Vol. 37 - N. 4
December 2018

Rivista Italiana di Colon-Proctologia
Founded in 1982

ISSN 1973-4905

PELVIPERINEOLOGY

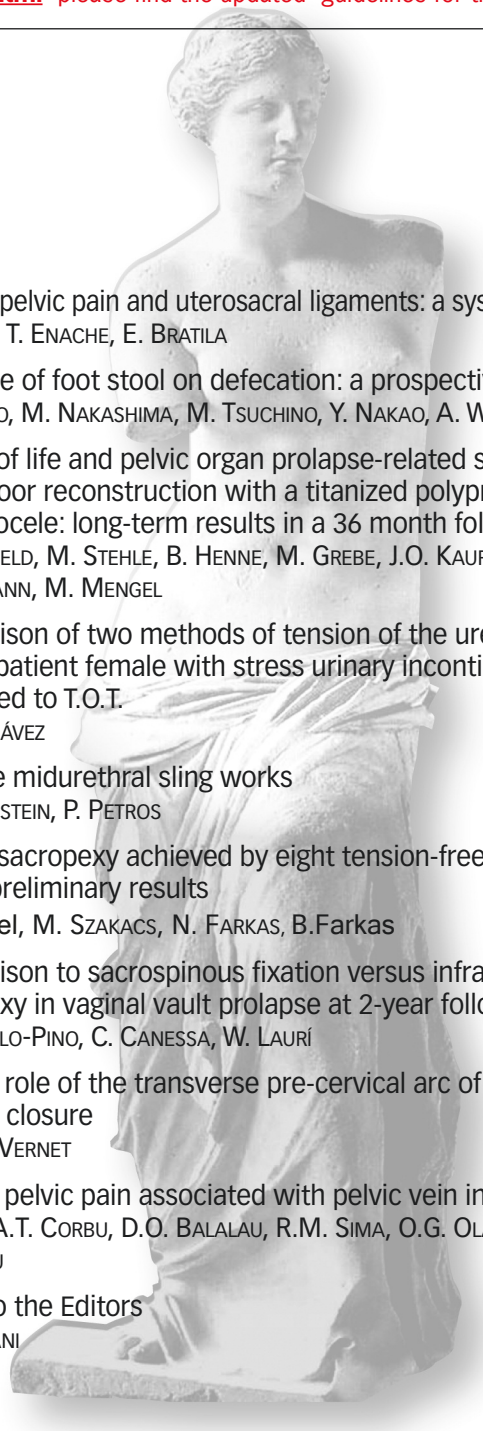
A multidisciplinary pelvic floor journal

www.pelviperineology.org

INSTRUCTIONS FOR AUTHORS

The manuscripts including tables and illustrations must be submitted to Pelviperineology only via the Isubmit system **www.isubmit.it**. This enables a rapid and effective peer review. Full upload instructions and support are available online from the submission site.

In **http://www.pelviperineology.org/pelviperineology_authors_instructions.html** please find the updated guidelines for the Authors.



Contents

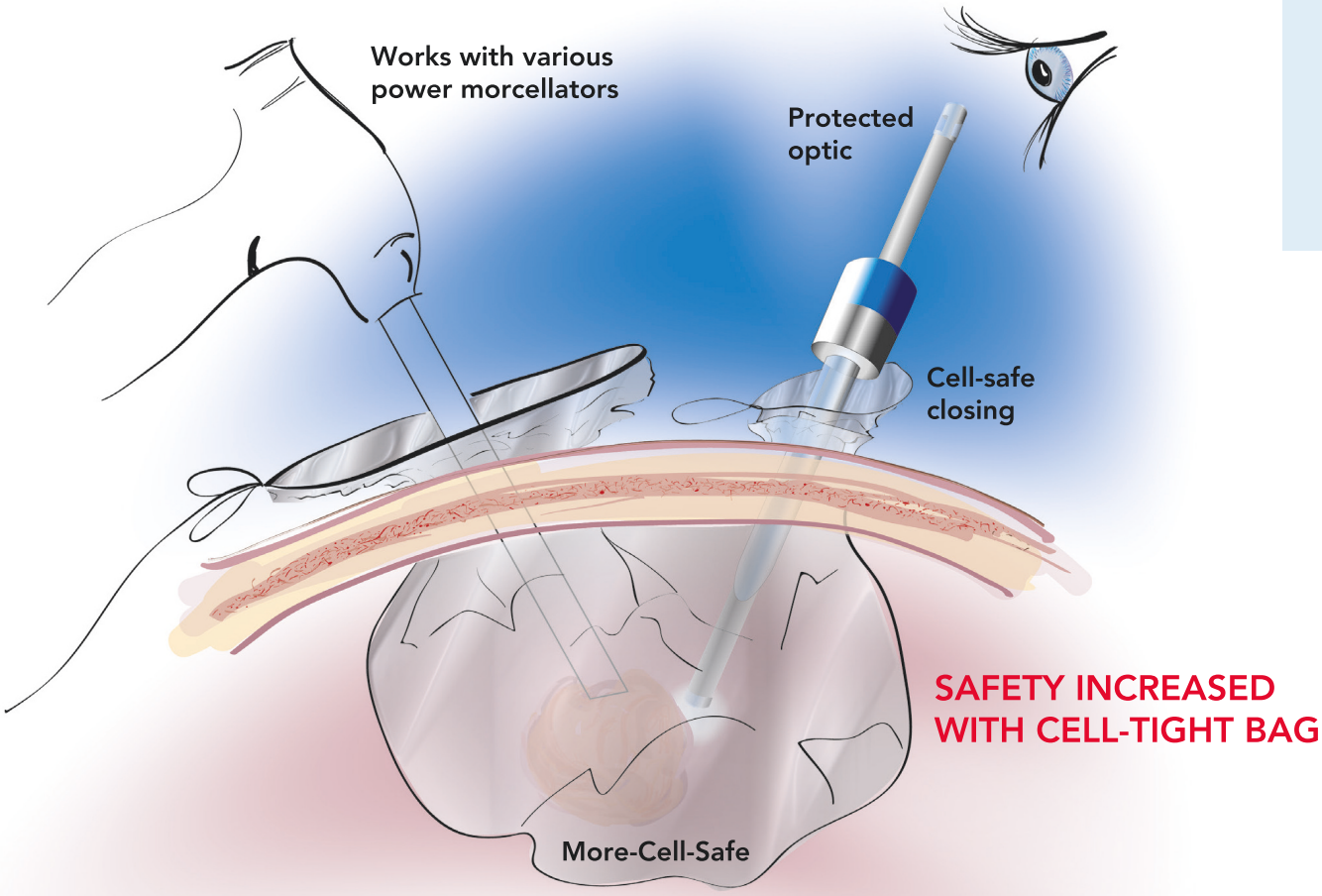
'Taxe Perçue' 'Tassa Riscossa' - Padova C.M.P.
Poste Italiane s.p.a.
Spedizione in Abb. Post. - 70% - DCB Padova

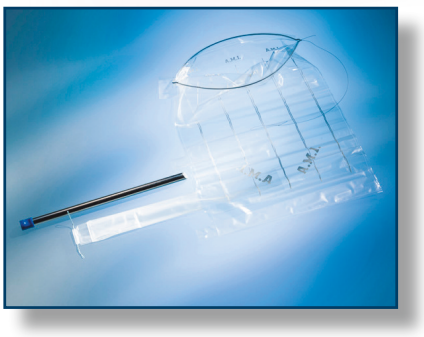
A.M.I.®

More-Cell-Safe

Increase Safety in Power Morcellation

The FIRST commercially available solution that demonstrates to significantly increase safety* against cell spillage in power morcellation.





System for reduction of cell spillage during power morcellation in laparoscopic surgery.

Feel confident with More-Cell-Safe

*Rimbach S. et al., 2015, A new in-bag system to reduce the risk of tissue morcellation, Arch Gynecol Obstet, DOI 10.1007/s00404-015-3788-9

A.M.I. GmbH . Im Letten 1 . 6800 Feldkirch . Austria . +43 5522 90505-0 . info@ami.at . **www.ami.healthcare**

Vol. 37
N. 4
December 2018

Rivista Italiana di Colon-Proctologia
Founded in 1982

PELVIPERINEOLOGY

A multidisciplinary pelvic floor journal

www.pelviperineology.org

Official Journal of the: International Society for Pelviperineology (www.pelviperineology.com)
Associaciòn LatinoAmericana de Piso Pelvico
Perhimpunan Disfungsi Dasar Panggul Wanita Indonesia
The Israeli Society of Urogynecology and Pelvic Floor
Romanian Uro-Gyn Society
Pelvic Reconstructive Surgery and Incontinence Association (Turkey)

Editorial Office: Benito Ferraro, Luisa Marcato
e-mail: benito.ferraro@sanita.padova.it - luisa.marcato@sanita.padova.it
Quarterly journal of scientific information registered at the Tribunale di Padova, Italy n. 741 dated 23-10-1982 and 26-05-2004
Editorial Director: Giuseppe Dodi (Direttore Responsabile)
Printer "Tipografia Veneta" Via E. Dalla Costa, 6 - 35129 Padova - e-mail: info@tipografiaveneta.it

Review

Chronic pelvic pain and uterosacral ligaments: a systematic review

DIANA BADIU[1], TRAIAN ENACHE[2], ELVIRA BRATILA[3]

[1] *Faculty of Medicine, "Ovidius" University of Constanta, Romania*
[2] *"Prof.Dr. Panait Sarbu" Obstetrics&Gynecology Hospital, Bucharest, Romania*
[3] *Department of Obstetrics&Gynecology, "Carol Davila" University of Medicine and Pharmacy, Bucharest, Romania*

Abstract: Introduction. According to the Integral System, chronic pelvic pain (CPP) in the female co-occurs with abnormal bladder emptying, urge and nocturia symptoms with a common causation, lax uterosacral ligaments (USLs). *Methods*. In our systematic review, the PubMed database was used for the literature search using the keywords algorithm which included "chronic pelvic pain" and "uterosacral ligaments". Relevant studies regarding CPP origin, USLs involvement in causation and symptom cure after surgical or non-surgical treatment were analysed in this review. *Results*. We found evidence that when USLs become lax, the gravity forces act on the uterus and vagina, develop congestion. In this respect, posterior compartment repair could be used in order to reinforce the USLs. *Conclusions*. CPP and other symptoms related to posterior zone of the pelvic floor were mainly due to USL laxity and repairing these ligaments restored its clinical manifestations, as predicted by the Integral Theory.

Keywords: Chronic pelvic pain; Uterosacral ligaments; Laxity; Pelvic floor; Posterior zone.

INTRODUCTION

Chronic pelvic pain (CPP) is a disabling disease which occurs in almost 20% of the female population[1], decreasing the patient's quality of life[2]. Although the pathogenesis of the disease is still said to be unknown, the main treatments include psychotherapy, drugs, laparoscopic nerve ablation, hysterectomy which implies the removal of the ovary and/or neuromodulation with better results[3,4].

CPP was described as being part of a specific symptom complex, according to the Integral Theory published in 1993[5,6] also known as the 'posterior fornix syndrome'. This comprises chronic pelvic pain, urge, nocturia, abnormal bladder emptying and is mainly due to laxity in apical support[7].

The USLs laxities were showed to be caused by age related collagen reduction from the ligaments or weakening from depolymerisation of hormones, at menstruation and especially during pregnancy[6]. Uterus represents the organ which sustains the main structure of the pelvic floor. Although it has such an importance, many physicians still recommend the removal of the uterus together with the ligaments in different pathologies.

Interestingly, at menopause, ovaries lose the production of estrogen and if another complication occurs like hysterectomy, the ligaments will not be able to maintain the pelvic floor structures. Moreover, by applying hysterectomy, the blood supply can be reduced to the vaginal apex, including USLs and cardinal ligaments. Taken together, all these negative factors start to develop the posterior zone symptoms[6]. Initially, in 1996, treatment of these symptoms was mainly achieved by uterosacral ligaments (USLs) plication[8]. However, because of these pathogenic factors which damage the main structural components of USL, collagen, tapes were added to create new collagen to structurally reinforce damaged USLs for cure of apical prolapse and posterior fornix symptoms[9].

Our systematic review aims to provide an emerging update about the relationship of USLs to causation of CPP and cure thereof by USL reconstruction.

METHODS

Literature Search

This systematic review was conducted by screening and gathering results of research papers from literature search in PubMed database. External sources were not used. Relevant studies were searched by using keywords algorithm: "chronic pelvic pain" [All Fields] AND "uterosacral ligaments" [All Fields].

Inclusion and Exclusion Criteria

The articles from the database with the keywords input were screened and analyzed (n = 15) with the PRISMA guidelines[10] using the following criteria: (i) original articles; (ii) published in English language; (iii) published within year 1986-2018; (iv) CPP origin, USL involvement, surgical and non-surgical treatment; (v) qualitative and/or quantitative studies; and (vi) studies assessing the involvement of USL in the CPP origin (Figure 1). We excluded conference abstracts, letters, and review articles.

Data Extraction

We gathered all of the full-text articles that met the inclusion criteria. The results from 5 research articles that are relevant to this review were extracted and analyzed. The outcomes of the studies were comprehensively analyzed and discussed.

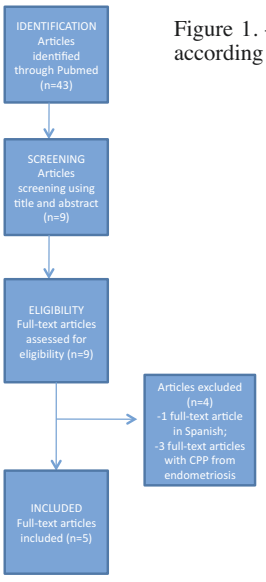


Figure 1. – Methodology for articles selection according to PRISMA review guidelines[10].

RESULTS

Study characteristics

We found 48 articles from which 5 were reviews (from which one had the full-text in French language). From 43 articles, we screened 9 full-text articles (34 were only abstracts from which 4 with only the title and 1 abstract with the text in Portuguese). From 9 full-text articles, we excluded 4 full-text articles: one with full-text in Spanish and the other three in which the CPP was referred to endometriosis cause. Finally, we included only 5 articles for analysis. Furthermore, we did not find any conference abstracts.

Studies that were used in this review where focusing more on CPP origin, USLs involvement, taken into consideration the surgical or non-surgical treatment (Table 1). The studies used in this review have a low to moderate level of certainty.

In the study of Liedl and contributors[11], the origin of CPP was the symptoms from apical prolapsed of 2nd or greater degree (POPQ, stages 2-4) including overactive bladder. After applying surgical treatment by using Integral Theory System with TFS, in order to repair the loose of cardinal and US ligaments, the patients presented improved symptoms and better clinical quality of life.

In another study[12], the authors made the surgical excision of the deep retractive pockets, improving in this way the symptoms such as CPP. It was also shown that women who had endometriosis in their deep retractive pockets, had significant improvement in deep dyspareunia and quality of life.

Another study made a combination of quantitative and semiquantitative techniques for the pain track[13]. The examination of the pain had different regions like pelvic abdominal wall, vulvar vestibule, pelvic floor and the vaginal vault. The study approach involved pain pressure threshold algometry and standardized numeric scale. By using these methods, it was showed to better quantify the pelvic pain complexity and that the pain in the abdominal walls, pelvic floor and USLs should be separately evaluated.

Another study[14] involved 487 women with chronic pain lasting more than 6 months with or without minimal endometriosis. The patients were randomized according to laparoscopic uterosacral nerve ablation (LUNA) group or no LUNA group. The main symptoms were achieved by using Visual Analogue Scale (VAS), Euro-QoL (EQ-5D) or EQ-VAS. The results of the study showed that LUNA did not result in improvements in pain, dysmenorrheal, dyspareunia, pelvic pain or QoL compared with no LUNA group (i.e. without pelvic denervation). In the protocol of The LUNA Trial Collaboration[15] it was tested the hypothesis if in women with CPP LUNA can alleviate pain at 12 month follow-up. After the surgery, questionnaires like VAS, an index of sexual satisfaction and the EuroQoL SD-EQ instrument was administered at 3, 6 and 12 months. The study showed that the LUNA effectiveness may be higher for central compared to non-central pain without any other associated diseases.

DISCUSSION

The role of uterosacral ligaments laxity in chronic pelvic pain

Although CPP represents a continuous important issue in daily medical practice, on many occasions it is underdiagnosed and undertreated by most of the physicians. A simple initially effective treatment was reinforcement of the ligaments laxity which supports the uterus and vagina[8].

Though vaginal USL plication showed an initial 85% improvement from the pain relief, there was further deteriorated in time[8]. Following this, insertion of a posterior vaginal sling showed a greater improvement of the symptoms[16].

One characteristic of this pain related to mechanical factors. The pain was exacerbated when standing and relieved on lying down. This is explained by the inadequately supported nerves being stimulated by gravitational forces. It is unfortunate that such pain is often attributed to psychological issues[17] which in fact may be secondary, not primary. It is therefore important that laxity in the posterior ligaments be first checked before considering other differentiating diagnosis like psychiatric case[8].

Knowing that the nerve fibers from USLs are visceral fibers, visceral innervations including those from T12-L1 and S2-4 would explain the pain distribution, although the stretching of the ligaments by gravity will also stimulate the nerve ending causing in this way pain.

The first step in reducing the pain is to ask the patient to lie down, decreasing the pressure[8]. Then, the second step could be represented by pessary application which can provide the normal mechanical support of the ligaments[8]. The congestion characteristics could be explained by the following: uterus is supported by both cardinal and USLs, assisted together with the pelvic floor muscles. When the ligaments become lax, the gravity forces acting on the uterus could develop congestion by "kinking" of the pelvic veins, preventing in this way the outflow[18].

TABLE 1. Comparison of the included full-text articles.

References	CPP origin	USLs involvement	After surgical treatment	Non-surgical treatment
7	2nd degree or greater uterine/apical prolapse	Loose of USLs	USL repair using TFS by applying Integral Theory System	–
8	Deep retraction pockets in the posterior cul de sac	USLs elasticity	Pockets excision (defined as estimated to be greater than 0.5 cm)	–
9	Hypothesized areas: - abdominal wall; - vulva; - pelvic floor; - vaginal vault	Traction applied to USLs	–	Using pain pressure threshold algometry and standard numeric scale
10	Nerve trunks interruption in the USLs	Operative of nerve trunks interruption in the USL by laparoscopic uterosacral nerve ablation	–	Visual analogue scale questionnaire at 3 and 6 months and 1,2,3 and 5 years at women with CPP with or without laparoscopic uterosacral nerve ablationtreatment
11	The Lee-Frankenhauser sensory nerve plexes and parasympathetic ganglia in the USLs	Nerve trunks interruption by laparoscopic uterosacral nerve ablation	Laparoscopic uterosacral nerve ablation	–

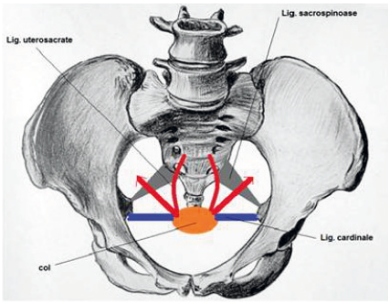


Figure 2. – The posterior vector resultant of the ligaments supporting the cervix.

The posterior compartment repair of the pelvic floor

The looseness or laxity of the vagina and its ligaments supports can cause CPP, organ prolapse, urge and stress incontinence, nocturia, voiding dysfunction, faecal incontinence and constipation[19,20].

The pain usually appears from the inability of USLs laxity to support the nerves near the ligaments. These nerves are stretched by gravity or during intercourse and cause CPP. This pain is almost invariably associated with other symptoms like nocturia, faecal incontinence and obstructed defecation[20].

It is important to understand that tissue structure is often displaced laterally (e. g. cardinal ligaments, USLs, rectovaginal fascia, pubocervical fascia, hammock, and perineal body). Therefore, effective posterior compartment surgical techniques are required to bring the tissues together in the anatomically normal position[21].

Physiologically, the uterine ligaments provide the posterior cervical support component of the uterine cervix, and the cardinal ligaments provide the lateral component. Transmitted in biomechanical language we speak of a "tension in the thread" that opposes the displacement of the cervix, one rearward oriented and the other the side. The result of these forces is a vector with posterolateral orientation (Figure 2).

Any reconstruction technique should target the ligament reconstruction whose vector result is similar to the physiological result. The disappearance of postoperative pain should confirm the cause-effect relationship between USLs and CPP.

Limitations and Future Research Suggestions

It is known that CPP is specific for the posterior zone. The diagnosis of posterior zone is detected when the patient has urgency nocturia, and especially CPP[22]. The limitation of our study consisted in that we followed only the USLs involvement without assessing the state of the perineal body which constitutes part of the back ligaments.

CONCLUSIONS

A key symptom related to posterior zone is the CPP. Knowing that the main underlying anatomical defect is deficiency and/or laxity of USL, the repair of these ligaments can lead to restoration of the structure and function, the clinical symptoms and manifestations.

DISCLOSURE STATEMENTS

The authors declare no conflict of interest.

REFERENCES

1. Breivik H, Collett B, Ventafridda V, Cohen R, Gallacher D. Survey of chronic pain in Europe: prevalence, impact on daily life, and treatment. Eur J Pain 2006; 10 (4): 287-333.
2. Yosef A, Ahmed AG, Al-Hussaini T, Abdellah MS, Cua G, Bedaiwy MA. Chronic pelvic pain: pathogenesis and validated assessment. Middle East Fertility Society Journal 2016; 21: 205-21.
3. Fall M, Baranowski AP, Elneil S, Engeler D, Hughes J, Messelink EJ et al. EAU guidelines on chronic pelvic pain. Eur Urol 2010; 57 (1): 35-48.
4. Zabihi N, Mourtzinos A, Maher MG, Raz S, Rodriguez LV. Short-term results of bilateral S2-S4 sacral neuromodulation for the treatment of refractory interstitial cystitis, painful bladder syndrome, and chronic pelvic pain. Int Urogynecol J Pelvic Floor Dysfunct 2008; 19 (4): 553-7.
5. Petros PE. Pelvic pain in pregnancy may be caused by uterosacral ligament laxity and may be associated with nocturia, urgency and abnormal bladder emptying. Acta Obstet Gynecol Scand 2011; 90 (9): 1050.
6. Petros P. The Integral System. Central European Journal of Urology 2011; 64 (3): 110-9.
7. Petros P, Ulmsten U. The posterior fornix syndrome: a multiple symptom complex of pelvic pain and abnormal urinary symptoms deriving from laxity in the posterior fornix. Scandinavian Journal of Urology and Nephrology 1993; 27 (Supplement 153 - PART IV): 89-93.
8. Petros PP. Severe chronic pelvic pain in women may be caused by ligamentous laxity in the posterior fornix of the vagina. Aust N Z J Obstet Gynaecol 1996; 36 (3): 351-4.
9. Petros PE. New ambulatory surgical methods using an anatomical classification of urinary dysfunction improve stress. Urge and Abnormal Emptying Int Urogynecoi J 1997; 8: 270-8.
10. Moher D, Liberati A, Tetzlaff J, Altman DG, PRISMA GROUP. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. PLoS Med 2009; 6 (7): e1000097.
11. Liedl B, Inoue H, Sekiguchi Y, Haverfield M, Richardson P, Yassourides A, Wagenlehner F. Is overactive bladder in the female surgically curable by ligament repair? Cent European J Urol 2017; 70: 53-9.
12. Yeung PP Jr, Ian Logan, Gavard JA. Deep retraction pockets, endometriosis, and quality of life. Frontiers in Public Health 2016; 4: 85.
13. Fenton BW, Grey SF, Reichenbach M, McCarroll M, Von Gruenigen V. Phenotyping chronic pelvic pain based on latent class modeling of physical examination. Hindawi Publishing Corporation, Pain Research and Treatment 2013; Vol 2013, Article ID 891301, http://dx.doi.org/10.1155/2013/891301.
14. Daniels J, Gray R, Hills RK et al. Laparoscopic uterosacral nerve ablation for alleviating chronic pelvic pain. A Randomized Controlled Trial. JAMA 2009; 302 (9): 955-61.
15. The LUNA Trial Collaboration. A randomised controlled trial to assess the efficacy of Laparoscopic Uterosacral Nerve Ablation (LUNA) in the treatment of chronic pelvic pain: The trial protocol [ISRCTN41196151]. BMC Women's Health 2003; 3: 6.
16. Petros P, Richardson P. TFS posterior sling improves overactive bladder, pelvic pain and abnormal emptying, even with minor prolapse. A prospective urodynamic study. Pelviperineology 2010; 29: 52-5.
17. Beard R, Reginald P, Pearce S. Psychological and somatic factors in women with pain due to pelvic congestion. Br J Obstet Gynaecol 1988; 245: 413-21.
18. Petros PP. Severe chronic pelvic pain in women may be caused by ligamentous laxity in the posterior fornix of the vagina. Aust. NZ J Obst. Gynaecol 1996; 36 (3): 351-4.
19. Petros PE, Swash M. The Musculoelastic Theory of anorectal function and dysfunction. J Pelviperineology 2008; 27: 89-93.
20. Liedl B. Male and female urinary incontinence from the viewpoint of the pelvic floor surgeon. Urologe 2010; A 49: 289-303.
21. Wagenlehner F, Bschleipfer T, Liedl B, Gunnemann A, Petros P, Weidner W. Surgical reconstruction of pelvic floor descent: Anatomic and functional aspects. Urologia Internationalis 2010; 84: 1-9.
22. Petros PE, Bornstein J. Vulvar vestibulitis may be a referred pain arising from laxity in the uterosacral ligaments – a hypothesis based on 3 prospective case reports. ANZJOG 2004; 44: 483-6.

Correspondence to:
Diana Badiu - 1st University Street - Constanta 900470 - Romania E-mail:dianabadiu@yahoo.com

Original article

Influence of foot stool on defecation: a prospective study

SHOTA TAKANO, MIDORI NAKASHIMA, MASAHIRO TSUCHINO, YUYA NAKAO, ATSUSHI WATANABE

Department of Functional Anorectal Disorder, Coloproctology Center Takano Hospital, Kumamoto, Japan

Abstract: Objective: The aim of this study was to determine the efficacy of adding a foot stool to help facilitate defecation in patients with fecal outlet obstruction. *Methods*: Patients (n=53) who experienced evacuation difficulties between June and October 2016 were enrolled in this prospective non-randomized single group study. Cinedefecography was performed with and without a foot stool. Anorectal angle (ARA), perineal plane distance (PPD), and puborectalis length (PRL) during rest and straining in both positions were measured from the radiographs. Rectal pressure was measured with the lateral position and sitting with and without a foot stool. *Results*: There was no significant difference between with and without a foot stool in ARA, PPD and PRL. In the upper body bent forward group, the time to evacuation was significantly shorter with a foot stool compared to without a foot stool (123 vs 91 sec, p=0.04). The difference of rectal pressure between the lateral position and sitting position significantly increased with a foot stool compared to without a foot stool (22.1 vs 16.7 mmH_2O, p<0.01). The difference of rectal pressure between with and without a foot stool increased in the upper body bent forward position compared to the upright sitting position (5.4 vs 1.9 mmH_2O, p<0.01). *Conclusion*: The findings suggest that using a foot stool with structure is a more efficient method for defecation. However, the upper body bent forward position is also important. This technique may be useful for retraining patients with constipation.

Keywords: Constipation; Defecation posture; Defecography; Fecal outlet obstruction; Foot stool.

INTRODUCTION

Fecal outlet obstruction lowers the quality of life (QOL) of patients with functional constipation. Outlet obstruction may be attributed to the following causes: non relaxation of the puborectalis muscle, anismus, rectal prolapse, rectocele and rectal hyposensitivity.

Tsuchino et al assessed rectal and anal pressure during defecation with the patient in a bending position rather than in a normal sitting position[1]. Moreover, Takano et al reported the efficacy of bending the upper part of the body forward on defecation[2] and they named this posture the "Thinker Position". However, some patients have also experienced evacuation difficulties with this position.

Findings in the literature indicate that the squatting position is superior to the traditional upright sitting position for defecation[3,4]. However, sudden changes in defecation habits such as altering the position from sitting to squatting or introducing a special commode may add psychological stress and cause incomplete evacuation. The closest position to squatting on a western commode is using a foot stool (foot step). We hypothesized that adding a foot stool in conjunction with structure would help facilitate defecation. Therefore, the aim of this prospective non-randomized single group study was to assess the efficacy of a foot stool on defecation.

PATIENTS AND METHODS

The risks of added x-ray exposure were disclosed to all the patients and informed consent to participate in the study was obtained. The inclusion criteria were patients experiencing constipation and who were scheduled to undergo cinedefecography. The indications for defecography were symptoms of evacuation difficulty and a feeling of incomplete evacuation. A diagnosis of constipation and outlet obstruction were made using the criteria for the functional defecation disorders of ROME IV. The exclusion criteria were patients who were under 18 years of age, pregnant and/or had prior rectal surgery. This study was approved by the institutional review board (IRB).

Cinedefecography technique

Patients were administered a phosphate enema 30 minutes prior to the procedure. They were then placed in the left lateral decubitus position and approximately 100 mL of barium paste was injected into the rectum. The barium paste was mixed with oatmeal until it reached a Bristol type 4, stool consistency. The patient was then asked to sit on a commode and lateral films of the pelvis were taken during the pushing phase in a sitting position with and without a foot stool (Figure 1a).

Manometry technique

Pushing rectal pressure examinations were performed with and without a foot stool in the upright sitting position and the upper body bent forward position. Rectal pressure was assessed using an anorectal function testing kit (GMMS Gastrointestinal Manometry System: GMMS-200, Star Medical, Tokyo, Japan).

Interpretation of data

Patient characteristics (i.e. gender, age, comorbidity, and prior perianal surgery) were retrospectively obtained from the medical records. Anorectal angle (ARA), perineal plane distance (PPD), and puborectalis length (PRL) in rest and during straining were measured from the radiographs. ARA was defined as the angle between the axis of the anal canal and the distal half of the posterior rectal wall[5-7]. PPD was predetermined to be the vertical distance between the ARA position and an imaginary line drawn between the pubic symphysis to the tip of the coccyx. PRL was measured as the distance between the ARA and the pubic symphysis[7,8].

a b c

Figure 1. – a, Upright sitting position without a foot stool; b, Upper body bent forward position with a foot stool; c, Upper body backward with a foot stool

TABLE 1. Comparison of cinedefecography measurements between with and without foot stool.
ARA anorectal angle, PPD perineal plane distance, PRL puborectalis length.

	Without foot stool	With foot stool	p value
ARA (o)	140.1	143.5	0.41
PPD (cm)	98.9	98.3	0.89
PRL (cm)	128.3	130.1	0.62
Length to evacuation (min)	100.7	95.8	0.32
Evacuation rate (%)	60.1	67.4	0.25
Evacuation volume (g)	144.9	167.7	0.12

TABLE 2. Comparison of pushing rectal pressure between the vertical position and upper body bent forward without/with foot stool.

	Without foot stool	With foot stool	p value
Sitting strait	85.1	86.9	0.71
Bending forward	84.5	89.9	0.18

Sacral Slope (SS) was measured from the radiography and defined as the angle between the superior line of the sacrum and the horizontal line. The difference of SS between with and without a foot stool was calculated. When the patient bent the upper body forward with a foot stool the SS became wider, and when the patient bent the upper body backwards the SS became narrower.

Statistical analysis

Previous studies have determined that the mean pelvic floor location increased from 1.3 cm compared to the recumbent and sitting positions[8]. Therefore, the effect size to determine a clinically relevant difference for this study was preset at 1.3 cm for PPD. With an alpha of 0.05 and a beta of 0.9, approximately 20 patients were needed for this study. The paired t-test was used to compare the sets of measurements for both positions and P values less than 0.05 were considered statistically significant.

RESULTS

Out of the 53 patients enrolled in the study, 25 of them were female with an average age of 70.2 (range: 21-90) years. Twenty-three of the patients used the upper body bent forward position with a foot stool and 30 of them used the upper body bent backwards position. The mean values of ARA, PPD and PRL during straining with or without a foot stool are shown in Table 1. There was no significant difference between with and without a foot stool in ARA, PPD or PRL.

Pushing rectal pressure showed no significant difference between with and without a foot stool in both the upright sitting position and the upper body bent forward position (Table 2).

In the upper body bent forward group, the time to evacuation was significantly shorter with a foot stool compared to without a foot stool (123 vs 91 sec, p=0.04). The difference of rectal pressure between the lateral position and the upright sitting position significantly increased with a foot stool compared to without a foot stool (22.1 vs 16.7 mmH_2O, $p<0.01$). The difference of rectal pressure between with and without a foot stool increased in the upper body bent forward position compared to the upright sitting position (5.4 vs 1.9 mmH_2O, $p<0.01$). The results for time to evacuation, rectal pressure comparing the lateral position and the upright sitting position, and rectal pressure comparing with and without a foot stool are shown in Figures 2, 3 and 4, respectively.

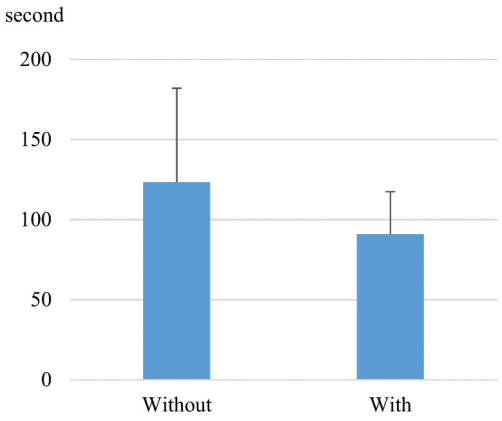


Figure 2. – Time to evacuation using valium paste without/with a foot stool. Time to evacuation is shorter with a foot stool than without a foot stool.

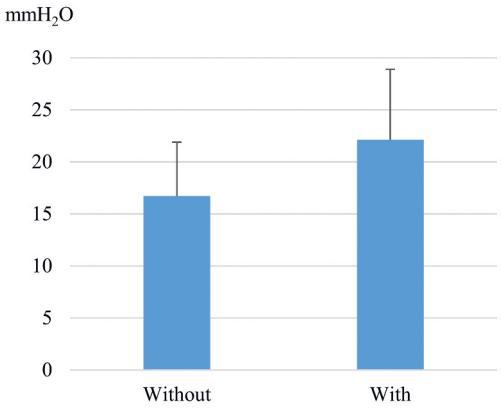


Figure 3. – The difference of rectal pressure between the lateral position and the sitting position without/with a foot stool. The difference is larger using a foot stool than without one.

DISCUSSION

Defecation is a very important part of human life. Fecal outlet obstruction is defined as "difficulty in evacuation or emptying of the rectum which may occur even with frequent visits to the washroom". Moreover, body position during defecation is an important element of defecation. Historically, humans have squatted in order to defecate[3,9] and this practice still continues today in underdeveloped countries[10]. While squatting for defecation continues to be the principal position in Asia and Africa, Western populations have become accustomed to sitting on a commode[3]. The widespread use of a sitting toilet began during the 19th century when sewage systems were developed to improve sanitation as cities and populations grew[11]. Compared with the sitting position, squatting was associated with significantly less time to achieve a sensation of satisfactory bowel emptying and a lower degree of subjectively assessed straining[3]. Rad found that ARA and PPD were greater in subjects who squatted versus those who sat (ARA 132 vs 92; PPD 8.4 vs 6.6 cm, respectively)[12]. The rectoanal angle of squatting (126°) for defecation was larger than the normal sitting position (100°) ($P < 0.05$), and was also larger than the hip-flex sitting position (99°) ($P < 0.01$)[4]. Tagart found that the ARA straightens with fully flexed hips—corresponding to the squatting position assumed for defeca-

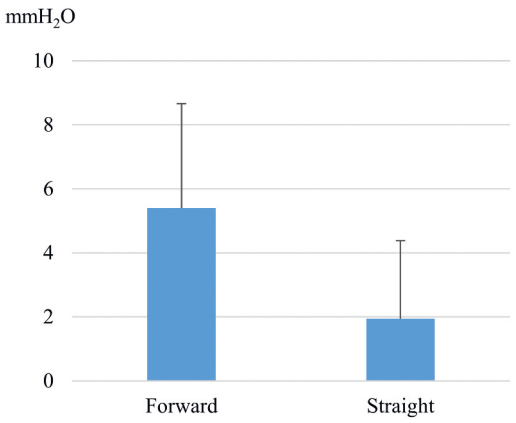


Figure 4. – The difference of rectal pressure between the upper body bent forward position and the backward position without and with a foot stool.

tion—and converts the rectoanal outlet into a straight canal, thereby facilitating rectal emptying[13]. Takano found that 22 patients were unable to evacuate the barium paste and therefore underwent cinedefecography in the upper body bent forward (Thinker) position. "The Thinker" position had a significantly wider ARA than the sitting position (113° vs. 134°, respectively; p = 0.03), larger PPD (7.1 vs. 9.3 cm, respectively; p = 0.02), and longer PRL (12.9 vs. 15.2 cm, respectively; p = 0.005) during straining. Eleven patients experienced complete evacuation in "The Thinker" position[2].

The present study demonstrated a wider ARA, larger PPD and longer PRL but no significant difference was found between with a foot stool and without a foot stool. The difference between our study and the previous study is the selection of the patients. In the previous study conducted by Takano et al, all 21 patients were unable to defecate in the upright sitting position[2]. However, in this study the patients who experienced evacuation difficulties were all enrolled whether or not the patient was able to evacuate the barium paste. Therefore, ARA, PPD and PRL did not reveal a significant difference. Now we have data for 22 patients who were unable to evacuate the barium paste without a foot stool and who underwent cinedefecography with a foot stool. Cinedefecography revealed a wider ARA with a foot stool than without a foot stool.

Other studies have found differences among the various positions. Altomare et al noted that when the patient sits on a commode, the ARA opens wider than it does in the standing position[14]. Rao et al reported on the influence of body position on defecation using a water-filled balloon and manometory. In the prone position, one third of the subjects had dyssynergia and half of them could not expel the paste (artificial stool). When sitting with a distended rectum, most subjects displayed normal defecation patterns and the ability to expel stool. The authors reported that the sitting position appears to be more conducive to defecation than the lying position. In addition, the manometric recordings during attempted defecation showed that the intrarectal pressure was lower in the left lateral position than in the sitting position[15].

The findings revealed in this study suggest that the rectal pressure is higher in patients who use the upper body bent forward position with a foot stool than without a foot stool. The average age of the patients in our present study is higher than in our previous study (Takano et al, 2014). This seems to indicate that for older patients, rectal pressure is more important for defecation than the relaxation of the pelvic muscles.

Tsuchino et al found that there was a higher rectal pressure and lower anal pressure in the upper body bent forward position. Furthermore, they stated that this position creates a higher intraabdominal pressure that seems to help facilitate evacuation[1].

CONCLUSIONS

The findings suggest that a foot stool in conjunction with structure is a more efficient method for defecation. However, the upper body bent forward position is also very important. This technique may be useful for retraining patients with constipation. However, this study has some methodological limitations. Further studies are needed to verify these findings.

DISCLOSURE STATEMENTS

We declare no conflict of interest.

REFERENCES

1. Tsuchino M, Yamashita K, Bouda T, Kai Y, Takano S, Takano M. A Study of the Relationship Between Continence Function and Defecatory Posture. Journal of Japanese Society of Stoma and Continence Reha 2008; 24: 34-38.
2. Takano S, Sands DR. Influence of body posture on defecation: a prospective study of "The Thinker" position. Tech Coloproctol 2016; 20: 117-121.
3. Sikirov D. Comparison of straining during defecation in three positions: results and implications for human health. Dig Dis Sci 2003; 48: 1201-1205.
4. Sakakibara R, Tsuoyama K, Hosoi H et al. Influence of Body Position on Defecation in Humans. Low Urin Tract Symptoms 2010; 2: 16-21.
5. Jorge JM, Wexner SD, Marchetti F et al. How reliable are currently available methods of measuring the anorectal angle? Dis Colon Rectum 1992; 35: 332-338.
6. Felt-Bersma RJ, Luth WJ, Janssen JJ, Meuwissen SG. Defecography in patients with anorectal disorders. Which findings are clinically relevant? Dis Colon Rectum 1990; 33: 277-284.
7. Jorge JM, Wexner SD, Ehrenpreis ED, Nogueras JJ, Jagelman DG. Does perineal descent correlate with pudendal neuropathy? Dis Colon Rectum 1993; 36: 475-483.
8. Habib FI, Corazziari E, Viscardi A, Badiali D, Torsoli A. Role of body position, gender, and age on pelvic floor location and mobility. Dig Dis Sci 1992; 37: 500-505.
9. Haubruch W, Constipation. In: Berk J, ed. Bockus Gastroenterology; 4th ed.; 1985, 111.
10. Boles R. Constipation. JAMA 1927; 89: 1766-1770.
11. Singer C. History of Technology. The Industrial Revolution 1958; 507-508.
12. Rad S. Impact of Ethnic Habit on Defecographic Measurements. Arch Iranian Med 2002; 5: 115-117.
13. Tagart RE. The anal canal and rectum: their varying relationship and its effect on anal continence. Dis Colon Rectum 1966; 9: 449-452.
14. Altomare DF, Rinaldi M, Veglia A, Guglielmi A, Sallustio PL, Tripoli G. Contribution of posture to the maintenance of anal continence. Int J Colorectal Dis 2001; 16: 51-54.
15. Rao SS, Kavlock R, Rao S. Influence of body position and stool characteristics on defecation in humans. Am J Gastroenterol 2006; 101: 2790-2796.

Correspondence to:
Shota Takano - 3-2-55 Oe, Chuo-ku - Kumamoto 862-0971 - Japan
E-mail: micg@takano-hospital.jp

Multidisciplinary UroGyneProcto Editorial Comment

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

Gyneco... Takano's article is quite interesting if considered from an obstetrical point of view. The postural postpartum attitude is in fact an effective procedure to solve many obstructed labor situations, as demonstrated by the Authors in case of fecal outlet obstruction.

The degree of inclination of the delivery channel is a fundamental point in the dynamics and mechanics of labor, such as the alignment of the anal canal for stool ejection. This alignment creates the ideal conditions for the pelvic entrance to be in line with the uterine and fetal body, making the uterine contraction more ergonomic and the progression of the fetus without difficulty.

The type of dorsal curvature, the anti or retroversion of the pelvis, the type of contracture of the muscles, the position and orientation of the lower limbs condition the movements of each individual element of the pelvis which constitutes a functional unit.

It is known that, in the presence of a slowing down or stopping of the progression of the part presented in the second stage of labor, it is useful to make the woman taking up the crouched position on the heels, which increases the bispynous and bituberal diameter by 2 cm and 1 cm respectively.

Another useful position to align the fetus with the pelvis and to increase the diameters of the pelvic inlet is the sitting position reclined forward.

These postures accelerate the fetal descent into the delivery channel in obstetrics and reduce the expulsive effort with respect to the horizontal position, as well as Takano shows a significant decrease of time to fecal evacuation and increased rectal pressure in the upper body bent forward.

Finally, as in obstetrics the different postures have different indications depending on the cause of obstructed labor and of the proper stage, it would be interesting to evaluate the effect of different postures depending on the cause of fecal outlet obstruction due to relaxatio (rectocele or rectal prolapse) compared to those from hypertone (anismus or contracture of puborectalis muscle).

REFERENCE

Regalia-Fumagalli A. Promoting delivery. Carrocci Faber Ed., 2013

Correspondence to:
PDr Chiara Alessi
Obstetrics and Gynecologic Unit. AO Padova
e-mail: chiara.alessi@aopd.veneto.it

Uro... The authors suggest that using a foot stool with structure is a more efficient method for defecation. We know that micturition in the woman takes place in a sitting position and that normally the urine emission is facilitated by a straightening of the urethra without a "thinker position". In the male this does not happen because a rectilinealization of the urethra is not possible for the length of the male urethra and for the presence of surrounding anatomical structures.

In this context it is clear that the "thinker position" is not necessary for urination in both sexes and that the assumption of a possible thinker position becomes necessary exclusively to increase the intravesical pressure during urination in patients who are affected by detrusor acontractility or in those who have an orthotopic neobladder.

Correspondence to:
Salvatore Siracusano
Associate Professor of Urology
University of Verona
Email: salvatore.siracusano@univr.it

Original article

Quality of life and pelvic organ prolapse-related symptoms after pelvic floor reconstruction with a titanized polypropylene mesh for cystocele: long-term results in a 36 month follow-up

CHRISTIAN FÜNFGELD[1], MARGIT STEHLE[1], BIRGIT HENNE[2], MARKUS GREBE[3], JAN OLIVER KAUFHOLD[4], DIRK WATERMANN[5], MATHIAS MENGEL[6]

[1] Klinik Tettnang GmbH, Tettnang, [2]St. Elisabeth Krankenhaus, Leipzig, [3]Städtisches Krankenhaus, Dresden-Friedrichstadt, [4]Klinikum Ludwigsburg, [5]Evangelisches Diakoniekrankenhaus, Freiburg

Abstract: Pelvic organ prolapse (POP) significantly impairs the function of bladder, bowel and sexuality and reduces quality of life (QoL). The aim of POP surgery is the reconstruction of the pelvic organ anatomy and improvement of QoL. Conventional native tissue repair has a higher recurrence rate compared to the implantation of an alloplastic mesh. An increased risk of adverse events with first generation-meshes and no significant improvement of QoL is still a matter of debate. The purpose of this study was to investigate anatomical stability, complications, improvement of QoL, and the influence on POP-related symptoms after 36 months. 289 women with a symptomatic cystocele > grade I were treated with a titanium coated polypropylene mesh (TiLOOP® Total 6, pfm medical ag). POP-related QoL and symptoms were evaluated pre- and postoperatively. Mean age of patients was 67 ± 8 years. Preoperative POP-Q grades were diagnosed as following: 47.1% with grade II; 49.8% with grade III, and 3.1% with grade IV. Postoperatively, 21.8% of patients were cured (grade 0), 62.7% were diagnosed with grade I, 15.1% with grade II, and 0.4% with grade IV. The recurrence rate in the treated anterior compartment was very low (2.4% after twelve and 1.9% after 36 months, respectively). Concerning POP-related symptoms patients' condition improved. Furthermore, QoL improved significantly in all nine investigated domains ($p < 0.001$, Wilcoxon test). Therefore, implantation of a second generation-mesh can be offered to patients with a recurrent or a high-grade prolapse after extensive patient information on the risks and benefits of mesh-supported POP repair.

Keywords: Pelvic organ prolapse; Quality of life; Surgical mesh.

INTRODUCTION

Pelvic organ prolapse (POP) is a common disease prevalent in 50% of parous women and can significantly reduce patients' quality of life (QoL)[1]. Pelvic organs, such as the uterus, bladder and/or bowel can descend because of failing of the pelvic soft tissue support (ligaments, connective tissue, etc.) and weakness of the vaginal wall. Affected women show various urinary, bowel and sexual symptoms resulting in a profoundly impaired QoL[1-4]. Treatment alternatives range from non-surgical therapies, which are mainly focused on minimization of risk factors, to a great variety of surgical options including abdominal (open or laparoscopic) and minimal-invasive transvaginal techniques with or without the use of surgical meshes[1]. Nowadays, native tissue repair with sacrospinal (*Amreich-Richter)* or uterosacral ligament fixation is the preferred surgical method for the treatment of a cystocele and apical prolapse via the transvaginal approach.

The reconstruction of the anatomical location of organs of the true pelvis is the aim of every surgical intervention. However, the functional result is more important for affected patients than anatomically correct reconstruction. QoL is highly dependent on the function of the bladder and bowel, sexuality and pelvic pain. Furthermore, long term stability is of great interest. Due to the high rate of recurrent POP with conservative native tissue treatment options[1,5] alloplastic meshes were established. Current literature indicates a lower recurrence rate after POP reconstruction with surgical meshes[1,5,6]. Nevertheless, the high rate of mesh-associated adverse events of first generation meshes discredited these materials and therefore, discussions are still controversial[6-9]. The aim of this observational study was to investigate the expected anatomic stability and furthermore, the number of adverse events, the effect on QoL and POP-related symptoms after cystocele correction with a modern type 1a polypropylene mesh with titanium containing coating in a long term follow up.

METHODS

Patient and study design

This prospective observational study was carried out at nine German hospitals (clinicaltrials.gov, NCT01084889). Two hundred ninety-two patients with cystocele or POP ≥ grade II (International Continence Society [ICS] classification using the Pelvic Organ Prolapse Quantification [POP-Q] system[10]) or patients with grade I prolapse with symptoms requiring surgical intervention were included in the study. Primary procedures as well as surgery for recurrence were permitted. Exclusion criteria were defined as status post mesh implantation in the anterior compartment, status post pelvic radiation, and previous systemic steroid therapy. All patients were able to understand the nature, goals, benefits, results and risks of the study and were briefed in detail about the study. The participants had the right to revoke their consent at any time. Primary endpoints were defined as the erosion rate during the first twelve months of observation and patients' QoL six months postoperatively[11,12]. Secondary endpoints included documentation of all adverse events during the study course, and feasibility of mesh implantation. Additionally, QoL after twelve and 36 months was assessed[13]. The data were anonymized in accordance with the German Data Protection Act, making it impossible for third persons to identify patients. The protocol of the clinical trial was assessed positively by ethic committees as required by the professional code. The study was supervised through external auditing and 100% monitoring. Patients were examined at six, twelve and 36 months postoperatively. Patients' QoL was recorded using the German version of the validated Prolapse Quality-of-Life (P-QoL) questionnaire[14,15]. The anatomical results were assessed using the POP-Q system.

Surgical method and mesh implant

A titanized polypropylene mesh (TiLOOP® Total 6, pfm medical ag) with a pore size of > 1mm was implanted via the transvaginal route for cystocele correction. Subsequent to a longitudinal full thickness incision of the anterior vaginal wall the cystocele was dissected. Implantation of the alloplastic mesh was achieved using a tunneler for transobturator and ischiorectal placement. The mesh was then fixed distally, laterally and apically with the apical fixation at the sacrospinal ligament (Figure 1). Additional surgical procedures such as reconstruction of the posterior compartment, hysterectomy or placement of a suburethral sling were allowed. Complete information on the surgical procedure(s) was documented. Patients received vaginal estrogen and a single-dose antibiotic agent.

Anatomical outcome

Anatomical results were determined using the validated standard international classification for prolapse surgery published by the ICS in 1996: the POP-Q system[10]. The location of the defective structures is assessed and the severity of the prolapse is measured. All defined points in the three compartments of the pelvic floor (anterior: Aa, Ba; apical: C, D - cervix or vaginal apex; posterior: Ap, Bp) are quantified regarding their distance to the hymenal ring. Thus, the classification of the degree of the prolapse is standardized, quantifiable and reproducible. POP-Q measures were assessed preoperatively and six, twelve and 36 months after the implantation of the surgical mesh.

Prolapse-related quality of life

Impairment of patients' QoL caused by prolapse induced symptoms and particularly bladder or bowel dysfunctions are of superficial interest. However, prolapse sensation, dyspareunia and pelvic pain reduce QoL, too. During this clinical investigation patients' QoL was assessed using the validated German version of the P-QoL questionnaire[14]. Data was collected prior to implantation and six, twelve and 36 months postoperatively. The P-QoL questionnaire consists of 40 questions considering patients' perception of their general state of health, the impact of the prolapse, role limitations and physical limitations, questions about patients' personal relationships including sexuality, emotions, sleep and other personal limitations. The higher the score the higher the impairment of QoL (0 = no limitations, 100 = lowest QoL). Patients were free not to answer individual or all questions on their QoL.

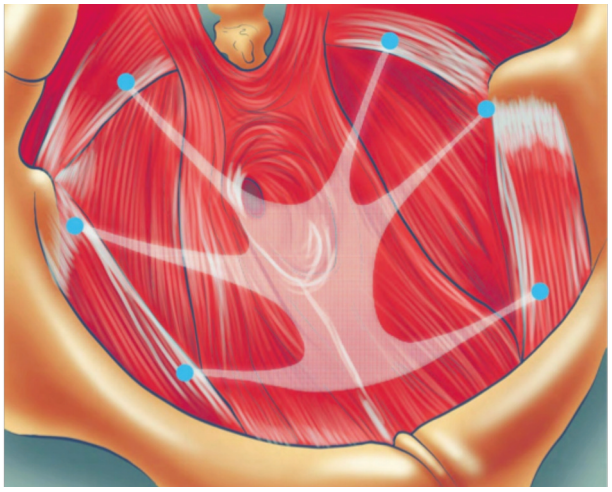


Figure 1. – Distal, lateral and apical fixation of the 6-arm surgical mesh TiLOOP® Total 6 (pfm medical ag).

Statistical analysis

Statistical analysis was done using IBM SPSS, version 22. Wilcoxon test was used for the statistical analysis of patients' pre- and postoperative QoL. For subgroup analysis concerning recurrence Chi-squared test was used. Concerning analyses on erosions, POP-Q and QoL Mann-Whitney U-test was used.

Clinical Event Committee

All adverse events reported during the study course were evaluated by an independent committee of experts (Clinical Event Committee, CEC) using the Common Terminology Criteria for Adverse Events (CTCAE, version 4.0)[16]. The experts were selected based on their clinical and scientific experience. To confirm their independence all members disclosed their (financial) interests.

RESULTS

Demography

During the recruitment phase 292 patients were included whereby 289 were treated with the medical device under investigation. Two patients withdrew their consent and for one patient mesh implantation appeared not to be suitable intraoperatively. Six months after implantation 280 patients were available for follow up, at twelve months data on 286 patients were collected and after 36 months 269 patients were followed up. During the study course two patients died for reasons irrespective of the study treatment.

On average patients were aged 67 ± 8 years (43-87 years) and BMI amounted to 27 ± 4 kg/m² (17-37 kg/m²). Birth rate accounted for 2.3 ± 1.2 children. Concerning patients' history of gynecological treatments 31.8% (92/289) of patients had a hysterectomy and 14.9% (43/289) were previously operated on for prolapse. 34.9% (101/289) of patients underwent a conventional posterior colporrhaphy for rectocele repair in addition to the study treatment (mesh implantation in the anterior compartment). Simultaneous implantation of a posterior surgical mesh was conducted in 25.6% (74/289) of patients and in 36.3% (105/289) of cases the uterus was removed.

Anatomical results

The validated international POP-Q system was used to determine the severity of prolapse prior implantation and at every follow up during the clinical study[10]. Preoperative grade II prolapse was reported for 47.1% (136/289) of patients; 49.8% (144/289) were diagnosed with grade III, and 3.1% (9/289) of patients had a grade IV prolapse according to the ICS definition.

Concerning the anterior compartment 2.4% (7/286) of patients presented with a recurrence twelve months postoperatively and a further 1.9% (5/269) after 36 months. However, in addition to the anterior recurrent descensus 1.0% (3/286) was as well diagnosed with a concomitant apical/posterior descensus twelve months postoperatively and another 1.5% (4/269) after 36 months, respectively.

Regarding anatomical stability in general 14.0% (40/286) were diagnosed with a recurrent descensus during the first twelve months of observation and a further 5.2% (14/269) showed up with recurrent prolapse after 36 months. Out of the patients suffering from recurrent descensus only 22.2% (12/54) showed recurrent descensus in the anterior compartment either solely or in addition to recurrent descensus in the apical/posterior compartment. Thus, the majority of patients presented with de novo or recurrent descensus in the counter compartment during the observation period of

36 months (42 of 54 patients). However, in the late follow up after 36 months 21.8% (55/252) were cured with no prolapse (grade 0); for 62.7% (158/252) of patients a grade I prolapse was reported; 15.1% (38/252) had a grade II prolapse, and 0.4% (1/252) were diagnosed with a grade IV prolapse.

Prolapse-related quality of life

Data on patients' QoL was collected by the P-QoL questionnaire considering nine different domains including personal relationships[14]. During the course of the study a continuously significant improvement of QoL was reported ($p < 0.001$, Wilcoxon test, Table 1 and Figure 2). As early as six months after implantation of the surgical mesh patients' QoL was improved even for the domain "personal relationships" ($p < 0.001$, Wilcoxon test). During the twelve and 36 months follow up further improvement of QoL was stated by the patients. However, improvement of QoL between the twelve and 36 months follow up was stagnating but still significantly improved compared to the preoperative conditions ($p < 0.001$, Wilcoxon test).

Prolapse-related symptoms

Prior to implantation, the major factors impairing patients' QoL were prolapse sensation, pulling pain in the womb area, urinary disorders (voiding dysfunction, stress urinary incontinence (SUI), urge urinary incontinence (UUI)), dyspareunia, and anorectal disorders (Table 2).

Concerning the prolapse symptoms described preoperatively the following results were obtained in the postoperative observation period (see also Table 3 and Figure 3):

Foreign-body sensation was reduced from 77.9% (225/289) before implantation to 3.7% (10/269) after 36 months. Pulling pain in the womb area was described by 48.4% (140/289) of patients prior to implantation of the surgical mesh compared to 2.6% (7/269) 36 months postoperatively. Differences concerning SUI were inferior (39.8% (115/289) preoperatively vs. 33.8% (91/269) 36 months postoperatively). The amount of patients suffering from UUI was reduced from 36% (104/289) preoperatively to 8.9% (24/269) after 36 months; concerning rectal incontinence 4.8 % (14/289) of patients were affected prior to implantation of TiLOOP® Total 6 and 1.9% (5/269) after 36 months. Dyspareunia was reduced from 15.6% (45/289) to 6.3% (17/269). Defecation disorder differed only slightly (12.1% (35/289) preoperatively vs. 10.4% (28/269) 36 months postoperatively).

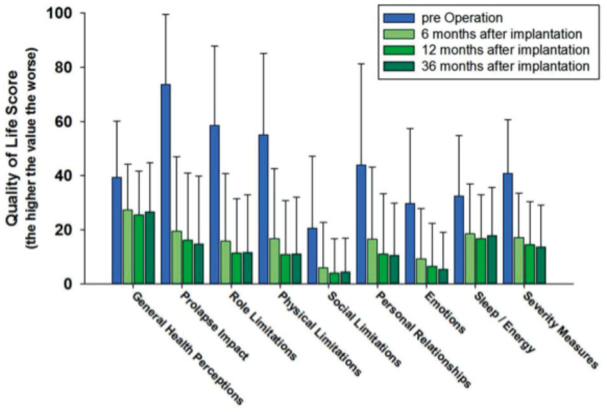


Figure 2. – Development of patients' QoL during the observation period of 36 months: Significant improvement six, twelve and 36 months postoperatively in all investigated domains (general health perceptions, prolapse impact, role, physical and social limitations, personal relationships, emotions, sleep/energy and severity measures.

Adverse events

Adverse events were documented during the course of the study. An independent CEC assessed all events using the CTCAE code. After discounting erroneous or duplicate reports 176 adverse events were evaluable. Out of these 109 were classified as serious and 67 as non-serious adverse events. No adverse event was reported to be probably or definitely related to the study device. The majority of adverse events were classified as "renal and urinary disorders" or "reproductive system and breast disorders" according to the CTCAE code. "Urinary incontinence" was most common accounting for about one fourth of all adverse events.

As described previously, intra- and perioperative complications were rare[11,12]. Bladder lesions were diagnosed in 1.7% (5/289) of patients; ureteral injury, bleeding requiring blood transfusion, urinary tract infection or infected hematoma just after discharge from hospital was reported for 0.3% (1/289) in each case. Both infections were treated conservatively. Positional pain was described by 0.3% (1/289) of treated patients.

Furthermore, concerning the first primary endpoint previously published data reported on the amount of erosions occurring during the first twelve months of the study[11,13].

TABLE 1. Quality of life prior and after implantation of TiLOOP® Toal 6 (P-QoL questionnaire) - The higher the score, the lower the quality of life. Mean values and standard deviation (SD) were calculated for the anamnestic data, and after 6, 12 and 36 months.

	pre-OP		6-M-FU		12-M-FU		36-M-FU	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
General state of health	39.3	21.0	27.2	17.0	25.5	16.3	26.5	18.2
Negative impact of prolapse	73.5	26.7	19.4	27.6	16.2	24.8	14.7	25.1
Role limitations	58.5	29.2	15.8	24.9	11.3	20.1	11.6	21.4
Physical limitations	55.0	30.2	16.6	26.0	10.9	19.9	11.1	21.0
Social limitations	20.6	26.5	6.0	16.7	3.9	12.8	4.2	12.7
Personal relationships	43.8	37.5	16.5	26.8	11.0	22.2	10.4	19.5
Emotions	29.6	27.7	9.3	18.6	6.5	15.9	5.4	13.7
Sleep/Energy	32.4	22.4	18.5	18.5	16.7	16.3	17.7	17.9
Severity of symptoms	40.8	19.8	17.1	16.4	14.4	16.0	13.5	15.5
p-value	na		< 0.001		< 0.001		< 0.001	

TABLE 2. History of symptoms (prior to implantation)

	N	%
Foreign-body sensation	225	77.9
Pulling pain in womb area	140	48.4
Prolapse sensation	233	80.6
At least one of the aforementioned symptoms	278	96.2
Dyspareunia	45	15.6
Micturition problems	136	47.1
Urge urinary incontinence (UUI)	104	36.0
Stress urinary incontinence (SUI)	115	39.8
Grade I	91	31.5
Grade II	24	8.3
Mixed urinary incontinence	61	21.1
Defecation disorder	35	12.1
Rectal incontinence	14	4.8

TABLE 3. Development of symptoms during observation period of 36 months.

	Baseline		6-M-FU		12-M-FU		36-M-FU	
	N	% of 289	N	% of 280	N	% of 286	N	% of 269
Foreign-body sensation	225	77.9	10	3.6	17	5.9	10	3.7
Pulling pain in womb area	140	48.4	25	8.9	17	5.9	7	2.6
SUI	115	39.8	105	37.5	94	32.9	91	33.8
UUI	104	36.0	31	11.1	29	10.1	24	8.9
Rectal incontinence	14	4.8	5	1.8	9	3.1	5	1.9
Dyspareunia*	45	15.6	17	6.1	19	6.6	17	6.3
Defecation disorder	35	12.1	19	6.8	28	9.8	28	10.4

* At anamnesis the question was binary and had to be answered by "yes" or "no". At later visits, an additional answer option "not assessable" was provided.

Briefly, 10.5% (30/286) of patients were diagnosed with erosion during the first twelve months. Out of these, 56.7% (17/30) were either conservatively treated or an outpatient procedure under local anesthesia was sufficient. Surgical intervention under general anesthesia was necessary in 43.3% (13/30) of the cases. However, no mesh explantation was required. Altogether, patients described no symptoms in 46.7% (14/30) of the reported erosions.

No unknown or unexpected events occurred and none of the reported events was probably or definitely related to the product under investigation.

DISCUSSION

Recurrence of prolapse is one of the major topics of many clinical studies concerning mesh-assisted prolapse repair. Current literature indicates that the rate of recurrences can be significantly reduced using alloplastic meshes compared to native tissue repair[1,6,17]. The results of the present study with 289 patients are in line with this revealing a low recurrence rate in the anterior compartment 36 months postoperatively. Furthermore, the risk for recurrent descensus in the posterior compartment is reduced to one third by uterus preservation (21.3% vs. 7.6%). To the best of our knowledge, this has not been described in the scientific literature so far.

QoL can be improved independent of the procedure for prolapse correction[6,8,18]. Differences between native tissue repair and mesh-assisted surgery with respect to the improvement of QoL are minor and significance levels differ depending on the clinical study[8,18]. The results of the present study show a statistically significant improvement of patients' QoL after implantation when compared to QoL prior implantation in all investigated domains ($p < 0.001$). Furthermore, a gradual improvement of patients' QoL from six to 36 months occurred. Analyses of changing or improving main prolapse symptoms are merely addressed in most studies. However, the Integral Theory by Peter Petros elucidates the relation of prolapse symptoms, functionality of the pelvic floor and anatomical defects[19]. Therefore, the development of prolapse symptoms starting from preoperative conditions over an observation period of 36 months postoperatively was investigated during this clinical study. The main focus was on prolapse sensation, micturition disorders, SUI, UUI, fecal incontinence, defecation disorders, pain in the womb area, and impairment of sexuality. As expected, almost all patients reported on an improved prolapse sensation after anatomical reconstruction and simultaneously a low rate of recurrences was described. Concerning UUI symptoms 84.8% of patients with preoperative symptoms were free of symptoms at the 36 months follow up. De novo UUI was described merely for 5.75% which is in line with current literature reporting on a reduction of urge symptoms by apical fixation[20]. Concerning SUI the results are different. In some cases SUI continues after implantation of an alloplastic mesh, partially patients are cured completely or patients develop a de novo SUI as observed in 20.3% (58/286) of patients after six months in the present study. This corresponds to current data describing a higher rate of de novo SUI after mesh-assisted cystocele correction compared to conventional colporrhaphy[1]. Data on pelvic pain is rare as this symptom is usually not taken into account in clinical studies on POP repair. Here, we considered pelvic pain explicitly. The results show that the amount of patients affected by pelvic pain was significantly reduced from 48.4% prior implantation to 2.6% after 36 months. This supports the hypothesis by Petros that pelvic pain can be caused by POP[19,21].

Implantation of surgical meshes is not recommended in sexually active women, since an increased risk of dyspareunia after implantation of alloplastic meshes has been described in the scientific literature[22]. However, the rate of dyspareunia was reduced from up to 24%[22] to as low as 3%[1]. The rate of de nove dyspareunia was very low. One should bear in mind that a large percentage of affected patients is not sexually active due to comorbidities, no or impotent partner or no interest.

60.2% of the cystocele correction was accompanied by a reconstruction of the posterior compartment. In 34.9% of cases native tissue repair was conducted while a posterior mesh was implanted in 25.3% of posterior surgeries. Due to this additional treatment, no assessment of the reduction of fecal incontinence (4.8% preoperatively vs. 1.9% postoperatively) and defecation disorders (12.1% preoperatively vs. 10.4% postoperatively) is possible. Thus, it is not possible to evaluate if the anterior or posterior reconstruction surgery causes the improvement of anorectal function.

The aforementioned results of this prospective multicenter study are an important contribution to the still ongoing discussion of alloplastic meshes in POP repair. However, the rate of erosions is still a matter of controversial debate and should be addressed in future studies, too. The sponsor of this current clinical study finished another observational study on a polypropylene mesh with titanium containing coating with an extended pore size of 3 mm and reduced weight (TiLOOP® PRO A, pfm medical ag; NCT02690220). Results of this trial with 52 patients are promising and will be published soon.

There are some limitations of this clinical study which should be taken into account. First of all, there was no control group and thus, it is not assessable if the improvement of patients' QoL after the implantation of a surgical mesh is superior compared to native tissue repair. Furthermore, concomitant or later surgeries in the pelvic area were performed and thus, it is not possible to evaluate if the anterior or posterior reconstruction surgeries cause the significant improvement of patients' symptoms and QoL. Additionally, the study was sponsored by pfm medical ag. However, study data was monitored objectively and supervised by an independent clinical event committee which ensured the objectivity of the presented data.

CONCLUSION

This prospective multicenter clinical trial to investigate the long-term effects of the use of titanized meshes with a distal, lateral and apical fixation revealed anatomical stability. Concerning the anterior compartment recurrence rate was low and far lower than reported for native tissue repair.

Improvement of QoL was highly significant in all considered areas. Typical symptoms of POP such as prolapse sensation, micturition problems, UUI, pelvic pain and sexual disorder were significantly reduced. Mesh-assisted POP reconstruction has its specific risks as every surgical procedure[1,6,9]. However, the results of this study demonstrate these risks to be acceptable since patients benefit from a significant improvement of QoL. Therefore, the reconstruction of POP using alloplastic meshes can be offered to patients after a thorough patient information and discussion of all risks, benefits and alternative treatment options. Patients with recurrent POP or a higher grade prolapse in a primary setting may benefit from the good results on long-term stability to avoid reoperation for recurrences.

ACKNOWLEDGEMENTS

We would like to thank Dr. Lutz Sternfeld for his support during the study and Arim Shukri for his analysis of the statistical data. Our thanks go also to Dr. Angelika Greser for the critical review of the manuscript.

CLINICAL TRIALS REGISTER AND FUNDING

US National Library of Medicine, clinicaltrials.gov: NCT01084889. The study was sponsored by pfm medical ag, Cologne, Germany.

DISCLOSURES

The authors state that they have no conflicts of interest beyond the activities listed below. The activities listed here had and have no effect on the results of the study or the study's publication. Christian Fünfgeld: speaker's fees from pfm medical, Serag Wiessner, BARD, AMS, AMI, Astellas, Recordati, Promedon; Mathias Mengel: speaker's fees from pfm medical, AMI; Markus Grebe: speaker's fees from pfm medical; Dirk Watermann: speaker's fees for research from Serag Wiessner, fees from AMS and Johnson & Johnson; Margit Stehle, Brigit Henne, Jan Kaufhold: none.

REFERENCES

1. Deutschen Gesellschaft für Gynäkologie und Geburtshilfe (DGGG) and Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF), Diagnostik und Therapie des weiblichen Descensus genitalis. 2016.
2. Slieker-ten Hove MC, Pool-Goudzwaard AL, Eijkemans MJ, Steegers-Theunissen RP, Burger CW, Vierhout ME et al. The prevalence of pelvic organ prolapse symptoms and signs and their relation with bladder and bowel disorders in a general female population. International urogynecology journal and pelvic floor dysfunction 2009; 20 (9): 1037-45.
3. Mengel M, Stehle M, Henne B, Grebe M, Kaufhold J, Watermann D et al. Entwicklung des Miktionsverhaltens unter Belastungsbedingungen und Lebensqualität nach netzgestützter Zystozelenkorrektur Development of voiding behaviour under stress conditions and quality of life after mesh-based cystocele repair. Gynäkologische Praxis 2015; 39 (3): 10.
4. Weber AM, Walters MD and Piedmonte MR. Sexual function and vaginal anatomy in women before and after surgery for pelvic organ prolapse and urinary incontinence. Am J Obstet Gynecol 2000; 182 (6): 1610-5.
5. Denman MA, Gregory WT, Boyles SH, Smith V, Edwards SR and Clark AL, Reoperation 10 years after surgically managed pelvic organ prolapse and urinary incontinence. Am J Obstet Gynecol 2008; 198 (5): 555 e1-5.
6. Maher C, Feiner B, Baessler K, Christmann-Schmid C, Haya N and Marjoribanks J, Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse. Cochrane Database Syst Rev 2016; 2: Cd012079.
7. US Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health and Center for Biologics Evaluation and Research, UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse: FDA Safety Communication. 2011.
8. Glazener CM, Breeman S, Elders A, Hemming C, Cooper KG, Freeman RM et al. Mesh, graft, or standard repair for women having primary transvaginal anterior or posterior compartment prolapse surgery: two parallel-group, multicentre, randomised, controlled trials (PROSPECT). Lancet 2017; 389 (10067): 381-392.
9. Chapple CR, Cruz F, Deffieux X, Milani AL, Arlandis S, Artibani W et al. Consensus Statement of the European Urology Association and the European Urogynaecological Association on the Use of Implanted Materials for Treating Pelvic Organ Prolapse and Stress Urinary Incontinence. Eur Urol, 2017.
10. Bump RC, Mattiasson A, Bo K, Brubaker LP, DeLancey JO, Klarskov P et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Am J Obstet Gynecol 1996; 175 (1): 10-17.
11. Fünfgeld CM et al. Zystozelenkorrektur mit alloplastischen Netzen. Frauenarzt 2015; 56 (12).
12. Farthmann J, Mengel M, Henne B, Grebe M, Watermann D, Kaufhold J et al. Improvement of pelvic floor-related quality of life and sexual function after vaginal mesh implantation for cystocele: primary endpoint of a prospective multicentre trial. Arch Gynecol Obstet 2016; 294 (1): 115-121.
13. Funfgeld C, Stehle M, Henne B, Kaufhold J, Watermann D, Grebe M et al. Quality of Life, Sexuality, Anatomical Results and Side-effects of Implantation of an Alloplastic Mesh for Cystocele Correction at Follow-up after 36 Months. Geburtshilfe Frauenheilkd 2017; 77 (9): 993-1001.
14. Lenz F, Stammer H, Brocker K, Rak M, Scherg H, Sohn C. Validation of a German version of the P-QOL Questionnaire. Int Urogynecol J Pelvic Floor Dysfunct 2009; 20 (6): 641-649.
15. Digesu GA, Khullar V, Cardozo L, Robinson D, Salvatore S. P-QOL: a validated questionnaire to assess the symptoms and quality of life of women with urogenital prolapse. Int Urogynecol J Pelvic Floor Dysfunct 2005; 16 (3): 176-181.
16. National Cancer Institute, Common Terminology Criteria for Adverse Events (CTCAE) 4.03, N. C. Institute, Editor. 2010, National Cancer Institute: National Cancer Institute.
17. Scientific Committee on Emerging and Newly-Identified Health Risks SCENIHR, Opinion on the safety of surgical meshes used in urogynecological surgery 2015.
18. Maher C, Feiner B, Baessler K, Schmid C. Surgical management of pelvic organ prolapse in women. Cochrane Database Syst Rev 2013; 4: CD004014.
19. Petros PE and Woodman PJ. The Integral Theory of continence. Int Urogynecol J Pelvic Floor Dysfunct 2008; 19 (1): 35-40.
20. Jager W, Mirenska O, Brugge S. Surgical treatment of mixed and urge urinary incontinence in women. Gynecol Obstet Invest 2012; 74 (2): 157-64.
21. Petros PE, Goeschen K. Der weibliche Beckenboden, ed. S. Verlag. 2009. 228.
22. Deutschen Gesellschaft für Gynäkologie und Geburtshilfe (DGGG) and Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF), Descensus genitalis der Frau - Diagnostik und Therapie. 2006.

Correspondence to:

Christian Fuenfgeld - Emil-Muench-Straße 16 - Tettnang 88069 - Germany
E-mail: chr.fuenfgeld@t-online.de

Original article

Comparison of two methods of tension of the urethral medium tape in patient female with stress urinary incontinence submitted to T.O.T.

WALTER MONTAÑO CHÁVEZ

Urologist Surgeon, Urology Service of Hospital Obrero No 1, La Paz Bolivia

Abstract: Introduction: The placement of middle urethral tape is the most common approach for women with I.U.E (stress urinary incontinence). Unfortunately, there is no standardized method to give tension to the tape, which can cause possible obstruction in the bladder outlet. *Objectives:* To evaluate the urinary flow and post voiding residual, comparing two tension methods. *Material and Method:* A case-control study was conducted in 75 women diagnosed with I.U.E, who underwent placement of a T.O.T tape; using two methods for calibration: one with Foley urethral catheter No 16F (5.3mm) with interposition of scissors May (3mm) and another using Hegar dilators 8mm inside the urethra and 4mm between the urethra and the tape. The patients were evaluated in pre- and postoperative (3 months) the: Q (max), and post-void residue. *Results:* 36 patients underwent tension of the tape on Foley urethral catheter 16F + scissors (controls) and 39 with dilators Hegar 8 / 4mm (cases). The Q (max) Pre-operative of the control group was 40.2 +/- 2.6 and in the Post-operative 27.6 +/- 4.1 (P: 0.044). In the case group, the preoperative Q (max) was 39.1 +/- 2.1 and the postoperative Q (max) of 31.1 +/- 2 (P: 0.000). The post-micturition residue of the control group was 9.2 +/- 6 ml and in the postoperative period it increased to 19.1 +/- 22 ml, in the case group the preoperative residue was 7.9 +/- 6.5 ml and the postoperative period decreased to 3, 6 +/- 4.7 (p: 0.0000). The variation of the Post Voiding residual in the control group of -4.3 +/- 4.4 and in the case control group of 9.9 +/- 22 (p: 0.0002). *Conclusion:* The case group (method 8/4) showed a statistically significant improvement in Q (max) and postoperative post voiding residual in relation to the control group (catheter + scissors), who presented 11% of overcorrections (p: 0.048).

Keywords: Middle urethral; Stress urinary incontinence; T.O.T. tape.

INTRODUCTION

The International Continence Society (ICS) defines stress urinary incontinence (I.U.E) as the loss of urine that occurs before exertion or exercise or secondary to sneezing or coughing[1]. This situation is related to two physiopathological factors: urethral hypermobility and intrinsic sphincter deficit.

UI is not a disease that endangers the life of the patient, but significantly deteriorates the quality of life of the sufferer, since it reduces their self-esteem and diminishes their autonomy[2].

Surgical treatment is aimed at increasing the support of the urethra and thereby increasing the urethral resistance during the efforts. In cases with clear urethral hypermobility, and even in non-severe intrinsic sphincter insufficiency or associated with a fixed urethra, tension-free urethral suspension techniques (minimally invasive TVT or TOT techniques) have become the reference tests and they have displaced colposuspension techniques like Burch's, which for years was the most effective technique. The tension-free urethral suspension techniques are based on the Petros and Ulmsten studies, which propose a new conception of pelvic dynamics (Petros integral theory)[3], and consists of placing a synthetic material tape (made of monofilament braided polypropylene) below the urethra, towards the posterior pubic surface in the case of TVT or towards the obturator holes in the TOT, as a reinforcement of the pubourethral ligament. It is assumed that these tapes are placed "without tension".

The original description had an accurate guide on how to establish the desired distance between the tape and urethra. Ulmsten et al. described the distance to achieve as: "Placing a 16-Charrière Foley catheter in the urethra and a Metzenbaum scissor between the urethra and the tape"[4]. Delorme defined the distance between the tape and the urethra as "a visible distance of a few millimeters"[5].

Unfortunately, there is no standardized method to give tension to the tape, which can cause possible obstruction in the bladder outlet.

For its standardization, several alternatives have been proposed, such as those by Ludwig S et al. that proposes the TOT 8/4 where it is observed in 83% of the patients the tape is between 3 to 5 mm below the urethra[6].

OBJECTIVES

The objective of the study was to evaluate the urinary flow and post voiding residual, comparing two tension methods of the suburethral tape during the surgery of T.O.T for I.U.E.

MATERIAL AND METHODS

A case-control study was carried out in 75 women diagnosed with Stress Urinary Incontinence, using Urogynecological and Urodynamic exams and who were eligible for this study. They were subjected to tape placement T.O.T according to the Delorme technique; using for calibration two methods: one with Foley urethral catheter No 16F (5.3mm) with interposition of scissors May (3mm) called "controls" and another using Hegar dilators 8mm urethral and 4mm between the urethra and tape called "cases".

The patients were evaluated in pre and postoperative (3 months) the: Q (max), and postvoid residual

Exclusion criteria: It was decided to exclude patients who presented:

Urinary urgency or urge urinary incontinence; Previous incontinence surgery; Prolapse of pelvic organs ≥ stage II; Pelvic radiotherapy; Use of uroselective drugs, and neurological diseases.

RESULTS

Of the total number of patients, and in a randomized manner, 36 patients underwent surgery with tape tension on a 16F Foley Catheter with May Scissors interposition (controls) and 39 patients with Hegar dilators urethral 8mm and 4mm between the urethra and the tape (table 1).

TABLE 1.
Preoperative.

Variable	Cases	Controls	Statistical test	Value of p
N	39	36		
Age (years)	52.3 +/- 7.2	53.7 +/- 7.1	*Student' t*	0,39
SLUT time (years)	4.1+/- 0.9	4.1 +/- 1.3	*Student' t*	0,73
No cloths / day	3,6 +/- 0.8	2,9 +/- 0.9	*Student' t*	0,0004 (*)
Body Mass Index	25 +/- 1,8	25.5 +>/- 2.1	*Student' t*	0.097
Parity	2.7 +/- 1.1	2.8 +/- 1.1	*Student' t*	0.64
DM2	20.5 %	16.7 %	Chi squared	0.34
Obesity	38.5%	55.6%	Chi squared	0,074
Arterial hypertension	10.3%	2.8%	Fisher's exact test	0.204
Caesarean section	12.8%	11,1%	Fisher's exact test	0.55
Q (max) Pre-Operative	39.1 +/- 2.1	40.2 +/- 2.6	*Student' t*	0,044 (*)
VLPP	88.5 +/- 17.3	85.4 +/- 19.6	*Student' t*	0,48
Post Voiding Residue (ml)	7.9 +/- 6.5	9.2 +/- 6	*Student' t*	0.35

Postoperative

Variable	Cases	Controls	Statistical test	Value of p
N	39	36		
Q (max) Post-Operative	31.1+/-2	27.6 +/- 4.1	*Student' t*	0,0000 (*)
Loss of urine PO	10.3 % (4)	11.1% (4)	*Fisher's exact test*	0.598
Post Voiding Residue (ml)	3,6 +/- 4,7	19,1 +/- 22	*Student' t*	0,0000 (*)
Re operation	0	11,1% (4)	*Fisher's exact test*	0,048 (*)
Post-Voiding residual variation	-4,3 +/- 4.4	9,9 +/- 22	*Student' t*	0.0002 (*)

The average Q (max) in the Pre-operative of the control group was 40.2 +/- 2.6 and in the Post operative 27.6 +/- 4.1 with statistically significant improvement (P: 0.044).

In group case, the average preoperative Q (max) was 39.1 +/- 2.1 and the post-operative one of 31.1 +/- 2 also being statistically significant (P: 0.000).

The average post-void urine residue of the control group in the preoperative period was 9.2 +/- 6 ml and in the post-operative group it increased to 19.1 +/- 22 ml, while in the case group the preoperative post-micron residue was 7.9 + / - 6.5ml and the postoperative period decreased to 3.6 +/- 4.7 (p: 0.0000).

The variation of the Post Voiding residual in the control group of -4.3 +/- 4.4 and in the case control group of 9.9 +/- 22 shows a statistically significant reduction (p: 0.0002).

Two patients in the control group had increased post-void volumes due to overcorrection, which had to be submitted to removal of the tape at 3 months.

DISCUSSION

The musculoelastic mechanism proposed for continence[2], stretches and narrows the proximal urethra against a competent pubourerthral ligament (PUL). Narrowing a tube increases its resistance to flow, inversely by the 4th power of the radius (Poiseuille's Law). An adequately tightened PUL is required to restore this closure mechanism[2]. However, this exponential effect works both ways. It means that the tightening of the sling has to be very precise. With any sling operation, excessive tension on the sling will constrict the urethra and cause urinary retention. On the other hand, excessive looseness of the sling will cause ongoing SUI. In our comparative study, the methodology using the Hegar dilators inside the urethra and between the urethra and tape obviously more closely approximated the natural physiology with fewer retention states.

CONCLUSION

Patients undergoing TOT surgery with adjustment method 8/4 (cases) presented statistically significant improvement of Q (max) and postoperative post voiding residual in relation to the group submitted to calibration with Foley Catheter + scissors (controls), who presented in 11%, overcorrection with increased post voiding residue (p: 0.048).

DISCLOSURE STATEMENTS

There was no conflict of interest, informed patient consent was obtained, and the study was approved by the local ethical committee.

REFERENCES

1. Abrams P, Cardozo L, Fall M, y cols. The standardization of terminology of lower urinary tract function. Report from the standardization subcommittee of the International Continence. Society. Neurourol Urodyn 2002; 21 (2): 167-78.
2. Espuña Pons, M. Incontinencia de orina en la mujer. Med Clin (Barc) 2003; 120: 464-472.
3. Petros, P.E., Ulmsten, U.I. An integral theory of female urinary incontinence. Experimental and clinical considerations. Acta Obstet Gynecol Scand Suppl 1990; 153: 7-31.
4. Ulmsten U, Henriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogyn J Pelvic Floor Dysf 1996; 7: 81-86.
5. Delorme E. Transobturator urethral suspension: miniinvasive procedure in the treatment of stress urinary incontinence in women. Progres en Urologie. 2001; 11: 1306-1313
6. Ludwing S, Sturmm M, Mallmann P, Jager W, TOT 8/4: A Way to standardize the surgical procedure of a transobturator tape. Biomed Res. Epub 2016 Feb 15.

Correspondence to:
Walter Gustavo Montaño Chavez - Calle Brazil s/n - La Paz 591 La Paz - Bolivia
E-mail: wgmontanoch@hotmail.com

Original article

How the midurethral sling works

BURGHARD ABENDSTEIN[1], PETER PETROS[2]

[1] *Department of Obstetrics and Gynecology, Bezirkskrankenhaus, Hall in Tirol, Austria*
[2] *University of NSW School of Medicine Dept of Surgery, St Vincent's Hospital, Sydney, Australia*

Abstract: Though the midurethral sling (MUS), the gold standard operation for cure of urinary stress incontinence has been in use for almost 30 years, few surgeons understand the anatomical basis for how it works. The original explanation given in 1990 was that the pubourethral ligament (PUL) weakened due to birth related collagen damage. The MUS tape shortened and reinforced the PUL by creation of a collagenous neoligament. This neoligament restored the distal and proximal urethral closure mechanisms. The closure mechanisms were further validated by simultaneous measurement of intra and extra urethral and bladder pressures, video ultrasound imaging after placing a haemostat on one side of the vagina to support the damaged PUL and in 2014 by a mathematical model which showed that any explanation which relied on the pressure equalisation theory would need a pressure The midurethral sling (MUS) is the most studied operation in the history of Urogynecology, validated by more than 2000 studies. Few know its history, fewer how it works. Even today, what some consider as the peak body for incontinence science, the International Consultation for Incontinence, attributes urethral closure to pressure transmission theories, none of which can explain why a tape placed at midurethra can restore continence. Absent from ICI is any mention of the Integral Theory (1) on which the first commercial MUS, the TVT was based (2). The aim of this comment is to present the original scientific work which led to the MUS and further experiments which sought to validate the original mechanisms proposed.

Keywords: Midurethral sling; Integral theory; Pressure transmission; Pubourethral ligament.

INTRODUCTION

1986-1990

The discovery of the MUS began with two unrelated observations in the mid 1980s. A hemostat applied at midurethra, fig. 1, (so it could not obstruct) controlled urine loss on coughing *without bladder neck elevation*. The second observation was an implanted Teflon tape created a dense collagenous tissue reaction around it. It was hypothesized that the cause of urinary stress incontinence (USI) was collagen deficiency in the pubourethral ligament (PUL) and that a tape implanted in the exact position of PUL would create new collagen to reinforce it. Experimental implantation of the tape in 13 canines validated this hypothesis and created a new surgical principle, creation of an artificial collagenous neoligament[3]. Between 1988 and 1989, prototype MUS were performed in 30 women. The position of the bladder neck relative to the symphysis was determined preoperatively with radio-opaque dye in the balloon of a Foley catheter at rest and straining. The midurethrally placed Mersilene tape was configured as an inverted 'U' on rectus sheath with its arms descending into the vagina, so the tape could be lowered if the patient could not pass urine. At a certain point, all 30 patients could pass urine freely and were continent on coughing. A 2nd standing xray was taken[1].

Xray findings All 30 patients were initially cured with no bladder neck elevation, even those with pre-op bladder neck below the lower border of symphysis. These findings invalidated the concept of a 'pressure equalization zone'. Other xray findings were: a forward force pulling distal urethra forwards against the tape: a backward force pulling the Foley balloon backwards against the tape; a 3rd downward force pulling the Foley balloon downward. Only muscle forces could explain these observations; forwards: anterior part of pubococcygeus muscle (PCM); backwards: levator plate (LP); downwards: conjoint longitudinal muscle of the anus.

Conclusions from the 1990 experiments

A muscle-based closure mechanism was acting against a PUL of optimum length to close both distal urethra and bladder neck.

* a rise in intraabdominal pressure closes the urethra

Question Why a PUL of optimum length? A striated muscle requires a firm anchoring point to contract efficiently. If the insertion point, in this case PUL is loose, the closure muscles effectively lengthen, their contractile forces weaken and urethra cannot be closed. This explanation can be easily tested by gently supporting the PUL with a haemostat placed on one side immediately behind the symphysis. This controls urine loss on coughing.

A further clinical test (late 1980s). A small group of patients with USI were asked to arrive with a full bladder. These were given extra fluid until they felt an urge to empty. Application of the one-sided hemostat test controlled USI. With the haemostat in place, they were asked to relax and pass urine. Those who succeeded were asked to strain down. This accelerated the stream. This test demonstrated 1. The mechanism of the MUS is not obstructive. 2. If the pressure transmission theory were valid, the urine stream should have diminished or stopped.

1995

Local anesthesia methodology for MUS allowed an experiment which tested both pressure transmission theory and the proposed musculoelastic mechanism[1] for truth or falsity. Pressure transducers were placed in equivalent positions inside and outside the bladder and urethra[4]. Pressure readings were made during coughing. As expected, the pressure inside the bladder was lower, between 2 and 5 cm H_2O less than outside the bladder. However, the pressure inside the urethra was in every case between 5 and 21 cm H_2O *greater* than the pressure outside. These findings confirmed the action of a reflex muscular mechanism and at the same time invalidated the pressure transmission theory. The pressure readings were carried out with vaginal incision open and repeated when the vagina was sutured. With open flaps, all patients lost large streams of urine on coughing, even when there were major rises in intraurethral pressure during coughing: in the 4 patients tested, midurethral pressure rise was 78, 94, 112, and 170% greater than resting. On tightening the flaps (without elevation) full continence was restored in all patients.

1999

Under video ultrasound control[5], a haemostat placed exactly in the position of PUL, on one side of the urethra,

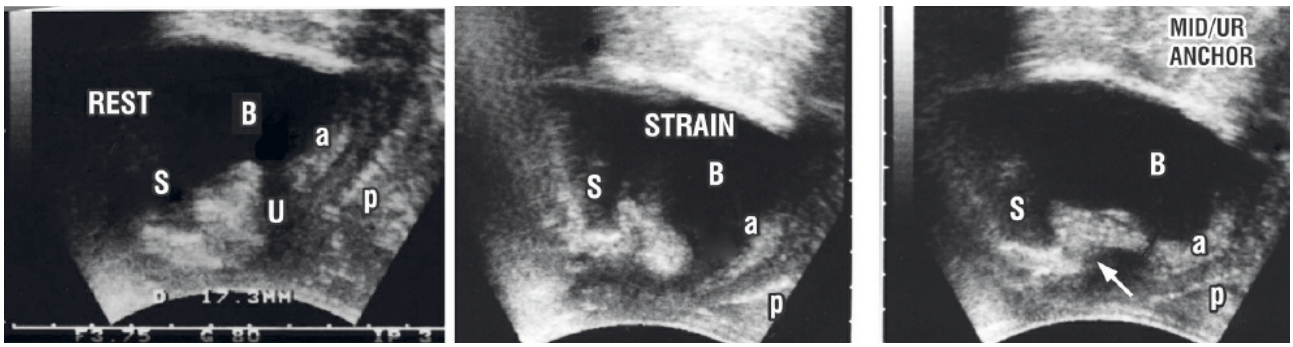


Figure 1. – A firm pubourethral ligament 'PUL' is required for urethral and bladder neck closure.
Left figure, 'REST' S=symphysis; U=urethra; B=bladder; a=anterior vaginal wall; b=posterior vaginal wall.
Middle figure 'STRAIN' A lax PUL cannot support the posterior urethral wall. This allows the posterior pelvic muscles to stretch the vaginal walls 'a' and 'b' backwards; this pulls open the posterior urethral wall. The urethra opens out (funnels) both proximally and distally.
Right figure 'MID/UR ANCHOR' Pressing upwards with a hemostat (arrow) restores PUL length and the strength of the muscle forces which contract against PUL; 'a'&'b' visibly tension; distal urethral and bladder neck closure.

controlled most of the urine loss on coughing, fig. 1. In those patients where there was some residual leakage on coughing, plicating the suburethral vagina with a 2nd curved haemostat restored continence. Both closure mechanisms as hypothesized[1] were validated . Note closure at bladder neck and distal urethra in fig1. It is evident on examination of fig. 1, that a PUL of specific length is required to restore continence and urethrovesical geometry. Pressure transmission theories cannot explain fig. 1. Only oppositely acting vector forces acting against a competent PUL can explain distal urethral and bladder neck closure.

2014

A mathematical model based on known biomechanical tissue characteristics estimated that a bladder pressure 2 orders of magnitude (100 times) was needed to open out the urethra from the inside for normal micturition[6]. The same pressure requirement would apply for closure from the outside in, the pressure transmission theory.

CONCLUSION

The MUS works by restoring the anchoring point for the opposite closure muscles PCM and LP.

CONFLICTS OF INTEREST

Burghard Abendstein has no conflicts of interest. Peter Petros is the co-inventor of the midurethral sling.

REFERENCES

1. Petros PE & Ulmsten U. An Integral Theory of female urinary incontinence. Acta Obstet. et Gynecol. Scand. 1990; Supp. 153; 69; 1-79
2. Ulmsten U, Henriksson L, Johnson P, and Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence, Int. Urogynecol. J. 1996; 7: 81-86.
3. Petros PE & Ulmsten U, Papadimitriou J. The Autogenic Neoligament procedure: A technique for planned formation of an artificial neo-ligament. Acta Obstet. et Gynecol. Scand. 1990; Supp. 153; 69; 43-51.
4. Petros PE & Ulmsten U. Urethral pressure increase on effort originates from within the urethra, and continence from musculo-vaginal closure. Neurourology and Urodynamics 1995; 14: 337-350.
5. Petros PE, Von Konsky B. Anchoring the midurethra restores bladder neck anatomy and continence. Lancet 1999; 354: 9193: 997-998.
6. Bush M, Wagenlehner F, Liedl B, Petros P. "A finite element model validates an external mechanism for opening the urethral tube prior to micturition in the female", World Journal of Urology 2015; 33: 1151-1157.

Correspondence to:
Peter P. Petros
University of NSW, Professorial Unit,
St Vincent's Hospital Sydney, Australia
Email: pp@kvinno.com

Original article

Vaginal sacropexy achieved by eight tension-free fixing arms mesh- preliminary results

CHRISTIAN GOEPEL[2], MIKLOS SZAKACS[1], NELLI FARKAS[3], BALINT FARKAS[1,*]

[1] *Department of Obstetrics and Gynaecology University of Pecs Clinical Centre, Pecs, Hungary*
[2] *Vivantes Humboldt Clinic, Pelvic Floor and Incontinence Centre, Berlin, Germany*
[3] *University of Pecs, Institute of Bioanalysis, Pecs, Hungary*
* *Member of the MTA-PTE Human Reproduction Scientific Research Group, Hungarian Academy of Sciences (MTA), Budapest, Hungary.*

Abstract: Objective: Surgical techniques utilizing six arm synthetic meshes for apical prolapse repair has been established, and debated in the last few years. Such vaginal hysteropexy (HPX) has several advantages over abdominal or laparoscopic HPX, although even through transsacrospinous fixation the apical reinforcement is not perfect. Our aim was to achieve optimal apical support by multivectoral apical suspension with the use of eight arm polypropylene vaginal mesh. *Methods:* In a prospective preliminary study design, 29 patients with pelvic organ prolapse quantification (POP-Q) system stage II-IV anterior and central compartment prolapse were included. They underwent the implantation of an eight arm polypropylene mesh, through a single anterior vaginal incision. The fixation has been achieved through dual transobturator and dual apical (sacrospinous and sacrotuberal) sutureless anchoring. *Results:* we experienced significant improvement in the prolapse after surgery in all patients. The mean Aa point was ascended from 1.1 cm to –2.9 cm, consequently the mean Ba point changed from 2.5 cm to –2.9 cm, and the mean C point climbed from 0.6 cm to –7.5 cm after the surgery. All patients were subjectively satisfied after the intervention. During the 12 week follow up period no mesh extrusion and no dyspareunia were noted. *Conclusions:* the vaginal implantation of the eight arm mesh comes with high patient satisfaction rates, and achieves vertical vector stabilization of the vaginal apex through sacrotuberal fixation, although further studies with more participants are required to assess the effectiveness of the approach.

Keywords: Pelvic organ prolapse; Sacropexy; Surgical treatment; Vaginal mesh; Pelvic reconstructive surgery.

INTRODUCTION

Pelvic organ prolapse (POP) is a relatively common disease, which is described as a loss of anatomical support of the pelvic organs leading to impairment of normal function and diminished quality of life[1]. The apical suspension of the pelvic organs is achieved by the attachment of the vaginal apex to the pelvic walls and the sacrum through the upper paracolpium, which has been reported to be the keystone of the female pelvic organ support as described in a landmark publication from Petros[2]. The loss of integrity in DeLancey Level I support is arise from several reasons ranging from obstetric related injuries, menopause, genetic factors, chronically increased intraabdominal pressure, pelvic floor trauma to spina bifida, and will eventually lead to apical vaginal prolapse[3].

The treatment of symptomatic apical defects can be conservative (pelvic floor exercise, vaginal pessary, electrostimulation and biofeedback therapy), or surgical, through pelvic reconstructive surgery. Currently sacral fixation of the uterus, or the vaginal vault after hysterectomy, via abdominal, laparoscopic and robotic approaches utilizing polypropylene xenograft , or abdominal fascia , or fascia lata autografts are considered to be the mainstream of interventions , despite vaginal sacrospinal fixation and vaginal mesh surgical techniques also provide good anatomical cure of prolapse[4,5]. However vaginal surgical approaches utilizing synthetic meshes for apical prolapse repair has been well established , they are also intensively debated in the last few years[6,7]. Although we are well aware of the recent findings about the mesh related complications reported in the literature , and the raising concerns about graft use in prolapse surgery , based on our results and experiences our study group is continuously devoted toward the use of vaginal grafts in POP surgery . Recently Guyomard and Delorme introduced a vaginal mesh with six transfixing pelvic straps providing anteroposterior and lateral suspension as a feasible and effective way of the anterior and central compartment reconstruction[8]. Despite the
respected results of the vaginal surgical technique, it not seemed to be optimal, because the apex is only suspended in a single vector direction toward the sacrospinous ligament. Therefore our aim was to mimic normal anatomy, and to establish an optimal surgical technique to enforce apical support by multivectoral (sacrospinous and sacrotuberal ligament anchored) suspension with the use of a partially absorbable polypropylene vaginal mesh with eight fixing arms.

MATERIALS AND METHODS

Study population and data collection

This study was approved by the Institutional Ethical Review Board. In a prospective cohort study, 29 women suffering from symptomatic POP-Q stage II-IV anterior and central compartment prolapse, who were intended to be treated with vaginal surgery, were included. Patients underwent diagnosis, therapy and follow up at the Vivantes Humboldt Clinic's Pelvic Floor and Incontinence Centre (Berlin, Germany) between January 1st 2017 and January 31st 2018. All patients provided their written informed consent to participate. All patients reported vagina bulging with correlated urinary symptoms (urgency, hesitency, frequency, prolonged urinary stream and feeling of incomplete emptying) or sexual dysfunction (dyspareunia, decreased lubrication and decreased sensation, arousal or orgasm). Patients with active infections of the pelvis or vagina, such as vaginitis, urinary tract infection or pelvic inflammatory disease, and patients who were noncompliant or unlikely to participate in the follow up (they did not attend their check ups) were excluded. Follow up examinations were carried out 3 month after surgery. Baseline demographic data, age, parity, medical history, menopausal state, sexual activity and BMI were recorded.

Evaluation of POP

All women were examined according to the International Urogynecological Association (IUGA) guidelines, and all terminology currently used refers to the recommendations of the International Continence Society (ICS). The level of altered pelvic anatomy was assessed by using the pelvic organ quantification system (POP-Q)[9]. All examinations were carried out in an outpatient setting, where patients were positioned in standard lithotomy position, physicians were utilizing anteri-

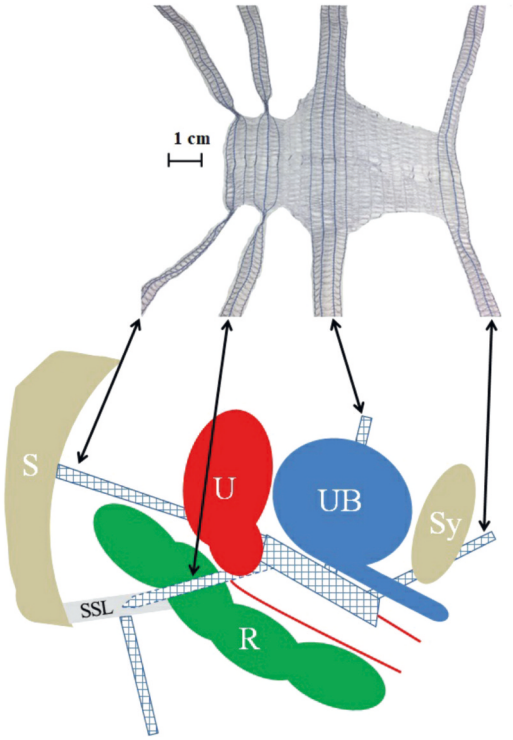


Figure 1. – Schematic picture of the mesh position and the anchoring points of the fixing arms. Abbreviations: S – sacral bone; Sy – symphysis bone; U – uterus; UB – urinary bladder; R – rectum; SSL – sacrospinous ligament.

or and posterior vaginal retractors, while patients performed Valsalva manoeuvres, in order to reveal the predominant compartment of prolapse. The POP-Q stage, the level of prolapse in each compartment, the genital hiatus, the vaginal length, and the vaginal introitus size (measured by fingerbreadths) were examined as described earlier by *Farkas* et al (2016). Involuntary loss of urin was assessed by stress test in lithothomy and upstand positions, and with the demonstration of urethral funnelling with ultrasound (US). Pelvic floor US also revealed the urethral length, level of prolapse and the pelvic anatomy. Post voiding residual volume was objectively assessed through catheterisation pre and postoperatively , moreover urin culture was carried out preoperatively.

Description of the surgical methods

The development of the method was based on the description of a six fixation straps nonanchored vaginal mesh by Goyumard and Delorme[8]. Patient underwent the antero-posterior placement of a partially absorbable polypropylene mesh with eight fixing straps, by an experienced surgeon (C. G.), who carried out all the operations in exactly the same manner. The position of the mesh is shown in Figure 1, and was as following: after infiltrating the anterior vaginal wall with *epinephrine* containing physiological saline (1 ampulla *epinephrine* in 500 ml in isotonic NaCl solution) a single incision midline colpotomy was carried out. The vaginal epithelium was then dissected bilaterally from the underlying pre-vesical tissue in a manner of intensive hydro dissection, fine scissor preparation (push- spread technique), and digital separation until reaching the obturator membranes , the sacrospinous , and sacrotuberal ligaments bilaterally . In the created space a 6 cm wide and 10 cm long cross-shaped piece of partially absorbable polypropylene mesh with a pore size of 2 x 4 mm (SERATOM® E+ PA MR, ref# SN218 MR,
Serag-Wiessner, Germany) was placed without fixing sutures under the pre-vesical tissue. The stabilizing tape arms were

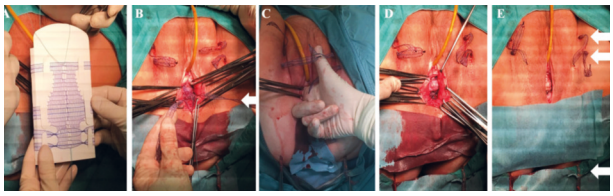


Figure 2. – Demonstration of the mesh introduction. A 6 x 10 cm long partially absorbable MR visible mesh with eight fixation straps was introduced (A) after midline colpotomy . The transobturator and the transgluteal trans-sacrospinous straps are inserted bilaterally as described by Guyomard and Delorme. The sutureless placement the final two tapes in direction sacrum are (B - arrow) carried out under manual guidance overlaying the sacrotuberal ligament (C). The final sub-vesical position of the partially absorbable tension-free mesh can be seen (D). As a final step the mesh is covered with vaginal ep- ithelium, arrows representing the visible transobturator and trans - sacrospinous fixing straps (E). No vaginal tamponade was used

placed in four positions: anterior (1-2.) and posterior (3-4.) transobturator, trans- sacrospinous (5-6.) and sacral-sacrotuberal ligament (7-8.) by out-in method, except for the last two straps, which were just placed under digital guidance over the anatomic structures retroperitoneal. As a final step the vaginal epithelium was closed with a nonlocking continuous everting mattress sutures (Figure 2).

Statistical analysis

Statistical analyses were performed by using IBM SPSS Statistic 20 (IBM Corporation, Armonk, NY, USA) at the University of Pecs, Institute of Bioanalysis. The sample size (n) was 29. Continuous measurements are summarized and presented as averages and standard deviations (SD), categorical data is presented as observed or as percentages. For the independence analysis between the categorical variables Mann-Whitney and Independent Student's t-test performed. To determine whether there is a significant difference between the expected frequencies and the observed frequencies in one or more categories Chi-square test was used. Statistical significance was set at $p < 0.05$.

Results Demographic data

The average age of the study population was 68 years ± 9 SD (min: 49, max: 77), and the mean parity was 2.0 ± 1.19 SD per patient (min: 0, max: 4). The study population had average weight of 72.41 kg and height of 1.63 m, resulting in a mean BMI of 27.14 ± 4.47 kg/m^2 (min: 21.77, max: 41.02). All patients were in menopause. A total of 13 patients (44) were sexually active, from which all of them

Table 1. Data related to the midurethral sling surgery.

Characteristics Prolapse POP-Q Stage	**Preoperative**	**Postoperative**	**p value**
Anterior compartment (cystocele) n (%)			
I	0	0	
II	3 (10)	0	
III	16 (56)	0	< 0.05
IV	10 (34)	0	< 0.05
Apical compartment (uterus or vaginal vault) n (%)			
I	7 (24)	0	< 0.05
II	7 (24)	0	< 0.05
III	5 (17)	0	
IV	3 (10)	0	
Posterior compartment (rectocele) n (%)			
I	14 (48)	14 (48)	
II	4 (14)	4 (14)	
III	1 (2)	1 (2)	
IV	1 (2)	1 (2)	

complained about sexual dysfunction. The majority of the participants (90%) had no prior gynecological surgeries, and all together 2 women (7%) underwent vaginal hysterectomy, with simultaneous anterior and posterior colporraphy due prolapse indication in their history, and one patient had a laparoscopic sacrohysteropexy (3%).

Evolution of POP-Q scores after tape implantation surgeries

We experienced major improvement in the anterior and in the central prolapse after surgery in all patients, but no change in the posterior compartment (Figure 3). We managed to observe significant shift in the Aa points (from –0.93 cm ±0.90 SD to –2.86 cm ±0.59 SD) and in the Ap points (from –1.71 cm ±1.38 SD to –2.54 cm ±0.74 SD). Moreover a major significant development was also observed in the C point (from –1.86 cm ±3.54 SD to –7.07 cm ±1.05 SD) and in the D point (from –3.17 cm ±3.72 SD to –7.68 cm ±2.70 SD) positions. Interestingly significant improvement was observed in the posterior compartment (Ba point from 2.36 cm ±0.95 SD to –2.93 cm ±0.26 SD; Bp point from –1.39 cm ±1.31 SD to –2.32 cm V 0.72 SD). In the further POP-Q variables (GH, PB and TVL) no significant differences were calculated before and after the surgery (Table 1).

Subjective and objective outcomes

All patients were subjectively satisfied after the intervention. The pre and postoperative functional urinary symptoms are listed in Table 2.

Those patients (n=11) who had positive stress cough test prior surgery were found to be stress incontinent after surgery. During the follow up period *de novo* SUI occurred in two patients (6%). We observed a significant fall in the amount of the rest urin after surgery , obtained by catheterisation , and in parallel the disappearance of urge symptoms (Table 2). Perioperatively no visceral injury and no haemorrhage was observed (preoperative mean Hgb lev - el 132 g/L ± 14 .4 SD , Htc 38 .93 L/L ± 10 .58 SD ; postoper - ative mean Hgb level 118 .5 g/L ± 14.8 SD , Htc 34 .6 L/L ± 11 .42 SD). The mean close - to - cut operation time was 60 .52 min ± 27 .56 SD . The mean hospital stay was 3 days / 2 nights. During the 3 month follow up period no mesh extru - sion and no prolapse recurrence were noted.

DISCUSSION

To our knowledge, this is the first study which demonstrates a vaginal surgical technique, utilizing a partially absorbable polypropylene vaginal mesh , in order to provide multivectoral apical suspension and successfully treat central and anterior zone prolapse in order to mimic normal anatomy . In the current study , 29 women with symptomatic stage II-IV apical prolapse and traction or pulsion cystoce - les underwent single incision vaginal mesh implantation with eight fixing straps , and after 3 month all of them were referred themselves to be symptomless.

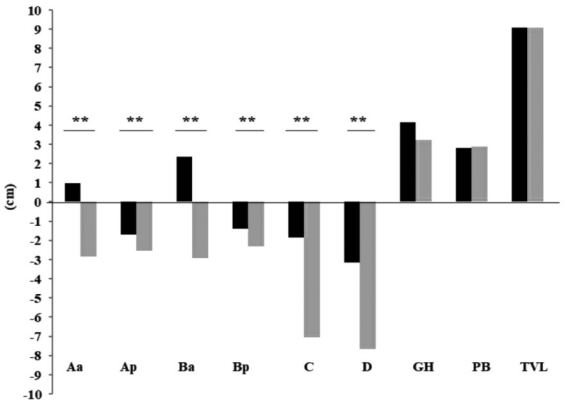


Figure 3. – Evolution of the POP-Q variables before (black diagrams) and after (grey diagrams) the surgery. The x axis represents the distances of the landmark points from the hymen in centimeters. Asterisks represent significant statistical difference between the values calculated by Mann-Whitney test (** $p < 0.01$).

TABLE 2. Functional symptoms of the study participants prior and after surgery.

Urinary symptoms	before surgery (n)	after surgery (n)	p value
No SUI (%)	62.1 (18)	58.6 (17)	
SUI	37.9 (11)	44.8 (13)†	
No urgency	55.2 (16)	0	<0.01
Urgency with incontinence	44.8 (13)	0	<0.01
Non-voiding dysfunction	0.06 (2)	0	
Voiding dysfunction with no residual	0	0	
Voiding dysfunction with residual	44.82 (13)	0	<0.01
Residual urin (mean ± SD ml)	64.44±60.97	15.41±19.33	< 0.05

The development of the currently used prosthesis incorporated the transobturator lateral suspension technique (to repair the pubecervical fascia deficiency) described by Eglin et al.[9], based on the theories of Petros[2], and the transgluteal sacrospinous ligament fixation technique[10], furthermore aimed to achieve sacral fixation. Since apical and paravaginal defects are manifestations of the same phenomenon, in this regard, the simultaneous correction of both defects is rational[11]. Moreover the proper apical support can only be achieved if the surgical repair is aimed to mock the normal anatomic force vectors, originate from the uterosacral ligament (USL) and cardinal ligament (CL), which ensures stability and flexibility of the uterus as well as provide apical support.

Concerns about the safety and morbidity of mesh and graft use in POP surgery ultimately questioned the justification of synthetic mesh materials in vaginal prolapse surgeries. Despite vaginal mesh placement provides better cure of prolapse then other techniques[6,12] the international debate is based on the mounting evidence reported in the literature about mesh related complications[13], and the US Food and Drug Administration (FDA) safety warning regarding transvaginal mesh complications[14]. The increased number of litigations led to a ban on the use of vaginal mesh in several countries (Scotland, UK), however the findings are not concordant. The PROSPECT study concluded that patients undergo primary transvaginal mesh placement has no symptomatic or anatomic benefit in short term[15], although other study groups found contradictory results and reported that vaginal mesh is feasible and effective way of treatment in medium term[16-18]. Despite the dilemma of the use of transvaginal mesh in POP surgeries, based on our experience our study group is not intending to discard the vaginal operative route from the surgical inventory.

A common reason against mesh is the high number of *de novo* SUI after mesh repair of the middle zone and apical defects, with an incidence ranging between 8.6-23%[19-21]. We found a persistency of stress symptoms in all preoperatively SUI patients and we experienced *de novo* stress appearance in 6 % (n=2) in the study group. Another contradictory view against synthetic allograft implantation is the high risk of mesh exposure[19]. Although in recent studies this complication is reported to occur between 7.7-10.1%[20-21], in our current study we found no tape exposure during

the relatively short follow up period, however long term follow up examination is necessary to evaluate the clinical outcome of the intervention from that perspective.

On the other hand there are several undoubted advantages of synthetic allograft use in the operative management of anterior and central compartment defects compared to other approaches. The above described method results high patient satisfaction, short hospitalization, and excellent stabilization of the vaginal apex and the anterior wall. The method is considered to be real minimal invasive techniques, with a preferred cosmetic result. While a recent study failed to report significant differences in cost between laparoscopic sacrohysteropexy and vaginal mesh correction for the treatment of POP (mean 5985.7 €, CI 95 %: 5613.14 versus mean 6534.31€, CI 95%: 6290.36), we found an average cost of 3840€ / mean 3 days/2 nights hospital stay per eight arm mesh implantation, therefore we concluded that single incision vaginal sacropexy is a cost effective surgical approach to treat anterior and central defects.

Self-critical considerations are highlighting the limitation of our preliminary study, which is the low number of participants, the short duration of follow up, the lack of comparative studies, and the long learning curve of the intervention. Therefore further long term studies with more participants, and in addition postoperative magnetic resolution scan verifications of the mesh position are required to assess the effectiveness of the approach. Disadvantage of the method is, that it has no impact on coexisting stress urinary incontinence (SUI), therefore a second step operation is required to overcome all the urinary symptoms.

The strongpoint of our study is the demonstration of new and innovative operative technique in order to overcome anterior and central compartment defects, through a multivectoral apical suspension, which allows vertical apex stabilization. In conclusion the vaginal implantation of the eight arm mesh comes with high patient satisfaction rates, results painless elevation, and achieves vertical vector stabilization of the vaginal apex through sacral fixation therefore it is a reasonable alternative of laparoscopic sacrohysteropexy.

DISCLOSURE STATEMENTS

The authors declare no personal o financial conflict of interest to disclose.

REFERENCES

1. Mouritsen L. Classification and evaluation of prolapse. Best Pract Res Clin Obstet Gynaecol. 2005; 19: 895-911.
2. Petros P. The integral system. Cent European J Urol. 2011; 64 (3): 110-9.
3. DeLancey JO. The anatomy of the pelvic floor. Curr Opin Obstet Gynecol. 1994; 4: 313-6.
4. Maher C. Surgery for women with apical vaginal prolapse. Cochrane Database Syst Rev 2016; 1: 10.
5. Coolen AWM, Bui BN, Dietz V, Wang R, van Montfoort APA, Mol BWJ, Roovers JWR, Bongers MY. The treatment of post-hysterectomy vaginal vault prolapse: a systematic review and meta-analysis. Int Urogynecol J. 2017; 12: 1767-1783.
6. Maher C, Feiner B, Baessler K, Schmid C. Surgical management of pelvic organ prolapse in women. Cochrane Database Syst Rev. 2013 Apr 30; (4): CD004014.
7. Glazener CM, Breeman S, Elders A, Hemming C, Cooper KG, Freeman RM et al. Mesh, graft, or standard repair for women having primary transvaginal anterior or posterior compartment prolapse surgery: two parallel-group, multicentre, randomised, controlled trials (PROSPECT). Lancet 2017; 389: 381-392.
8. Guyomard A, Delorme E. Transvaginal treatment of anterior or central urogenital prolapse using six tension-free straps and light mesh. Int J Gynaecol Obstet 2016; 133: 365-9.
9. Eglin G, Ska JM, Serres X. Transobturator subvesical mesh. Tolerance and short-term results of a 103 case continuous series. Gynecol Obstet Fertil 2003; 31: 14-9.
10. Bump RC, Mattiasson A, Bo K, Brubaker LP, DeLancey JOL, Klarsov P et al. The standardization of terminology of female pelvic organ prolapsed and pelvic floor dysfunction. Am J Obstet Gynecol 1996; 175: 291-20.
11. Ulmsten U, Petros P. Intravaginal slingplasty (IVS): an ambulatory surgical procedure for treatment of female urinary incontinence. Scand J Urol Nephrol 1995; 29: 75-82.
12. Larson KA, Luo J, Guire KE, Chen L, Ashton-Miller JA, DeLancey JO. 3D analysis of cystoceles using magnetic resonance imaging assessing midline, paravaginal, and apical defects. Int Urogynecol J 2012; 23: 285-93.
13. Jia X, Glazener C, Mowatt G, MacLennan G, Fraser C, Burr J. Systematic review of the efficacy and safety of using mesh or grafts in surgery for anterior and / or posterior vaginal wall prolapse 2008. http://www.nice.org.uk/guidance/index.jsp?action=byID&o=11363 (accessed June 30, 2008).
14. Maher C. Anterior vaginal compartment surgery. Int Urogynecol J Pelvic Floor Dysfunct 2013; 24 (11): 1791-1802.
15. Food and Drug Administration. Safety communications - UPDATE on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse: FDA safety communication. 2011. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm (accessed 23 May 2016).
16. Glazener CM, Breeman S, Elders A, Hemming C, Cooper KG, Freeman RM, Smith AR, Reid F, Hagen S, Montgomery I, Kilonzo M, Boyers D, McDonald A, McPherson G, MacLennan G, Norrie J. Mesh, graft, or standard repair for women having primary transvaginal anterior or posterior compartment prolapse surgery: two parallel-group, multicentre, randomised, controlled trials (PROSPECT). Lancet 2017; 389: 381-392.
17. Murphy M, Holzberg A, van Raalte H, Kohli N, Goldman HB, Lucente V. Time to rethink: an evidence-based response from pelvic surgeons to the FDA Safety Communication: "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse". Int Urogynecol J 2012; 23: 5-9.
18. Lo TS, Al-Kharabsheh AM, Tan YL, Pue LB, Hsieh WC, Uy-Patrimonio MC. Single incision anterior apical mesh and sacrospinous ligament fixation in pelvic prolapse surgery at 36 months follow-up. Taiwan J Obstet Gynecol 2017; 56: 793-800.
19. Notten KJ, Essers BA, Weemhoff M, Rutten AG, Donners JJ, van Gestel I, Kruitwagen RF, Roovers JP, Dirksen CD. Do patients prefer mesh or anterior colporrhaphy for primary correction of anterior vaginal wall prolapse: a labelled discrete choice experiment. BJOG 2015; 122: 873-80.
20. Kontogiannis S, Goulimi E, Giannitsas K. Reasons for and Against Use of Non-absorbable, Synthetic Mesh During Pelvic Organ Prolapse Repair, According to the Prolapsed Compartment. Adv Ther 2017; 2139-2149.
21. Maher C, Feiner B, Baessler K, Christmann-Schmid C, Haya N, Marjoribanks J. Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse. Cochrane Database Syst Rev 2016; 2: CD012079.
22. Misraï V, Rouprêt M, Cour F, Chartier-Kastler E, Richard F. De novo urinary stress incontinence after laparoscopic sacral colpopexy. BJU Int 2008; 101: 594-7.

Correspondence to:

Balint Farkas, MD, Med. Habil. Department of Obstetrics and Gynaecology University of Pecs Clinical Centre, 17. Edesanyak Str., Pecs, Hungary, H-7624. Phone: +36-72-536-360/ ext.0827, Fax: 0036-72-536-000 E-mail: dr.balint.farkas@gmail.com

Original article

Comparison to sacrospinous fixation versus infracoccygeal sacropexy in vaginal vault prolapse at 2-year follow-up

EDGARDO CASTILLO-PINO[1], CÉSAR CANESSA[2], WASHINGTON LAURÍA[3]

[1] *Urogynecology and Pelvic Floor Unit. Department of Obstetrics and Gynecology. University of the Republic. School of Medicine. Clinical Hospital Montevideo. Uruguay*
[2] *Department of Surgery. University of the Republic. School of Medicine. Clinical Hospital Montevideo. Uruguay.*
[3] *Department of Obstetrics and Gynecology. University of the Republic. School of Medicine. Clinical Hospital Montevideo. Uruguay.*

Abstract: Objective: The aim of this study was to compare the efficacy, outcomes and complications of sacrospinous ligament fixation (SSLF) with native tissue repair and infracoccygeal sacropexy with transvaginal mesh (TVM) in the management of vaginal vault prolapse. *Material and Methods:* We recruited 63 women with stage 3, or greater prolapse, according to the pelvic organ prolapse quantification (POP-Q) system, requiring surgical correction. They were randomized in two groups: SSLF (n = 31) and TVM (n = 32). The primary outcome was the absence of POP-Q stage ≥3 prolapse at 24 months, and secondary outcomes were perioperative events, complications and reoperations. The participants were followed for the next 2 years, with scheduled evaluation. *Results:* Clinical and demographic data did not differ significantly between the two treatment groups. Success in the TVM group was 84.3% (27/32) compared to 61% (19/31) in the SSLF group. Although there was not statistically significant differences between the groups, the prolapse recurrence trend was lower in the TVM group (RR 0.73). Recurrent prolapse occurred most frequently in the vaginal anterior wall (14.3%). The mesh exposure rate was 9.3%. Neither serious adverse events nor deaths occurred in either group. *Conclusion:* Our results showed that vaginal repair with mesh surgery was more successful in terms of reducing recurrent prolapse than the traditional sacrospinous colpopexy, 24 months after surgery.

Keywords: Native repair tissue; Pelvic organ prolapse; Sacrospinous fixation ligament; Surgical mesh; Vaginal vault suspension.

INTRODUCTION

Pelvic organ prolapse may occur in up to 50% of parous women[1]. The lifetime risk of undergoing stress urinary incontinence (SUI) or pelvic organ prolapse (POP) surgery by the age of 80 is 20%[2].

An increased prevalence of pelvic organ prolapse is estimated in the coming years. The result is more corrective surgeries and higher costs related to women's health care[3]. The precise incidence of vaginal vault prolapse after hysterectomy is difficult to define and was estimated to range from 0.2-43%[4,5].

The International Continence Society (ICS) defines apical vaginal prolapse as a descent of the vaginal cuff scar below a point that is 2cm less than the total vaginal length above the plane of the hymen[6].

Vaginal vault prolapse treatment is surgical and supports several approaches (abdominal, vaginal or laparoscopic) and different repair strategies, with synthetic mesh or with the patient's own tissues.

Sacrocolpopexy has proven an effective surgical treatment for apical vaginal prolapse, with 90% long-term success rates[7,8,9].

The safety and effectiveness of synthetic mid-urethral slings influenced the introduction of transvaginal mesh for pelvic organ prolapse. Transvaginal mesh placement kits using needles for bilateral fixation to ligaments sacrospinous were introduced in 2004 to create a hammock supporting the apex and anterior or posterior vaginal walls (depending on placement) and avoid abdominal surgery[10].

In July 2011, the U.S. Food and Drug Administration[11] issued a security statement noting that "serious complications associated with surgical mesh for vaginal repair of pelvic organ prolapse are not rare". They also add "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair"[12]. This has prompted responses and publications by many experts that transvaginal mesh can have some value because of the risk of recurrent prolapse after repairswith each patient's own local tissue[12,13,14].

Therefore, our study sought to compare, at a 2-year follow-up, the efficacy, outcomes and complications of two techniques for the treatment of vaginal vault prolapse: sacrospinous ligament fixation (SSLF) colpopexy with native tissue repair and infracoccygeal sacropexy with transvaginal mesh (TVM).

MATERIALS AND METHODS

This trial included women clinically diagnosed with vaginal vault prolapse stage 3 or greater -according to pelvic organ prolapse quantification (POP-Q)- who were candidates for reconstructive surgery for vaginal apical prolapse. The study was approved by the ethics committee and conducted at the Medical School of the University of the Republic, Montevideo, Uruguay, from October 2012 to October 2015.

The inclusion criteria were women with asymptomatic or symptomatic POP-Q stage ≥3 vault prolapse who had given their informed consent. Exclusion criteria included recurrent prolapse, vaginal or urinary infection in progress with diabetes, coagulopathies, anticoagulant therapy or vaginal length less than 6cm or more than 12cm, and patients who do not give their informed consent.

The allocation process was conducted by computer using a sample randomization the day before surgery. The participants were assigned to an SSLF or a TVM group and informed of their allocation before the procedure. Both procedures were performed by two surgeons from the surgical team with a previous learning curve.

All the patients were examined with the POP-Q system and underwent urodynamics with prolapse reduction. Participants with a positive stress test were considered as having occult stress urinary incontinence (OSUI).

We prefer to use a preoperative vaginal oestrogen cream for 4 weeks. Prophylactic antibiotics were given perioperatively (3g of intravenous ampicillin/sulbactam).

Anaesthesia was epidural, except in patients with contraindications or technique failure, in which case general anaesthesia was administered. Operating time was from colpotomy to cessation of colporrhaphy.

Unilateral sacrospinous colpopexy (SSLF) is suitable for restoration of a functional vagina[15,16]. A longitudinal inci-

sion is made in the posterior vaginal vault. Either the right or left rectal pillar, which separates the rectovaginal space from the pararectal space, is penetrated by blunt or sharp dissection. The opening in the rectal pillar is widened, exposing the superior surface of the pelvic diaphragm, including the coccygeus muscle, which contains the sacrospinous ligament.

A Breisky-Navratil retractor can be placed medially to mobilize and protect the rectum and expose the deeply located sacrospinous ligament. Any anchoring suture to the ligament should be performed 1-2cm medial to the ischial spine toavoid trauma to pudendal nerve and vessels. Weusually perform vaginal apical suspension unilaterally to the right sacrospinous ligament. Using a long needle holder with non-absorbable monofilaments sutures (Prolene ®) two threads are passed through the coccygeus muscle and the sacrospinous ligament at the predetermined point. The two sutures are placed in the vaginal wall avoiding catching the mucosa, and more than 1cm of the suture line.

After enterocele and rectocele repair and vaginal wall closure, the non-absorbable sutures fix the vaginal wall to the sacrospinous ligament. The previously placed sutures in the sacrospinous ligament are tied individually with the vaginal apex directed under finger guidance to the uppermost position.

Infracoccygeal sacropexy with mesh(TVM) was initially described as a minimally invasive surgical option to restore vaginal vault support[17,18]. A longitudinal incision is made in the posterior wall of the vagina. Make the pararectal dissection towards the ischiatic spine and palpate it with the index finger. Then, make a punctiform cutaneous incision in the gluteus, 3cm lateral and 3cm down from the anus, on both sides. Introduce the trocar through two small incisions into the ischiorectal fossa and through the levator ani muscles towards the 1-cm medial ischial spine.

Introduce a mesh tape onto the trocar tip and pull it back through the trocar's path. Perform a similar passage on the opposite side. Suture the intravaginal polypropylene mesh to the apex of the vagina with non-absorbable and fixed without tension. Pull the arms until the vagina is in anatomic position. Cut the mesh excess at perineal body level and cut the excess from the arms. The vaginal epithelium is closed. We used kit-Nazca R ® synthetic mesh (Promedon, Córdoba, Argentina). The kit includes one synthetic mesh (permanent implant involving polypropylene monofilament central mesh between two arms of the same material), and two posterior needles designed for use with the mesh implantation.

Colpopexy techniques were associated with anterior colporrhaphy in 33% and midurethral sling in 11% of the patients. All patients underwent perineorrhaphy. All participants had the indwelling urethral catheter removed 48 hours after surgery and the vagina is packed with moist gauze for 24 hours.

The participants were monitored for the next 2 years, with scheduled evaluations six weeks, then 3, 6, 12 and 24 months after surgery. At each evaluation, the women were interviewed regarding spontaneous micturition and lower urinary tract symptoms, defecation and bowel dysfunction pelvic pain, buttock pain and postoperative dyspareunia.

The outcomes measured were objective success rates at POP-Q point C defined as - 1cm and 0 postoperatively, frequency of complications and recurrent prolapse, and reoperations. Recurrent prolapse was defined as any POP-Q point C beyond the hymen 12 months after surgery, or any POP reoperation within 12 months after surgery.

We initially estimated 58 patients were required for an 80% chance -a significant 5% level- of detecting an increase in the primary outcome measure from 60% in the SSLF group[5,21] to 90% in the TVM group.

The statistical analysis was performed with SPSS 18.0 version (SPSS Chicago, IL USA) using Fisher's exact test, X2 test, relative risks (RRs) with 95% confidence intervals (CIs) and test for independent samples $P<0.05$ considering what was statistically significant.

RESULTS

Seven of 72 patients screened did not meet the inclusion criteria, 2 women refused to take part in the study and 63 patients consented and were randomized. Thirty-one underwent SSLF and 32 TVM and were followed up for 24 months. There was no loss to follow-up.

Both groups were similar in demographics and preoperative variables, as seen in Table 1.

The mean age was 58 years (range 47-72) in the SSLF group and 56 years (range 45-70) in the TVM. 74% and 68.75% of the SSLF and TVM groups respectively were in their menopause. Vaginal parity > 2 was 80% and 75% of the SSLF and TVM groups respectively.

All the patients had had a previous hysterectomy, 35% through vaginal and 65% through abdominal access. Posterior compartment defects were more frequent than anterior compartment (cystocele 33%, rectocele 46% and enterocele 54%).

There was no difference in age, parity, body mass index (BMI), menopause status, previous hysterectomy surgery, apical defects and follow-ups, or in preoperative scores for any urodynamic parameters between the groups.

Epidural anaesthesia was used in 93. 5% of the SSLF procedure and 90.6% of the TVM procedure, and general anaesthesia was used in 6.5% of SSLF cases and 9.4% of TVM cases.

Mean operating time was significantly shorter in the TVM group than in the SSLF group (23 minutes versus 45 minutes; $p< 0.01$). Hospital discharge occurred within 72 hours.

Perioperative complications for procedures are listed in Table 2.

Perioperative complications in the SSLF group included one bladder injury repaired intraoperatively without sequelae. Two patients in the SSLF group and one patient in the TVM group were transfused perioperatively, and 6 women

TABLE 1. Participant characteristics.

Variable	SSLF group (n= 31)	TVM group (n=32)	P value
Age (years)	58 (SD 7.54)	56 (SD 7.67)	0.571
Status menopause	23 (74)	22 (68,75)	0.836
BMI (kg/m^2)	27,79 (SD 2.67)	26,92 (SD 2.90)	0.219
Vaginal parity > 2	25/31 (80)	24/32 (75)	0.590
Prior hysterectomy vaginal	10/31(32.3)	12/32 (37.5)	0.663
Prior hysterectomy abdominal	21/31 (67.7)	20/32 (62.5)	0.663
Cystocele	11/31(35.4)	10/32 (31.3)	0.530
Rectocele	16/31 (51.6)	13/32 (40.6)	0.707
Enterocele	18/31 (58)	16/32 (50)	0.348
Occult SUI	4/31 (13)	3/32 (9,4)	0.656

Abbreviations: SUI, stress urinary incontinence; POP, pelvic organ prolapse; BMI, body mass index; SSLF, sacrospinous ligament fixation; TVM, transvaginal mesh.

TABLE 2. Complications at 24 months following surgery.

Complication	SSLF group (n= 31)	TVM group (n=32)	P value*
Significant Hemorrhage	2 (6.45)	1 (3.12)	0.613
Urinary infection	3 (9.67)	3 (9.37)	1.000
Bladder injury	1 (3.22)	0	0.492
OAB "de novo"	3 (9,7)	3 (9,4)	1.000
SUI "de novo"	1 (3,2)	1 (3,1)	1.000
Postoperative ileus	2 (6.45)	1 (3.12)	0.613
Pelvic pain	2 (6.45)	1 (3.12)	0.613
Buttock pain	1 (3.22)	3 (9.37)	0.613
Dyspareunia "de novo"	2 (6.45)	4 (12.5)	0.672
Stenosis vaginal	2 (6.45)	1 (3.12)	0.613
Mesh exposure	0	3 (9.37)	0.238

Abbreviations: SSLF, sacrospinous ligament fixation; TVM, transvaginal mesh; OAB overactive bladder, SUI, stress urinary incontinence. * Test de Fisher.

with urinary tract infection were recorded, 3 in each group (Table 2). Subsequently demonstrated by a positive uroculture study. Escherichia Coli was the most commonly isolated germ (4 cases). All patients improved with antibiotics according to the sensitivity of the antibiogram.

Eight out of 63 patients presented urinary incontinence. Six of them were cases of "de novo" overactive bladder and 2 "de novo" stress urinary incontinence (SUI), understood as previously continent patients developing symptoms of stress incontinence after reparative prolapse surgery.

Only one patient in the SSLF group (1/31) presented buttock pain (3.2%) and three patients (3/32) in the TVM group (9.37%). Buttock pain was self-limited and never lasted over 4 weeks after intervention. All patients improved with oral analgesics.

Forty-six of the 63 cases were sexually active. "De novo" dyspareunia and hispareunia were reported in 2 of the SSLF group and 4 of the TVM group. Of 6 cases of dyspareunia, 3 required surgical correction. We observed vaginal stenosis in 2 out of 31 women in the SSLF group and 1 out of 32 in the TVM group. Two of the three vaginal stenosis cases required surgical correction.

The presence of vaginal stenosis and dyspareunia in our patients is attributed to excessive anterior or posterior vaginal wall tissue cutting. There were no vascular, bowel or ureteral injuries, fistulas or lesions to the sciatic nerve. There were three cases of mesh exposure in the TVM group (3/32).

All patients received local oestrogen administration and reoperation for treatment.

Follow-ups averaging two years demonstrated there was a significant reduction in the extent of prolapse according to the POP-Q including point C in both groups compared with preoperative assessment.

The objective success rate (with POP-Q stage 0 or 1 prolapse at all vaginal sites) was 27 of 32 in the TVM group, compared with 19 of 31 in the SSLF group. Prolapse recurrence was reduced in the TVM group (RR: 0.73).

In both groups, recurrent prolapse occurred most commonly in the anterior (10/63 or 15.8%), posterior (7/63 or 11.1%) and apical (4/63 or 6.35%) compartments. Of nine women with recurrences in the posterior compartment (posterior wall and apex), two had undergone open sacral colpopexy and another seven had undergone vaginal repair with mesh.

DISCUSSION

Our results showed that vaginal repair with mesh surgery was more successful in terms of reducing recurrent prolapse than traditional sacrospinous colpopexy 24 months after surgery.

A percentage of recurrence was found in our study with a 24-month follow-up. Distribution by segments: anterior 15.8%, posterior 11.1% and apical 6.35%. In apex vaginal prolapse surgery, reoccurrence is most frequent in the anterior wall. Additionally, 13 of the 31 patients treated by unilateral sacrospinous colpopexy presented recurrent prolapse (42%). One patient was recorded with recurrence in three compartments and another with recurrence in the anterior and posterior compartments. The transvaginal mesh group showed 5 of 32 patients with recurrent prolapse (15.6%).

Complications arising from mesh insertion are well described[1,5]. In our study, the prevalence of vaginal mesh exposure (9.37%) is similar to rates reported for vaginal surgery[1,5]. These cases were resolved by releasing the mesh and vaginal closure. Mesh exposure through vaginal epithelium has been one of the most serious complications reported, with a global frequency of 10%.

The 2013 Cochrane review[1] observed that abdominal sacrocolpopexy was superior to a variety of vaginal procedures with a decreased rate of recurrent vault prolapse. The vaginal approach facilitates pelvic floor relaxation repair, especially colporrhaphy and perineorrhaphy. Nevertheless, sacrospinous colpopexy was shorter to perform and less expensive, with the advantage of early return to daily activities. Early cohort studies of sacrospinous colpopexy show the operations are effective for vaginal apex support[1]. In 243 patients who underwent sacrospinous colpopexy and vaginal repairs, with a 73-month follow-up, showed prolapse recurrence of anterior, posterior, and apical segments was 37.4%, 13.6% and 8.2% respectively[19].

Another matched case-control study comparing iliococcygeus suspension and sacrospinous colpopexy for vaginal vault prolapse reported results equally effective with similar complication rates[20]. The same author found, at 2-year follow-up, in a randomized trial comparing abdominal sacrocolpopexy and vaginal sacrospinous fixation that there was no difference in objective cure rates between the groups[7].

There have been many studies on SSLF, which have revealed a recurrence rate of 2.4% to 19%[5,21]. The advantage of bilateral SSFL is the symmetry of the procedure, which restores anatomy closer to normality with low morbidity and good anatomic and functional subjective results[22].

Withagen et al[23] compared mesh and conventional repair in patients with recurrent prolapse. The failure rate at 1-year follow-up was 45% in the conventional repair group and 10% in the mesh group.

TABLE 3. Participant characteristics.

Outcomes	SSLF group (n= 31)	TVM group (n=32)	RR (95% IC)
Objective success (POP-Q stage ≤l 1)	19 (61)	27 (84,3)	0.73 (0.53-1.00)
Anatomic recurrence of anterior vaginal wall	7 (22.58)	3 (9.37)	2.41 (0.68-8.48)
Anatomic recurrence of posterior vaginal wall	6 (19.35)	1 (3.12)	6.16 (0.79-48.53)
Anatomic recurrence of apical vaginal (Point C ≥ - 1)	3 (9.67)	1 (3.12)	3.10 (0.34-28.19)

Abbreviations: SSLF, sacrospinous ligament fixation; TVM, transvaginal mesh; POP-Q, pelvic organ prolapse quantification.

In a meta-analysis of clinical trials and observational studies evaluating apical prolapse repair, the authors reviewed 3425 patients from 24 studies employing vaginal mesh kits and reported a lower operation rate for recurrent POP (1,3% at 17 months)[24]. The 2016 Cochrane review found limited evidence in the use of transvaginal mesh compared to native repair tissue for apical vaginal prolapse[25].

The strength of our study is that the surgical interventions were performed by only two skilled surgeons. Although our study was implemented as a randomized trial, it may have some limitations. One limitation is that the sample size was not enough to detect the difference that we initially expected. Nevertheless, our data may be considered in future systematic reviews.

In conclusion, our study showed improvements in objective outcomes at 2 years, following transvaginal surgery with mesh augmentation in the apical vault compared to sacrospinous fixation with native tissue repair. The transvaginal mesh had an objective success rate with lower complications and reoperation rate. However, the risk of mesh exposure remains an issue for consideration and evaluation in future. More randomized controlled studies are needed to assess the effectiveness and safety of surgery for vaginal repair with mesh and long-term outcomes.

DISCLOSURE STATEMENTS

The authors have no conflict of interest, informed patient consent was obtained, and the study was approved by the local ethical committee. The authors declared that this study has received no financial support.

REFERENCES

1. Maher C, Feiner B, Baessler K, Schmid C. Surgical management of pelvic organ prolapse in women. Cochrane Database Syst Rev (4) 2013; doi: 10.1002/14651858.CD004014.pub5
2. Wu JM, Matteus CA, Conover MM et al. Lifetime risk of stress urinary incontinence or pelvic organ prolapse surgery. Obstet Gynecol 2014; 123: 1201-1206.
3. Wu JM, Hundley AF, Fulton RG, Myers ER. Forecasting the prevalence of pelvic floor disorders in US women: 2010 to 2050. Obstet Gynecol 2009; 114: 1278-1283.
4. Dallenbach P, Kaelin-Gambirasio I, Jacob S et al. Incidence rate and risk factors for vaginal vault prolapse repair after hysterectomy. Int Urogynecol J 2008; 19: 1623-1629.
5. Barber MD, Maher CF. Apical prolapse. Int Urogynecol J 2013; 24: 1815-1833.
6. Abrams P, Cardozo L. Falt M et al. The standardization of terminology of lower urinary tract function: report from the standardization Sub Committee of the International Continence Society. Neurourol Urodyn 2002; 21 (2): 167-178.
7. Maher C, Baessler K, Glazener CM et al. Surgical management of pelvic organ prolapse in women. Cochrane Database Systematic Review (3) 2007; Cd 004014. Cochrane Collaboration and the National Institute for Clinical Excellence (NICE UK)
8. Tate SB, Blackwell L, Lorenz DJ et al. Randomized trial of fascia lata and polypropylene mesh for abdominal sacrocolpopexy: 5-year follow-up. Int Urogynecol J 2011; 22: 137-143.
9. Betschart C, Cervigni M, Contreras Ortiz O et al. Management of apical compartment prolapse (uterine and vault prolapse): A FIGO Working Group report. Neurourol Urodyn. 2015; Oct 20. doi: 10.1002/nau.22916. [Epub ahead of print]
10. Walters MD, Ridgeway BM. Surgical treatment of vaginal apex prolapse. Obstet Gynecol 2013; 121: 354-374.
11. FDA. Update on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse: FDA Safety Communication. July 13, 2011. Retrieved from: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm
12. Murphy M, Holzberg A, van Raalte H et al. Time to rethink: an evidence-based response from pelvic surgeons to the FDA safety communication: "UPDATE on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse". Int Urogynecol J 2012; 23: 5-9.
13. Dwyer PL, Riss P. The mesh debate. Int Urogynecol J 2012; 23: 1-2.
14. Brubaker L, Shull B. A perfect storm. Int Urogynecol J 2012; 23: 3-4.
15. Richter K [The surgical treatment of the prolapsed vaginal fundus after uterine extirpation. A contribution on Amreich's the sacrotuberal vaginal fixation] Die operative Behandlung des prolabiert ensche in den grundesnach Uterus extirpation Beitrag zur Vaginae fixatio Sacrotuberalis nach Amreich Geburtshilfe Frauenheilkd 1967; 27: 941-954.
16. Richter K. Massive eversion of the vagina: pathogenesis, diagnosis and therapy of the "true" prolapse of the vaginal stump. Clin Obst Gynecol 1982; 25: 897-912.
17. Petros PE. New ambulatory surgical methods using an anatomical classification of urinary dysfunction improve stress, urge, and abnormal emptying. Int Urogynecol J 1997; 8: 270-277.
18. Petros PE. Vaginal prolapse II. Restoration of dynamic vaginal supports by infracoccigeal sacropexy. An axial day-case vaginal procedure. Int Urogynecol J 2001; 12: 296-303.
19. Paraiso MF, Ballard LA, Walters MD et al. Pelvic support defects and visceral and sexual function in women treated with sacrospinous ligament suspension and pelvic reconstruction. Obstet Gynecol 1996; 175: 1423-1430.
20. Maher CF, Murray CJ, Carey MP et al. Iliococcygeus or sacrospinous fixation for vaginal vault prolapse. Obstet Gynecol 2001; 98: 40-44.
21. Nyyssonen V, Talvensaari-Mattila A, Santala M. Posterior intravaginal slingplasty versus unilateral sacrospinous ligament fixation in treatment of vaginal vault prolapse. ISRN Obstet Gynecol, 2013; ID 958670, 5 pages.
22. Mothes AR, Wanzke L, Radosa MP, Runnebaum IB. Bilateral minimal tension sacrospinous fixation in pelvic organ prolapse: an observational study. Eur J Obstet Gynecol Reprod Biol 2015; 188: 1-5.
23. Withagen MI, Milani AL, den Boon J et al. Trocar-guided mesh compared with conventional vaginal repair in recurrent prolapse: a randomized controlled trial. Obstet Gynecol 2011; 117: 242-250.
24. Diwadkar GB, Barber MD, Feiner B et al. Complication and reoperation rates after apical vaginal prolapse surgical repair: a systematic review. Obstet Gynecol 2009; 113: 367-373.
25. Maher C, Feiner B, Baessler K et al. Surgery for women with apical vaginal prolapse. Cochrane Database of Systematic Reviews 2016, Issue 10. Art. No.: CD012376. DOI: 10.1002/14651858.CD012376.

Correspondence to:

Edgardo Castillo Pino - Avenida Italia s/n - Montevideo 11600 Montevideo - Uruguay
E-mail: castillopino@gmail.com

History

The key role of the transverse pre-cervical arc of Gil-Vernet in urethral closure

JOSÉ M. GIL-VERNET

Centro de Urología Gil-Vernet, Teknon Medical Center, Barcelona, Spain

The precervical arc of Gil-Vernet (Figure 1), was described circa 1951 by Salvador Gil-Vernet, famous Urologist/Anatomist and grandfather of the author[1]. This structure was key to the conceptualization of the proximal and distal urethral closure mechanisms by Petros & Ulmsten and in the Integral Theory itself[2]. In the original 1990 description for urethral closure[1], three opposite directional muscle forces stretched the urethra in opposite directions to tension it against the pubourethral ligament (PUL), figure 2. The downward vector force (downward arrow, figure 2), then rotated the proximal vagina and bladder base around the transverse precervical arc of Gilvernet (figure 1) ['S', figure 2] to close ("kink") the bladder neck. This was the first time in the literature where the function of this anatomical discovery by Professor Salvador Gil Vernet (1892-1987) was described.

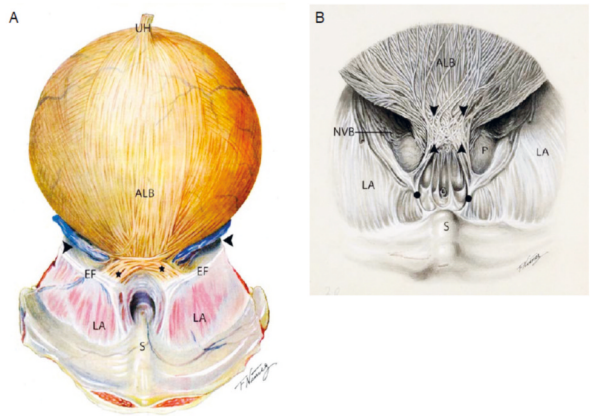


Figure 1. – *Transverse precervical arc*. Original drawing from Salvador Gil-Vernet's collected works (circa 1951). *A* UH: urachus; ALB: detrusor anterior longitudinal bundle; vesicoprostatic sulcus with vasculo-nervous bundle (arrowheads); EF: endopelvic fascia; S: symphysis pubis; transverse precervical arc (stars). *B* NVB prostate neurovascular bundle; transverse precervical arc (arrowheads); pubovesical ligament (filled circles).

REFERENCES

1. Gil-Vernet JM. Morphology and fuction of vesico-prostate-urethral musculature. Ed. Canova, Treviso 1968.
2. Petros PE & Ulmsten U. An Integral Theory of female urinary incontinence. Acta Obstetrica et Gynecologica Scandinavica 1990; 69 Supp. 153: 1-79.

Correspondence to:
Dr. JM Gil-Vernet Sedó
Centro Médico Teknon
Vilana 12 - Barcelona 08022 - Spain
email: centrogilvernet@gmail.com

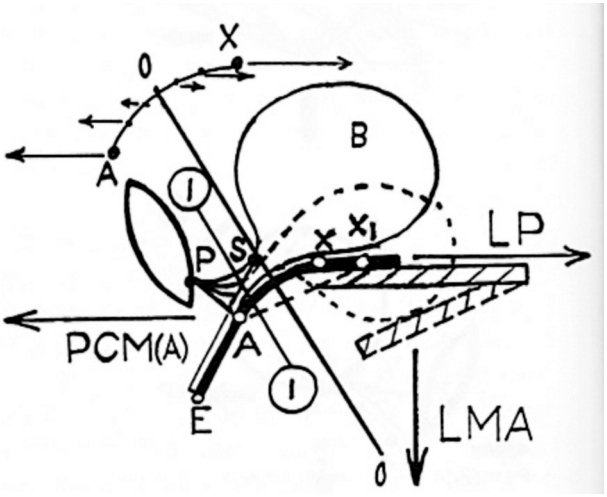


Figure 2. – *Original diagram* ACTA Obstet. et Gynecol. Scand. 19901.
Urethral closure I-I is the resting position of bladder neck. The heavy black line represents the vagina. During effort PCM (A) the anterior portion of m.pubococcygeus pulls the distal vagina A-E forwards against the pubourethral ligament 'P-A' to close distal urethra from behind and firmly anchor the distal urethra. Levator plate (LP) pulls backwards against P-A extending the proximal vagina from X to X1 and bladder neck to 0-0. X is the vesico-vaginal ligamentous attachment of bladder base to the anterior vaginal wall immediately below the cervix. P-S is the pubovesical ligament which inserts into 'S', a fibro-muscular thickening in the lower anterior wall of bladder 'B' known as the 'pre-cervical arc of Gil Vernet'. LMA (conjoint longitudinal muscle of the anus) contracts downwards against the cardinal/uterosacral ligaments to pull down on the anterior border of LP. This ultimately pulls down X1 to effect closure at bladder neck much like kinking a hose.
Urinary stress incontinence (USI) causation. In the original description for urinary stress incontinence (USI) causation, (1) the pubourethral ligament P-A loosens (elongates) and the bladder base/urethra complex "opens out' (funnels), exactly as what happens during micturition when PCM(A) relaxes. LP/LMA vectors (arrows) open out the vagina (heavy black line, fig1) and bladder base/urethra between X1 and A and urine is lost. In the prototype operation, the length P-A was restored by the midurethral sling tape, which also restored the distal and bladder neck closure mechanisms1.

Original article

Chronic pelvic pain associated with pelvic vein incompetence

LIANA PLES[1,2], ADINA TEODORA CORBU[1,2], DENISA OANA BALALAU[1,2], ROMINA MARINA SIMA[1,2], OCTAVIAN GABRIEL OLARU[1,2], ANCA DANIELA STANESCU[1,2]

[1] *Carol Davila University of Medicine and Pharmacy, Bucharest, Romania*
[2] *Department of Obstetrics and Gynecology, St. John Hospital - Bucur Maternity, Bucharest*

Abstract: Introduction: Chronic pelvic pain (CPP) is a spectrum of symptoms including pain, tension in the lower abdomen, dyspareunia, dyskinesia, dysuria or dysmenorrhea. The conditions responsible for CPP are various but in more than 60% cases the diagnosis cannot be established. Ultrasound is a useful tool in the evaluation of those patients. *Material and method:* We retrospectively evaluated the ultrasound scans and physical examination of the patients who presented in our clinic for pelvic pain between Jan 2016-Jan 2018. We retrieved only the patients who reported at least one of the symptoms compatible with CPP and reviewed the files. A chart with relevant characteristics -age, parity, main complaints, transvaginal ultrasound was completed. We searched for abnormal pelvic vascular patterns suggestive for incontinent pelvic veins. *Results:* In a two years period 2437 women asked for genital examination in "Bucur" Obstetrics and Gynecology Clinic. For 326 women abdominal pain was the main complaint but only 128 met the criteria for CPP. In 31 of them ultrasound transvaginal scan revealed abnormal vascular patterns of the pelvic veins (enlarged, tortuous vessels) suggestive for congestion and incontinent veins. *Conclusions:* Congestion of the pelvic veins can be responsible for about 30% of the CPP especially in multiparous women. Ultrasound using Doppler is useful in order to establish incontinence of the pelvic veins.

Keywords: Chronic pelvic pain; Doppler ultrasound; Pelvic congestion syndrome; Pelvic veins diameter; Pelvic veins incompetence.

INTRODUCTION

The underlining causes of chronic pelvic pain in women suffer great variety, with most of the pathology being easily diagnosed and treatable (e.g.: painful bladder syndrome, irritable bowel syndrome, adhesions, adenomyosis, endometriosis, pelvic inflammatory disease etc.). The concern for gynecologists is the idiopathic chronic pelvic pain in women, because of the lack of diagnosis criteria and accessibility to imaging techniques worldwide. The definition of the symptom, represented by chronic pelvic pain, refers to lower abdominal or pelvic pain, for more than 6 months, perceived by women in a continuously or intermittent manner with no relation to menstrual cycles, intercourse or pregnancy[1]. There are no guidelines referring to the definition of chronic pelvic pain[2], but the constant characteristic that appears in every given definition worldwide is the duration over 6 months of pelvic pain. The incidence of chronic pelvic pain is estimated around 24%[3,4,5], but with the lack of accepted definition or diagnosis criteria, incidence may vary among countries. Beside dull persisting pelvic pain, dysuria, dyspareunia, dysmenorrhea, dyskinesia may be associated[6], implying the need for a differential diagnosis, and treatment. Because of its impact not only upon women's functionality but psychological effect, many patients experiencing anxiety or depression[7], therapeutic objectives have a tendency towards symptomatic relief, for a long period of time.

The pathophysiology behind the appearance of incompetent pelvic veins is similar to that of peripheral vein insufficiency[8], where valvular leaflet's function declines, making retrograde blood flow a cause for the extension in venous diameter. Furthermore, the gravid uterus and the circulatory overdistention that appears in pregnancy contribute to the vicious circle responsible for pelvic vein incompetence[2].

Patient examination should include a pain history (precipitating and alienating factors, response to prior treatment, sexual activity, urination, defecation), represented through a variety of scoring systems, with the most commonly used in literature being the Visual Analog Scale. Physical pelvic examination is based on external examination of the genitals (looking for inflammatory or dermatological conditions, vulvar malignancies, varicose veins of the perineum or lower limbs), speculum examination and unidigital or bimanual examination, in search for pelvic tenderness in the right and left pelvic floor, cul-de-sac, bladder base, uterus and adnexa[9].

Laboratory testing has limited value and should be used as a differential diagnosis. Pregnancy should be excluded.

This study offers our clinic's perspective upon the association between chronic pelvic pain and pelvic vein incompetence, the objective being: finding statistically significant correlations between pelvic congestion syndrome and variables like: parity, uterus position, associated pathology etc.

MATERIAL AND METHODS

Study design

We conducted an observational retrospective study, which took place in our clinic: Saint John Hospital-"Bucur" Maternity, in Bucharest, in a period of 2 years from Jan 2016 to Jan 2018. The objectives were to find among women searching for medical care, those complaining of pelvic pain, and to identify the association of chronic pain and incompetent pelvic veins, as well as finding statistically significant correlations with several variables, such as: age, associated pathology (ascites, abdominal surgery), uterus position, parity.

Selection of patients

We review the files of 2437 patients who underwent genital examination, in our clinic, during two years period of time. 326 of them searched for medical care, complaining of pelvic pain. The criterions used for defining chronic pelvic pain were: pain in the lower abdomen, which lasted for more than 6 month, with no identifiable etiology until the examination. We did not take under consideration, for the inclusion criteria, variables like: age, parity, associated pathology or surgery. Instead, based on these particular items, statistically significant association with chronic pelvic pain and pelvic vein diameters were searched and made. 128 patients met the criteria for chronic pelvic pain, all of which underwent ultrasonography for identification and diagnosis of gynecologic pathology.

Ultrasonography examination was conducted in each case. With the patient supine, in a gynecological position, a

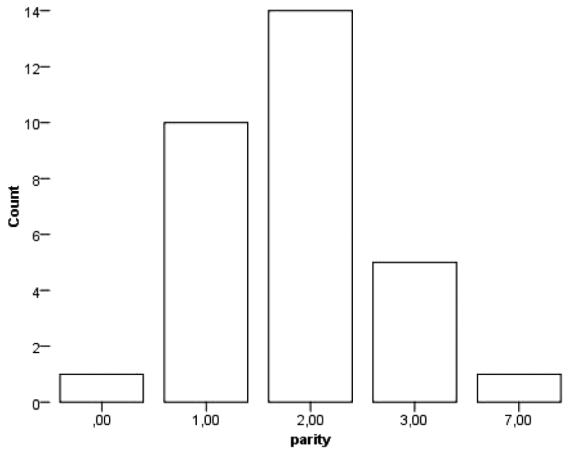


Figure 1. – Parity prevalence chart.

transvaginal transducer in Mode B was used to identify pelvic masses, uterine fibroids or other abnormalities. Color Doppler mode with low velocity scales was used to assess the pelvic veins and its diameters, and also the presence or absence of retrograde venous flow.

Statistical analysis

A data base was obtained, consisting of the patients who had abnormal patterns of the pelvic veins on ultrasound examination, and variables like: age, smoking character, parity, associated pathologies, history of surgery, presence of ascites, uterine position, and pelvic vein diameters. The presence or absence of venous reflux when the Valsalva maneuver was performed was noted while assessing the vein diameter.

The statistical analysis was performed with specific using SPSS 20.0.Crosstabulation, T student test, Chi square test were applied for numeric variable. We analysed the correlation among parameters using bivariate tests such as Pearson or Spearman correlations. P value was considered statistically significant for $p<0.05$ or 0.01 in selected situations.

RESULTS

Thirty one women were found to have abnormal patterns of the pelvic vein on ultrasonography examination, when presented with chronic pelvic pain in the emergency room

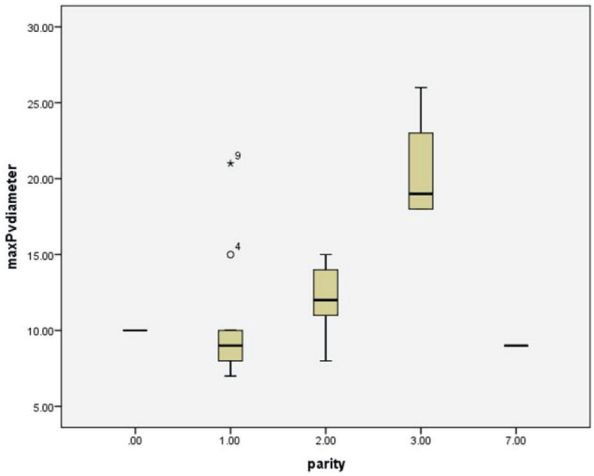


Figure 2. – Correlation between parity and maximum pelvic vein diameter.

Correlations

			ascites	uterineposition
Spearman's rho	ascites	Correlation Coefficient	1.000	-.485**
		Sig. (1-tailed)	.	.003
		N	31	31
	uterineposition	Correlation Coefficient	-.485**	1.000
		Sig. (1-tailed)	.003	.
		N	31	31

**. Correlation is significant at the 0.01 level (1-tailed).

Figure 3. – Correlation between uterine position and ascites.

or as outpatients, from January 2016 to January 2018. We considered being abnormal, a diameter of the pelvic veins (ovarian vein, internal iliac veins) that exceeded 6 mm. In 71% of the cases, the diameter even exceeded 10 mm. The biggest diameter found was 26 mm, and was the case of a 51 years old, tertiparous woman.

Mean age was 39 years old, the frequency of the smokers was almost equal to that of the non-smokers (46,5% vs 49,6%).

The majority did not have an associated gynecological pathology (54,8%), but where identifiable, the majority of the patients had uterine fibroids (25,8%), followed by: ovarian cyst, uterine polyp, istmocel (6,5%). Of those found to have fibroids, 87,5% also had a maximum pelvic vein diameter over 10 mm.

In terms of parity, most of the women examined for chronic pelvic pain were multiparous, fourteen of thirty one being tertiparous with ages between 37 and 52 years old (Figure 1).

Increased parity was correlated with greater pelvic vein diameters. All of the secundiparous patients had diameters of the pelvic veins greater than 8 mm, while all of the tertiparous patients had pelvic vein diameters greater than 10 mm (Figure 2).

Ascites was found in 41,9% patients, 69,2% of which had a pelvic vein diameter greater than 10 mm. Also we noted that the prevalence of ascites was bigger in women with retroverted uterus than in those with anteverted position (Figure 3, Figure 4).

Valsalva maneuver was used in all cases while performing Doppler ultrasonography, to evaluate the presence or absence of a retrograde venous flow. In ten of all women included in this study, a retrograde venous flow was ob-

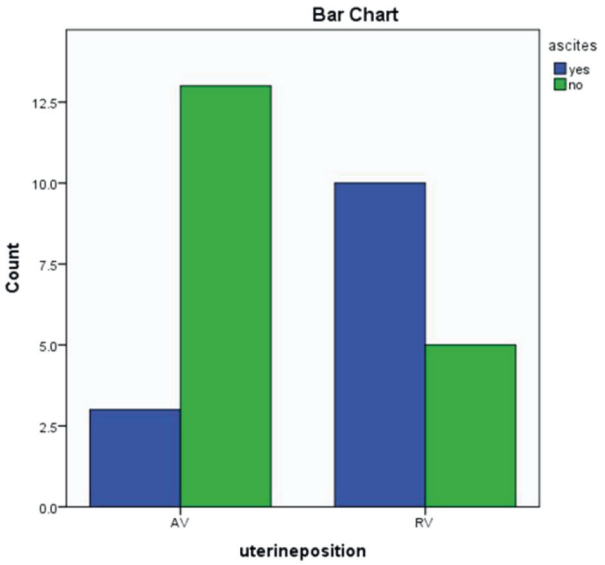


Figure 4. – Association between uterine position and ascites.

Correlations

uterineposition			parity	maxPvdiameter
AV	parity	Pearson Correlation	1	.150
		Sig. (2-tailed)		.579
		N	16	16
	maxPvdiameter	Pearson Correlation	.150	1
		Sig. (2-tailed)	.579	
		N	16	16
RV	parity	Pearson Correlation	1	.648**
		Sig. (2-tailed)		.009
		N	15	15
	maxPvdiameter	Pearson Correlation	.648**	1
		Sig. (2-tailed)	.009	
		N	15	15

**. Correlation is significant at the 0.01 level (2-tailed).

Figure 5. – Correlation between uterus position, parity and pelvic vein diameter.

served. 80% of these had diameters of the pelvic veins greater than 10 mm.

Uterus position was assessed also by ultrasonography, resulting 48,4% patients having retroverted uterus and 51,6% anteverted uterus. We calculated the mean pelvic vein diameter for each group and concluded that retroverted uterus was associated with greater pelvic vein diameter (13,46 mm vs 12,12 mm in anteverted uterus).

Parity and retroverted uterus was the association of factors that correlated with greater pelvic vein diameters (Figure 5, Figure 6).

DISCUSSION

Chronic pelvic pain has a profound mark on women's life, affecting functionality, economical status, psychological status, overall the quality of life. Therapeutic management is based on symptom relief, and improvement of functionality.

Ultrasonography, either transabdominal or transvaginal approach, represents the first imagistic step in evaluating women with chronic pelvic pain, having 96% sensitivity, 100% specificity, with positive and negative predictive value of 100% and 94%, respectively[3]. It can diagnose pelvic masses, uterine fibroids, endometriosis etc. The most common findings: enlarged pelvic vein diameters,

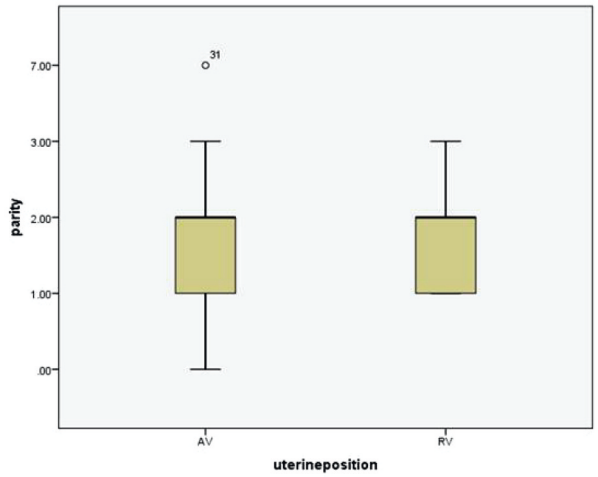


Figure 6. – Uterus position and parity chart.

retrograde venous blood flow (pelvic vein incompetence)[10], when associated with chronic pelvic pain, define the term "pelvic congestion syndrome". Recent literature reviews consider pelvic vein incompetence as the etiopathogeni for chronic pelvic pain, but robust case-control and blinded studies are yet to be conducted, in order to unify definitions and diagnosis techniques. 11-28% of the investigations for women with chronic pelvic pain, describe also incompetent pelvic veins[3]. There are many imaging techniques used to differentiate primary pelvic vein incompetence (known as idiopathic) from secondary PVI. Ultrasonography, laparoscopy, magnetic resonance, venography, may diagnose pathologies such as: deep vein thrombosis, Nutcracker syndrome[11], May-Thurner syndrome, which are all responsible for chronic pelvic pain and pelvic vein incompetence.

This study highlighted a positive relationship between chronic pelvic pain and pelvic vein incompetence in multiparous women, cases with retroverted uterus, or presence of ascites. Higher pelvic vein diameters were directly proportional with parity, and frequently seen in women with retroverted uterus. The incidence of retroverted uterus, in women with chronic pelvic pain, is higher than in the general population (19%)[12,13] 41,9% of the women experiencing chronic pelvic pain, examined in our clinic, had previous pelvic or abdominal surgery, implying a possible risk factor for this symptom, maybe due to intraperitoneal adhesions[12], nerve or muscle damage.

Concerning the vein dilatations, the majority of patients (76,9%) had pelvic vein diameters greater than 10 mm, supporting the hypothesis of pelvic pain generated by venous stasis and pelvic congestion which is aggravated by prolonged standing and sitting.

Smoking has an intimate relation with chronic pain, many theories being involved. Some authors believe that smoking affects indirectly the musculoskeletal function[14], leading to chronic pain, other that nicotine plays a role in the signaling pathways[15,7,14]. In our study there was no indication for smoking-venous dilation association.

Study limitations

Due to the retrospective character of this study, a questionnaire regarding subjective perception of the pain or a pain-log could not be obtained. Also a psychological profile was not made for all patients, thus we could not objectify how psychological symptoms and pathologies, like anxiety or depression, affects or cause higher perception of pain.

CONCLUSIONS

This study offers validation of some variables being contributors to chronic pelvic pain and higher pelvic vein diameters. With a variety of causes and multiple factors involved, the diagnosis of incompetent pelvic vein is challenging. Doppler ultrasonography is an important tool used for identification of the possible causes for chronic pelvic pain and also for assessing the characteristics of the pelvic veins.

DISCLOSURE STATEMENTS

The authors declare no personal o financial conflict of interest to disclose.

REFERENCES

1. Champaneria R, Shah L, Moss J et al. Health technology assessment 2016; 20 (5).

2. Williams RE, Hartmann KE, Steege JF. Documenting the Current Definitions of Chronic Pelvic Pain: Implications for Research. Obstet Gynecol 2004; 103 (4): 686-691.
3. Health V. Pelvic vein incompetence: clinical perspectives. 2017: 439-447.
4. Latthe P, Latthe M, Say L, Gülmezoglu M, Khan KS. WHO systematic review of prevalence of chronic pelvic pain: a neglected reproductive health morbidity. BMC Public Health 2006; 6 (1): 177.
5. Ahangari A. Systematic Review Prevalence of Chronic Pelvic Pain Among Women: An Updated Review.
6. Yosef A, Allaire C, Williams C et al. Multifactorial contributors to the severity of chronic pelvic pain in women. 2016.
7. Barton SB, Kofoed BA, Doleys DM. Smoking and Narcotics Use among Chronic Pain Patients. Psychol Rep 1989; 64 (3_suppl): 1253-1254.
8. Bora A, Avcu S, Arslan H, Adali E, Bulut MD. The relation between pelvic varicose veins and lower extremity venous insufficiency in women with chronic pelvic pain. JBR-BTR 95 (4): 215-221.
9. Chronic Pelvic Pain in Women.
10. Park SJ, Lim JW, Ko YT et al. Diagnosis of Pelvic Congestion Syndrome Using Transabdominal and Transvaginal Sonography. Am J Roentgenol 2004; 182 (3): 683-688.
11. Gulleroglu K, Gulleroglu B, Baskin E. Nutcracker syndrome. World J Nephrol 2014; 3 (4): 277.
12. Neis KJ, Neis F. Chronic pelvic pain: Cause, diagnosis and therapy from a gynaecologist's and an endoscopist's point of view. Gynecol Endocrinol 2009; 25 (11): 757-761.
13. Juhan V. Chronic pelvic pain: An imaging approach. Diagn Interv Imaging 2015; 96: 9 97-1007.
14. Andersson H, Ejlertsson G, Leden I. Widespread musculoskeletal chronic pain associated with smoking. An epidemiological study in a general rural population. Scand J Rehabil Med 1998; 30 (3): 185-191.
15. Mitchell MD, Mannino DM, Steinke DT, Kryscio RJ, Bush HM, Crofford LJ. Association of Smoking and Chronic Pain Syndromes in Kentucky Women. J Pain 2011; 12 (8): 892-899.

Correspondence to:
Adina Teodora Corbu
Carol Davila University of Medicine and Pharmacy
Bucharest, Romania
E-mail: adinat.corbu@gmail.com

Letter to the Editors

I thank Dr. Gold for his comments on my paper *(Descending perineum syndrome: pathophysiology of fecal incontinence, Pelviperineology 2018; 37 (2): 57-62)* and I write to offer further comments.

The premise is that aim of paper was "to understand the types and pathophysiology of fecal incontinence in patients affected by DPS". The conclusions "Urge incontinence, related to external anal sphincter atrophy, is the predominant pattern of fecal incontinence" are supported by instrumental data and are not hypotheses or theories.

The participation of the pelvic floor at the fecal incontinence in the descending perineum syndrome is abundantly addressed in the discussion. "When rectoanal intussusception is combined with levator hiatal widening and levator plate descent, it can become the morphological pathology underlying DPS fecal incontinence[22]. It is difficult to provide a single pathophysiological framework for DPS fecal incontinence. Although a multifactorial etiology seems have an impact on a weak pelvic floor, it is very difficult to understand how much a single factor may destabilize the descending perineum. Surely a descending perineum possesses per se a pathological structure of pelviperineal muscles, perineal body and supportive elements of the endopelvic fascia that can lead to fecal incontinence. For example, lax suspensory ligaments that inactivate striated pelvic muscle forces[23], increased collagen breakdown such as a pathological etiology of urinary incontinence and pelvic organ prolapse[24], the observation that 45% of patients with joint hypermotility, stool evacuatory disorders and abnormal connective tissue also have fecal incontinence not due to sphincter dysfunction[25], are all evidence that an impaired pelvic floor may be associated with fecal incontinence". How much the individual muscles, puborectalis, pubococcygeus and ileococcygeus, are singularly involved in fecal incontinence, it is impossible, in the present state of instrumental diagnostics, to demonstrate such a thing objectively, as suggested by Dr. Gold. Returning to the aims of our paper, they were 1) to describe the clinical profile of fecal incontinence and 2) to identify the main pathophysiological mechanisms of fecal incontinence. As regards 1), we described an extensive data base, 1261 patients. As regards 2) we drew conclusions about pathophysiology based on our data. One view was that Levator ani muscle is part of the pelvic floor and its involvement in the descending perineum syndrome is supported by "levator hiatal widening and levator plate descent". These may well be, as Dr Gold states, hypotheses. As hypotheses, they are there to be questioned, to be proven or disproven, as Dr Gold has done. That is how medical science progresses. We appreciate Dr Gold's comment that the Integral Theory has not as yet been invalidated. Some, even many of the correlations made in our results may well be supportive of the Integral Theory. Some will not be. These would need a critical analysis involving far more than the short comment made here by Dr Gold. We invite Dr Gold and his colleagues to make such an analysis. We would, of course, be happy to assist any such endeavour.

FILIPPO PUCCIANI
Department of Surgery and Translational Medicine, University of Florence, Italy
Largo Brambilla 3 - Florence 50134 - Italy
E-mail: pucciani@unifi.it

ISPP

International Society of Pelvi-Perineology

CONGRESS 2019, OCTOBER 3-5 - TREVISO (ITALY)

PELVIC FLOOR DISORDERS: CURRENT STATUS, TECHNOLOGICAL ADVANCES AND PERSPECTIVE

PRESIDENTS OF THE CONGRESS:
Giulio Santoro & Giuseppe Dodi

ISPP PRESIDENT:
Ahmet Akin Sivaslioglu

ISPP CHIEF EXECUTIVE OFFICER:
Bruce Farnsworth

ISPP

International Society of Pelvi-Perineology

TOPICS:

PELVIC FLOOR ANATOMY, GENETICS AND HORMONES,
IMAGING PELVIC FLOOR, RECONSTRUCTIVE SURGERY,
NEUROPHYSIOLOGICAL CONTROL, PELVIC PAIN,
PELVIC FLOOR REHABILITATION,
POSTERIOR COMPARTMENT DISORDERS,
INCONTINENCE SURGERY

FOR INFORMATION: www.pelviperineology.com

A MINIMALLY INVASIVE AND EFFECTIVE BRIDGE BETWEEN CONSERVATIVE THERAPY AND SURGERY FOR BOWEL INCONTINENCE

secca®

EFFICIENT
Performed in an outpatient setting

SAFE
Less than 1% complication rate*

EFFECTIVE
Up to 84% of patients experienced significant improvement*

QUICK RECOVERY
Return to normal activities in a few days

SECCA PATIENTS **84%** experienced significant improvement

Greater Quality of Life

Less than **1%** complications

MEDERI™

Distributore esclusivo:

INNOVA medica SPA

DILAGENT®

Curative “exercises” for anal fissures, haemorrhoids, hypertonic muscles and postsurgical stenosis

DILAGENT is a **soft silicone** anal dilator.
It is indicated for the treatment of anorectal diseases caused by a hypertonic sphincter, namely anal fissures, haemorrhoids and painful spasms after surgical treatment of the anorectal segment. It is also effectively used in cases of postsurgical stenosis of the anal canal.

sapimed S.p.A.
www.sapimed.com