ISSN 1973-4905

Vol. 28
N. 4
December 2009

Rivista Italiana di Colon-Proctologia
Founded in 1982

PELVIPERINEOLOGY

A multidisciplinary pelvic floor journal

www.pelviperineology.org

Official Journal of Australian Association of Vaginal and Incontinence Surgeons, Integrated Pelvis Group, Perhimpunan Disfungsi Dasar Panggul Wanita Indonesia

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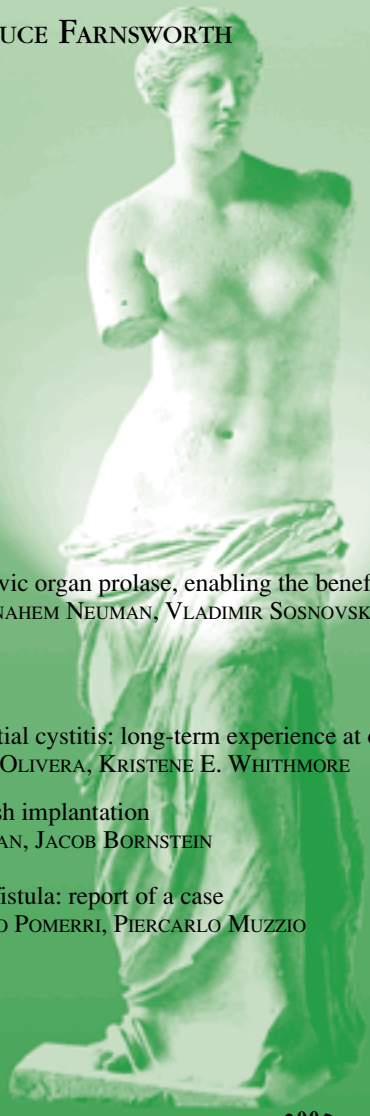

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Editorial Office: Luca Amadio, Enrico Belluco, Pierluigi Lucio, Luisa Marcato, Maurizio Spella
c/o Clinica Chirurgica 2 University of Padova, 35128, Padova, Italy
e-mail: editor@pelviperineology.org
Quarterly journal of scientific information registered at the Tribunale di Padova, Italy n. 741 dated 23-10-1982
Editorial Director: Giuseppe Dodi
Printer "La Garangola" Via E. Dalla Costa, 6 - 35129 Padova - e-mail: info@garangola.it

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Guest Editorial

Provocation

I think that sometimes, in order to deeper understand our position, it should be necessary to extrapolate what is contingent and observe the situation from a wider point of view.

Therefore we can attempt to ask ourselves: when we start an out-patients or a surgical session, which is the goal we really want to get and, most of all, who's staying in front of us? Certainly a person who expresses one need, or we can say, one wish to be recovered or at least to feel better or, amplifying the concept, a person that asks us to help him or her feel happier having a better quality of life.

As a result, it is a matter between two persons: one who needs his problem to be dealt and resolved in the best way and the other one, the doctor, who can offer his experience. The relationship between patient and doctor must therefore consist of confidence and trust. According to it, the doctor, the urogynecologist in particular, must face several challenges. Let's try to consider them: the first one is that of technology, of the methodology which is by now widely adopted like cystomanometry or fluometry, but even more of the new and more precise diagnostic tools (3D – 4D ultrasound, MRI, etc.) that, with no doubt, supply larger and more accurate series of data. As a matter of fact the diagnosis is just a list of numbers and data totally incomprehensible to the patient, and it is sometimes doubtful and interlocutory even for us. I think that we always should consider that a clinical approach must always contemplate the patient's history, her problems and expectations, her sick or suffering body and the real tangible chances that we can offer to her. The quality of life should be measured with numerical tests or with "doctor, I don't feel well" or "thanks doctor, now it's much better"?

Another topic concerns surgical techniques or technologies applied to surgery. Certainly, we are now many steps ahead compared to the Burch procedure, but do we always perfectly know what we are doing or trying to obtain and if we do things for our satisfaction as surgeons or for that of the patient? Are we really doing them for her sake? It's not likely to have clear certainty in the field of experimentation, but in this case also a bit of skepticism, caution and a serious concern of not harming for the pure ambition of "experimenting" is useful. Will our patients be buried under more and more complicated layers of meshes, prostheses, little anchors, etc.? Do we sometimes lose sight of them?

When our colleagues, who graduated over 20 years ago, started their hospital career, at least in Italy they didn't had to do with the bureaucratization of the present medical work, with diagnosis related reimbursements, hospital discharging forms, short hospital stay, costs and budget. These managing and normative concerns are with no doubt proper and useful, but I'm convinced that if the economical evaluation gains too much ground within the hospital work, the patient risks to become the object of a service, that is just the source of financial income. Patient's need could become the last concern for the managers of what quite improperly in Italy is called "hospital firm": as physicians, what kind of position do we want to take according to these new trends?

Furthermore, we live the EBM challenge: excellent methodologies and educational training, extremely useful. They actually are the only approach to overcome the level of personal feelings or the limit of a poor personal experience that is mostly not verifiable. Nevertheless they may be disappointing or, at least, interlocutory when we have to decide about new diagnostic or therapeutic devices. Most of the times the answer is that the number of cases is insufficient to express an assessment (evidence levels) or univocal recommendations. When we make the patient sign a four pages informed consent, she will tell us: "Doctor, do as you prefer; I come to you because I trust you".

Which is then the final challenge?

I think that, above all, the final challenge is that of welcoming (hospital equals hospitality) the persons that we are lucky to meet every day thanks to our marvelous job and for whom, hopefully most of the times, we are able to be good.

Reference/ www.medicinaepersona.org - Journal of Medicine and the Person

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Original article

Arguments for mesh implantation at the treatment of pelvic organ prolapse, enabling the benefit of uterine preservation: outcome in 459 procedures

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Abstract: Urogynecologists are constantly looking for simple, safe and durable methods to cure pelvic organ prolapse (POP). We used a novel surgical technique utilizing synthetic mesh (Prolift®, Gynecare, Summerville, NJ, USA) to reinforce the pelvic floor in cases of POP with high risk of recurrence, while preserving the uterus. The aim of this study was to analyze cure rates as well as peri-operative data and peri-operative complications. Patients with advanced POP and being at risk for recurrence were enrolled into the study and underwent Proift mesh implantation, hysterectomy was performed for indications other then prolapse or upon patient's request. Previous POP surgical reconstruction, first degree relative with significant pelvic floor fascial defect and poor pelvic supportive tissue were regarded as risk factors for POP recurrence. Pre-operative demographic data, operative details and immediate postoperative follow-up data were prospectively collected for all patients. A total of 459 POP patients were subjected to the mesh operation in an overnight setting. Two hundred and thirty patients (50%) were operated for prolapse of the anterior compartment, 229 (50%) for prolapse of the posterior compartment and 302 (66%) for both, with 85 (18%) of them undergoing implantation of both anterior and posterior pelvic floor meshes; the others had a single pelvic floor compartment mesh implantation with opposite side colporrhaphy. Uteri were preserved with 291 (95%) patients suffering uterine prolapse. Peri-operative complications included bladder penetration (1%) and rectal laceration (0.2%). Early and late adverse outcome were hematoma (1%), vaginal mesh exposure (2%) and recurrence (4%). Total un-favorable outcome was 7%. All these women were cured with no morbid sequela. The mesh POP reconstruction operation carries a low complication rate. Uterine preservation is feasible and safe. The current study supports the previously reported favorable therapeutic outcome of this procedure.

Key words: Mesh; Pelvic organ prolapse; Pelvic floor reconstruction.

INTRODUCTION

POP (pelvic organ prolapse) occurs in up to 50% of parous women. It causes a variety of urinary, bowel and sexual symptoms. POP is surgically treated in 11% of the total female population. Furthermore, up to 30% of those who undergo traditional non-mesh surgery will eventually go through repeat prolapse surgery, some of them following hysterectomy.[1-4]

Operation for POP cure, such as vaginal hysterectomy, colporrhaphy, with or without plication of the utero-sacral ligaments, as well as sacro-spineous and sacral colpopexies, are also associated with up to 30% recurrence rate, as determined by objective POP scoring and prolapse-related subjective symptoms. Previous POP surgical reconstruction, first degree relative with significant pelvic floor fascial defect and poor pelvic supportive tissue were regarded as risk factors for POP recurrence.[5-11]

Experience with abdominal wall herniorrhaphy showed that the mesh implant concept had a low recurrence rate, and it was therefore subsequently implemented for pelvic floor herniation repair.[12]

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

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

The first innovative procedure for the correction of the apical vaginal support defect and used a vaginal approach was replacement of the utero-sacral ligament by a synthetic sling positioned at the levator plate level was the Posterior Intra-Vaginal Sling (PIVS). Restoration of the uterosacral ligament support and re-suspend the uterine isthmus, making the addition of vaginal hysterectomy unnecessary.[13-18] By not removing the uterus, the cervical ring, a solid central pelvic anchoring point is preserved. This provides extra stability for the pelvic floor by recruitment of the related web ligamentary architecture for the pelvic reconstruction and avoids potential iatrogenic weakening of the pelvic floor due to surgical impairment of innervation and blood supply. In contrary, adding hysterectomy to mesh pelvic floor reconstruction significantly increases (O.R. = 15 add confidence intervals) the risk of post-operative vaginal mesh exposure. Other occasional adverse outcomes of hysterectomy are vaginal shortening and psychological effects in terms of the woman's body image and self esteem.[19-28]

This study goal is to evaluate the newly developed Profit operation for pelvic floor reconstruction without additive vaginal hysterectomy, in terms of cure and failure rates as well as related complications rates and safety.

PATIENTS AND METHODS

Patients experiencing stage 3 or 4 vaginal apical supportive defects, diagnosed clinically in accordance with the International Continence Society (ICS) Pelvic Organ Prolapse Quantification (POPQ) standard scoring system, and who were at increased risk for recurrence of the POP, were referred for Prolift® (Gynecare, Summerville, NJ, USA) implantation operation. Risk factors for recurrence included previous POP reconstruction surgery, first degree relative with a significant POP or poor pelvic floor tissue as assessed clinically.[29-32] Patients with mild POP and not at risk for recurrence were referred to conventional non mesh opera-

tions. Patients who had undergone previous pelvic irradiation, or with an immuno-depresive state, active infection, systemic steroid use or poorly controlled diabetes were excluded.

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

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

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

Patients presenting with additional significant features of pelvic floor relaxation underwent anterior or posterior colporrhaphy, as well as anti-incontinence surgery when indicated, at the same time as the Prolift® operation. Vaginal hysterectomy was carried out for indications other than prolapse or upon patient's request, otherwise was the uterus preserved. With these patients was the uterine cervix amputated if it was elongated.

Pre-operative demographic data, operative details and immediate postoperative follow-up data were prospectively collected for all patients. Intra-operative and post-operative complications of all patients were recorded prospectively. The patients were interviewed at the first and sixth postoperative months and yearly thereafter. Subjective data recording included symptoms as urgency, frequency, stress and urge incontinence of urine or feces, sexual function impairment, voiding habits and pelvic pain and bulging. The objective data collection was carried out by a non involved surgeon and included a physical pelvic examination, verification of urine or feces incontinence, and pelvic floor and organs assessment, in accordance with the ICS standards terminology.

RESULTS

Between January 2006 and January 2009, 459 Prolift® procedures were performed. All demographic, personal and clinical details are tabulated in Tables 1 and 2.

One hundred and fifty-six (34%) patients had undergone a previous hysterectomy – a third of them vaginaly and the rest abdominally. Two hundred and thirty patients (50%) had advanced prolapse of the anterior compartment, 229 (50%) had advanced prolapse of the posterior compartment and 302 (66%) had both. Nevertheless, only 85 (18%) needed implantation of both anterior and posterior Prolift®, the others had a single pelvic floor compartment Prolift® and opposite side colporrhaphy. Vaginal hysterectomy was performed in 12 patients (3%) – for indications other than prolapse or at the patient's request, 47 (10%) underwent partial amputation of a significantly elongated uterine cervix. Ninety-three patients (20%) underwent anti-incontinence surgery (TVT SECUR® or TVT-Obturator®, Gynecare, Summerville, NJ, USA) in addition to Prolift® implantation (Tab. 3). Five patients (1%) suffered intra-operative bladder injury; four were corrected vaginally and one required laparotomy, as the laceration was adjacent to the trigone. One suffered a rectal laceration that was corrected immediately, six (1%) lost more than 300 ml of blood intra-operatively, blood transfusion was not indicated. Eight (2%) had post-operative vaginal mesh exposure, resected at office, 32 (7%) had de-novo over-active bladder symptoms. Six (1%) patients had a post-operative hematoma within the pararectal fossa. These patients were treated orally with prophylactic broad-spectrum antibiotics; all patients with

TABLE 1. – *Patients' demographic and personal details.*

Age (Yrs, Av., range)	65 (43-91)
Parity (Av., range)	3.0 (0-6)
Chronic illness* (No, %)	184 (40%)
Previous hysterectomy (No, %)	156 (34%)
Vaginal (No, %)	58 (13%)
Abdominal (No, %)	98 (21%)

* Diabetes mellitus, bronchial asthma, hypertension, etc.

TABLE 2. – *Clinical data.*

Cystocele, C>2* (No, %)	230 (50%)
Rectocele, C>2* (No, %)	229 (50%)
Cystocele & rectocele, C>2* (No, %)	302 (66%)
Uterine prolapse, C*>2 (No, %)	307 (67%)
Previous POP reconstructive surgery (No, %)	289 (63%)
First degree relative with significant POP (No, %)	58 (13%)
Poor pelvic floor tissue (No, %)	162 (35%)

* According with the ICS POP-Q system.

Table 3. – *Operative details.*

Anesthesia	
408 (89%)	General (No, %)
51 (11%)	Regional (No, %)
Prolift® surgery	
230 (50%)	Anterior Prolift® (No, %)
229 (50%)	Posterior Prolift® (No, %)
{85 (18%)}	{Anterior & posterior Prolift® (No, %)}
302 (66%)	Additional surgery
12 (3%)	Contra lateral compartment colporrhaphy (No, %)
93 (20%)	Vaginal hysterectomy (No, %)
47 (10%)	Anti-incontinence surgery (No, %)
Cervical amputation	
291 (95%)	Preservation of prolapsed uterus (No, %)

adverse effects recovered with no morbid sequelae. The incidence of persistent and de-novo fecal constipation urinary emptying difficulties, bladder over activity symptoms and dispareunia are tabulated (Tab. 4). Seventeen patients (4%) presented with operative failure: four had recurrence of anterior compartment prolapse, one had posterior compartment prolapsed recurrence and 12 (3%) had apical recurrence. In 423 patients (92%) were the results satisfying, being both – free of complications and cured, as defined by the POPQ criteria (Tab. 4). This includes patient's satisfaction with the anatomical results and cure of the debilitating introital lump related to the prolapse as well as proper function of the pelvic organs: the vagina, the bladder and the ano-rectum.

Table 4. – *Operative and post operative (P/O) data.*

5 (1%)	Operative bladder injury
1 (0.2%)	Operative rectal laceration
3 (0.6%)	Operative bleeding > 300 ml
0 (0%)	Operative field infection (No, %)
6 (1%)	P/O hematoma (No, %)
4 (1%)	P/O granulation tissue
8 (2%)	P/O mesh protrusion (No, %)
4 (1%)	Further mesh segmental resection (No, %)
28 (27%)	P/O Persistent fecal constipation at previously constipated 104 patients (No, %)
0	De novo fecal constipation
9 (21%)	P/O persistent Difficult urination at previously obstructed 42 patients (No, %)
6 (1%)	De novo difficult urination
103 (44%)	P/O persistent OAB symptoms at previously 234 OAB patients (No, %)
32 (7%)	De novo OAB symptoms
14 (7%)	P/O persistent dispareunia at sexually active 211 patients (No, %)
15 (7%)	De novo dispareunia
4 (1%)	P/O post anterior Prolift® cystocele (No, %)
1 (0.2%)	P/O post posterior Prolift® rectocele (No, %)
12 (3%)	P/O apical prolapse (No, %)
423 (92%)	Patients satisfied with overall therapeutic results (No, %)

*OAB: Over active bladder.

DISCUSSION

A large scale study of women suffering advanced POP, undergoing the Prolift® procedure with prolapsed uterus preservation, is presented. The feasibility, curability and safety of this procedure do not appear to be inferior to previously reported operative techniques. In fact, this technique has less intra-operative and post-operative complications with relatively high short-medium terms cure rate.

There is sparse evidence-based data in the English literature regarding anatomical and functional long term outcomes of POP surgery for both – mesh and non-mesh operations. This is true for vaginal hysterectomy with advanced uterine prolapse, for paravaginal and site-specific prolapse repair and for abdominal sacral colpopexy. Nevertheless, vaginal sacrospinal fixation and abdominal sacrocolpopexy have remained the "gold-standard" for the repair of vaginal apical suspension defects.[33] Similarly, questions regarding the use of mesh, the preferred mesh type, size, shape and anchoring points for reinforcement of the pelvic floor compartment and for conservation of the prolapsed uterus remain unanswered for the time being. The decision as to which mesh to use – if at all, depends heavily on the individual surgeon's training and experience. This is obviously an insufficient basis for proper decision-making, which should clearly be evidence based.[34-44]

A Cochrane review analyzing 22 trials with 2368 patients showed that abdominal sacro-colpopexy (SCP) result in lower POP recurrence rates and less dispareunia than does vaginal colpo-sacro spineous fixation (VCSSF). On the other hand, VCSSF has the advantage of a shorter operation time and recovery period. Mesh implants were found to reduce prolapse recurrence following anterior vaginal wall reconstruction, and the vaginal approach was found to be superior to the trans-anal for posterior compartment repair. Many authors acknowledge that the paucity of relevant data regarding the operation of choice for POP does not provide adequate information to guide practice. At the same time it is recognized that non-mesh POP reconstructive surgery carries an unacceptably high rate of POP recurrence. Thus, and in spite of the relative lack of evidence-based information regarding long term efficacy and safety, the use of mesh grafts for POP vaginal reconstruction is growing rapidly. There is also considerable debate regarding the place of vaginal hysterectomy in POP surgery.[35-49]

Presented here is the peri-operative data regarding 459 advanced POP patients, being at risk for recurrence with conventional non-mesh POP repair operations. All had anterior or posterior Prolift® mesh implantation, 85 (18%) of them had both. Hysterectomies were not performed unless for indications other then uterine prolapse or upon patient's request. At the end of the first post-operative year was the failure rate 4% (17 Pts) with cumulative patient overall outcome satisfaction of 92% (423 Pts). The relatively low mesh vaginal protrusion incidence was achieved by implementation of some surgical steps, designed to avoid such.[50] Rates of post operative persistence and de-novo fecal constipation, urine flow obstruction, bladder over activity and dispareunia were found to be at rather low levels. Unfortunately, comparison of these to other operation for POP cure is not feasible on the grounds of lace with relative solid data. No significant or un-curable negative long term influence on patient's well being was recorded. Conservation of the prolapsed uterus does not seem to carry any deleterious effects, and probably the contrary is true. This includes shortening of hospitalization and recovery periods reducing potential hysterectomy related adverse outcome, including psychological and physical. Preservation of the prolapsed uterus permits recruitment of the residual pelvic ligamentary architecture, attached to

the uterine cervix, to the web of pelvic floor reconstruction. This is likely to further increase pelvic floor reinforcement. Pelvic floor mesh reconstruction operations involve extensive deep pelvic dissection. Hence, it is mandatory that surgeons be thoroughly familiar with the anatomy, with accurate surgical technique, potential hazards and preventive measures, and management of complications before embarking on the implantation of such meshes. It is suggested that surgeons undergo a meticulous training program with an expert prior to undertaking this procedure. [51]

Mesh implantation must be considered carefully for each potential candidate, taking into account that the ultimate goal is quality of life improvement, by correcting both the anatomical and functional derangements. It is widely agreed that mesh implantation should be further investigated prior to the retraction of recommendations regarding their usage.

CONCLUSIONS

The pelvic floor reconstruction mesh (Prolift®) operation, designed to prevent POP recurrence, provides a safe, feasible and curative surgical technique. POP reconstruction with anterior, posterior or total Prolift® was successfully achieved in 423 (92%) of 459 patients in this study group, with a reasonably low rate and severity of complications. Comparison with older operative techniques was not feasible because the absence of sufficient and solid relevant data. However, this rather new procedure, for either post-hysterectomy POP or for advanced uterine prolapse with or without uterine preservation involves potentially hazardous surgical steps, hence meticulous training is mandatory.

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Pelvic Floor Digest

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

FORUM

Do we see what we think we see? The complexities of morphological assessment. *Hamilton PW, van Diest PJ, Williams R, Gallagher Ag. J Pathol. EPUB: 2009-03-18.* There is a paucity of research in the field of decision-making. Understanding the complex processes involved in it is the starting point to improve both diagnostic reproducibility and the definition of diagnostic groups that underpin all our experiments. Reliable pathological interpretation for instance is vital to so many aspects of tissue-based research as well as being central to patient care. Work in this area should be encouraged since there are many opportunities and technologies available to support this type of research.

1 – THE PELVIC FLOOR

Pelvic reconstructive surgery in renal transplant recipients. *Shveiky D, Blatt A, Sokol AI et al. Int Urogyn J Pelvic Floor Dysf. EPUB: 2009-02-12.* This study describes an experience with pelvic reconstructive surgery in renal transplant recipients. Vaginal hysterectomies with vault suspension, anterior and posterior repairs, synthetic midurethral slings were safely performed without intraoperative or postoperative complications.

2 – FUNCTIONAL ANATOMY

Increased colonic transit in rats produced by a combination of a cholinesterase inhibitor with a 5-HT(4) receptor agonist. *Campbell-Dittmeyer K, Hicks GA, Earnest DL et al. Neurogastroenterol & Motil. EPUB: 2009-02-13.* The acetylcholinesterase inhibitor neostigmine and the 5-HT(4) receptor partial agonist tegaserod have a prokinetic activity and increase ACh at cholinergic synapses innervating intestinal smooth muscle. In combination, low doses of the two agents which did not produce significant effects alone, cause, as a synergistic effect, significant increase in fecal pellet output in rats. Combinations of higher doses did not display synergy. This may be a useful therapeutic approach to treat conditions associated with slow GI transit.

Influence of naloxone on rectal sensorimotor function in health. *Geeraerts B, V Oudenhove L, Vos R, et al. Neurogastroenterol & Motil. EPUB 2009-02-19.* Endogenous opioids are involved in both the regulation of gut motility and the processing of sensory information. Abnormal rectal motor physiology and visceral hypersensitivity are implicated in the pathogenesis of irritable bowel syndrome. The suppression of endogenous opioid function by naloxone on rectal sensorimotor function was studied in 18 healthy subjects with a rectal barostat. Naloxone does not alter rectal sensitivity but abolishes rectal adaptation in response to repeated balloon distention. These observations suggest that the endogenous opioid system is involved in control of rectal tone rather than rectal sensitivity.

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Multimedia anatomy

Pelvic floor disorders

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INTRODUCTION

Pelvic Floor Disorders is a Prima) Pictures software. Prima) Pictures was established in 1991 with the goal of creating a complete and medically accurate 3D mode) of the human anatomy. This mission was completed and the software is now widely adopted in education and is currently used for patients, practitioners, students, teachers and specialists in over 20 countries in the world. Prima) Pictures works on many customisation projects every year to tailor the mode) to the needs of training programs as well as to animate surgery or disease looking for detailed accurate knowledge, medicai and graphics expertise.

The representation of the body in the range of the software is unique because of its accuracy and details. It is derived from genuine medicai scan data that have been interpreted by a team of anatomists and then translated into three-dimensiona) images by an expert team of graphics specialists. The anatomy visuals are accompanied by three-dimensiona) animations that demonstrate function, biomechanics and surgical procedures. To supplement the core three-dimensiona) anatomy data there are clinical videos and texts written by some of the world's leading medicai specialists.

DESCRIPTION AND COMMENT

Pelvic Floor Disorders covers the anatomy of the female pelvis and pelvic floor in 3D images, alongside related text, bibliographical references and animations. Forty seven highly detailed and labeled views of the pelvis include muscles of the pelvic floor, reproductive system, urinary and digestive systems, bone regions, surface markings, neurology - including the lumbar plexus and sacral and coccygeal plexuses - and the autonomic nervous system.

The DVD has a comprehensive guide to all the tabs, tools, and icons. A box shows the Quickstart, Tutorial, and Getting Started text every time the application is used. It also includes an extensive clinical section covering diagnosis, treatment and rehabilitation of commonly presenting pelvic floor disorders. This helps in quickly understanding how to use the DVD-ROM and gives an overview of all the functions and contents. All structures have accompanying text and links to additional images including labeled coronai sections of the female pelvis and clinical slides. This device is easy to use and educationally immediate in its anatomie data. It allows a deep understanding of different structures and their relationships, being extremely useful for surgeons, urologists, gynecologists.

When initializing, the browser displays a list of ali available 3D views to quickly navigate around the selected subject. Selecting the "contents icon", a list of expandable folders containing text articles for all structures as well as slides, movies, animations, 3D views, clinical text, and patient information sheets, will open.

The Anatomy Section is very interesting, showing a large number views covering the anatomy of the pelvis and female reproductive system with alongside related text, not only in bi-dimensional piane (slides) but also in 3D. The images can be analyzed by focusing on the details by adding/removing layers of anatomy using the layer control at the bottom of the screen. Clicking on any structure inside the image, the related text appears to the right of the screen. The images can be rotated and zoomed; the structures can be underlined inside the images (the name of the structure appears when it's selected) or found inside the image once the topic has been selected in the displayed list. Besides the anatomical images there are superficial cutaneous representations of female abdominal-pelvic structures, with skin innervations, dermatomes and nervous supply. Also pelvis bones can be visualized apart, showing the different junctions with muscles, tendons and nerves.

Entering the *Clinical Information* icon it is possible to explore a range of pelvic floor disorders, such as pelvic organ prolapse, incontinence, and pain syndromes. Data on defmitions, physical examination, diagnosis and treatments are updated, with references in the literature, scientifically quite reliable. One can go back to anatomie images or slides by specific links. This section is useful for those who want a rapid revision on pelvic floor problems, or that approach for the first time to this subject and need a generai summary.

There is a specific section for *Patient Information on pelvic floor disorders*. It includes an extensive clinical section covering diagnosis, treatment and rehabilitation of commonly presenting pelvic floor disorders (prolapses, incontinences, pelvic pain syndromes, pelvic floor damages, and treatments) speaking about their definition, description, diagnosis and treatment, plus a dedicated patient education section with printable easy to understand information sheets (Kegel exercises, postpartum pelvic floor rehabilitation, etc.).

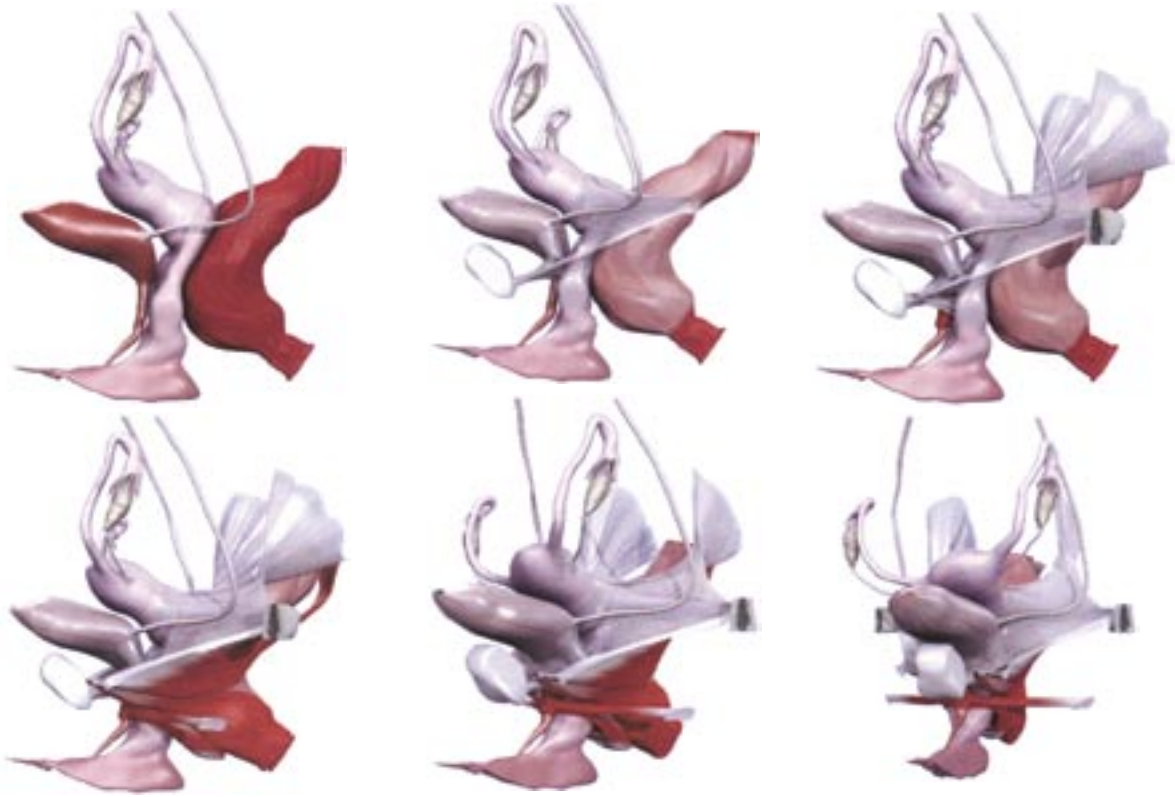
There is a *dynamic representation* of a pelvic floor that shows the relationships between muscles, ligaments and pelvic organs as a unique entity. There are animations on pelvic floor contraction, slides (coronai section through female pelvis) and movies that show some examples of genital prolapse of different type (anterior, posterior) and degree, or of pelvic floor real contraction movement from different perspectives with or without pelvic organs.

Finally through the *Search* icon clicking on a specific topic the entire contents of each title can be rapidly found. This function allows to search for any item (e.g. a 3D image or text article) contained within the title. Typing in a word or a short phrase as a search term, results will be displayed in the lower part of the window, divided in Anatomica! Names, Slide Structures, Clinical info text, Animation Titles, Slides and so on.

The *Index* icon lists all anatomica! structures, slides, movies, animations, 3D views, clinical text, and patient information sheets alphabetically so that the search will be easier. Everything can be saved and printed (for personal use, power point, classes, etc).

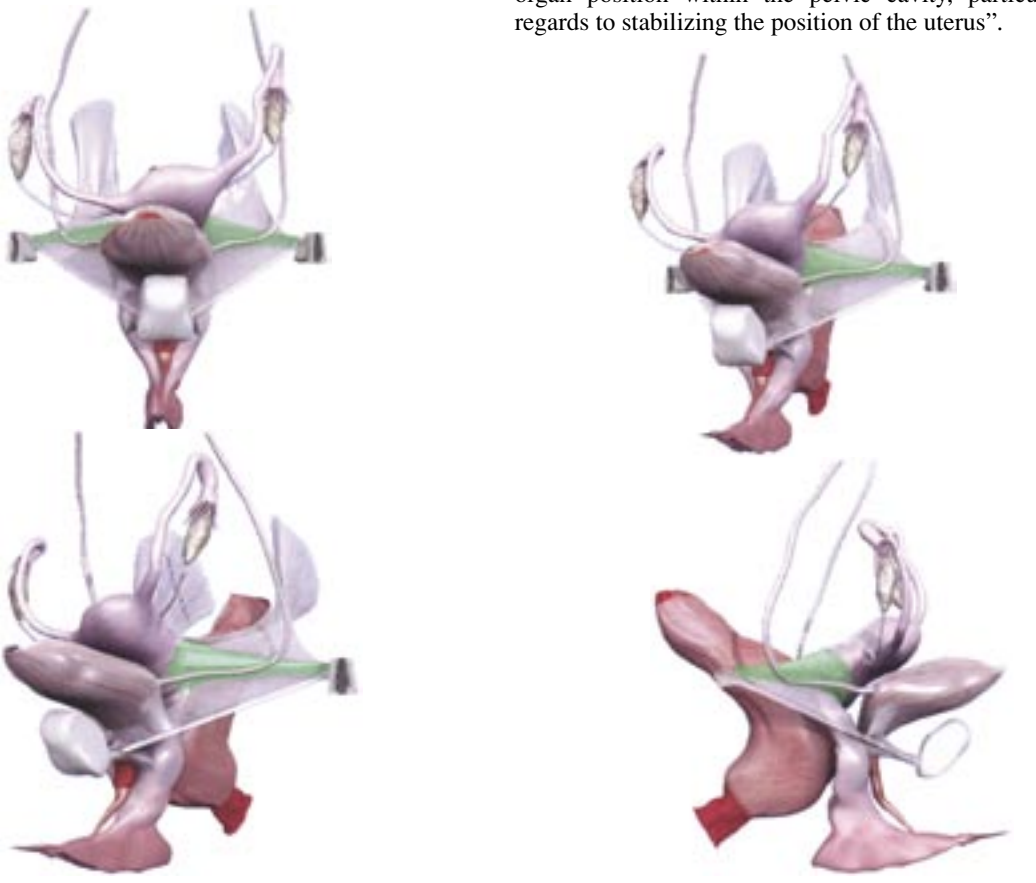
AN EXAMPLE FROM THE DVD-ROM: THE ENDOPELVIC FASCIA

The endopelvic fascia has a great interest in pelvic surgery. For this article some of the elements of endopelvic fascia have been selected trying to show what often is difficult to understand, as knowing exactly where a sling blindly goes through the fascia or a mesh is fixed or connected to the fascia or to the ligaments.



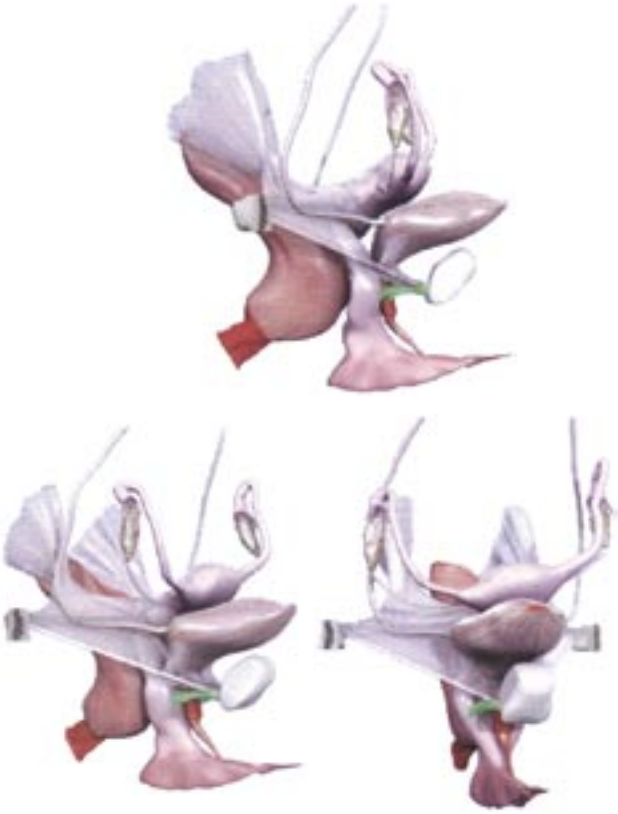
THE CARDINAL LIGAMENT

"Considered to be the posterolateral condensations of the endopelvic fascia, the cardinal ligaments, also known as the -transverse cervical ligaments, are sheets of connective tissue that extend from the lateral aspects of the cervix and the fornix of the vagina to the lateral pelvic wall. At the cervix, each merges with the cervical ring as well as the uterosacral, pubocervical and rectovaginal ligaments. In its course, the superior-most portion is located at the base of the broad ligament. Here, the uterine arteries and veins pass transversely through the cardinal ligaments to reach the cervix, while the ureters pass beneath them. The cardinal ligaments function together with the other fasciai ligaments of the female reproductive tract to support and maintain organ position within the pelvic cavity, particularly in regards to stabilizing the position of the uterus".



THE PUBO-URETHRAL LIGAMENT

"Considered to be an anterior condensation of the endopelvic fascia, the pubo-urethral ligament extends from the inferior surface of the pubic bone to the middle part of the urethra. It extends superiorly to the neck of the bladder as the pubovesical ligament. It acts to stabilize the urethra by preventing anteroposterior movement".



THE PUBOCERVICAL LIGAMENT

"Considered to be the anterosuperior condensation of the endopelvic fascia, the pubocervical ligament is a continuous sheet of connective tissue that extends from the body of the

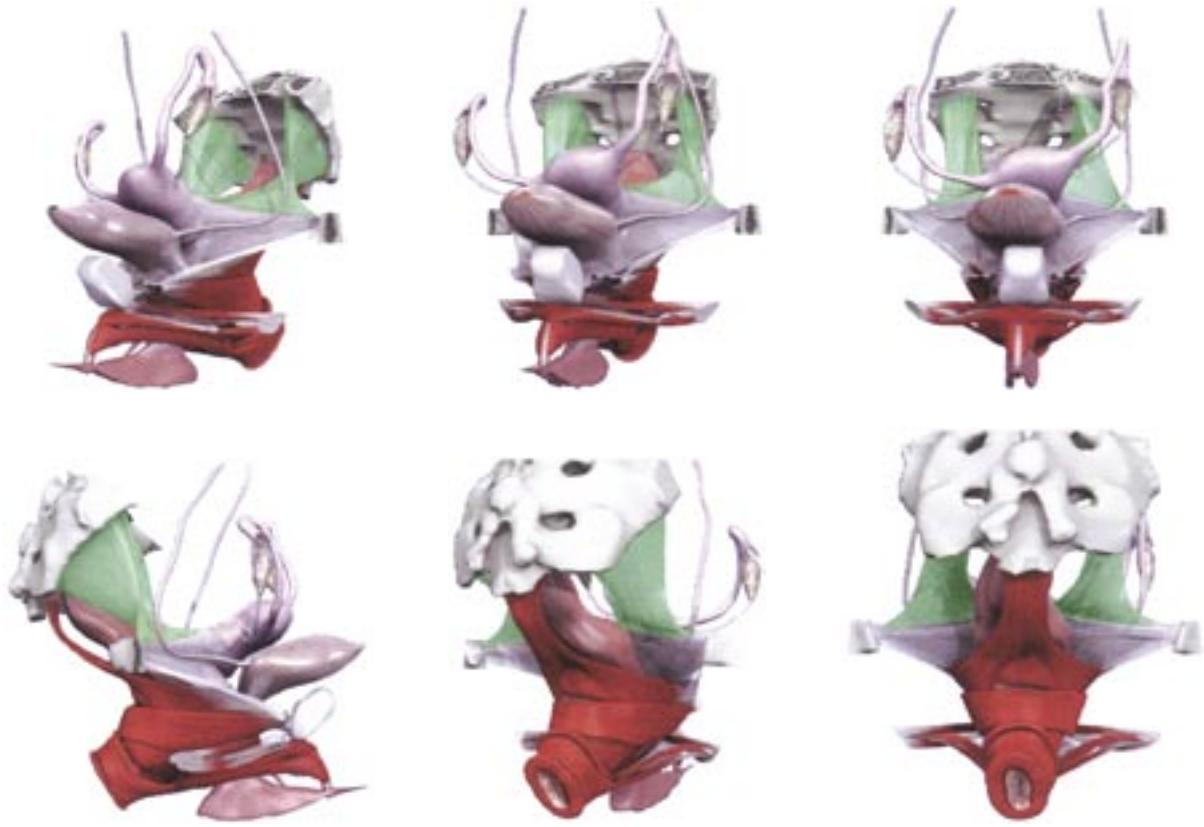
pubis to the anterior part of the cervical ring. It is anchored laterally to the tendineus arch of the pelvic fascia and is continuous with the pubovesical ligaments anteriorly and the transverse cervical ligaments posteriorly. The pubocervical ligament functions together with the other fasciai ligaments of the female reproductive tract to support and maintain organ position withing the pelvic cavity".

THE UTEROSACRAL LIGAMENT

"Considered to be the posterosuperior condensations of the endopelvic fascia, the uterosacral ligaments are condensed mix of fibrous connective tissues and smooth muscle fibres that connect the cervix to the sacrum. The paired ligaments emerge posterolaterally from the cervix where they are merged with the cervical ring and cardinal ligaments; they ascend posteriorly to attach with the presacral fascia to the anterior surface of the fourth to first sacral vertebrae. On their course they envelop visceral branches of the internai iliac vessels (uterine, vaginal and rectal arteries) and the inferior hypogastric plexus. The uterosacral ligaments function together with the other fasciai ligaments of the female reproductive tract to support and maintain organ position within the pelvic cavity, particularly in regards to the uterus".

CONCLUSION

Primal Pictures warns that the material on this software is for educational purposes only and is not intended to represent the test approach, method or procedure for the situations discussed, but just to present various approaches, procedures, views, or analysis of several authors that may be helpful to others who face similar situations. The DVD-ROM is for noncomrnerciallnon-profit use and includes private educational use, lectures to students and colleagues and patient education handouts. Non-commerciallnon-profit use is allowed and does not require any additional permission or license. Its public domain and commercial/for profit use includes websites, books, videos, TV programmes, Journal article, used in medicai devices.



A *Getting Start Guide* allows training through the product by getting used to the images and their visualizing options, saving, printing and the DVD contents. A technical support staff can be contacted for assistance at techsupport@primalpictures.com.

Minimum requirements are: operating systems: Microsoft® Windows XP or Vista and MAC OSX 10.3-10.5. Processor speed: 1.5GHz with 512MB of RAM, 200MB free disk space for all platforms. Screen display: 1024x768 screen. DVD-ROM drive.

Primal Pictures has a range of other DVDs available: Radiological Cross Sectional Interactive Anatomy with multi-detector CT: Thorax, Abdomen and Pelvis; Anatomy for Urology; Interactive Functional Anatomy 2nd Edition - 2009 release; Interactive Complete Human Anatomy Series. Full details can be found at www.primalpictures.com and online trials are available at www.anatomy.tv.

Pelvic Floor Digest

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3 – DIAGNOSTICS

Validation of Spanish versions of the Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ): a multicenter validation randomized study. *Omotosho TB, Hardart A, Rogers RG et al. Int Urogyn J Pelvic Floor Dysf. EPUB: 2009-02-14.* Valid and reliable Spanish versions of the PFIQ and PFDI have been developed using back translation and by randomizing 44 bilingual women to complete the Spanish or English versions of the questionnaires (weighted kappa statistics assessed agreement for individual questions, interclass correlation coefficients (ICC) compared primary and subscale scores, and Cronbach's alpha assessed internal consistency of Spanish versions).

Three-dimensional endoanal ultrasonography: intraobserver and interobserver agreement using scoring systems for classification of anal sphincter defects. *Norderval S, Dehli T, Vonen B. Ultrasound in Obst & Gyn. EPUB: 2009-02-19.* To determine the degree of intraobserver and interobserver agreement for an experienced and an inexperienced sonologist using an endoanal ultrasound defect score system and the Starck score for ultrasonographic assessment of anal sphincter defects, datasets of 55 women were included and their sphincter defects were classified. Intraobserver and interobserver agreement was acceptable for both scoring systems. The experienced sonologist obtained a higher degree of intraobserver agreement than did the inexperienced sonologist.

4 – PROLAPSES

Multiple perineal abscesses and sinus tracts as a complication of vaginal mesh. *Lewicky-Gaupp C, McGuire EJ, Fenner DE. Int Urogyn J Pelvic Floor Dysf EPUB: 2009-02-21.* A 54-year-old woman with constant perineal pain, and copious, foul-smelling vaginal discharge after anterior and posterior placement of a synthetic mesh and mid-urethral sling 3 months earlier, was found to have two vaginocutaneous sinus tracts (to the left ischiorectal fossa and to the left labia majora), as well as bilateral abscess cavities within the ischiorectal fossae. The posterior mesh was completely excised, the tracts were opened, and the wound was packed and allowed to heal by secondary intention.

Clinical, physiological and radiological assessment of rectovaginal septum reinforcement with mesh for complex rectocele. *Zbar AP, Ansari A. Brit J Surg. EPUB 2009-02-19.*

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Original article

Sacral neuromodulation treatment for refractory interstitial cystitis: long-term experience at one center

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Abstract: The objective of this study is to examine the long term efficacy of sacral neuromodulation for the treatment of refractory interstitial cystitis. All patients diagnosed with interstitial cystitis who received sacral neuromodulation from 1998 to 2002 were approached for participation in this study. After informed consent was obtained subjects were mailed questionnaires consisting of a global response scale and several questions regarding the average number of voids per day and night. Fifty-six patients were identified and were mailed questionnaires. Twenty-eight patients (50%) responded to the questionnaire packet. The mean length of time of sacral neuromodulation was 4.3 years. The mean voiding interval for the subjects improved from voiding every 1.22 hours to every 2.57 hours after implantation (p=.001). Nocturia rates improved from 3.43 voids per night to 2.20 voids per night (p<.001). 89% of subjects reported an improvement of symptoms over time. This study indicated that there may be a long term benefit of sacral neuromodulation for the treatment of refractory interstitial cystitis.

Key words: Sacral neuromodulation; Interstitial cystitis.

INTRODUCTION

Interstitial Cystitis (IC), characterized by pelvic pain, nocturia, urinary urgency, and urinary frequency is a chronic condition with unknown etiology and no available cure.[1-3] It is estimated to affect 60 per 100,000 to 200 per 100,000 people worldwide.[2,4] The goal of therapy is to reduce symptoms and improve the quality of life of people with this disease. Conservative therapies include a low acid diet, physical therapy and behavioral therapy. Medical therapy includes the use of pentosan polysulfate sodium (FDA approved for the treatment of IC), anti-cholinergic medications, oral bladder analgesics, and bladder instillations with analgesic medications.[5-11] If a patient fails to obtain relief from the above therapies then at this center we offer sacral neromodulation.

The InterStim® System (Medtronic Corporation, Minneapolis, MN) is a sacral neuromodulation system FDA approved to treat urinary urge incontinence, urinary urgency and frequency, and non-obstructive urinary retention. Its mechanism of action is not completely established, however it is hypothesized to stimulate the somatic afferent nerve at the third sacral nerve root, which will inhibit the activity of the pontine micturition center.[12-15] Long-term efficacy has been demonstrated in the treatment of these conditions for up to 13 years.[16, 17] Several studies have demonstrated that this therapy can be effective in the treatment of IC; [18-25] however, available long-term data is minimal. We sought to evaluate the long-term efficacy of sacral neuromodulation for the treatment of IC.

MATERIALS AND METHODS

A retrospective chart review was performed on all patients from 1998 to 2002 who underwent a permanent implantation of the InterStim® device for the symptoms of IC following a successful Stage 1 test period. All patients had attempted and failed at least two conservative or medical therapies before being offered sacral neuromodulation. All patients were diagnosed with IC using the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) criteria.[26] The patients were mailed questionnaires consisting of a global response assessment scale (GRA) and several questions regarding the frequency of voiding.[27,28] Follow up phone calls were performed to ascertain receipt of the questionnaire and encourage completion. Paired t-test and Wilcoxon signed-rank tests were used for statistical analysis. The Institutional Review Board at Graduate Hospital approved this study.

RESULTS

Fifty-six patients, all female, were identified and mailed the questionnaires. Twenty-eight patients (50%) responded. Mean age at the time of implant was 57 years old (range 28-93). Mean length of time of sacral neuromodulation was 4.3 years (range 3.2-6.3 years). The mean number of reprogramming visits after implantation was 2.2 visits per year over the lifetime of the implant. The majority of reprogramming visits occurred during the first year with a mean of 4.5 visits over the first year and then decreased each year thereafter with an average of 0.9 reprogramming visits at the fourth year, post implant.

Patient's voiding interval significantly improved from baseline. Prior to the placement of the implantable pulse generator (IPG), the patients were voiding on average, every 1.22 hours. After the IPG was implanted this improved to voiding every 2.57 hours (p=.001) (Tab. 1). The patient's nocturia rates improved 64%, decreasing from 3.43 voids *per night* to 2.20 voids *per night* (p<.001) (Tab. 1). Fifteen (54%) patients indicated marked improvement, six (21%) patients indicated moderate improvement, four (14%) patients indicated mild improvement, two (7%) patients indicated no change, and one (4%) indicated moderately worse symptoms from the global response assessment. (Fig. 1). Overall, 24 patients (89%) reported an improvement in their symptoms, and three patients (11%) reported either no change or worsening of symptoms.

Twenty-eight out of fifty-six (50%) patients did not respond to the questionnaires. Of those that did not respond, nine (16% of the total) were lost to follow up, ten (18% of the total) had the device explanted and three (5% of the total) had turned the device off. The remaining six (11% of the total) were incapable of responding secondary to a terminal illness or death (Tab. 2).

The research project was conducted at The Pelvic and Sexual Health Institute, Philadelphia, PA

TABLE 1. – *Long-term follow-up statistics. Nocturia rate pre- and post-implant and voiding interval pre- and post-implant. Statistical difference was seen pre- and post-implant.*

	n.	*Pre-implant Mean (SD)*	*Post implant Mean (SD)*	*Difference Mean (SD)*	*P-value*
Nocturia	28	3.43 (1.4) voids	2.20 (1.2) voids	1.21 (1.6) voids	<.001
Voiding Interval (hours)	28	1.22 (0.8)	2.57 (1.5)	1.38 (1.8)	.001

TABLE 2. – *Non-responders. Reasons for non-responders: lost to follow up, device explanted, device turned off, or unable to respond.*

	Number of non-responders	*Percentage of the total sample*
Lost to Follow Up	17	16
Device Explanted	10	18
Device turned off	3	5
Unable to respond	6	11

DISCUSSION

Prospective trials have shown that sacral neuromodulation can have short term improvement in the symptoms of IC.[19, 21, 24, 25] These studies followed patients an average of 14-15 months after implantation. This current study indicates that there is a potential long term (average 4.3 years) efficacy for the symptomatic treatment of IC. The need for reprogramming decreased every year to just under one reprogramming visit per year after four years of use.

Of those that responded, 89% reported improvement in symptoms. Of those that completed the questionnaires, the patients reported an improvement in voiding interval by 1.38 hours and a decrease in nocturia by 1.21 voids per night. If all of the non-responders were considered treatment failures, then the success rate of this therapy would decrease to 45%. This response rate is still superior to long term results of pentosan polysulfate sodium, an FDA approved medication for interstitial cystitis. In a long term analysis of pentosan polysulfate sodium for the treatment of IC, Jepsen et al. found that only 6.2% to 18.7% of patients reported improvement from the therapy.[29] In a meta-analysis of the efficacy of pentosan polysulfate sodium for the treatment of IC over a three month period, Hwang et al. found that 37% of subjects reported improvement of pain, 28% reported improvement in urgency, 54% reported improvement in frequency, and 48% reported improvement in nocturia.[30] In the context of these studies, it would appear that sacral neuromodulation may be a valid therapy for IC.

Due to the nature of the study design these results can be affected by recall bias. The treatment of IC often uses a multi-modal approach combining both medical and conservative therapies simultaneously. Due to the nature of combining multiple therapies, it is difficult to state that improvement of symptoms is solely due to one of their treatments and not others. In order to better understand the effect of sacral neuromodulation on IC, a prospective trial has begun by the principal author that is designed to remove these possible confounding variables.

Only 10 of the 56 patients (18%) had their devices explanted. This corresponds to other published explant rates for patients with interstitial cystitis.[31] The rate of explant in non-IC patients has been reported to be approximately 10%.[15, 16] This is not well understood, however, a theory for this could be that the therapy does not appear to control the pain as much as it controls the urinary urgency and frequency. If patients expect the InterStim therapy to control their pain substantially, they may become disappointed and request the device be removed.

Patients suffering from refractory IC may benefit from sacral neuromodulation therapy with the InterStim device. This therapy appears to maintain high efficacy rates over an average of 4.3 years. This therapy has shown to significantly decrease nocturia rates and improve voiding intervals. The majority of patients in this study found their IC symptoms improved over several years.

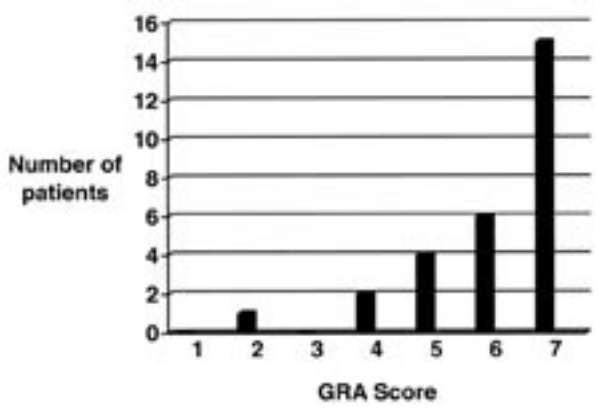

Fig. 1. – *Global Response Assessment.* Global response scores for those that had the device implanted, 7 being the best score and 1 being the worst score. Most patients found this device helped their symptoms compared to those who thought it made their symptoms worse. *Legend:* Global Response Scale: 1 - Markedly Worse; 2 - Moderately Worse; 3 - Slightly Worse; 4 - No Change; 5 - Mild Improvement; 6 - Moderate Improvement; 7 - Marked Improvement.

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5 – RETENTIONS

Oral mucosal grafts urethroplasty for the treatment of long segmented anterior urethral strictures. *Xu YM, Sa YL, Fu Q et al. World J Urol. EPUB: 2009-02-14.* Combined two oral mucosal grafts substitution urethroplasty is an effective technique for the treatment of long, complex segmented urethral strictures. In 25 patients followed-up for 6-72 months, urethrocutaneous fistulas developed in 2, and urethral stricture in 1 who needed urethral dilations, after which he voided well with a urinary peak flow of 26.4 ml/s.

Decreased colonic transit time after transcutaneous interferential electrical stimulation in children with slow transit constipation. *Clarke MC, Chase JW, Gibb S. et al. Journal of Pediatric Surgery EPUB: 2009-02-24* Idiopathic slow transit constipation is diagnosed by demonstrating delayed colonic transit on nuclear transit studies and describes a clinical syndrome characterised by intractable constipation. A possible new treatment is interferential therapy, which is a form of electrical stimulation that involves the transcutaneous application of electrical current and in children can speed up colonic transit significantly compared to placebo.

6 – INCONTINENCES

Sacral Nerve Modulation and other treatments in patients with faecal incontinence after unsuccessful pelvic floor rehabilitation: a prospective study. *Koch SM, Melenhorst J, Uluda_ O, Baeten CG et al. Colorectal Dis. EPUB: 2009-02-18.* Patients whith faecal incontinence were included in a multicentre study and treated with standardized pelvic floor rehabilitation. Those with an unsuccessful result who were eligible for sacral nerve modulation were included in the present study while failures at test stimulation received another treatment. Clinical outcome, Vaizey scores and quality of life (EQ-5D and HAQL) indicated a 49% overall success rate in patients with SNM with a significant improvement disease specific quality of life compared to other treatment.

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Original article

Reconstruction of pelvic organ prolapse: the role of mesh implantation and the need for vaginal hysterectomy

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Abstract: Pelvic organ prolapse non-mesh reconstruction entails unacceptably high recurrence rate, thus mesh augmentation is indicated for long lasting prolapse cure and avoids the need for hysterectomy of the prolapsed uterus.

Key words: Mesh; Pelvic organ prolapse; Pelvic floor reconstruction.

GENERAL CONSIDERATIONS

The precise incidence of pelvic organ prolapse (POP) is unclear. POP encompasses many sub-groups such as vaginal wall relaxation, uterine prolapse, post-hysterectomy vaginal vault prolapse and others; POP occurs in up to 50% of parous women. Up to 30% of all females suffer from pelvic floor relaxation to a degree that has a negative impact upon their quality of life. The affected women occasionally require manual assistance to urinate and frequently report frequency, urgency and urge incontinence as well as sexual and bowel function-related symptoms. The lifetime risk of undergoing prolapse surgery is one in eleven; moreover up to 30% of those who do undergo surgery will eventually have repeat prolapse surgery, some of them following hysterectomy. Since POP is age-related it is assumed that its incidence will further increase with aging of the population.[1-3]

The commonly performed non-mesh repairs for apical suspension in POP are the abdominal sacro-colpopexy and vaginaly approached sacro-spineous fixation (SSF) operation. Both requires a rather deep para-rectal pelvic dissection and are often associated with significant intra-operative bleeding. Reported complications following these procedures include post-operative dispareunia, buttock pain, urinary and fecal incontinence, cystocele and rectocele formation, altered defecation and constipation, bladder injuries, urinary retention and infections. However, the most worrying consequence of this operation is an unacceptably high prolapse recurrence rate, attributed to a large variety of pre-operative as wall as operative causative factors, among are obstetrical trauma, genetics, poor surgical technique ect. [4-6]

Neither simple colporrhaphy, with or without plication of the utero-sacral ligaments and vaginal hysterectomy, nor sacro-spineous and sacral colpopexies, seem to be the ideal procedure for repairing vaginal prolapse. Some authors observed that these surgical modalities are associated with up to 58% recurrence rate, as determined by objective POP scoring and prolapse-related subjective symptoms, while others report a recurrent surgery rate for pelvic floor reconstruction of 30%. Quality of life improvement following these operations has never been properly addressed.[7-14]

There are sparse evidence-based data in the English literature regarding anatomical and functional long term outcomes of all the above mentioned non-mesh POP surgery. Nevertheless, vaginal hysterectomy, vaginal sacro-spinal fixation and abdominal sacro-colpopexy have remained the "gold-standard" for the repair of vaginal apical suspension defects.

As POP is, in fact, bulging of viscera through a weakened pelvic floor and weakened vaginal walls. Terms used to describe the pelvic organ prolapse can be replaced by simply stating the specific herniation process. Cystocele and urethrocele are herniation of the anterior compartment of the pelvic floor; uterine, uterine cervix and post-hysterectomy vaginal vault prolapse are all central pelvic floor herniation; while enterocele, rectocele and perineal body tear are herniation of the posterior compartment of the pelvic floor. Endorsement of this approach improves understanding of the underlying process and suggests what ought to be the appropriate therapeutic approach, based on knowledge accumulated from hernia repair in other regions of the body.

Being less invasive, the vaginal approach is safer and is associated with fewer side effects, however, it does not last as long as the repair of post-hysterectomy vaginal vault prolapse using the abdominal approach. Similarly, questions regarding the use of mesh, the preferred mesh type, size, shape and anchoring points for reinforcement of the pelvic floor compartment and for conservation of the prolapsed uterus remain unanswered for the time being. The decision as to which mesh to use – if at all, depends heavily on the individual surgeon's training and experience. This is obviously an insufficient basis for proper decision-making, which should clearly be evidence based.[7-11]

A Cochrane review analyzing 22 trials with 2368 patients showed that abdominal sacro-colpopexy (SCP) result in lower POP recurrence rates and less dispareunia than does vaginal colpo-sacro spineous fixation (VCSSF). On the other hand, VCSSF has the advantage of a shorter operation time and recovery period. Mesh implants were found to reduce prolapse recurrence following anterior vaginal wall reconstruction, and the vaginal approach was found to be superior to the trans-anal for posterior compartment repair.[15-16]

Many authors acknowledge that the paucity of relevant data regarding the operation of choice for POP does not provide adequate information to guide practice. At the same time it is recognized that non-mesh POP reconstructive surgery carries an unacceptably high rate of POP recurrence. Thus, and in spite of the relative lack of evidence-based information regarding long term efficacy and safety, the use of grafts for POP vaginal reconstruction is growing rapidly. It is widely agreed that mesh implantation should be further investigated prior to the retraction of recommendations regarding their usage. Mesh implantation must be considered carefully for each potential candidate, taking into account that the ultimate goal must be the patient's quality of life improvement, by correcting both the anatomical and functional derangements. At present there are no any data-

based guidelines for proper patient and surgery selection, peri-operative management or surgical training. There is also considerable debate regarding the place of vaginal hysterectomy in POP surgery.[17-26]

The feasibility and safety of the mesh procedures does not appear to be inferior to previously reported operative techniques, and may in fact have less intra-operative and post-operative complications. The long-term effectiveness of this mesh pelvic floor reconstruction, with uterine suspension or after hysterectomy, has yet to be demonstrated by long term prospective studies.

Given that the recurrence rate following traditional non mesh vaginal apex re-suspension is unacceptably high, and that underlying genetic, traumatic and surgical co-factors contribute to progressive weakening of the endo-pelvic fascia, a surgical method with a low recurrence rate should be encouraged. Experience with abdominal wall herniorrhaphy showed that the mesh implant concept had a low recurrence rate, and it was subsequently implemented for pelvic floor herniation repair as well.[27]

However, unlike abdominal wall hernia vertical mesh repair, the vaginally implanted horizontal meshes are subjected to relatively high levels of physical pressure. This makes the vaginally implanted meshes prone to further prolapse unless they are well secured to solid pelvic structures.

The vaginally implanted meshes are covered by a thin, fragile layer of mucosa, compared to the thick abdominal wall coverage of the abdominal hernia mesh; hence erosion and mesh exposure are possible post-operative complications in the former. This is best achieved by spreading the mesh from one pelvic side-wall to the other, from the urethra and bladder neck to the vaginal apex, through the posterior compartment all the way down to the perineal body. In that way the pelvic organs are no longer supported by the defected endo-pelvic fascia that caused in fact the herniation, but rather with the synthetic fascial substitution. Wide dissection is generally required to achieve proper repair and to ensure adequate support.

With vaginal surgery one cannot achieve the degree of pre-operative sterilization of the surgical field that one can with abdominal operations. At best the level of sterility will not exceed the level of "clean-contaminated" sterilization, due to our inability to totally disinfect the vagina. Hence, mesh materials that are designed to be anti-infectious are needed. Thes new macro-porous and mono-filament meshes discourage bacterial growth and colonization, and are preferred for use in vaginal pelvic floor reconstruction.

The SS and ATFP suspensions are the most anatomical of the repairs, hence, it is most unlikely that these ligament supports will result in future anterior or posterior vaginal vault defects. Yet, the SS ligaments provides a unique evel 1 anchoring point.[1] for the vaginal apex, thus many prefer using this rather then to suspemd the apex to the ATFP.

The results of early attempts to reduce the prolapse recurrence rate in POP surgery by means of the standard simple mesh implantation method as used in abdominal wall herniorraphy were disappointing. Failure rates and mesh exposure rates were extremely high and this method fell into disrepute. The reasons for failure were better understood later, as the intra-abdominal forces directed to the mesh implanted in the pelvic floor and the need for proper support as well as the need for whole full thickness vaginal wall mesh coverage was appreciated. The preferred anchoring method involves passing the mesh arms through the ligaments, since that probably results in longer lasting support than suture methods of mesh fixation.[28-29] The first operation to follow these principals is the Posterior Intra-Vaginal Sling (PIVS). This involves a vaginal approach, together with anatomical restoration of the uterosacral ligament suspension of the vaginal apex, and can be performed in a daycare setting. Magnetic resonance imaging showed that significant improvement in the restoration of the vaginal configuration was achieved in patients who underwent PIVS. The restoration of the uterosacral ligament support enables the surgeon to re-suspend the uterine isthmus, thereby avoiding the need for vaginal hysterectomy, even in the event of advanced uterine prolapse.[30-32] Currently, a large variety of pre-cut meshes are manufactured and offered for curing POP, each attached to certain safety, cure rate and specific complications.[33-50]

MESH CHOICE

Accurate diagnosis of all the prolapse features and site specific support requirements identification are mandatory for proper mesh choice. Isolated apical supportive defect at the central pelvic floor compartment might be present, with anterior or posterior compartments prolapse, or any combination of these. This determines the requested mesh shape. It is the coexistence of urinary stress incontinence that indicates the need for additional mid-urethral support. The elected mesh or combination of meshes should be providing support for all the prolapsed pelvic floor sites. One must beer in mind that some commercially available anterior compartment meshes are designed for cystocele repair only, while others provides the possibility to suspend the vagina, apical prolapse or the prolapsed uterus, by cervical ring attachment. Other meshes provide support the mid urethra, concomitantly with anterior compartment reconstruction, hence un-necessitating the need for an additional tape to support the mid-urethra separately. Other meshes are designed for posterior compartment reinforcement, some of provides the possibility to support the prolapsed uterus or vaginal apex at the same time. Whenever there is a need to treat several sites of pelvic supportive defects more than one mesh might be needed. The mesh texture need to be as soft and light as possible, none shrinking, small in dimensions, yet sufficient for comprehensive replacement of all defected areas of the endo-pelvic fascia, causing pelvic floor herniation. Thorough defected endo-pelvic fascia substitution with the artificial fascia is crucial for insuring long lasting support. Host against graft and graft against host reaction formation should be ruled out according with any particular mesh prior to usage, so should any mesh related bacteria nesting or harboring. This is generally the case with type 1 mono-filament macro-porous knitted meshes, not interfering with macrophages migration. Long lasting anchoring method were reported to involve ligament through passing mesh arms, thus the particular mesh attachments to the pelvic chosen supportive points should be proved before hands for long lasting support, preferably with mesh arms through ATFP or the evel 1 [1] providing SS ligaments anchoring. Mesh and arm delivery systems for mesh individually prepared or pre-cut kits should be proven to yield the desired correct mesh and arms placement at the pelvic floor. Some pre-cut meshes might be too small to provide the necessary complete coverage of the whole fascial defects, thus easier to place because less dissection is required. Others might provide relatively easy arm placing devices, but at the price of improper arm passage at the deep ligaments of the pelvis for appropriate high support. These meshes might be prone to operative failure and recurrent prolapse. One should not be tempted for these easy to apply kits but rather go for the highly curative ones. Bio meshes where not proven to yield any advantage over the synthetic ones and one should not endanger his patients with bio-hazards. Smilingly, the absorbable meshes where not reported to entail any superi-

ority and one should ask himself is there any potential benefit of a vanishing mesh in herniation repair at all. The list of available commercially manufactured products expends fast and the existing ones are regularly re-shaped, thus there is no point in referring to any particular currently available mesh. With this atmosphere of many newly designed meshes popping up almost monthly, one must be extra couches when choosing his own mesh. Of huge importance is solid clinical data, proving high cure rate and low rate of complications of mild nature.

SURGICAL ASPECTS

A comprehensive pelvic floor anatomic-functional reconstruction should be based upon firm, long-lasting suspension of the vaginal walls and apex to well establish fixed pelvic structures. These anchoring structures include the arcus tendineus fascia pelvis (ATFP) and the sacro-spineous (SS) ligament. The former lies along the lateral border of the Levator ani muscles, from the inferior pubic ramus and the obturator membrane anteriorly to the iscial spine posteriorly, while the latter connects the iscial spine to the sacrum. Another potential anchoring option is the pre-sacral fascia, which covers the sacral vertebrae longitudinally and provides a solid structure that can serve as a suspensory point to which to secure the vaginal apex. The two last mentioned providing probably superior true level 1 [1] apical support. Attaching the vaginal apex to one of these ligaments will presumably yield long lasting apical support, permitting restoration of the weakened pelvic floor and pelvic organ function. Since the ATFP is relatively easily accessible via the vagina, it is favored by some vaginal surgeons, while others prefer the SS ligament, since it is both: the most stable pelvic structure and offers the opportunity to establish a level 1 [1] high fixation for the uterus and the vaginal vault. Hence, this provides the best long term support. However, access to the SS requires wider and deeper pelvic dissection than requested to reach the ATFP.

Subsequently, debate arose regarding the issue of mesh versus slings: the question revolving around the adequacy of replacing the specific ruptured endo-pelvic ligaments with a synthetic sling. Some felt that the whole endo-pelvic fascia should be replaced with large mesh, similar to the way mesh implants are used with abdominal wall herniation repair. This obviously entails the use of large meshes. Others thought that replacing the thorn pelvic ligament by synthetic tapes is sufficient; hence the total mesh mass and related adverse outcome might be reduced. Another point of controversy with POP vaginal mesh implantation involves the preferred pelvic fixation methods. Some feel very strongly that the only long lasting fixation method is to pass wide mesh arms through the ligaments; others sutured the mesh to ligament, or used various stapling devices.[32-37]

The mesh should be secured to the vaginal walls and apex at one edge and to the elected supportive structure – the SS, utero-sacral, pre-sacral or the ATFP ligaments – along the other edge. It should take the place of the herniated weakened fascia and ligaments that led to prolapse of the central, anterior or posterior pelvic floor compartments. Thus, the post-hysterectomy vaginal vault prolapse, as well as the frequently co-existing cystocele and/or entero-rectocele, are corrected simultaneously. It is important to flatten the mesh meticulously before assembling the cut vaginal edges, to avoid post-operative infra-mucosal folding of the mesh, which can result in pain, including dispareunia. Securing the mesh in position, either by passing ligament mesh arms or by suturing, should ensure that the mesh is properly spread to replace the entire herniation that caused the endo-pelvic fascia defect.

Steps should be taken to minimize mucosal erosion and the hazards of vaginal mesh protrusion. These anti-erosive measures involve established, conventional tension-free surgical principles for herniation repair, applied to both vaginal wall tissue and the mesh. This also includes refraining from excessive vaginal mucosa trimming and dissecting below the sub-mucosal fascia, so as to preserve blood supply and nerve endings. Thus, ischemia, poor healing and tissue necrosis are avoided and likelihood of mesh exposure is reduced.[45]

THE ISSUE OF REMOVAL OR PRESERVATION OF THE PROLAPSED UTERUS

Hysterectomy can result in damage to the integrity and blood supply of the endo-pelvic fascia as well as to the innervation of the pelvic floor musculature, which might potentially contribute to the manifestation of later POP, vaginal wall un-healing and later mesh exposure. As there are no data regarding the effect of hysterectomy on the pathogenesis of POP, there is considerable debate as to whether vaginal hysterectomy improves or worsens the long term outcome of surgical reconstruction of POP and the necessity for repeat prolapse surgery. The natural history of the status of the pelvic floor post-hysterectomy has never been studied in depth to determine whether the prolapsed uterus should be removed or preserved in order to achieve long-term POP cure and minimize adverse effects. By the same token, the peri-operative complications and general improvement in quality of life, including the impact of hysterectomy on the female body image and sexuality, have not been studied in terms of comparing vaginal hysterectomy to preservation of the prolapsed uterus or uterine cervix

The cervico sacral, cardinal and cervico-pubic ligaments provide the spared cervical ring extra stability for the pelvic floor, by recruitment of these web architecture structures for the pelvic reconstruction. This perspective challenges the widely endorsed practice of routine vaginal hysterectomy with any uterine prolapse, a POP reconstructive operation which currently not well supported with solid data regarding safety and cure rates. Nevertheless, some level 2 evidence supports the preservation of the prolapsed uterus, or at least the uterine cervix. This may herald a change in the policy of almost automatic reference for vaginal hysterectomy whenever POP is present. Performing hysterectomy at the time of mesh pelvic floor reconstruction significantly increases the risk of post-operative vaginal mesh exposure, with the subsequent need for further operative intervention to deal with it. Vaginal shortening is also a not infrequent complication of hysterectomy, sometimes occurring to a degree that interferes with sexual intercourse. Apart from the negative effects on pelvic floor structure and function, vaginal hysterectomy carries operation-related complications, some of which can be health or life threatening. In addition, the psychological effects in terms of the woman's body image and self esteem must not be underestimated. Novel minimally invasive operative methods as well as increasing public awareness against unnecessary hysterectomies and permit preservation of the prolapsed uterus even with formerly accepted indication for hysterectomy, other then uterine prolapse as menorrhagia, endometrial polyps and uterine myomas.[17-26]

SURGEON TRAINING

Pelvic floor mesh reconstruction operations involve extensive deep pelvic dissection. Hence, it is mandatory that surgeons be thoroughly familiar with the anatomy, with accurate surgical technique, potential hazards and preventive measures, and management of complications before

embarking on the implantation of such meshes. It is suggested that surgeons undergo a meticulous training program with an expert prior to undertaking this procedure.[51] One should seek for proper training before adopting any new operation and maintain his skills with frequent operation performance.[49-50]

CONCLUSIONS

The mesh operations, designed to prevent POP recurrence, provides a safe and feasible surgical technique. However, this rather new procedure, for either post-hysterectomy POP or for advanced uterine prolapse with or without uterine preservation, needs to be proved effective in the long run. POP reconstructions with anterior and or posterior meshes were reported to successfully achieve POP cure, with a reasonable rate and severity of complications in comparison to older operative techniques. Mesh implantation with POP reconstructive surgery permits the preservation on vaginal hysterectomy, whose adverse outcome is well established, yet true contribution for POP cure it widely questionable.

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Triple therapy in refractory detrusor overactivity: a preliminary study. *Natalin R, Reis LO, Alpendre C et al. World Journal of Urology. EPUB: 2009-03-18.* To prospectively evaluate the impact of the "three-drug therapy" (antimuscarinic, alpha-blocker and tricyclic antidepressants) on the treatment of refractory detrusor overactivity, data from 27 consented patients were collected through a daily urinary chart and an urodynamic evaluation before and 60 days after treatment with a mean follow-up of 15 months. There was a significant increase on bladder capacity and decreases on urgency, urge-incontinence and frequency. Main side effects comprised dry mouth and constipation (40%). More studies are necessary to achieve more consistent data on the matter.

7 – PAIN

Treatment of endometriosis of uterosacral ligament and rectum through the vagina: description of a modified technique. *Camara O, Herrmann J, Egbe A et al. Human Reprod. EPUB: 2009-02-19.* The optimum way to diagnose endometriosis is by direct visualization of the implants. Four patients with a uterosacral ligament and rectal endometriosis, average tumour diameter 3.5 cm, complaining of rectal bleeding and lower abdominal pain in relation to their menstrual cycle were successfully treated with combined laparoscopic-transvaginal resection.

Adequate relief in a treatment trial with ibs patients: a prospective assessment. Passos MC, Lembo AJ, Conboy LA, Drossman DA et al. *Am J Gastroenterol*. EPUB: 2009-03-19. Adequate relief of irritable bowel syndrome symptoms as an end point in randomized controlled trials is inversely related to baseline symptom severity. However, if patients who report adequate relief at screening are excluded from study participation, baseline symptom severity is no longer confounded with a report of adequate relief at the study end point.

8 – FISTULAE

Fournier's gangrene: population based epidemiology and outcomes. *Sorensen MD, Krieger JN, Rivara FP et al. J Urol. EPUB: 2009-03-17.* A national database was used to investigate the epidemiology of Fournier's gangrene. Inpatients diagnosed with Fournier's gangrene who underwent genital/perineal débridement or died in the hospital were identified in 1,641 males and 39 females the cases representing less than 0.02% of hospital admissions. The overall incidence was 1.6/100,000 males, which peaked in males 50 to 79 years old with an overall case fatality rate of 7.5%.

Hidradenitis suppurativa. *Buimer MG, Wobbes T, Klinkenbijl JH. Br J Surg. EPUB: 2009-03-14.* is a. Despite its incidence, optimal medical or surgical treatment hidradenitis suppurativa remains unclear. On the basis of histological findings, this chronic, recurrent, suppurative cutaneous disease is considered inflammatory and originating from the hair follicle; therefore it is called also acne inversa. but Smoking seems to be a major triggering factor though the exact aetiology remains obscure. Treatment should be individualized according to the site and extent of the disease. Absolute cessation of smoking is essential. Management with antibiotics or other medications may relieve early symptoms, but radical surgery may be necessary for control and to prevent recurrence.

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Case report

A presacral epidermoid cyst presenting with a perineal fistula: report of a case

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Abstract: Presacral epidermoid cysts are rare lesions that become clinically evident only when complicated by pain or infection. Usually they are asymptomatic and diagnosis is unexpected at the time of a gynaecological or ano-rectal examination or as an incidental finding report on a radiological examination such as a pelvic CT scan or MRI performed for other reasons. We report the case of a young male presenting with a perineal fistula. Clinical examination, pelvic MRI and CT scan demonstrated a infected pre-sacral cyst with a anal fistulous tract. Difficulty in localising the cyst, proximity to sacral promontory, the need to preserve the integrity of both the rectal wall and the hypogastric nerves from surgical injury led to adoption of a combined laparoscopic and perineal procedure for its complete excision.

Key words: Presacral epidermal cyst; Retro-rectal space; Laparoscopy; Anal fistula.

INTRODUCTION

The human embryo has a true tail between the 28th and the 35th day of gestation. This is an extension of the primitive hindgut and, being caudal to the subsequent site of development of the anus, it is called the *tailgut*. It normally regresses completely by the 8th week of gestation.[1] A wide range of disembryogenic masses can derive from incomplete regression of the primitive hindgut. Remnants of the tailgut or notochord lead to the development of retro-rectal lesions. Most of them are benign and include epidermal and dermal cysts, rectal duplications, hamartomas and seminal vescicle or Mullerian cysts. A small number of them carry a malignant potential, arising from a benign lesion or from a primitive malignancy, such as a teratoma. These masses are almost exclusively localized in the presacral space which is located behind the posterior side of the rectal fascia, above the Waldeyer fascia, which is 3 cm above the pelvic muscles layer; below the abdominal peritoneal reflexion and in front of the sacrum. The rectal pillars, iliac vessels and ureters surround this space on each side. These masses are rarely found in other locations.[2]

They can occur at any age but retrorectal cysts are more frequently observed in female patients 12-35 years of age. The male-female ratio is 1:3. Because of their rarity, data on prevalence are lacking in the literature, with an incidence varying from 1.4 to 6.3%.[3]

CASE REPORT

A young male complaining a perineal fistula was referred to our outpatient department in October 2004. His clinical history included an asymptomatic prolapse of the mitral valve and a malformation of the L3-L4 vertebral bodies. His previous surgical history included appendectomy.

Because of the onset of a perineal fistula associated with sacrococcygeal pain he underwent a careful exploration of the fistulous tract. Subsequent positioning of a drainage tube immediately resulted in the passage of a great quantity of pus and of a hair tuft. Palpation of a retrorectal mass during rectal digital examination lead to the suspicion of a presacral abscess. Therefore the patient underwent a recto-sigmoidoscopy, pelvic CT and MRI scan which showed a presacral fluid mass of 7x2x2 cm without any apparent relationship with the rectum (Fig. 1). The following trans-rectal ultrasound (TRUS) confirmed the presence of a dishomogeneous liquid mass, extending to the pelvic floor without any apparent fistulous communication with the rectal lumen (Fig. 2). Through a posterior parasacral incision a large part of the presacral mass was removed but the complete excision was not possible as the superior pole resulted too far away. Thus a *Malecot* tube was inserted from the perineal fistula to the cranial remnant of the abscess. Histology performed on the specimen resulted in an *infected epidermoid cyst* without malignant degeneration (Fig 3). Furthermore a following fistulography through the previously positioned tube with contemporary endorectal enema showed an elongated shaped cyst located at S2 level, confirming that no rectal fistula was present (Fig. 4). Eight weeks after the first operation the patient underwent a combined laparoscopic and perineal surgical procedure to completely remove the fistulous tract and the retrorectal cyst. This procedure was performed by an experienced laparoscopist and a colorectal surgeon at the same time. An x-ray of the specimen was done to check its complete excision (Fig. 5). Patient was discharged after 7 days completely recovered.

No signs of infection, fistula, sexual or voiding dysfunction or rectal injury were reported during 4 years of follow up.

DISCUSSION

Presacral cysts are rare entities. Other retro-rectal space lesions include tumors, such as chondromas arising from notochord vestiges and, more frequently in males, anterior

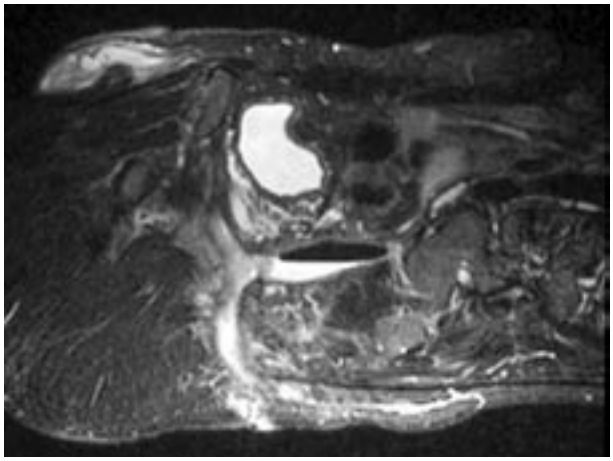

Fig. 1. – With patient in horizontal position, presence of fistulous tract from right gluteal region in communication with elongated vertical cavity containing liquid and air. The image shows no relationship with rectal lumen.

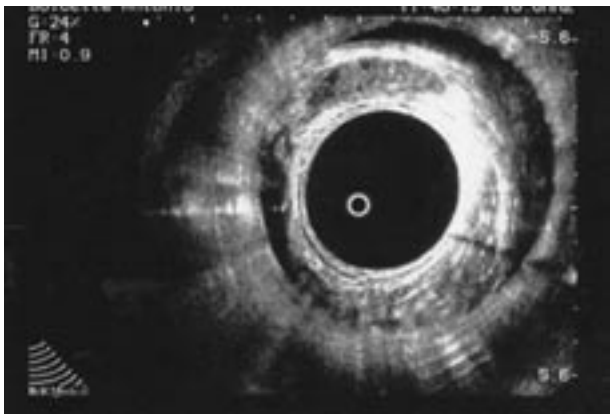

Fig. 2. – With patient in Sims position, evidence of ipoechoic tissue in the posterior perirectal space corresponding to the most caudal portion of the infected cyst. The development of fistulous tract to perineal skin appears to circle the rectum also from the lateral left side.

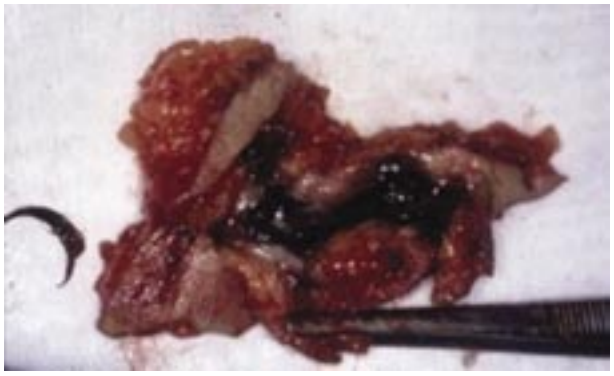

Fig. 3. – Operatory specimen after posterior excision. Notice the presence of hair tuft.

sacral meningocele, neurolemmomas, ganglioneuromas, neurofibrosarcomas, bony cysts or lymph nodes from rectal cancer.[3] The exact prevalence is not known but data coming from referral centers estimate an incidence of 1/40000-1/63000 of admitted patients.[4, 5]

Higher incidence in female patients seems to respond to a clinical bias. In fact gynaecological and proctological examination on young girls allows an earlier detection of presacral cysts than in males. Usually asymptomatic, they grow slowly and become clinically evident because of sense of rectal fullness, tenesmus, sacro-coccigeal pain or infection. Although most of presacral lesions present benign features, malignancy can always be possible. Careful rectal examination is essential and represent the first step for the correct diagnosis. Tenderness, mobility and smooth surface represent benign features whereas a hard, sharp, fixed and painful mass suggest the presence of malignancy. As rectal digital examination is sensitive but not specific,[6] anoscopy and full colonoscopy must be performed in order to exclude a rectal cancer or other colonic lesions. FNAB should be avoided because of high risk of infection (especially if performed through the posterior rectal wall) or malignant seeding. The high incidence of recurrence and the possibility of misdiagnosis [7] suggest that the complete excision must be the procedure of choice, reserving biopsies of specimen just in cases of great suspicion of malignant tumors that require highly demolitive surgery. Allowing a good vision of the sacral nervous plexus and avoiding large rectal mobilization, the posterior surgical approach is interesting, but considering our experience it should be reserved for retrorectal cysts whose superior pole is palpable during rectal examination. For lesions not fully reachable at digital exploration, abdominal approach gains a better view of pelvic organs and allows to isolate the cyst completely, once the rectum has been mobilized.

In the case reported the patient was complaining presacral pain, fever and a perineal fistulous orifice. For this reason the patient was firstly treated with the position of

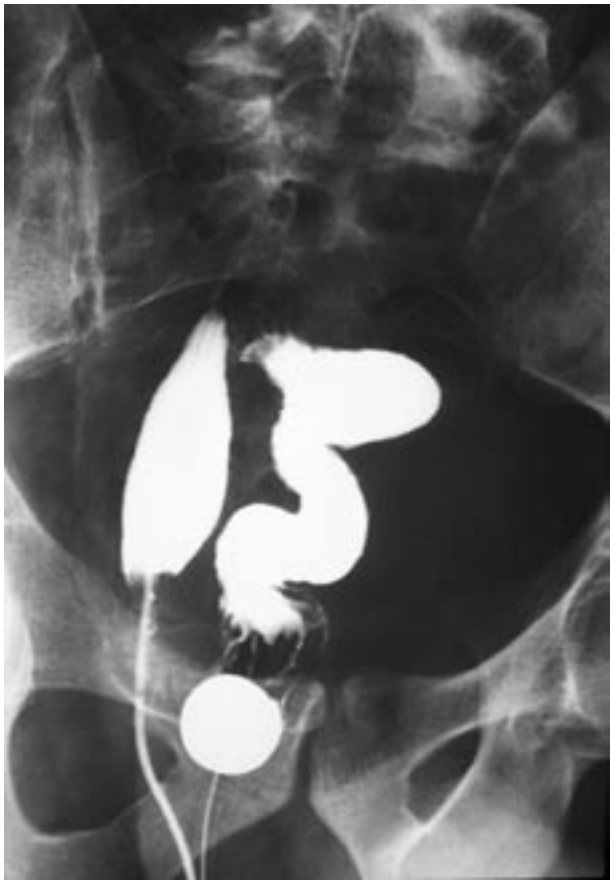

Fig. 4. – Injecting contrast through the perineal fistula (Malecot tube), dullness of fistulous tract for 6 cm. Just right to ano-rectal junction, visualization of vertical shaped cyst whose measures are 7x2x2 cm. The superior pole of the cyst appears 1.5 cm far from upper side of S1 body.

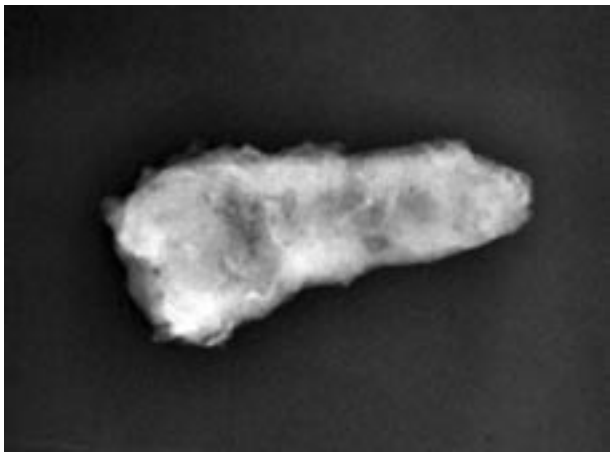

Fig. 5. – Radiologic control after laparoscopic excision of retro-rectal cyst remnant.

a drainage tube. The subsequent output of pus mixed with hair suggested the hypothesis of a disembryogenic infected cyst. TRUS is a sensitive method for analysis of the rectal wall and the perirectal space, helping to distinguish solid from liquid lesions. In our case the position of the cyst, its extension and size and its relationship with the rectal wall were determined. Because of its better definition of the soft tissues, MR allowed to evidence the longitudinal cyst of 7x2x2 cm with an air fluid level and a gross fistulous tract directing to the perineal skin. Because of the vertical development of the cyst with its superior pole at the sacral promontory, an abdominal operation became necessary to remove the cyst remnant combined with a perianal fistulectomy. Laparoscopy allows a good vision of the deepest part of the pelvis preserving nerves, vessels, ureters and providing less discomfort for the patient and a shorter and less expensive hospital stay. Furthermore, rectum mobilization necessary to reach the retrorectal space, results easier and less time-expensive when performed through a laparoscopic dissection. Contemporary anal fistula excision allowed to complete the procedure without necessity of other surgical operations.[7, 8]

For this reasons, when possible, the combination of laparoscopic and pelvic procedure represents the best alternative to classic laparotomy for high presacral infected cysts, avoiding long hospital stay and reducing patient's discomfort.

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Anastomotic-vaginal fistula (AVF) after anterior resection of the rectum for cancer - occurrence and risk factors. *Matthiessen P, Hansson L, Sjödahl R, Rutegård J. Colorectal Dis. EPUB: 2009-02-18.* To assess recto-vaginal fistula after anterior resection of the rectum for cancer with regard to occurrence and risk factors, 20 female patients who developed a symptomatic fistula were compared with 32 who developed conventional symptomatic leakage and 338 who did not leak. Patients with AVF had lower anastomoses and decreased BMI compared with those with conventional leakage. Risk factors for AVF in multivariate analysis were anastomosis < 5 cm above the anal verge, preoperative radiotherapy and UICC cancer stage IV. Previous hysterectomy was not a risk factor. The need for abdominal reoperation and defunctioning stoma is not different from patients with conventional leakage.

9 – BEHAVIOUR, PSYCHOLOGY, SEXOLOGY

Ageing, mate preferences and sexuality: a mini-review. *Oberzaucher E, Grammer K. Gerontology. EPUB: 2009-02-21.* Sexuality never ceases to be part of a relationship. With increasing age, reproduction loses importance, while pair bonding functions remain relevant. The evolutionary constraints that lead to the evolution of sexual reproduction are framed by the better repair mechanisms of fatal mutations, as well as the need for variable immune systems imposed on large organisms by parasites, such as viruses and bacteria. These factors affect mate choice, especially as regards the gene complex that encodes the immune system. The need to increase both the likelihood of gametes to encounter each other as well as sufficient provision of nutrition for the offspring then leads to the evolution of two sexes: large numbers of small mobile sperms ensure that gametes meet, whereas large egg cells full of energy provide for the zygote, thus leading to a developmental advantage. The asymmetric investment in the offspring affects also cognitive strategies. Men place more importance on youthfulness and fertility than women, who regard resource holding potential as a more relevant criterion. Consequently, jealousy is connected in females to endangered access to resources, in males to paternal uncertainty.

10 – MISCELLANEOUS

Endoscopic closure of the natural orifice transluminal endoscopic surgery (NOTES) access site to the peritoneal cavity by means of transmural resorbable sutures: an animal survival study. *von Renteln D, Eickhoff A et al. Endoscopy. EPUB: 2009-02-14.* Endoscopic closure of the transgastric access site is still a critical area of active research and development into NOTES. Endoscopic gastrostomy closure by means of resorbable sutures was performed in 10 female domestic pigs in an animal survival study. Mean suturing time was 26 minutes (range 14 - 35 minutes). One case of gallbladder perforation occurred during peritoneoscopy and the pig was sacrificed due to peritonitis.

Erratum

In Vol 28, issue 2, pag. 50 (Complex pelvic problems - a multidisciplinary perspective), corresponding Author: Marco Soligo Servizio di Uroginecologia, U.O. Ginecologia e Ostetricia, Ospedale San Carlo Borromeo, Milano, *add*
E-mail: marcosoligo@fastwebnet.it

Rectogesic® 4mg/g trinitroglicerina

Pomata rettale

RIASSUNTO DELLE CARATTERISTICHE DEL PRODOTTO

1. DENOMINAZIONE DEL MEDICINALE Rectogesic 4 mg/g pomata rettale

2. COMPOSIZIONE QUALITATIVA E QUANTITATIVA Trinitroglicerina: 4 mg/g Un grammo di pomata rettale contiene 40 mg di trinitroglicerina in propilenglicole corrispondente a 4 mg di trinitroglicerina (TNG). In 375 mg di questa formulazione sono contenuti all'incirca 1,5 mg di TNG. In ogni grammo di pomata rettale sono inoltre contenuti 36 mg di propilenglicole e 140 mg di lanolina. Per l'elenco completo degli eccipienti, vedere paragrafo 6.1.

3. FORMA FARMACEUTICA Pomata rettale. Formulazione in pomata biancastra, omogenea, opaca.

4. INFORMAZIONI CLINICHE 4.1 Indicazioni terapeutiche La pomata rettale Rectogesic 4 mg/g è indicata per alleviare il dolore associato a ragade anale cronica. Nel corso dello sviluppo clinico, il farmaco ha evidenziato un modesto effetto sul miglioramento dell'intensità del dolore medio giornaliero (vedere paragrafo 5.1). **4.2 Posologia e modo di somministrazione** Via di somministrazione: uso rettale. **Adulti:** Per applicare la pomata è possibile utilizzare una protezione sul dito, ad esempio una pellicola adesiva o un copridito (acquistare i copridito separatamente in farmacia o presso un rivenditore di forniture chirurgiche o la pellicola adesiva nel supermercato più vicino). Per il dosaggio, posizionare il dito lungo la linea da 2,5 cm indicata sul cartone che contiene Rectogesic e applicare una striscia di pomata della lunghezza della linea sull'estremità del dito premendo delicatamente il tubetto. La quantità di pomata deve essere pari a circa 375 mg (1,5 mg di TNG). Inserire quindi delicatamente il dito con la protezione nel canale anale fino alla prima articolazione interfalangea ed applicare la pomata con movimenti circolari alla parete del canale. Una dose di pomata da 4 mg/g contiene 1,5 mg di trinitroglicerina. Questa dose deve essere applicata in sede intra-anale ogni dodici ore. Il trattamento puo essere prolungato fino alla diminuzione del dolore, fino ad un massimo di 8 settimane. Rectogesic deve essere utilizzato quando il trattamento conservativo è risultato insufficiente per la cura dei sintomi acuti delle ragadi anali. **Anziani:** Non ci sono indicazioni relative all'uso di Rectogesic negli anziani. **Pazienti con compromissione epatica o renale:** Non ci sono indicazioni relative all'uso di Rectogesic nei pazienti con compromissione epatica o renale. **Bambini e adolescenti:** L'uso di Rectogesic non è raccomandato nei bambini e negli adolescenti al di sotto di 18 anni a causa della mancanza di dati sulla sua sicurezza ed efficacia. **4.3 Controindicazioni** Ipersensibilità al principio attivo o a uno qualsiasi degli eccipienti della pomata o in caso di reazioni idiosincrasiche ad altri nitrati organici. Trattamento concomitante con sildenafil citrato, tadalafil, vardenafil e con i donatori di NO (ossido di azoto), come altri derivati della TNG ad azione lunga, quali isosorbide dinitrato, amile o butile nitrito. Ipotensione ortostatica, ipotensione o ipovolemia non corretta, poiché l'impiego della trinitroglicerina in queste condizioni potrebbe indurre ipotensione grave o shock. Aumento della pressione intracranica (ad esempio trauma cranico o emorragia cerebrale) o circolazione cerebrale inadeguata. Emicrania o cefalea ricorrente. Stenosi aortica o mitralica. Cardiomiopatia ipertrofica ostruttiva. Pericardite costrittiva o tamponamento pericardico. Forte anemia. Glaucoma ad angolo chiuso. **4.4 Avvertenze speciali e precauzioni d'impiego** Il rapporto rischio/beneficio della pomata Rectogesic deve essere stabilito su base individuale. In alcuni pazienti può manifestarsi cefalea grave in seguito al trattamento con Rectogesic. In alcuni casi è consigliabile effettuare una rivalutazione del dosaggio appropriato. Nei pazienti in cui il rapporto rischio/beneficio viene ritenuto negativo, è necessario sospendere il trattamento con Rectogesic su consiglio medico e iniziare un nuovo trattamento terapeutico o chirurgico. Rectogesic deve essere utilizzato con cautela nei pazienti affetti da patologia epatica o renale grave. Evitare una eccessiva ipotensione, soprattutto per periodi di tempo prolungati, visti i possibili effetti nocivi a carico di cervello, cuore, fegato e reni dovuti ad una scarsa perfusione e al conseguente rischio di ischemia, trombosi e alterata funzionalità di tali organi. Occorre consigliare ai pazienti di passare lentamente dalla posizione coricata o seduta a quella eretta al fine di ridurre al minimo l'ipotensione ortostatica. Tale consiglio è particolarmente importante per i pazienti ipovolemici e in terapia diuretica. L'ipotensione indotta da trinitroglicerina può essere accompagnata da bradicardia paradossa e da aumento dell'angina pectoris. È possibile che gli anziani siano maggiormente suscettibili all'insorgenza di ipotensione ortostatica, soprattutto nell'alzarsi di scatto. Non ci sono indicazioni relative all'uso di Rectogesic negli anziani. L'alcol può potenziare gli effetti ipotensivi della trinitroglicerina. Se il medico decide di prescrivere una pomata a base di trinitroglicerina a pazienti affetti da infarto miocardico acuto o insufficienza cardiaca congestizia, occorre procedere con un attento monitoraggio clinico e emodinamico per evitare il potenziale rischio di ipotensione e tachicardia. Interrompere il trattamento se aumenta il sanguinamento associato a emorroidi. Questa formulazione contiene propilenglicole e lanolina che possono causare irritazioni e reazioni cutanee (es. dermatite da contatto). Se il dolore anale persiste, può essere necessario eseguire una diagnosi differenziale per escludere altre possibili cause. La nitroglicerina può interferire con il dosaggio delle catecolamine e dell'acido vanilmandelico nelle urine poiché aumenta l'escrezione di queste sostanze. Il trattamento concomitante con altri prodotti medicinali deve essere affrontato con cautela. Vedere paragrafo 4.5 per informazioni specifiche. **4.5 Interazioni con altri medicinali ed altre forme di interazione** Il trattamento concomitante con altri vasodilatatori, farmaci bloccanti dei canali del calcio, ACE inibitori, beta-bloccanti, diuretici, antipertensivi, antidepressivi triciclici e tranquillanti maggiori, così come il consumo di alcol, possono potenziare l'effetto di abbassamento della pressione indotto da Rectogesic. Pertanto valutare attentamente il trattamento concomitante con questi medicinali prima di iniziare la terapia con Rectogesic. L'effetto ipotensivo dei nitrati è potenziato dalla somministrazione contemporanea di inibitori della fosfodiesterasi, es. sildenafil, tadalafil, vardenafil e teofillina (vedere paragrafo 4.3). Rectogesic è controindicato nel trattamento concomitante con farmaci donatori di NO (ossido di azoto), quali isosorbide dinitrato, amile o butile nitrito (vedere paragrafo 4.3). L'acetilcisteina può potenziare l'effetto vasodilatatore della trinitroglicerina. Il trattamento concomitante con eparina diminuisce l'efficacia dell'eparina stessa. È necessario eseguire uno stretto monitoraggio dei parametri della coagulazione del sangue e la dose di eparina deve essere adattata di conseguenza. La sospensione di Rectogesic può indurre un brusco aumento del PTT (tempo di tromboplastina parziale). In tal caso può essere necessario ridurre il dosaggio di eparina. La somministrazione contemporanea di trinitroglicerina può indurre una riduzione dell'attività trombolitica dell'alteplasi. La somministrazione concomitante di Rectogesic e diidroergotamina può aumentare la biodisponibilità della diidroergotamina ed indurre vasocostrizione coronarie. Non si può escludere l'eventualità di una diminuzione della risposta terapeutica a Rectogesic in seguito all'assunzione di acido acetilsalicilico e farmaci antinfiammatori non steroidei. **4.6 Gravidanza e allattamento Gravidanza:** Non vi sono dati adeguati riguardanti l'uso della trinitroglicerina in donne in gravidanza. Gli studi su animali sono insufficienti per evidenziare gli effetti sulla gravidanza, sullo sviluppo embrionale/fetale, sul parto e sullo sviluppo postnatale (vedere paragrafo 5.3). Rectogesic non deve essere usato durante la gravidanza. **Allattamento:** Non è noto se la trinitroglicerina venga escreta nel latte umano. Considerati i potenziali effetti dannosi sul bambino allattato al seno (vedere paragrafo 5.3) l'uso di Rectogesic non è raccomandato durante l'allattamento. **4.7 Effetti sulla capacità di guidare veicoli e sull'uso di macchinari** Non sono stati effettuati studi sulla capacità di guidare veicoli e sull'uso di macchinari. Rectogesic, soprattutto al primo impiego, può indurre in alcuni pazienti vertigini, capogiri, visione offuscata, cefalea o affaticamento. I pazienti dovrebbero essere dissuasi dal guidare veicoli o usare macchinari durante il trattamento con Rectogesic. **4.8 Effetti indesiderati** Nei pazienti trattati con la pomata rettale Rectogesic 4 mg/g, la più frequente reazione avversa legata alla terapia consisteva nella cefalea dose/dipendente, che si è verificata con un'incidenza del 57%. La tabella riportata di seguito mostra le reazioni avverse che si sono verificate durante gli studi clinici, suddivise per classi organo-sistema. All'interno di ciascuna classe organo-sistema, le reazioni avverse sono state raggruppate in base alla frequenza nel seguente modo: molto comune (> 1/10), comune (> 1/100 < 1/10), non comune (> 1/1000 < 1/100).

Classe sistemico-organica	Frequenza	Reazione avversa
Patologie del sistema nervoso	Molto comune	Cefalea
	Comune	Vertigini
Patologie gastrointestinali	Comune	Nausea
	Non comune	Diarrea, disturbi anali,vomito, sanguinamento rettale, disturbi rettali
Patologie della cute e del tessuto sottocutaneo	Non comune	Prurito e bruciore anale
Patologie cardiache	Non comune	Tachicardia

Le reazioni avverse alla pomata contenente trinitroglicerina al 2 % (usata nella profilassi dell'angina pectoris) sono in genere dose-dipendenti e la maggior parte di esse è la conseguenza dell'attività vasodilatatoria. La cefalea, che può essere di grado severo, è l'effetto collaterale più frequentemente riportato. Negli studi clinici di fase III condotti sulla pomata rettale Rectogesic 4 mg/g, l'incidenza di cefalea lieve, moderata e grave è stata, rispettivamente, del 18%, 25% e 20%. I pazienti con anamnesi di emicrania o cefalea ricorrente erano esposti a un rischio maggiore di sviluppare cefalea durante il trattamento (vedere paragrafo 4.3). La cefalea può ricorrere a ogni somministrazione giornaliera, soprattutto alle dosi più elevate. La cefalea può essere trattata con analgesici leggeri, es. paracetamolo, ed è solitamente reversibile con l'interruzione del trattamento. Possono inoltre verificarsi capogiri transitori, occasionalmente legati ad alterazioni della pressione sanguigna. L'ipotensione non si verifica con frequenza, ma in alcuni pazienti può essere sufficientemente grave da giustificare l'interruzione della terapia. Si riportano casi di sincope, angina in crescendo e ipertensione "rebound" anche se non sono frequenti. Le reazioni allergiche alla trinitroglicerina non sono comuni e quelle riportate sono per lo più casi di dermatite da contatto o eruzioni fisse da farmaco in pazienti a cui la trinitroglicerina è somministrata in formulazione pomata o cerotti. Sono stati registrati pochi casi di vere e proprie reazioni anafilattoidi, e tali reazioni si possono presentare in pazienti che ricevono trinitroglicerina con qualsiasi via di somministrazione. In casi estremamente rari, dosi terapeutiche di nitrati organici hanno causato metaemoglobinemia in pazienti apparentemente normali. Raramente si è osservato rossore come reazione avversa da altri prodotti contenenti trinitroglicerina. **4.9 Sovradosaggio** Un accidentale sovradosaggio di Rectogesic può causare ipotensione e tachicardia riflessa. Non si conosce nessun antagonista specifico degli effetti vasodilatatori della nitroglicerina e nessun intervento è stato sottoposto a studio controllato quale terapia per il sovradosaggio di nitroglicerina. Poiché l'ipotensione associata a sovradosaggio di nitroglicerina è causata da venodilatazione e da ipovolemia arteriosa, una terapia prudente in questa situazione deve essere indirizzata all'aumento del volume di liquido nel circolo sistemico. Può essere sufficiente il sollevamento passivo delle gambe del paziente, ma possono rendersi necessari anche un'infusione endovenosa di soluzione fisiologica normale o di liquido similare. In casi eccezionali di ipotensione grave o shock, possono rendersi necessarie misure di rianimazione. Un dosaggio eccessivo può inoltre dare luogo a metaemoglobinemia. In tal caso, intervenire con un'infusione di blu di metilene.

5. PROPRIETÀ FARMACOLOGICHE 5.1 Proprietà farmacodinamiche Categoria farmacoterapeutica: Rilassanti della muscolatura - Codice ATC: C05AE 01. La principale azione farmacologica della trinitronitroglicerina è mediata dal rilascio di ossido di azoto. Quando la pomata a base di trinitronitroglicerina viene applicata per via intra-anale, si ottiene un rilassamento dello sfintere anale interno. L'ipertonicità della parte interna dello sfintere anale, ma non di quella esterna, rappresenta un fattore di predisposizione alla formazione delle ragadi anali. I vasi sanguigni della zona di transizione anale (anoderma) scorrono attraverso lo sfintere anale interno (SAI). Pertanto una ipertonicità dello SAI può indurre una diminuzione del flusso ematico e causare ischemia in questa regione. La distensione del retto produce un riflesso inibitorio della zona retto-anale e il rilassamento dello sfintere anale interno. I nervi che mediano questo riflesso si trovano nella parete dell'intestino. Il rilascio del neurotrasmettitore NO da questi nervi svolge un ruolo significativo nella fisiologia dello sfintere anale interno. Nello specifico, l'NO media il riflesso inibitorio retto-anale nell'uomo, producendo un rilassamento dello SAI. È stato stabilito il legame che esiste tra ipertonicità dello SAI, spasmo e presenza di una ragade anale. I pazienti con ragade anale cronica hanno una pressione anale massima media a riposo significativamente maggiore rispetto ai controlli; il flusso ematico nel derma anale in pazienti con ragade anale cronica era significativamente minore rispetto ai controlli. Nei pazienti le cui ragadi guarivano in seguito a sfinterotomia è stata dimostrata una riduzione della pressione anale e un miglioramento del flusso ematico dell'anoderma, con una ulteriore evidenza della natura ischemica della ragade anale. L'applicazione topica di un donatore di NO (trinitroglicerina) provoca il rilassamento dello sfintere anale, con la conseguente riduzione della pressione anale e miglioramento del flusso ematico anodermico. **Effetto sul dolore** In tre studi clinici di fase III è stato dimostrato che la pomata rettale Rectogesic 4 mg/g, controllata con placebo, migliora l'intensità del dolore medio giornaliero, misurato su una scala analogica visiva di 100 mm,associato a ragade anale cronica. Nel primo studio, la pomata rettale Rectogesic 4 mg/g riduceva l'intensità del dolore medio giornaliero, nell'arco di 21 giorni, di 13,3 mm (39,2 mm al basale) rispetto ai 4,3 mm (25,7 mm al basale) con placebo (p<0,0063) e nell'arco di 56 giorni la riduzione era, rispettivamente, di 18,8 mm contro 6,9 mm (p<0,0001). Questo corrisponde ad un effetto del trattamento (differenza tra la modifica percentuale per Rectogesic e placebo) pari al 17,2% in 21 giorni, ed al 21,1% in 56 giorni. Nel secondo studio, la pomata rettale Rectogesic 4 mg/g riduceva l'intensità del dolore medio giornaliero, nell'arco di 21 giorni, di 11,1 mm (al basale 33,4 mm) rispetto ai 7,7 mm (al basale 34,0 mm) con placebo (p<0,0388) e nell'arco di 56 giorni la riduzione era, rispettivamente, di 17,2 mm contro 13,8 mm (p< 0,0039). Questo corrisponde ad un effetto del trattamento del 10,6% in 21 giorni e del 10,9 % in 56 giorni. Nel terzo studio, Rectogesic 4 mg/g pomata rettale riduceva l'intensità del dolore medio giornaliero, nell'arco di 21 giorni, di 28,1 mm (al basale 55,0 mm) rispetto ai 24,9 mm (al basale 54,1 mm) con placebo (p<0,0489) e nell'arco di 56 giorni la riduzione era, rispettivamente, di 35,2 mm contro 33,8 mm (p<0,0447). Questo corrisponde ad un effetto del trattamento del 5,1% in 21 giorni e dell'1,5% in 56 giorni. **Effetto sulla cicatrizzazione** In tutti e tre gli studi, la cicatrizzazione delle ragadi anali nei pazienti trattati con Rectogesic 4mg/m pomata rettale non è risultata statisticamente differente rispetto al trattamento con placebo. Rectogesic non è indicato per la cicatrizzazione delle ragadi anali croniche. **5.2 Proprietà farmacocinetiche**Il volume di distribuzione della trinitroglicerina è di circa 3L/kg la quale viene eliminata da tale volume in percentuali di tempo estremamente rapide, con una conseguente emivita sierica di circa 3 minuti. Le percentuali di clearance osservate (vicine a 1 L/kg/min) superano ampiamente il flusso ematico epatico. Le sedi note del metabolismo extra-epatico comprendono i globuli rossi e le pareti vascolari. I prodotti iniziali del metabolismo della trinitroglicerina sono il nitrato inorganico e 1,2 e 1,3-dinitro-glicerolo. I dinitrati sono vasodilatatori meno efficaci rispetto alla trinitroglicerina, ma permangono più a lungo nel siero. Non si conosce quale sia il loro contributo al rilassamento dello sfintere anale interno. I dinitrati sono ulteriormente metabolizzati in mononitrati non vasoattivi e da ultimo in glicerolo e diossido di carbonio. In sei soggetti sani, la biodisponibilità media di trinitroglicerina rilasciata nel canale anale tramite pomata allo 0,2% era pari a circa il 50% della dose da 0,75 mg. **5.3 Dati preclinici di sicurezza Tossicità a dose ripetuta** Non sono stati condotti studi sulla tossicità sistemica di Rectogesic. I dati pubblicati indicano che dosi orali elevate di trinitroglicerina possono avere effetti tossici (metaemoglobinemia, atrofia testicolare e aspermatogenesi) nel trattamento a lungo termine. Questi aspetti non risultano tuttavia particolarmente pericolosi per l'uomo in condizioni di uso terapeutico. **Mutagenicità e carcinogenicità** I dati sugli studi preclinici con TNG rilevano effetti genotossici esclusivamente nel ceppo di Salmonella typhimurium TA1535 carente del sistema di riparazione ed effetti carcinogenici.Tuttavia, l'eventualità di un aumentato rischio carcinogenico è considerata estremamente ridotta in condizioni di uso terapeutico. **Tossicità sulla riproduzione** Gli studi sulla tossicità riproduttiva effettuati nel ratto e nel coniglio tramite somministrazione endovenosa, intraperitoneale e cutanea di trinitroglicerina, non hanno rivelato effetti avversi sulla fertilità o sullo sviluppo embrionale alle dosi che non inducevano tossicità materna. Non sono stati osservati effetti teratogeni. Nel ratto sono stati osservati effetti fetotossici (calo ponderale alla nascita) a dosaggi superiori a 1 mg/kg/d (IP) e 28 mg/kg/d (via cutanea) in seguito a esposizione uterina durante lo sviluppo del feto.

6. INFORMAZIONI FARMACEUTICHE 6.1 Elenco degli eccipienti Propilenglicole, Lanolina, Sesquioleato di sorbitano, Paraffina dura, Paraffina morbida bianca. **6.2 Incompatibilità** Non pertinente. **6.3 Periodo di validità** 15 mesi. Dopo la prima apertura: 8 settimane. **6.4 Precauzioni particolari per la conservazione** Non conservare a temperatura superiore ai 25°C.. Non congelare. Tenere il tubetto ben chiuso. **6.5 Natura e contenuto del contenitore** 30 g. Tubetti in alluminio con tappo bianco a vite in polietilene non perforante. **6.6 Precauzioni particolari per lo smaltimento** Nessuna istruzione particolare.

7. TITOLARE DELL'AUTORIZZAZIONE ALL'IMMISSIONE IN COMMERCIO ProStrakan Limited. Galabank Business Park. Galashiels. TDI 1QH - UK - Tel. 01896 664000 - Fax. 01896 664001

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9. DATA DELLA PRIMA AUTORIZZAZIONE/RINNOVO DELL'AUTORIZ-ZAZIONE 23 maggio 2007

10. DATA DI REVISIONE DEL TESTO 26 giugno 2009

Miglioramento della Qualità di Vita [1]

Rectogesic® 4mg/g
trinitroglicerina *pomata rettale*

Rapida remissione della sintomatologia dolorosa da ragade anale cronica [2]

1,5 mg di GTN ogni 12 ore fino a 8 settimane[3]

Utilizzare l'apposita guida di 2,5 cm per erogare la corretta dose di farmaco

Classe C
€ 73,09
1 tubo = 40 giorni

Depositato presso AIFA in data 30/11/09

Bibliografia

1) *Griffin N et al. Quality of life in patients with chronic anal fissure. Colorectal Disease 2004; 6: 39-44.*
2) *Sands L et al. Pain relief from 0.2% and 0.4% glyceryl trinitrate ointment in patients with chronic anal fissure. ECCP/EACP 2nd Annual Meeting, Bologna, Italy, 15-17 September 2005.*
3) *RCP Rectogesic*

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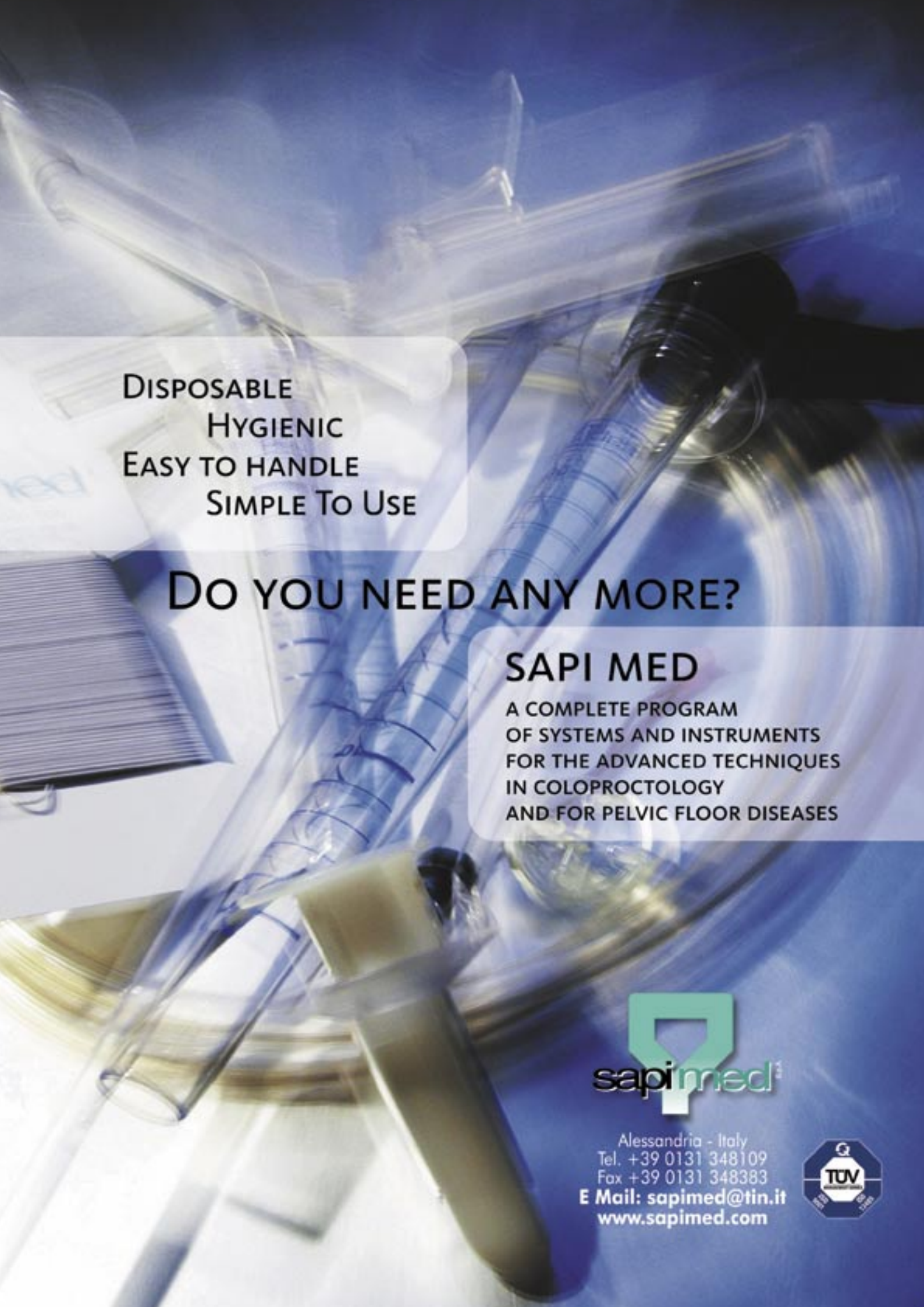
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