pathology, who have previously undergone tubal occlusion by this method.

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TABLE 2. – Articles published (1990 – April 2009) of migration of Filshie clips to other organs excluding the urinary bladder. It shows patient main presentation, interval between clip application and organ from which Filshie clip was expelled or extruded.
 • Exact period not stated in source text, duration approximated from publication year and dates in text.

	Reference	Presentation	Pre-operative and operative conditions	Duration after tubal occlusion	Site of migration	Means of expulsion/extrusion/ removal
Peritoneal cavity	Daucher and Weber (2006) ¹¹	Diffuse mid-abdomen and RLQ pain	<ul style="list-style-type: none"> • Uncomplicated NVD (7 weeks prior to sterilisation) • Uncomplicated procedure • Nil anatomic abnormalities 	2 years	Left clip - attached to peritoneal surface of anterior cul-de-sac, left of bladder reflection Right clip - attached to right broad ligament	Surgical removal
	Kalu et al. (2006) ¹²	1 year history LIF pain, deep dyspareunia and dysuria	<ul style="list-style-type: none"> • Uncomplicated procedure 	3 years	Left clip - Peritoneum of left uterosacral ligament Right clip - Peritoneum in uterovesical pouch	Surgical removal
	Loddo et al. (2008) ¹³	Nil symptoms Removal requested for religious reasons	<ul style="list-style-type: none"> • Past history LSCS (3) 	6 years	Peritoneal defect of pouch of Douglas	Surgical removal
Anterior abdominal wall	Amu and Husemeyer (1999) ⁴	5 week history painful swelling around umbilicus	<ul style="list-style-type: none"> • Normal pelvic anatomy • Evidence of inactive endometriosis on right uterosacral ligament 	3 years	Subcutaneous tissue of anterior abdominal wall	Surgical removal
	Lok et al. (2003) ¹⁴	3 day history painful lump below umbilicus 3 months later, pain and purulent discharge from abscess formed whilst waiting for elective surgery	<ul style="list-style-type: none"> • Past history LSCS (2) • Postpartum sterilisation • Uncomplicated procedure • Normal pelvic anatomy • Nil pelvic pathology 	5 years	Subumbilical anterior abdominal wall	Spontaneous extrusion from abscess and subsequent removal
	Krishnamoorthy et al. (2004) ¹⁵	3 week history increasing pain over abdominal lump 3 day history greenish discharge from lump	<ul style="list-style-type: none"> • Past history LSCS (2) & NVD • Dense omental and bowel adhesions • Laparotomy required for placement 	5 years	Subumbilical anterior abdominal wall	Spontaneous extrusion from abscess
	Tan et al. (2004) ¹⁶	Yellowish vaginal discharge 6 weeks post partum LIF pain from 6 weeks post partum Left-sided premenstrual pain at 2 years post-partum	<ul style="list-style-type: none"> • Post-partum sterilisation • Uncomplicated procedure 	<ul style="list-style-type: none"> • Initial presentation (6 weeks & 11 weeks) <i>Loss to follow up</i> • Second presentation at 2 years 	Subcutaneous tissue at anterior abdominal wall with surrounding granuloma and abscess formation	Surgical removal
Perianal/Pararectal tissues	Pandit (2004) ¹⁷	Passage of Filshie clip rectally	<ul style="list-style-type: none"> • Uncomplicated procedure • Normal pelvic anatomy 	6 weeks	Transperitoneal migration to rectum	Extruded per rectum
	Hasan et al. (2005) ¹⁸	Vague lower abdominal pain and loose motions (2001) Recurrent perianal abscess (2004)	<ul style="list-style-type: none"> • Nil pelvic pathology 	12 years	Perianal tissues - perianal abscess with formation of fistula in ano	Surgical removal
	Buczacki et al. (2007) ¹⁹	5 month history discharging lesion around anus (apparent fistula in ano)	<ul style="list-style-type: none"> • Not reported 	15 years	Pararectal tissues	Surgical removal
	Dua and Dworkin (2007) ²⁰	4 month history recurrent peri-anal abscess with fistula formation Bleeding from fistula at menses	<ul style="list-style-type: none"> • Uncomplicated procedure • Nil subsequent intraabdominal pathology 	3 years	Apex of ischiorectal fossa	Surgical removal
Groin	Garner et al. (1998) ²¹	3 day history of lump in right groin	<ul style="list-style-type: none"> • Initial unsuccessful sterilisation • Subsequent successful sterilisation 1 year later 	? 5 years*	Femoral hernia - 3 clips identified within sac	Surgical removal
	Khalil and Reddy (2006) ²²	2 week history irreducible, tender right groin lump	<ul style="list-style-type: none"> • Not reported 	~20 years	Groin with inguinal sinus formation following excision of inflammatory mass	Spontaneous expulsion per inguinal sinus
	Verma and Oteri (2007) ²³	4 week history constant pain and lump in right groin with low-grade fever, loss of weight and general malaise	<ul style="list-style-type: none"> • Not reported 	13 years	Right groin with extraperitoneal abscess formation	Surgical removal
Colon	Denton et al. (1990) ²⁴	12 hours history constant severe RIF pain and nausea	<ul style="list-style-type: none"> • Not reported 	2 years	Appendiceal lumen	Surgical removal
	Connolly et al. (2005) ⁸	2 day history RIF pain with nausea	<ul style="list-style-type: none"> • Past history ventrosuspension • Uncomplicated procedure • Omental adhesions in right pelvis divided at time of sterilisation 	10 years	Caecum - erosion into tissue with surrounding induration	Surgical removal
Vagina	Kale and Chong (2008) ²	Passage of Filshie clip per vagina during menses	<ul style="list-style-type: none"> • Post-partum sterilisation • Uncomplicated procedure 	5 years	? Vagina	Spontaneous expulsion per vagina

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Duplex ureter damaged during laparoscopic hysterectomy

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Abstract: Purpose: This paper presents the case of a 43 year old woman who developed a uretero-vaginal fistula from a previous undiagnosed duplex ureter following a laparoscopic assisted vaginal hysterectomy. Results: The patient presented with 6 weeks of vaginal discharge and the fistula was diagnosed by CT urogram. The fistula and ureteral defect were repaired and a ureteroneocystostomy was formed. Conclusion: Duplex ureters are an anatomic anomaly which, if unrecognised, can complicate surgery. Ureteral injury is a recognised complication of pelvic surgery which is often diagnosed post operatively.

Keywords: Duplex, Ureter, Hysterectomy, Fistula

A 43 year old woman was referred to a urology clinic 6 weeks post laparoscopic assisted vaginal hysterectomy. Post operatively, she had ongoing vaginal discharge which was thought to be urine. She had no significant flank pain and renal function was normal on blood tests. Investigation with CT urogram identified previously undiagnosed duplex ureters on the right side (see figure 1) and a pelvic collection indicating a uretero-vaginal fistula. Both the upper and lower moieties were hydronephrotic. The right upper pole duplex ureter appeared obstructed at the level of the bladder and the right lower pole ureter was continuous with the collection (see figure 2). The left ureter appeared normal. Cystoscopy and retrograde pyelogram showed partial transection of the right lower pole ureter approximately 1cm from the vesicoureteral junction, the medial ureteral orifice (upper pole ureter) was not able to be cannulated due to bladder deformity adjacent to the urinoma. An open surgical repair was conducted through a Pfannensteil incision. The duplex ureters were found as in the CT; the lower pole ureter partially transected and the upper pole ureter intact but obstructed due to extrinsic compression and tissue inflammation. The duplex ureters were then both transected near the bladder, joined in parallel and reinserted into the bladder through a single tunneled ureteroneocystostomy. Two double pigtail ureteral stents were placed in the ureters. A flexible cystoscopy was performed two weeks later, the neo-ureteral orifice was healing well and the stents were removed. A follow up renal ultrasound showed no evidence of hydronephrosis and the patient has been discharged from clinic.

DISCUSSION

Duplex ureters have an estimated incidence of 0.8-1.8% and are more commonly found in women. Duplex collecting systems occur equally on the right and left sides and bilateral duplication anomalies occur in 15% of cases.^{1, 2} Abnormalities are described as double (no communication between two ureters), bifid (dual origin to single distal ureter) or abortive (single origin to dual distal ureters). Duplex systems are implicated in childhood urinary tract infections, hydronephrosis and parenchymal scarring but are often identified as incidental findings. The patient noted above had an undiagnosed double ureter system despite previous CT and ultrasound of the abdomen and pelvis.

Ureteral injury is a recognized complication of urological, gynaecological, general and vascular surgeries. Historically 75% of ureteral injuries occurred during gynaecology procedures however the proportion has changed with the increased prevalence of endoscopic ureteral procedures.^{3, 4} The incidence of ureteral injury during hysterectomy is under 1% however is higher in laparoscopic compared to abdominal or vaginal approaches.⁵ Iatrogenic injuries are most common in the distal third of the ureter and are more

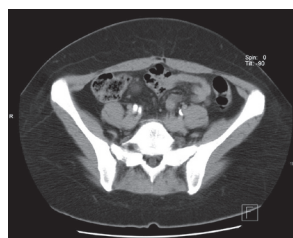


Fig. 1. – Axial CT showing right sided duplex ureters.



Fig. 2. – Coronal CT showing right sided ureters in communication with pelvic collection.

likely to be detected intraoperatively in urological operations compared to other surgeries.⁴ Careful inspection of the ureters at the end of pelvic operations is recommended and, in cases of suspected injury, intraoperative investigation with methylene blue should be considered.⁶ Typically, as in this case, a ureteral injury is not noticed during the procedure and presents post-operatively. Injuries not recognized and repaired may progress to urinomas, hydronephrosis or ureteral fistulae, presenting late with fever, flank pain or nausea. Management depends on the location and extent of the ureteral injury and can range from a simple ureteral stent to more complex ureteroureterostomies and bladder flap repairs.

This case illustrates an often missed intraoperative injury and highlights the importance of awareness of anatomic anomalies during surgical procedures.

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Pelvic floor disorders, internationally shared language, standardized procedures, surgical innovation and clinical evidence

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Language is the specific way of communication among humans; it modifies to suit different needs, in order to follow technologic evolution, customs, habits and life style. It changes through a long process of development along the years. Our children, for example, speak a language different from ours, consisting of mobile SMS or MMS or through internet. These differences may cause problems to communication.

Scientific data, clinical information or medical results should be expressed in a unique way, respecting rules and technical terms, using a language internationally shared and validated.

Misunderstanding can be the result of the absence of a precise language, leading to wrong diagnoses and therapies. A unique terminology is necessary to obtain clinical evidence.

Concerning urinary continence and prolapse, this effort started over twenty years ago, when a group of American urologists and gynaecologists published a study on the standardisation of terminology on Female Pelvic Organ Prolapse and Pelvic Floor Dysfunction.¹

The reasons for the interest in the international community for a common language in pelvic floor disorders are easily understood. Pelvic floor dysfunctions are nowadays increasingly being correlated with the elderly population over 60, and severely affect the sanitary expenses. DeLancey has stated, "genital prolapse is an epidemic ready to explode". This is why gynaecologists and urologists, industry and politics are so interested in the subject. A bad management will further affect the social costs of the problem. Verifying the efficacy of treatments and comparing the results in patients with genital prolapse and urinary incontinence would reduce health costs, which is particularly needed in a worldwide economic crisis. The International Continence Society (ICS) has produced different attempts to standardise terminology, diagnostic methods and therapies, producing guidelines that are internationally accepted, but not widely used².

Christopher Chapple, in an editorial in *Neurourology and Urodynamics* states³: "I hope you agree that these examples of areas where we need to develop consensus on terminology are important ones and we should all strongly support the efforts of the Standardization Committee, which working through the International Continence Society its sister organizations will continue and progress the debate relating to standardization of terminology related to functional disorders affecting the lower urinary and gastrointestinal tracts". But nowadays different classifications of prolapse and incontinence are still used whose clinical evidence is far from being "the real" evidence. The existence of a still confounding terminology is witnessed also in another editorial by M. Soligo⁴: "Posterior pelvic floor dysfunction: there is an immediate need to standardize terminology".

The clearest example of the multitude of terms on the pelvic floor is related to the defects of the posterior vaginal wall. The posterior defects are indicated with terms like "rectocele", "posterior vaginal prolapse", "posterior colpocele": are these synonymous or do they refer to different conditions? This language problem is evident on searching in Pubmed:

with "posterior colpocele" 5 works can be found; 16 with "descensus of posterior wall", 127 with "posterior vaginal prolapse" and 605 with the keyword "rectocele". Titles are a clear denunciation of the problem. Moreover in three out of five coloproctologic articles "obstructed defecation syndrome" (ODS) is named arbitrarily identifying rectocele and obstructed defecation. ODS is a multifactorial syndrome *sometimes* associated to rectocele, two conditions that might need to be treated in different ways, and the risk of damage is evident when surgery is chosen in a wrong way. Epidemiology predictions on pelvic floor dysfunctions are amazing: the 500.000 surgical procedures/year in the United States will increase from 27% to 31% of the population in 2020, doubling in 2050. The companies are ready to face this increase with new meshes and other devices "ready to use" and easily implantable.

One may suspect that all the difficulties which exist as regards the standardization of terminology and procedures can be useful for the marketing of medical devices in order to allow anarchic therapeutic paths, with an important potential damage to the patients.

New procedures and prostheses amazingly are sprouting without the support of any scientific evidence, and with no guarantees in case of adverse events, that sometimes are extremely serious.

The lack of control by the scientific societies on these procedures and those who perform them is surprising. Appeals are arising from many authoritative urogynecologists. Donald Ostergard⁵ in 2007 wrote in the *International Urogynecology Journal*: "*New procedures and materials for incontinence and prolapse are proliferating rapidly. Surgical procedures were developed by physicians and carried their names, but over the last 15 years, these procedures are developed by industry and bear the trade names of the companies selling the kits needed to perform them. The Food and Drug Administration approves devices, not procedures, and does not require submission of efficacy or adverse-event data to gain this approval by the 510-K process. Evidence-based medicine is lacking in the performance of these procedures that may be considered experimental by an insurance company or malpractice carrier with denial of payment or coverage. Physicians and hospitals are exposing themselves to financial, legal, and ethical risks when performing or allowing such procedures to be performed. Informed consent from the patient cannot be obtained. We must not confuse medical marketing with evidence-based medicine*". The question of the author is: *what about the future?*

The problem is that industry is making its business, while the role of scientific societies on the control of the procedures with randomized studies is lacking. It is necessary to answer the following question: is the aim of prolapse surgery to reduce the vaginal bulging or rather to restore the pelvic function and improve the quality of life considering the possible complications? The position of some scientific societies is embarrassing, because some of their members perform technical training for surgical procedures, while their role should be the research of clinical evidence. Belonging to a scientific society and working for industry is

contradictory behavior, although is not a crime: it is a clash of interests. The risk is that companies control international societies and this is becoming a legal even more than an ethical problem.

In conclusion surgeons will continue to perform procedures that they feel they are the best for their patients. Industry will continue to develop and promote new materials and devices in the hope of simplifying procedures and improving outcomes, as they realize how big is this market. With time, the available options will only increase. While ideally we would like level one evidence to support what we do, it is unrealistic to expect that this will be available in a timely fashion.

In the meantime, we can only *hope* that surgeons will honestly report their results and complications whatever procedure they are performing. This is the ethical challenge of surgeons.

In 2009 Paulo Palma⁶ discussing the ethical challenge of surgical innovation stated: *"How can specialty societies help? Societies should play a major role working on guidelines, defining minimum follow-up before publishing the initial series of patients, selecting acceptable studies, and stimulating publications of data, including complications. These actions would help to improve the standards of surgical innovation."*

Wall and Brown published for the American College of Obstetricians and Gynecologists (ACOG) a study entitled "Commercial pressures and professional ethics: troubling revisions to the recent ACOG Practice Bulletins on surgery for pelvic organ prolapsed"⁷ concluding that *"commercial interests are reshaping the practice of gynecological surgery by promoting the use of trochar and mesh surgical kits for the treatment of stress incontinence and pelvic organ prolapse... the ethical implications of changes in surgical practice that are driven by commercial interests are discussed."*

We point out the dangers inherent in the adoption of new procedures without adequate and documented evidence to support their safety and efficacy." The ACOG Practice Bulletins on Pelvic

Organ Prolapse⁸ were altered without explanation to

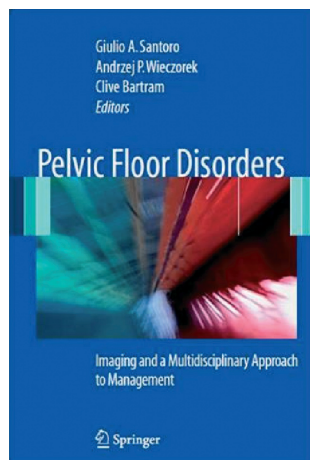
downplay the experimental nature of some commercial products. In so doing, ACOG is not meeting its fiduciary responsibilities to patients and is undermining important professional values. The editorial of CA Matthews "The surgical sales representative: examining a new role in urogynecology"⁹ gives further light on this matter⁹.

We strongly hope that new debates will be opened by the scientific community.

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Pelvic Floor Disorders

Imaging and Multidisciplinary Approach to Management

Santoro, Giulio; Wieczorek, Andrzej P.; Bartram, Clive I. (Eds.)

Forewords by James Fleshman, András Palkó, Peter Sand

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Dramatic improvement in imaging techniques (3D ultrasonography, dynamic magnetic resonance) allows greater insight into the complex anatomy of the pelvic floor and its pathological modifications. Obstetrical events leading to fecal and urinary incontinence in women, the development of pelvic organ prolapse, and mechanism of voiding dysfunction and obstructed defecation can now be accurately assessed, which is fundamental for appropriate treatment decision making. This book is written for gynecologists, colorectal surgeons, urologists, radiologists, and gastroenterologists with a special interest in this field of medicine. It is also relevant to everyone who aspires to improve their understanding of the fundamental principles of pelvic floor disorders.



International Pelvic Floor Dysfunction Society

International Federation of Gynecology and Obstetrics

7th IPFDS WORLD CONGRESS AND FIGO TASK FORCE MEETING Palermo, Italy, May 10-12/2010

Abstracts

Pelvic organ prolapse repair with or without concomitant burch colposuspension in patients with or without urinary incontinence: an up-date of two randomised surgical controlled trials

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INTRODUCTION AND STUDY PURPOSES

In pelvic floor prolapse (POP) repair, an anti-incontinence procedure is sometimes performed concomitantly in incontinent women or, as a prophylactic measure, in continent.

To evaluate the impact of Burch Colposuspension (BC), as an anti-incontinence procedure, in patients with or without urinary incontinence (UI) who underwent abdominal POP repair.

MATERIALS AND METHODS

Two randomised controlled trials (RCT) were updated. RCT I: Forty-seven women suffering from POP and urinary incontinence (UI) were randomly assigned to abdominal POP repair and concomitant BC (24 patients; group A) or POP repair alone without any anti-incontinence procedure (23 patients; group B). RCT II: 66 continent women suffering from POP were randomly assigned to abdominal POP repair and concomitant BC (34 patients; group C) or POP repair alone without any anti-incontinence procedure (32 patients; group D).

Primary end-points were anatomical outcome and changes in

incontinence status; secondary endpoints were changes in subjective symptoms and Quality of Life (QoL).

RESULTS

RCT I. Median follow-up was 65 months (range 47-107); 2 patients (1/A and 1/B) were lost at follow-up. In group A 13/23 (56.5 %) were still incontinent after surgery compared with 10/22 patients (45.4%) in group B ($p=0.298$). RCT II. Median follow-up was 97 months (range 72-134); 4 patients were lost at follow-up (3/C and 1/D). In group C 9/31 (29%) patients were incontinent compared with 5/31 (16%) in group D ($p=0.553$). The inter-group difference was significant only for B vs. C ($p=0.039$) and B vs. D ($p=0.005$). UDI-6 and IIQ-7 scores improved in all groups ($p < 0.0001$).

CONCLUSIONS

Long-term results cast doubts as to whether BC should be performed during POP repair in continent women. BC did not improve outcome significantly in incontinent women.

Pelvic floor repair using cr-mesh (AMI) in women with uterine prolapse stage III-IV. Preliminary results

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INTRODUCTION AND STUDY PURPOSES

The aims of this abstract are to describe a total pelvic reconstructive procedure using CR-Mesh (A.M.I.) and to present the preliminary results conserving the uterus in women with uterine prolapse stage III-IV.

MATERIALS AND METHODS

Between 1st September 2009 and 10th March 2010, we proposed pelvic floor repair using CR-Mesh (A.M.I.), conserving the uterus, to all women who required surgical treatment for uterine prolapse stage III-IV (POP-Q classification). The surgical technique suited the following concepts: 1. fixation of the anterior and of the posterior compartments to the De Lancey Level I apical support1 (by bilateral suspension to the medial end of the sacro-spinous ligament); 2. recreation of the De Lancey Level II lateral support1 (using transobturator and transileo-coccygeus slings); 3. recreation of the De Lancey Level III distal support1 (by recreating bladder neck support and by reinforcing perineal body using superficial slings).

RESULTS

During the considered period of time, 22 patients underwent the

operation. During the pre-surgical consultation, 20 of the 22 patients had concomitant cystocele stage III-IV and 14 rectocele stage III-IV. No blood transfusion was necessary. Bladder perforation occurred in one case. Five of the 22 patients had postoperative pain (6-8 VAS) persisting for two weeks. Thirteen patients were reviewed 3 months after surgery: none of them had recurrence of the prolapse (considering prolapse $>$ or = stage I); no mesh exposure was observed; 3 patients had de novo stress urinary incontinence.

CONCLUSIONS

According to the peri-operative and short-term follow up results, pelvic floor repair using CR-Mesh (A.M.I.) seems to be a safe technique to correct pelvic organ prolapsed stage III-IV. Anatomical and functional results, quality of life and sexual function questionnaires must be assessed with a long-term follow-up to confirm the effectiveness and safety of the procedure.

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Apical suspension at the time of hysterectomy: randomized trial of three surgical techniques

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INTRODUCTION AND STUDY PURPOSE

Aim of the study was to compare three surgical techniques for central compartment suspension after hysterectomy in patients with

stage 3-4 utero-vaginal prolapse: posterior intravaginal slingplasty (PIVS), laparoscopic sacrocolpopexy (LCSP), McCall colposuspension (MCS).

MATERIALS AND METHODS

Fifteen consecutive women were randomly assigned to PIVS or LCSP or MCS.

Postoperative assessments were performed at one, six, 12 months, then annually from surgery.

During each visit, objective findings of pelvic support defects were assessed using the POP-Q staging system. Pelvic relaxation of up to stage one (POP-Q) was accepted as cured, and relaxation at stage two or higher was considered as recurrent case. Symptoms were assessed by questionnaire and visual analogue scales. Statistical analysis was performed with Mann Whitney U test, t-test and χ^2 as appropriate. A value of $p < 0.05$ was considered statistically significant.

RESULTS

Patients' demographic characteristics and follow up were similar in both groups. All patients underwent hysterectomy. McCall

colposuspension and PIVS were quicker than LCSP (mean operating time: MCS 76, PIVS 95, LCSP 151). Neither intrasurgery rectal injury nor haemorrhage occurred. No haematoma formation or vaginal erosion was observed post surgery. Mean duration hospital stay was shorter in LCSP than the others techniques. At 14,8 months' follow up there were no recurrence involving the central segment of the vagina (C: PIVS -5,4 LCSP -6,4; McCall -4,6). Total vaginal length was longer in LCSP (TVL 9,2) than the others two methods. Postoperative cystocele occurred in 2 women after PIVS, significantly higher than LCSP group.

Symptom scores and quality of life were similar.

CONCLUSION

All procedures appear to be equivalent from a point of view of anatomy, function and impact on quality of life. Current available data don't allow reaching conclusions about long term efficacy and late complications of these procedures.

A single prosthesis for simultaneous repair of stress urinary incontinence and cystocele

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INTRODUCTION AND STUDY PURPOSE

The rationale for this procedure is to reinforce the pubourethral ligaments and the vesicovaginal fascia, addressing Stress Urinary Incontinence (SUI) and Cystocele as well

MATERIALS AND METHODS

A total of 100 patients cystocele grade III or higher enrolled this trial. Sui was present in 50 % of patients. The mean age was 57 years. The procedure was begun with a midline vertical incision made in the vaginal wall from the mid urethra to the cervix. Dissection is made to the medial edge of the ischio-pubic branch. Supra pubic points are marked 3 cm apart at just above of the pubic bone. Transobturator marks using as landmarks: genitofemoral folds at the level of the clitoris, than 3 cm below and 3 cm lateral. The index finger is used to protect the urethra and guide the needle in the pre pubic path all the way to the supra pubic mark. A small skin incision facilitates the exit of the needle. The handle is removed exposing the crochet tip. The arms of the graft are connected to the tip of the needles. The mesh is pulled the length till the Armpits take the superior part of the body of the mesh to the mid urethra with no tension. The helical needles are insert parallel to the ascending ramus of the pubic bone, till it exits through the vaginal incision. Vaginal incision is closed using overlap technique, reinforcing the suburethral hammock

and avoiding contact of the suture line with the mesh. The patients were followed and prolapse evaluated using the POP-Q System. Sexuality was evaluated using the IFFI questionnaire and lower urinary tract symptoms (LUTS) using the OABq-SF questionnaire.

RESULTS

The follow-up ranged from 3 to 24 months, mean 13 months. The mean values of the preoperative POP-Q were: Aa=0, Ba=+2 and post operatively Aa= -3 and Ba=-2. Mesh exposition was noted in 6% of the patient and treated conservatively in four, with good results. There were a single case of prolapse recurrence. SUI was cured in 40 out of 50 (80%) patients. There were only one patient with "de novo" SUI. Dyspareunia was noted in 2 patients. Statistical analysis disclosed significant improvement in sexuality and LUTS and no significant change in dyspareunia.

CONCLUSION

These results suggest that this monoprosthesis are safe and effective, adding the advantage of correcting SUI at the same time. Because treating severe anterior vaginal prolapse with mesh results in a 20-30% of "de novo" SUI, not observed in this series, we suspect that this approach may have a beneficial prophylactic effect on "de novo" SUI as well.

Treatment of vaginal erosion of transobturator tape using a pelvisoft patch: a series of 6 cases

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INTRODUCTION AND STUDY PURPOSE

We describe a unique technique in which a piece of biological mesh (pelvisoft) is interposed between the vagina and the eroding TOT mesh. The vagina is then closed with absorbable sutures. This is hypothesised to decrease the risk of recurrence of mesh erosion whilst not compromising the continence achieved by the transobturator tape.

MATERIALS AND METHODS

All 6 cases of tape erosion were diagnosed within 12 months of primary surgery. Two patients had GYNECARE TVT™-O tapes and four patients had Safyre™, Promedon TOT tapes.

RESULTS

In 3 cases out of 6, the erosion was successfully managed using a plug of pelvisoft mesh. These cases had no recurrence of erosion, but incontinence recurred to a minor degree in one case. Of the unsuccessful cases, one patient had early intercourse and one patient was on long term steroid therapy which might have contributed to recurrence of erosion.

CONCLUSIONS

Our experience suggests that pelvisoft graft interposition may help salvage an eroding midurethral tape. Patients need to be warned that the success rate is around 50% and the option of excision of the tape should be considered.

Surgical management of stress urinary incontinence with urethral hypermobility associated with low stage anterior vaginal wall prolapse: a comparison among three techniques

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INTRODUCTION AND STUDY PURPOSES

In the last decade, retropubic tension-free vaginal tape (TVT) has become the gold standard for the surgical treatment of female stress urinary incontinence (SUI), considering its high cure rates and limited invasiveness.1 To lower the complication rate of TVT (mainly due to

vascular and visceral injuries), the transobturator route, both from the outside to the inside (TOT) and from the inside to the outside (TVT-O), is now widely used.2 Recently, in order to overcome urinary retention and thigh pain observed with the transobturator route, single incision devices have been developed.3 Aim of this study was to evaluate the

efficacy and safety of TVT-O, TOT and the novel, single incision TVT-Secur in the treatment of SUI associated with low stage (I-II) anterior vaginal wall prolapse.

MATERIALS AND METHODS

We evaluated a total of 141 women with SUI and low stage cystocele (≤ 2 stage). All subject underwent a complete physical examination, PoP-Q staging, cough test, Q-tip test, and urodynamics. 50 patients were treated with TOT, 54 with TVT-O and 26 with TVT-Secur.

Thirty-five patients in the TOT group (15 fascial repairs and 20 synthetic mesh), 28 patient in the TVT-O group (20 fascial repairs and 8 synthetic mesh) and 8 in the TVT-Secur group (6 fascial repair and 2 synthetic mesh) underwent anterior vaginal wall prolapse repair. Operative times, blood loss, and intra-operative complications were recorded. Follow-up visits were scheduled 3, 6 and 12 months after the procedures. At the 12 month follow-up, patients underwent physical examination, PoP-Q staging, urodynamic testing and onset of complications was recorded.

RESULTS

Operative times were significantly lower in the TVT-Secur group in comparison with the other two devices. Intraoperative complications were one case of bladder neck injury in the TOT group, one case of vaginal wall tear and one case of severe (300 cc) blood loss in the TVT-Secur group. Short-term complications were groin/thigh pain (8 cases in the TOT group and 5 in the TVT-O group) and urinary retention

(2 cases in the TOT group and 2 cases in the TVT-O group). Twelve months after the procedure de novo urge incontinence was present in 2 cases in the TOT group, 1 cases in the TVT-O group and 3 cases in the TVT-Secur group. We also observed vaginal erosion in two cases of the TOT group and one case in the TVT-Secur group. Cure rates for SUI were 92%, 91.1% and 85% for TOT, TVT-O and TVT-Secur, respectively. Anatomical correction of the cystocele was achieved in all patients and no relapse was observed.

CONCLUSIONS

The three devices appeared to be safe and effective in the surgical treatment of SUI. TVT-Secur showed shorter operative time and reduced bladder obstruction and thigh pain, though presenting higher de novo urgency rates. To better evaluate complications and the possibility of performing TVT-Secur under local anesthesia and in an office setting, more studies, with a randomized study design are needed.

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Impact of tension-free suburethral sling positioning for the treatment of female stress urinary incontinence on sexual function: a comparison between TVT-O and TVT-Secur

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INTRODUCTION AND STUDY PURPOSES

Stress urinary incontinence (SUI) is the most common form of female urinary incontinence. It has a significant impact on quality of life and seems to have a negative effect on the sexual life of those affected. 1 Transobturator tension-free techniques for the surgical treatment of SUI have been shown to be efficient and safe, 2 but their effects on sexual function have not been fully elucidated, with some studies reporting an improvement, others reporting a worsening and others being equivocal.3 Furthermore, data on sexual function of women treated with the last generation, single incision slings are lacking. Aim of this study was to evaluate sexual function in women undergoing surgery for SUI and to compare the impact of TVT-O and TVT-Secur on sexual quality of life.

MATERIALS AND METHODS

We enrolled for the study 75 women who underwent TVT-O (n = 38) or TVT-Secur (n =37).

Inclusion criteria were: stress urinary incontinence from at least two years diagnosed with clinical examination and urodynamic testing and with an age > 40 years. Exclusion criteria were: previous surgical procedure for urinary incontinence, isolated or prevalent urge incontinence, prolapse of pelvic organs with a PoP-Q stage ≥ 2 and contraindications to these surgical procedures. TVT-O procedure was performed according to the technique described by de Leval, while TVT-Secur procedure was performed with the hammock approach. During the follow-up visit at 6 and 12 months, women completed a questionnaire on their sexual life (Lemack's questionnaire).

RESULTS

Seventy-two patients returned the completed questionnaire, but two of these questionnaires were incomplete, thus leaving a total of 70

questionnaires for the analysis. Sixty-five patients were sexually active. Mean frequency of intercourses did not show significant differences before and after the procedure. 27.8% of patients treated with TVT-O and 29.5% of patients treated with TVT-Secur reported an improvement in satisfaction during intercourses. Two (5.3%) patients in the group treated with TVT-O and one (2.7%) in the group treated with TVT-Secur reported a worsening of sexual satisfaction. After the procedure, coital incontinence episodes were significantly reduced in both groups.

CONCLUSIONS

Our results suggest that the impact of minimally invasive anti-incontinence procedure such as TVT-O and TVT-Secur on female sexual function did not differ according to the device used (TVT-O vs. TVT-Secur), and that both devices do not have a negative impact on sexual function and, in some instances, induced an improvement of sexual performances, probably due to the reduction of coital incontinence. The relatively higher rate of patients experiencing a worsening of sexual function after TVT-O may be considered a consequence of the small sample studies and needs to be confirmed in a wider, prospective, randomized trial.

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Retropubic versus transobturator tict procedures: a comparative study

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INTRODUCTION AND STUDY PURPOSE

Midurethral tension-free procedures are becoming the first-line surgical treatment for female stress urinary incontinence (SUI). Leanza-Gasbarro-Caschetto published a Tension-free Incontinence Cystocele Treatment (TICT) in 2001. TICT consists on using a polypropylene fly shaped mesh made up by a central body (positioned under both

urethra and bladder) and two wings which cross the Retzius: retropubic TICT (r-TICT), the prepubic space: prepubic TICT (p-TICT) and the transobturator foramen: Transobturator TICT (T-TICT). The aim of this study was to compare both efficacy and morbidity of retropubic versus transobturator tension-free incontinence cystocele treatment (TICT) procedures.

MATERIALS AND METHODS

449 women with urodynamic stress incontinence allocated to 2 treatment groups were evaluated: 229 were treated with R-TICT and 220 (B-group) by means of T-TICT. There were 22 dropouts from follow-up, among them 14 (229-14=215) in the former and 10 (220-12=208) in the latter. Other pelvic defects were solved during the same operation for a complete repair of pelvic floor. Comparisons of group means were performed with "t student" test for independent samples.

Proportions were compared with chi-square test (χ^2). A logistic regression analysis was performed to control for covariates that differed in our two groups despite randomization.

King's Health Questionnaire was used to evaluate Life Quality.

RESULTS

The average follow up was 46 months (range 7-90 months).

R-TICT group: subjectively SUI was cured in 190 (88.4%), objectively, SUI was cured in 191(88.8%)of patients; cystocele in 175 (81.3%).

There were no cases of bladder perforation, Retzius haematoma, abscess formation, postoperative haemorrhage or retro pubic bleeding requiring laparotomy. Post operative complications included 8 (3.7%) (RR<1) cases of voiding difficulties owing obstruction, 4 (1.8%) cases of de novo instability and 6 (2.8%) cases of erosion and 2 (0.9%) cases of granuloma. The eight cases of voiding difficulties were solved as follows: seven by adjustment of mesh and one by cutting the basis of mesh in fifth postoperative day. Pollakisuria was found in 20 (9.3 %) cases. Urgency was found in 36 (16.7 %), urge incontinence in 7 (3.2%) cases. During follow-up one pelvic procedure was requested. Postoperative Q tip test average was 22 degrees (range 9-42).

T-T.I.C.T group: Subjectively, incontinence was cured in 178 (85.6%). Objectively, S.U.I. was cured in 179 (86.1%).The cystocele was cured 175/208(84.1%)patients.

Postoperative complications included neither cases of "de novo"

instability nor obstruction, whereas 15 (7.2%) patients suffered from urge-incontinence, 13 (6.2%) patients from urgency and 28 (3.8%) patients from pollakiuria. There were 6 cases (2.9%) of erosion treated by the excision of protruding mesh without suturing vaginal skin and the pelvic floor was not compromised. During follow-up two other pelvic procedures were requested. Postoperative Q tip test average was 25 degrees (range 12-50).

We found significant difference in VAS scores and in the majority of the main domains in King's Health Questionnaire regarding preoperative and postoperative data ($p<0.001$), whereas the results of both procedures were comparable.

Subject satisfaction was not significantly different between retro and retro pubic TICT: 88 versus 90%.

CONCLUSION

In a long term follow-up both procedures are effective ($p>0.001$) and sure for solving both the functional and the anatomic defect of the anterior compartment. Comparing with the retro pubic TICT, the transobturator one is simpler and less obstructive, nevertheless both procedures are successful and with highly significant improvement in QoL. Retro pubic is more effective than the transobturator technique (88.4% versus 85.6%) regarding SUI solution but the difference is not significant.

	subjective SUI	objective SUI	CYSTOCELE
R-TICT 215 (100%)	190 (88.4%)	191(88.8%)	175/215 (81.4%)
T-TICT 208 (100%)	178 (85.6%)	179 (86.1%)	175/208(84.1%)
χ^2	0,50	0,51	0,38
p	0,47774	0,47375	0,53746

Women's views about botulinum toxin treatment, outcomes and complications. A questionnaire based survey

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INTRODUCTION AND STUDY PURPOSE

In recent years there has been an increasing use of the botulinum toxins for the management of detrusor overactivity. Botulinum toxin is not licensed for this purpose and there is ongoing investigation for long-term efficacy and safety.

The aim of this study was to evaluate the women's views about botox treatment, outcomes and complications.

MATERIALS AND METHOD

Women with detrusor overactivity were recruited between January 2008 and September 2009.

Women were divided into two groups. Group A included treatment naïve women whereas group B included those who were resistant to anticholinergics.

All women were requested to fill out a multiple choice questionnaire regarding lower urinary tract symptoms (LUTS), whether they would consider botulinum toxin, severity of LUTS and complications they would find acceptable to undergo this treatment.

RESULTS

261 women with a mean age of 58 years (range 38-78) were studied. 224 were treatment naïve women while 37 were non responders to anticholinergics. Only 49.6% of women in the group A and 54% in the group B would accept Botulinum toxin. Out of the women in group A who would accept this treatment up to 75% would accept a risk \leq 15% of using clean intermittent self catheterization (CISC) ; 88% of women considered an acceptable cure rate \geq 70%. Finally up to 77% would expect to become continent after treatment. In the group B who would accept treatment, 76% of women would accept a risk \leq 15% of using CISC, while 86% of them considered an acceptable cure rate \geq 70%. Finally, up to 76% would expect to become continent after treatment.

CONCLUSIONS

Acceptance of Botulinum toxin involves a complex interaction of efficacy and possible complications. The balance of these factors changes the acceptability of the treatment. No differences were found between treatment naïve women and non responders to anticholinergics.

Post-hysterectomy axial versus MC Call vaginal suspension: a comparison study

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INTRODUCTION AND STUDY PURPOSE

The repair of the apical prolapse may be performed either abdominally or vaginally. Both operation may be carried out with or without prosthesis. Among no-prosthesis vaginal procedurer, the most common technique described in the literature for apical prolapse is uterosacral Mc Call suspension (MCS), initially described in 1957 by Milton McCall. Whereas the axial suspension (AVS) was originally described by Leanza in 2003 as an apical suspension procedure performed vaginally, employing all the ligamentary apparatus (uterosacral, cardinal and adnexial peduncle). This study tried to compare both efficacy and morbidity of Axial Vaginal Suspension (AVS) versus (vs) Mc Call suspension (MCS), after hysterectomy.

MATERIALS AND METHODS

536 women with uterine prolapse (grades 1-2 or 3 HWS) were randomly alternatively allocated to 2 treatment groups. 16 refused the operation (536-16=520). 260 were treated with MCS (A-group) and 260 (B-group) by means of AVS. There were 24 dropouts from follow-up, among them 15 (260-15=245) in the former and 19 (260-19=241) in the latter.

Mean age was 61 years (range 44-84). 430/536 (88.2%) patients referred in their history only vaginal births, the others both vaginal and either one or more caesarean sections. Mean parity was 3.5 (range 1-10). Patients were followed up at 6 weeks, 6 months and annually. Before the operation multichannel urodynamics was done. 150/520 (26.9%) patients suffered from stress urinary incontinence (SUI) undergoing needle or mininvasive antincontinence procedure. Following hysterectomy, besides apical suspension, isolated defects

of either anterior or posterior compartment were solved vaginally, in the optics of complete restore of pelvic floor. All the points Aa, Ba, C, Ap, Bp, D, TVL and VH (according to POP-Q) were evaluated. Comparisons of group means were performed with "t student" test for independent samples. Proportions were compared with chi-square test (χ^2). A logistic regression analysis was performed to control for covariates that differed in our two groups despite randomization. King's Health Questionnaire was used to evaluate Life Quality.

RESULTS

Mean follow up was 80 months (range 12-96). Anatomic pelvic cure is shown in tab.1.: apical compartment A-group 73.5% vs B-group 80.9%.

TABLE 1 – Anatomic Results

	MCS	AVS	χ^2	p
Cure apical compartment	180/245 (73.5%)	219/241 (80.9%)	23,86	<0.00001

Impact of sacral neuromodulation implant for overactive bladder (OAB) on female sexual function: a prospective study

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INTRODUCTION AND STUDY PURPOSE

Women's sexuality and female sexual function (FSF) are complex issues modulated by multiple factors during a woman's entire life cycle. Lower urinary tract symptoms (LUTS) are age-related factors that have a profound impact on physical, social and sexual well-being. Sacral Neuromodulation (SNM) may have a positive effect on sexuality, though few studies have so far evaluated its impact on female sexual function. The aim was to prospectively assess changes in sexual function, clinical outcome and quality of life after SNM in female patients with OAB and their possible correlation with improvement in urinary symptoms and quality of life indexes.

MATERIALS AND METHODS

Between May 2003 and December 2008, 30 consecutive female patients (median age 53 years, range 35-79) with OAB underwent the two-stage procedure of SNM.

Only 16 (53%) patients were considered eligible; these completed a bladder diary, the Female Sexual Function Index (FSFI), the status of health questionnaire (SF36) and the Incontinence Quality of Life Index (I-QoL) before implantation and on follow-up examinations.

SUI was solved in 89% of A-group and in 91% of B-group.

Only 3 patients (1.2%) of MCS and 1 (0.4%) complained of dyspareunia. No cases of rectal trauma, nerve injury, ischioanal abscess, postoperative haematoma were observed. Blood transfusion was necessary in one case of both groups.

MCS vs AVS showed a variation of POP-Q "C" point: -6 vs -8 (P 0.00009; t-student: 5,96 and TVL (7 vs 10 (P<0.0001, t-student:17.4).

We found significant difference in VAS scores and in the majority of the main domains in King's Health Questionnaire regarding preoperative and postoperative data (p<0.01). Subject satisfaction was statistically significant in both procedures (93.1% versus 95.8 %).

CONCLUSIONS

MCS and AVS are effective apical suspensions. Furthermore, owing to the employ of all the legamentary apparatus the AVS procedure is associated to a significant lower risk of apical recurrences.

RESULTS

The results were analyzed before implantation, on mid-term follow-up (MFU) (median MFU 22.5 months) and on final follow-up (FFU) (median FFU period 36.3 months).

Correlations between differences in FSFI scores and in clinical outcome, and between differences in FSFI, SF36 and I-QoL scores were evaluated.

Regarding sexuality, the mean improvement in the total FSFI score was 27.9% on MFU and 29.3% on FFU. Only 4 patients (25%) showed a >50% improvement in global FSFI score on MFU, and 3 (25%) on FFU.

A significant correlation was found between clinical improvement and improvement in sexual function. No significant correlation was found between differences in FSFI and quality of life indexes (I-QoL and SF36).

CONCLUSION

Our results demonstrate that improvement in the quality of sexual function in female patients with OAB correlates with improvement in urinary symptoms.

Two natural pregnancies in a patient with severe uterine prolapse

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INTRODUCTION AND STUDY PURPOSES

Uterine prolapse is a common gynecologic condition and it is extremely rare during pregnancy.1 Still few cases are described in literature, especially on its correlation with subsequent pregnancy. At the present, there is only a report of natural term pregnancy with initial procidentia uteri.2

MATERIALS AND METHODS

Here we report an exceptional case of two pregnancies in a prolapsed uterus.

Furthermore, we found one report on natural term pregnancy with initial uterus prolapse 2 and one case of in vitro fertilization and embryo transfer term, pregnancy on an initially complete uterine prolapse.3

A 36-year-old pregnant woman, gravida 3, para 1, presented in the antenatal outpatient clinic at 38 weeks of gestation complaining of uterine prolapse and amenorrhea.

RESULTS

Five years earlier, the subject had her first spontaneous vaginal delivery, after 39 weeks of gestation and after 7-hour labor. A living

male baby weighing 2950 g, with Apgar scores of 10/10, was delivered. Subsequently, total uterine prolapse (POP-Q IV) was already observed and, for this reason, a pelvic reconstruction operation was scheduled. However, she missed the appointment and was lost to follow-up. Two years later the patient had her first pregnancy on a prolapsed uterus and the delivery was performed by a caesarian section after 38 weeks of gestation. A living male baby weighing 3150 g, with Apgar scores of 10/10, was delivered. Two years later the patient had a second pregnancy on a prolapsed uterus. Elective caesarian section was performed, a living female baby weighing 3030g, with Apgar scores of 10/10, was delivered.

The postnatal period was uneventful and she was discharged home 4 days later in good health and normal postpartum uterine involution was observed.

CONCLUSIONS

In conclusion, our case illustrates that pregnancy during uterine prolapse is possible and an elective cesarian section near term is the safest mode to delivery.

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Treatment of interstitial cystitis with chondroitin sulphate for patients already treated with hyaluronic acid

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INTRODUCTION AND STUDY PURPOSE

Interstitial cystitis (IC) is a chronic, severely debilitating bladder disease. Its features consist of excessive voiding urgency and frequency, nocturia, chronic suprapubic and pelvic pain, dyspareunia and negative urine cultures. The course of the disease is usually marked by flare-ups and remissions. IC is diagnosed by cystoscopy associated to bladder hydrodistention and eventual biopsy. The etiology is unknown but probably is related to many factors, including autoimmune ones. The role of the mast cells is still under investigation. Medical conditions associated with IC are: allergies, irritable bowel syndrome, fibromyalgia, asthma. One common etiologic theory is based on a glycosaminoglycan component defect in the mucin layer that protects the uroepithelium.

MATERIALS AND METHODS

From January 2001 to October 2009 fifty-two patients were treated following a protocol characterized by weekly intravesical instillations of hyaluronic acid (HA) (Cystistat®) for 6 weeks and afterwards monthly as maintenance therapy until recovery. From November 2009 to March 2010, twenty-eight patients were enrolled in our study and the enrolment is still open. In all patients the therapeutic protocol consists of intravesical instillations of CS (20 mL) weekly for 6 weeks and afterwards monthly for 6 months. The aim of our study was to evaluate the efficacy and tolerability of chondroitin sulphate (CS) (Uracyst®) intravesical instillations in patients affected by IC not satisfied by the therapy with HA.

RESULTS

All patients reported a symptomatic improvement. One patient reported improvement already from the first treatment compared to the previous with HA.

CONCLUSIONS

In this very preliminary experience, the administration of intravesical CS appears to be more effective subjectively, after a few treatments compared to HA as demonstrated by an improvement in quality of life.

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Estimation of pelvic floor movements by using a 3d computational model

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INTRODUCTION AND STUDY PURPOSE

Dysfunction of the pelvic floor muscle (PFM) may lead to urinary incontinence, pelvic organ prolapse, sensory and emptying abnormalities of the lower urinary tract and pain.

Exercises of PFM are reported in the literature to be one of treatment methods of physiotherapy. Today imaging techniques such as magnetic resonance imaging (MRI) have a potential of yielding more detailed information about muscle morphology and action during PFM contraction. The main goal of the present work is to evaluate pubovisceral muscle (PVM) displacements in prolapsed women using a 3D computational model.

MATERIALS AND METHODS

Using MRI, a 3D geometric model of PVM was created (Figure 1). Based on the developed geometry a finite element model 1 (a numerical technique suitable for biomechanical simulation) representing the PVM was generated.

RESULTS

Comparing the 3D model of the non-prolapsed with the prolapsed woman we may notice a difference in the morphology of the structure, which can characterize an anatomical difference between them. Another

finding was in the process of muscle activation, where prolapsed women cannot reach similar levels of non-prolapsed at rest, even for an intensity of contraction of 100%.

CONCLUSIONS

Computational models have been employed to investigate female SUI also during physical and daily activities.² In the present, based on the Finite Element Method, 3 3D computational models of the pelvic floor were developed. The presented 3D model of the PVM was an attempt to evaluate the muscle deformation under a simulated pressure and active contractions. The results may indicate that in prolapsed patients muscle strengthening may not be sufficient in restoring the muscle original anatomy observed in non-prolapsed women.

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