Vol. 36 - N. 4
December 2017

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

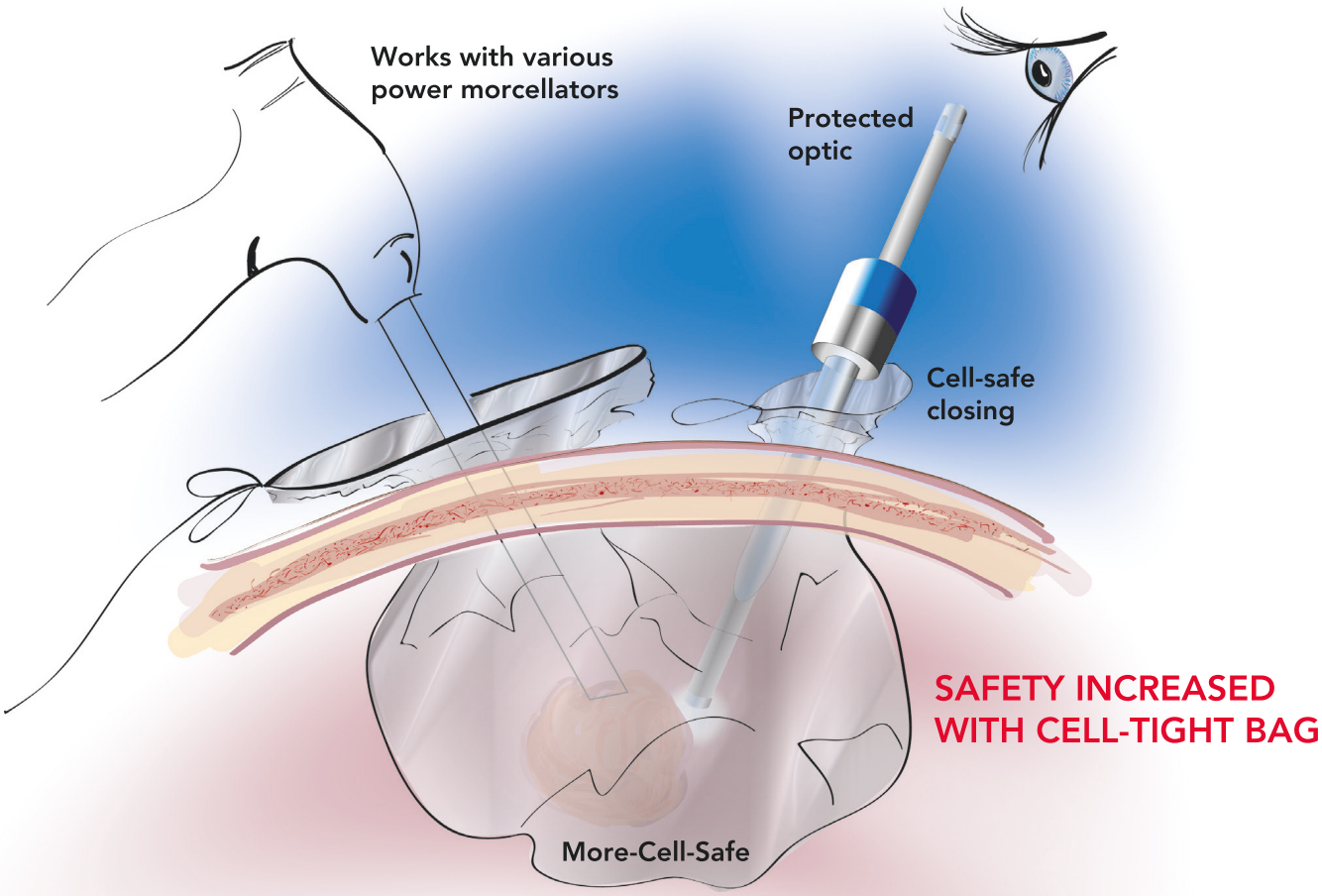
'Taxe Perçue' 'Tassa Riscossa' - Padova C.M.P.
Poste Italiane s.p.a.
Spedizione in Abb. Post. - 70% - DCB Padova

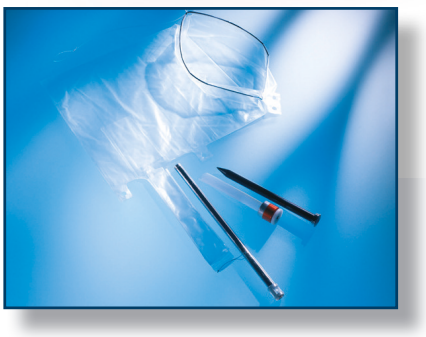
A.M.I.®

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. 36
N. 4
December 2017

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

Editorial

Pelviperineology in Latin America

We thank the editors for this invitation to provide a short snapshot of Pelviperineology in Latin America. It can be described in one word, *vital*. Certainly there are large numbers of patients, potentially 620, million! Certainly there is a major lack of financial and logistic resources, insufficient doctors in some of the countries, even vital medicines in some. Far from acting as a hindrance, these conditions have inspired the Latin American doctors to become widely open to technology which can assist their patients. Nowhere is the saying *"Necessity is the mother of invention"* more applicable than in Latin America. Many of the new minimally invasive vaginal procedures have been invented or modified to suit these conditions. Dedicated university units act as a focus to teach new effective methods all over Latin America. Teaching is by small to medium meetings held regularly in many different countries, too numerous to list here. The Internet has been widely and intelligently applied. The "Global Pelvic Network" using "Whats app" is but one example. Large numbers of questions are asked covering all parts of Pelviperineology, by Urologists, Gynecologists, Coloproctologists and others *on a daily basis*. Amazingly, these discussions initiated for Latin American surgeons, are now being joined by experts from North America, Europe, Oceania, Asia, many of international stature. This learning/teaching innovation is unique. It was inspired and initiated by the University of Campinas, a true leader in pelvic floor innovation world-wide.

The yearly meetings of ALAPP, the Latin American Pelvic Floor Society are of a very high standard and are widely attended. The 2017 meeting featured a large number of highly instructive practical workshops, cutting edge lectures on chronic pelvic pain, gender assignment, Integral Theory, delivered by local and international experts, all of whom paid their own way to the conference. This is a deliberate policy of ALAPP, brought in to avoid the bias which commercially endorsed lectures often bring. Some 75 abstracts were presented and a selection of these were published in Pelviperineology Journal.

We cordially invite all readers of Pelviperineology to the upcoming ALAPP meeting in Mexico City 28th February to 3rd March 2018.

PAOLO PALMA, NUCELIO LEMOS
Editors Pelviperineology
ppalma@uol.com.br, nucelio.lemos@gmail.com

Original article

Is there a correlation between simulated operations, urodynamics (vlpp) and urethral mobility?

JULIANE DE FÁTIMA AGOSTINI TIECHER[1], PAULO CÉSAR RODRIGUES PALMA[2], CÁSSIO LUIS ZANETTINI RICCETTO[3]

[1] *Master studente of Faculty of Medical Sciences at the State University of Campinas - Unicamp - julitiecher@yahoo.com.br*
[2] *State University of Campinas - Unicamp - prof.palma@gmail.com*
[3] *State University of Campinas - Unicamp - cassioriccetto@gmail.com*

Abstract. *Introduction*: The diagnosis of stress urinary incontinence is based on history and physical examination and, if necessary, could be associated with additional tests especially the urodynamic. The Integral Theory, developed a new way to evaluate patients with stress urinary incontinence, known as 'Simulated Operations'. These techniques are maneuvers performed during the stress test (cough), to identify the defects of the urethral support elements that cause incontinence. *Objectives*: 1. To establish a correlation between simulated operations with the *Valsalva leak point pressure* (urodynamics)*;* 2. To correlate the simulated operations with the result of the Q-tip test; 3. To correlate intensity of symptoms with simulated operations through the pad test. *Material and Methods:* From May 2012 to February 2015 82 women with stress urinary incontinence were evaluated. All patients underwent simulated operations that consisted of four maneuvers during the cough test observing if there was urinary leakage during the maneuvers. For the maneuver 1, the atraumatic clamp was applied unilaterally at the pubourethral ligament insertion on the inferior border of the pubis (simulating the plication of the pubourethral ligament). In the maneuver 2, a clamp was used to plicate the vaginal mucosa at the level of the midurethra (simulate the plication of the urethropelvic ligament). In the 3rd maneuver, the index finger is placed in the suburethral region without tension. The 4th maneuver is the same maneuver 3 *with* tension. The Q-tip test has been used for evaluation of urethral mobility and the one-hour pad test to measure the severity of urinary leakage. The simulated operations were compared with the values of *Valsalva leak point pressure*, Q-tip test and pad test. *Results:* When performing the maneuvers 1, 2 and 3, most patients did not have urinary leakage. There was a significant association between *Valsalva leak point pressure* and the cessation of stress urinary incontinence with the maneuvers 1, 2 e 3 (p = 0.008, OR 0.965; p = 0.0140, OR 0.953; p = 0.0002, OR 0.949, respectivamente às manobras 1, 2 e 3, com IC 95%). During the maneuver 4, no patient presented had leak urine. The Q-tip test was statistically significant with maneuvers 2, 3 and 4. The pad test did not show statistical correlation with the simulated operations. *Conclusion:* The simulated operations demonstrated correlation with *Valsalva leak point pressure* and urethral mobility. Their use in clinical practice is recommended.

Keywords: Stress urinary incontinence; Simulated operations; Urodynamic study; Valsalva leak; Point pressure; Q-tip test; Pad test.

INTRODUCTION

Urinary incontinence (UI) is a frequent health problem among women[1] that affects quality of life and restricts social life because of the physical discomfort and embarrassment it causes. The International Continence Society (ICS) defines stress UI (SUI) as involuntary urine leakage during physical effort, sneezing, or coughing[2]. Approximately 12-55% of women will suffer from UI at some point during their lives[3]. Approximately 50% of all patients with UI present with SUI as the predominant or only symptom[4].

The diagnostic tests that assess SUI vary in complexity, from the urinary stress test to video urodynamic testing[5]. The Q-tip test helps to identify patients with urethral hypermobility, and urodynamic testing (which has improved the identification of voiding dysfunctions) has become a frequent test among patients with UI.

With proposal of the Integral Theory in the 1990s, a new concept was developed to explain and understand the various disorders of the pelvic floor and how they develop into voiding dysfunctions. According to this theory, pelvic organ prolapse and abnormal urinary and pelvic symptoms are primarily caused by the laxity of the vaginal connective tissue or supporting ligaments[6]. These structures are assessed during a physical examination using simulated operations (SOs) in which ligament defects are evaluated, either directly with a finger or with the help of a haemostatic clamp[7] with four different manoeuvres while the patients cough. Petros initially showed the importance of ligament integrity and, consequently, of the ligament-supporting tissues with regard to maintaining continence through two SO manoeuvres; most patients presented with interruption of urine loss after lateral compression of the urethra (which mimics the function of the pubourethral ligament) and the remaining patients did so after suburethral plication (which mimics urethropelvic support or hammock)[7].

In 2003, Petros investigated the anatomical origins and the clinical significance of the cough pressure transmission ratio (CTR; i.e., increased urethral pressure during coughing) by measuring it before and after unilateral midurethral anchoring. The CTR improved with urethral anchoring, which suggests that the connective tissue dysfunctions in patients with SUI are caused by ligament lesions and the laxity of the muscles that act on urethral closure[8].

Urodynamic testing is the most common type of test used to assess UI. Currently, the debate regarding the need to perform the test on patients with SUI symptoms is on-going[9]. More recently, the real importance of urodynamics in defining therapeutic procedures and establishing prognoses for patients with SUI is being questioned because it is not a predictor of success or failure for SUI surgery, and also, its high cost and invasive nature[9,10].

Performing SOs in association with a physical examination might contribute to a more precise SUI diagnosis. SOs exactly mimic what happens during midurethral sling surgery: where a tape is inserted in the exact positon of the pubourethral ligament to reinforce it as an anchoring point for the three opposite muscle vectors which activate urethral closure[6-8]. This study sought to correlate SOs with[1] other SUI diagnostic tests (i.e., urodynamics [Valsalva leak point pressure; VLPP] and the Q-tip test); and[2] the one-hour pad test.

MATERIALS AND METHODS

This prospective study compares SUI diagnostic and assessment methods.

The variables included a VLPP (urodynamic study performed according to ICS norms), simulated operation including four manoeuvres performed during the cough test with a haemostatic clamp to assess whether urine loss is stopped during the manoeuvre.

Manoeuvre 1. A haemostat clamp is unilaterally applied at the insertion of the pubourethral ligament in the inferior edge of the pubic bone, lateral to the paraurethral sulcus, to simulate the plication of the pubourethral ligament. Simultaneously, the patient is asked to cough. The test is considered positive when urine loss is interrupted during the abdominal effort manoeuvre (Figure 1).

Figure 1. – Manoeuvre 1: The application of a haemostatic clamp unilaterally at the insertion of the pubourethral ligament at the inferior edge of the pubic bone.

Manoeuvre 2. The suburethral region (mid-urethra) is plicated with the help of a clamp, simulating the plication of the urethropelvic ligament while the patient is asked to cough. The test is considered positive when loss of urine is interrupted during the abdominal effort manoeuvre (Figure 2).

Figure 2. – Manoeuvre 2: The plication of the suburethral region (mid urethra) with the help of a clamp simulating the plication of the urethropelvic ligament.

Manoeuvre 3. The mid-suburethral region is supported with the help of the index finger or a haemostatic clamp, while the patient is asked to cough. The test is considered positive when urine loss is interrupted during the abdominal effort manoeuvre (Figure 3).

Manoeuvre 4: The suburethral region is compressed with the help of the index finger (i.e., manoeuvre 3 with tension), while the patient is asked to cough. The test is considered positive when urine loss is interrupted during the abdominal effort manoeuvre.

Figure 3. – Manoeuvre 3: The support of the mid suburethral region with the help of the index finger or a haemostatic clamp.

Q-tip test: The Q-tip is introduced at level of the bladder neck, and its angular variation (measured in degrees) during the increase in abdominal pressure is assessed. A variation greater than 30º suggests urethral hypermobility[11].

Pad test (one hour): This test consists of placing a pad (of known weight). Next, the patient drinks 500 mL of water in 15 minutes. Over the next 30 minutes, the patients is instructed to walk around, ascend and descend stairs, sit down and stand up (10 times), cough hard (10 times), run in place for 1 minute, bend over to pick up an object (five times), and wash their hands in running water for 5 minutes. After one hour, the pad is weighed again[12,13].

All tests were performed when the patient expressed the urge to urinate or had a minimum bladder volume of 150 mL.

From May 2012 to February 2015, 82 women presenting with SUI as the primary symptom were selected from the Female Urology Clinic of the Unicamp Clinics Hospital. The women were diagnosed at their initial physical examination using the cough test. Of these patients, 50 underwent SO manoeuvres 1 and 2, and 82 patients underwent all four manoeuvres. All patients underwent the urodynamic study, the Q-tip test, and the pad test.

The patients included in this study agreed to participate and signed the Informed Consent Form (Annex 1). The Ethics and Research Committee of the Faculty of Medical Sciences of Unicamp (Comitê de Ética e Pesquisa da Faculdade de Ciências Médicas da Unicamp - CEP-FCM-Unicamp; registration number 02291012.5.0000.540) approved this study.

Patients who did not lose urine during stress manoeuvres as well as those with stage III or IV anterior wall prolapse were excluded from the study.

Statistical analyses

An exploratory data analysis was performed using frequencies and descriptive statistics. The Mann-Whitney U test was used to compare manoeuvres and quantitative variables. A logistic regression analysis was used to analyse the relationship between the manoeuvres and the factors under study. The significance level adopted was 5%.

Results

Of the 82 women assessed, 50 underwent manoeuvres 1 and 2, and all women underwent manoeuvres 3 and 4. Of the patients who underwent manoeuvres 1 and 2, 35 (70%) did not present urine loss after manoeuvre 1, and 45 (90%) had interrupted urine loss after manoeuvre 2. Of the 82 women assessed using manoeuvres 3 and 4, 61 (74.39%) had interrupted urine loss with manoeuvre 3. All 21 patients who needed a compressive manoeuvre (manoeuvre 4) had interrupted urine loss.

The analysis of the variables age, VLPP, Q-tip test, and pad test with regard to manoeuvre 1 showed a significant association between the manoeuvre and VLPP because the patients who had interrupted urine loss had VLPP values higher than those who maintained SUI during the test, p = 0.008 (OR = 0.965, 95% CIs = 0.941-0.989). The mean VLPP was 118.7 cmH_2O in the group that had stopped urine loss with manoeuvre 1 and 80.53 cmH_2O in the group that maintained UI during the manoeuvre (Table 1).

Each one-unit reduction in the VLPP value increased the risk of losing urine during manoeuvre 1 by 4%.

The Q-tip and pad tests were not significantly associated with manoeuvre 1.

TABLE 1. Comparison between manoeuvre 1 and the variables under study (n = 50).

Variable	Mean	Median	Standard Deviation	Min	Max	P-value
Age						
No loss	55.57	57.00	11.27	32.00	75.00	0.7536
Loss	55.20	54.00	7.26	46.00	70.00	
VLPP						
No loss	118.7	126.00	33.13	74.00	202.00	**0.0008**
Loss	80.53	73.00	27.17	36.00	169.00	
Pad test						
No loss	28.63	13.00	17.53	0.00	130.00	0.7424
Loss	38.87	12.00	40.89	4.00	176.00	
Q-tip test (in º)						
No loss	22.94	25.00	13.89	0.00	55.00	0.2177
Loss	17.27	15.00	8.79	0.00	35.00	

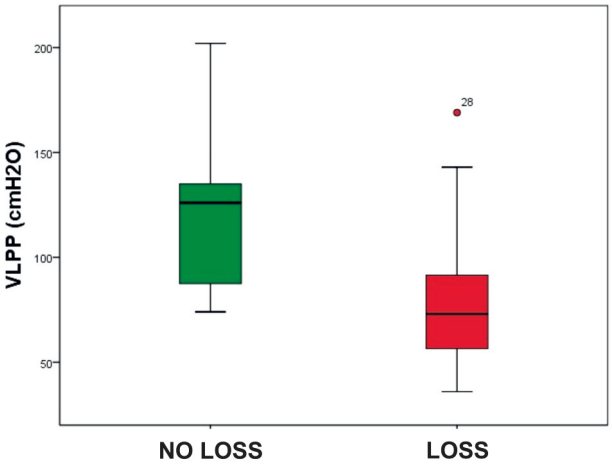


Figure 4. – VLPP relation among patients who don't have loss of urine and that kept the urinary loss.

When performing manoeuvre 2, we observed that most patients did not lose urine. An association was found between VLPP and the interruption of urine loss using this manoeuvre because patients who had interrupted urine loss had higher VLPP values, p = 0.0140 (OR = 0.953, 95% CIs = 0.912-0.997). The mean VLPPs for patients who did not lose urine and those who remained incontinent during manoeuver 2 were 111.5 cmH_2O and 68.60 cmH_2O, respectively. With each one-unit reduction in VLPP, the probability of losing urine using manoeuvre 2 increased by 5% (Table 2).

The Q-tip test was significantly associated with manoeuvre 2 because patients with higher Q-tip angle variation were those who did not lose urine during the manoeuvre (p = 0.0221).

The pad test was not significantly associated with manoeuvre 2.

TABLE 2. Comparison between manoeuvre 2 and the variables under study (n = 50).

Variable	Mean	Median	Standard Deviation	Min	Max	P-value
Age						
No loss	55.16	55.00	10.35	32.00	75.00	0.1604
Loss	58.20	60.00	8.70	47.00	70.00	
VLPP						
No loss	111.5	104.0	38.97	47.00	202.00	0.0140
Loss	68.60	73.00	20.85	36.00	92.00	
Pad test						
No loss	28.96	13.00	34.71	0.00	130.00	0.4761
Loss	56.40	32.00	70.73	6.00	176.00	
Q-tip (in º)						
No loss	22.62	25.00	13.31	0.00	55.00	0.0221
Loss	8.80	8.00	7.66	0.00	18.00	

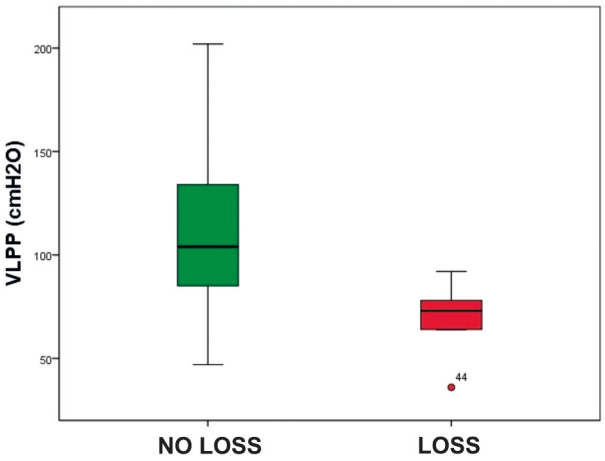


Figure 5. – VLPP relation among patients who don't have loss of urine and that kept the urinary loss.

When performing manoeuvre 3 (non-compressive suburethral support), we observed that patients who did not lose urine had higher VLPP values than those who continued to lose urine (p = 0.0002, OR = 0.949, 95% CIs = 0.899-1.003). The mean VLPPs for patients who did not lose urine with manoeuvre 3 and those who remained incontinent were 118 cmH_2O and 81 cmH_2O, respectively. Each one-unit increase in VLPP reduced the probability of losing urine using manoeuvre 3 by 3%.

The Q-tip test was significantly associated with manoeuvre 3 because patients who did not lose urine during the urethral support manoeuvre had a higher angle variation during effort than that of incontinent patients (p = 0.0001).

TABLE 3. Comparison between manoeuvre 3 and the variables under study (n = 82).

Variable	Mean	Median	Standard Deviation	Min	Max	P-value
Age						
No loss	55.64	55.00	11.18	31.00	75.00	0.0628
Loss	61.38	61.00	9.56	47.00	82.00	
VLPP						
No loss	115.32	118.0	37.41	46.00	202.00	0.0002
Loss	81.33	81.00	24.85	36.00	132.00	
Pad test (g)						
No loss	22.30	8.00	31.42	0.00	130.00	0.1888
Loss	31.43	20.00	38.78	1.00	176.00	
Q-tip (in º)						
No loss	23.33	25.00	13.23	0.00	55.00	0.0001
Loss	10.48	9.00	9.12	0.00	35.00	

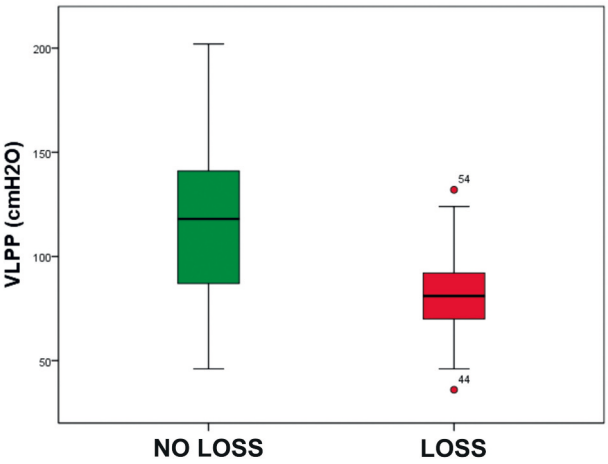


Figure 6. – VLPP relation among patients who don't have loss of urine and that kept the urinary loss.

Table 4. Comparison between the variables of patients who needed manoeuvre 4 to stop urine loss and those who did not lose urine using manoeuvres 1, 2, or 3 (n = 82).

	VLPP	Q-tip test	Pad test
Manoeuvre 1	p = 0.0012	p = 0.01745	p = 0.4064
Manoeuvre 2	p = 0.0197	p = 0.0279	p = 0.4064
Manoeuvre 3	p = 0.0002	p = 0.0001	p = 0.2832

No significant association was found between manoeuvre 3 and the pad test (Table 3).

During manoeuvre 4 (suburethral compression), no patient presented urine loss while coughing. A correlation was found between VLPP and the Q-tip test (Table 4).

DISCUSSION

While searching for less invasive SUI diagnostic methods, Petros developed SOs[7], which can often provide the information necessary to identify the type of UI via a physical examination because the specific ligament defects causing incontinence can be identified. In clinical practice, it is important to determine whether SUI is primarily caused by urethral hypermobility or a consequence of a deficiency in the intrinsic sphincter mechanism.

SOs have been previously described and tested[6,7]; however, the correlations between SOs and VLPP have never been discussed. VLPP values equal to or higher than 90 cmH_2O suggest urethral hypermobility, whereas those equal to or lower than 60 cmH_2O suggest intrinsic sphincter deficiency[14]; a VLPP between 60 and 90 cmH_2O is defined as a "grey area". In our study, SOs were compared with VLPP, the Q-tip test, and the pad test to assess the possible correlation between these SUI assessment tools. We performed an analysis of continuous data because the "grey area" of 60-90 cmH_20 includes numerous patients.

We observed correlations between all 4 manoeuvres and VLPP, showing that each increase in VLPP reduced the possibility of losing urine during the manoeuvres. Thus, SOs are a new, fast, and efficient way of assessing SUI. Furthermore, they are easy to perform in the physician's office. When performing an SO manoeuvre, it is possible to observe urethral mobility and estimate the severity of UI in patients who need manoeuvre 4 to interrupt urine loss. It is also possible to simulate the role of a sling surgery by performing suburethral support, thereby inferring the post-surgery result.

In 2011, a systematic review assessed the reclassification rate of the type of UI diagnosed via anamnesis with or without physical examination and after urodynamic testing. Only 9% of patients who had been diagnosed with SUI alone were reclassified as having mixed UI (MUI), and 7% were classified as suffering from detrusor hyperactivity. These changes suggest that unlike patients with MUI, the urodynamic testing of patients with SUI alone might not add much information to the clinical examination[15]. However, SOs complement a physical examination and improve clinical assessment accuracy using a simple and inexpensive approach.

In 2007, the UI Treatment Network (UITN) study reported that approximately 10% of women with a positive cough test who used an average of 3 pads/day did not show SUI in a urodynamic study[16]. That finding prompted a discussion of the role of urodynamics because urodynamics can fail to identify patients with typical symptoms of SUI. When using the Blaivas classification, type 0 UI corresponds to patients with SUI complaints who do not show urine loss on effort during video urodynamic testing[17]. This finding indicates that tests do not always reach maximum accuracy; however, when other tools with similar efficacy are available (e.g., SOs), it is possible to obtain a more accurate diagnosis.

Thus, SOs help clinicians to understand the structural defect that causes UI. If urine loss continues during manoeuvres 1, 2, and 3, then the patient likely suffers from severe incontinence, with the predominance of an intrinsic sphincter deficiency; the patient will most likely not have a satisfactory response to sling placement without tension. In contrast, if urine loss is interrupted during manoeuvres 1, 2, or 3, then the predominant defect causing SUI is likely urethral hypermobility.

By demonstrating the correlation between VLPP and SO, we showed that a physical examination plays an important role in simplifying the diagnosis and predicting the treatment outcomes of SUI.

CONCLUSIONS

SOs are easy to perform during physical examination and show a significant correlation with VLPP and the Q-tip test. The one-hour pad test was not correlated with SOs. The compressive manoeuvre characterised cases of severe UI, represented by the predominance of intrinsic sphincter deficiency. SOs improve the diagnosis of SUI in clinical practice and their use is recommended.

REFERENCES

1. Aparna D. Shah, Neeraj Kohli, Sujatha S. Rajan, Lennox Hoyte. The age distribution, rates, and types of surgery for stress urinary incontinence in the USA. Int Urogynecol J 2008, 19, 89-96.
2. Abrams P, Cardozo L, Fall M, Griffins D, Rosier P, Ulmsten U et al. The standardization of terminology in lower urinary tract function: report from the standardization sub-committee of the International Continence Society. Urology 2003, 61, 37-49.
3. Ward RM, Hampton BS, Blume JD, Sung VW, Rardin CR, Myers DL. The impact of multichannel urodynamics upon treatment recommendations for female urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 2008, 19 (9), 1235-41.
4. Milsom I, Altman D, Lapitan MC, Nelson R, Sillen U, Thom DH. Epidemiology of Urinary (UI) and Faecal (FI) Incontinence and Pelvic Organ Prolapse (POP). In: Abrams P, Cardozo L, Khoury S, Wein AJ, eds. Incontinence: 4th International Consultation on Incontinence. Paris, France: Health Publication Ltd 2009, 35-112.
5. Swift SE, Ostergard DR. Evaluation of current urodynamic test methods in the diagnosis of genuine stress incontinence. Obstet Gynecol 1995, 86, 85-91.

6. Petros P. Diagnosis of connective tissue damage. In: Petros PE (ed) The female pelvic floor-function, dysfunction and management according to the integral theory, 2nd ed. Springer, Berlin Heidelberg New York, 2006. p. 51-82.
7. Petros P, Konsky BV. Anchoring the medurethra restores bladder-neck anatomy and continence. The Lancet 1999, 354, 997-998.
8. Petros P. Changes in bladder neck geometry and closure pressure after midurethral anchoring suggest a musculo elastic mechanism activates closure, Neurology and Urodynamics 2003, 22, 191-7.
9. Palma P, Hermann V. Urodynamics and stress urinary incontinence: the dark side of a gold standard. Int Urogynecol J. 2007, 18 (12), 1385-6.
10. Glazener CMA, Lapidan MC (2006) Urodynamic investigations for the management of urinary incontinence in children and adults (Cochrane Review), *The Cochrane Library*,Issue 1.
11. Karram MM, Bhatia NN. The Q-tip test: standardization of the technique and its interpretation in women with urinary incontinence. Obstet Gynecol 1988, 71 (6 Pt 1), 807-11.
12. Bates P, Bradley W, Glen E et al. Fifth Report on the Standardization of Terminology of Lower Urinary Tract Function. Bristol International Society Committee on Standardization of Terminology. 1983.
13. Abrams, P, Blaivas JG, Stanton S, Andersen JT. The Standardization of Terminology of Lower Urinary tract Function. Neurourol.Urodyn 1988, 7, 403-26.
14. McGuire EJ, Fitzpatrick CC, Wan J Bloom D, Sanvordenker J, Ritchey M, Gormley EA. Clinical assessment of urethral sphincter function. J Urol 1993, 150, 1452-4.
15. Van Leijsen SA, Hoogstad-van Evert JS, Mol BW, Vierhout ME, Milani AL, Heesakkers JP, Kluivers KB. The correlation between clinical and urodynamics diagnosis in classifying the type of urinary incontinence in women. A systematic review of the literature. Neurol Urodyn 2011, 30 (4), 495-502.
16. Nager CW, Albo ME, Fitzgerald MP, McDermott S, Wruck L, Kraus S et al. Reference urodynamic values for stress incontinent women. Neurourol Urodyn. 2007, 26 (3), 333-40.
17. Blaivas JG, Olsson CA. Stress incontinence: classification and surgical approach. J Urol 1988, 139 (4), 727-31.

Correspondence to:
Juliane de Fátima Tiecher Rudge Ramos
Email: julitiecher@yahoo.com.br

Multidisciplinary commentary

Although this paper at first glance would appear be to be nothing more than esoteric to the majority of readers, the use of simulated operations is not new. The Trendelenburg test for varicose veins was first described in 1891 and quite simply uses a ligature around the thigh to compress the long saphenous vein and mimic the outcome of a high ligation at the sapheno-femoral junction. A positive test prevents the appearance of the varicosities on standing[1,2]. Medical students for centuries have been taught the benefit of pressure occlusion of the deep inguinal ring to diagnose hernia and predict outcome from herniorrhaphy.

In this very well described and elegant paper Tiecher et al. demonstrate techniques for interrupting urine loss in SUI and therefore predict the outcome of MUS surgery. Interestingly the findings correlate well with the results of mid-urethral sling (MUS) surgery when performed in well trained and expert hands[3]. The Integral Theory teaches that sling reinforces the pubourethral ligament and the apex of the MUS creates a rotation point around the apex of the sling upon which the three directional muscles forces act in order to prevent urine loss on coughing and straining. Manoeuvre-1 recreates the PUL and manouevre-2 recreates the external-urethral ligament (EUL) the importance of which are both critically detailed in the Integral Theory. The results in this paper would suggest that expert surgery would produce a 90% success rate for the MUS, exactly what was found in the 5 year study by Sivaslioglu 3.

As such the need for urodynamic testing is made obsolete. A good history followed by a careful examination, the basic tenets of good medicine, with the appropriate simulated operations is all that is need for a successful outcome for SUI surgery in well trained hands.

But there is an argument to take this further. The Integral Theory has shown the benefit of other ligament repair with the cure of other symptoms including urinary urgency, pelvic pain and ODS. Simulated operations could potentially be used in these circumstances.

In patients with urinary urgency the subject could allow the bladder to fill and at the point at which the urgency occurs could lie down and with a speculum carefully supporting the vaginal apex/posterior fornix would hopefully reduce the desire to urinate confirming the potential benefit to that patient of repairing the cardinal and uterosacral ligaments. Similarly patients with pelvic pain would experience a reduction in pain with a similar manoeuvre and pre- and post-test stroking of the introitus with a Q-tip could demonstrate benefit in vulvodynia.

For patients with ODS due to perineal descent, digital pressure on the perineum would improve subjective and possibly even objective 'push' and emptying by supporting the deep transverse perineal ligament. Concomitant support of the vaginal apex with a speculum and digital perineal pressure would do similar to those with ODS from apical descent, especially after hysterectomy.

This paper represents an exciting step forward in the management of patients with pelvic dysfunction, and as with all good research, opens far more doors than it could ever close.

REFERENCES

1. Smith, E.R., Varicose veins; the mechanics and significance of the doubly positive Trendelenburg test. Bull Meriden Conn Hosp, 1950, 3 (4), 86-9.
2. Trendelenburg, F., Über die Unterbindung der Vena saphena magna bei Unterschenkelvaricen. [Brun's] Beiträge zur klinischen Chirurgie, 1891, 7, 195-210.
3. Sivaslioglu, A.A. et al. A prospective randomized controlled trial of the transobturator tape and tissue fixation mini-sling in patients with stress urinary incontinence: 5-year results. J Urol, 2012, 188 (1), 194-9.

DARREN M. GOLD
Colorectal Surgeon, Senior Lecturer in Surgery,
St Vincent's Clinical School, UNSW, Sydney, Australia dandjgold@gmail.com

Original Article

Should we consider obesity a risk factor for pelvic organ prolapse?

BALINT FARKAS[1,*], PETRA GAL[1], SANDOR RACZ[1], PETER TAMAS[1,*], NELLI FARKAS[2], ZOLTAN NEMETH[3]

[1] *University of Pecs Clinical Centre, Department of Obstetrics and Gynaecology, Pecs, Hungary.*
[2] *Institute of Bioanalysis, Pecs, Hungary.*
[3] *Hospital St. John of God, Department of Gynaecology, Vienna, Austria.*
* *Member of the MTA-PTE Human Reproduction Scientific Research Group, Hungarian Academy of Sciences (MTA), Budapest, Hungary.*

Abstract. Objective: Obesity is a growing worldwide epidemic, with increasing prevalence in both children and adults. Although several publications and books describe obesity as a major risk factor of pelvic organ prolapse (POP), we assumed that obesity might not be a predisposing factor of symptomatic stage II or higher POP. *Methods:* In a prospective cohort study, 1911 women suffering from symptomatic POP were included. Their data was compared to 1995 age, and parity matching women, with no prolapse as control, from January 2009 to December 2016. Obesity was determined by calculating the body mass index (BMI). Detailed medical history and standard demographic data were revealed, and analysed using multivariate analysis. *Results*: The average age was 56 years ± 13 SD (min: 22, max: 89), and the mean parity was 2.04 ± 0.95 SD per patient (min: 0, max: 13). The study population had average weight and height, resulting in a mean BMI of 26.69 ± 4.45 kg/m^2 compared to the control group BMI 26.85 ± 5.56 kg/m^2. Two third (66.6 %) of the study population were in postmenopause with an average BMI of 27.14 ± 4.31 kg/m^2, while in premenopausal patients (33.4%) the BMI was found to be 25.78 ± 4.60 kg/m^2 respectively (p = 0.042). Multivariate analysis revealed no statistical significant difference between POP and control groups (p = 0.146). *Conclusion:* We emphasize that in our homogenous Caucasian Eastern-European population obesity might not act as a strong risk factor for symptomatic pelvic organ prolapse stage 2 or higher.

Keywords: Pelvic organ prolapse; Obesity; Risk factor.

INTRODUCTION

Pelvic organ prolapse (POP) is a condition of specific signs and symptoms that lead to impairment of normal function and diminished quality of life[1]. Almost all the experts of pelvic floor dysfunctions agree that the etiology of the disease is multifactorial and develops gradually over the years. Among the several risk factors of the disease, obesity provoked chronically increased intraabdominal pressure has been repetitively mentioned as one of the major risk factors of POP[2,3].

Obesity is a growing epidemic worldwide, with increasing prevalence in both children and adults[4]. The American Medical Association classifies obesity as a disease[5], which the World Health Organization considers to be the greatest public health issue of the 21st century[6]. More than half (65%) of the US population is overweight (25 > body mass index [BMI] < 30 kg/m^2), and the prevalence of obesity (BMI > 30 kg/m^2) is 34.9%[4,7]. Among adults in the European Union, these percentages are 50% and 10-30%, respectively. According to a recent survey among adults in Hungary, 30% of women and 26.7% of men were obese[8].

Although our study group acknowledge that increased abdominal pressure is considered to be a risk factor for POP, and also knowing that the relative importance, of each risk factor is not clearly established in the pathomechanism of the disease, our aim was to challenge obesity as a predisposing factor for symptomatic stage II or higher POP.

MATERIALS AND METHODS

Study population and data collection

Patients and study design

This prospective study was carried out at the University of Pecs Clinical Center, Pecs, Hungary, between 1 January 2009 and 31 December 2016, under the approval of the University of Pecs Institutional Ethical Review Board. Written informed consent was obtained from all enrolled patients. Women suffering from symptomatic POP (n=1911) were included. All women included in the study suffered from stage 2 POP or higher of either the anterior, middle or posterior compartment, or in combinations. All patients reported sensation of a bulge in the vagina with or without symptoms of urinary, bowel, or sexual dysfunction. Control subjects (n=1995) were matched with POP subjects by age, ethnicity and parity, and who were also hospitalized at our department for benign gynecological diseases such as uterine fibroids, abnormal bleeding, endometriosis, benign adnexal masses, or infertility, and were not pregnant, and had no malignant disease at the same timeframe. All the control patients were examined for the presence of prolapse. The following data were collected: basic demographics, maternal parity, age, height and weight, way of delivery, previous anti-POP operations, and the presence of urinary incontinence. The study population was further divided into two subgroups, based on the menopausal status. The postmenopausal group (n =1271) comprised women who had no regular menstrual cycle for at least 12 months. The premenopausal group (n = 640) comprised healthy fertile women who had regular menstrual cycles.

Diagnosis and classification 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 when patients were positioned in standard lithotomy position. Physicians were utilizing anterior and posterior vaginal retractors, while patients performed Valsalva manoeuvres, in order to reveal the predominant compartment of prolapse. The therapy offered was either conservative treatment with pessary or pelvic reconstructive surgery.

Determination of obesity

The level of obesity was based on the determination of the BMI, which was calculated as the woman's weight (in

kg) divided by the square of their height (in m^2) and was categorized as obese (BMI ≥ 30 kg/m^2), overweight (25 kg/m^2 < BMI < 30 kg/m^2), or normal weight (BMI < 25 kg/m^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 3.906. Continuous measurements are summarized and presented as averages and standard deviation (SD). To determine the predictive factors for POP, multivariate analysis, ordinal logistic regression was used. For the analysis of the differences in the examined factors between the POP and control groups, and for the comparison of the POP pre- and postmenopausal groups, independent sample Student t-test was performed. Statistical significance was set at $p < 0.05$.

RESULTS

Demographic data

Seven hundred and eighty seven patients received conservative treatment for symptomatic POP, and insertion of vaginal pessaries, while altogether 1124 patients were subject of reconstructive pelvic organ surgery surgeries. The medical history revealed that the study population underwent previously 220 abdominal, and 229 vaginal hysterectomies, 843 anterior and 801 posterior vaginal wall repair, 51 laparoscopic ventrofixation, 17 Manchester-Fothergill operations, 59 sacrocolpopexy, and 7 vaginal Mesh implantations. The average age in the study group was 56.13 years ± 13.19 SEM (min: 22, max: 89), respectively the mean age was 50.19 years ± 8.78 SEM (min: 35, max: 70) in the control group. Those who developed POP had a mean parity 2.02 ± 0.95 SEM per patient (min: 0, max: 13), and did not vary significantly from the controls (1.98 ± 0.91 SEM per patient), although the rate of spontaneous vaginal and cesarean delivery significantly altered between the POP (spontaneous vaginal 99.6 %, cesarean 0.4%) and the control groups (spontaneous vaginal 69%, cesarean 31%, p< 0.01). Demographic data of POP and control patients are summarized in Table 1.

TABLE 1. Demographic characteristics of the POP and the control patients.

Demographic characteristic	POP group	Control group	p[a]
Age (years)	56.13 ± 13.19	50.19 ± 8.78	<0.0001
Height (cm)	163.65 ± 6.33	164.59 ± 6.42	<0.0001
Weight (kg)	70.75 ± 17.23	72.71 ± 15.53	<0.0001
BMI (kg/m^2)	26.69 ± 4.45	26.85 ± 5.56	0.146
Parity	2.02 ± 0.95	1.98 ± 0.91	0.123
Vaginal delivery	1.98 ± 0.95	1.38 ± 0.87	0.0023
Cesarean delivery	0.07 ± 0.35	0.59 ± 0.37	0.0012

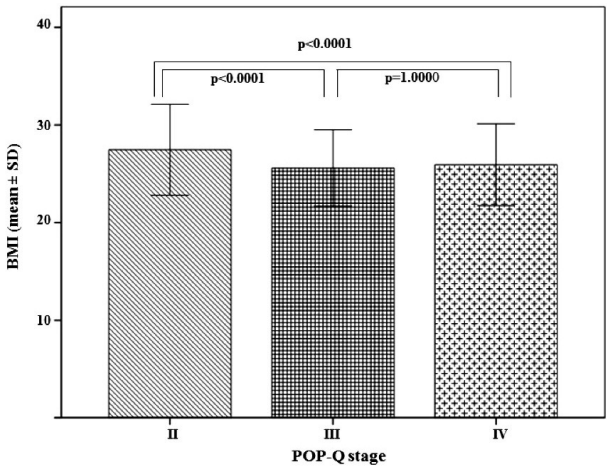


Figure 1. – One way ANOVA analysis, Bonferroni post hoc test comparison of BMI and POP severity, characterized by POP-Q stages (II-IV). The study population did not contain POP-Q I stage patients.

Obesity data

Mean weight and BMI of POP women were 70.44 ± 4.45 kg SEM (min: 44, max: 128) and 26.85 ± 5.56 kg/m^2 SEM (min: 18.19, max: 45.89). The mean weight and BMI of the control women were 72.71 ± 4.89 kg (min: 41, max: 145) and 26.84 ± 5.56 kg/m^2 (min: 22.19, max: 46.61), and we failed to demonstrate statistically significant differences between the groups ($p = 0.146$). Moreover only 21.6 % (413 /1911) of women with POP, and 26.2 % (5219 / 19953) of the control patients were found to be obese. Two third of the study group were postmenopausal women (1271 / 1911, 66.6%), and their BMI varied significantly from the premenopausal patients (640/1911, 33.4 %), with an average BMI of 25.77 ± 0.21 kg/m^2 SEM compared to 27.14 ± 4.30 kg/m^2 SEM (p = 0.042). The multiple comparisons of BMI and POP-Q stages revealed a slight, but significant decrease in BMI with advanced POP-Q stages (Figure 1). The logistic regression and the multivariate analysis demonstrated the significantly strong correlation between age, BMI, and POP, albeit the coherence was found to be negative (Table 2). We failed to demonstrate significant correlation between parity and POP (data not shown).

DISCUSSION

Although POP has been proposed to be a multifactorial disease, with a natural history of slow progression, the relative impact of each predisposing factor is not clear yet. According to the literature, multiparity seems to be the most important risk factor[10-12]. Several studies suggest that increased incidence of POP is associated with higher number of vaginal birth compared to caesarean delivery[10,11,13], which has been confirmed by our findings as well. Other obstetrical risk factors include operative vaginal delivery,

TABLE 2. Regression and multivariate analysis to reveal the predictive factors for POP. Coefficient estimates β and standard error se(β), and corresponding p-value are summarized.

	POP		Univariate analysis			Multivariate analysis		
Variable	Premenopausal (*n*= 640)	Postmenopausal (*n*= 1271)	*β*	SE (*β*)	*p*	*β*	SE (*β*)	*p*
Age (years)	41.00 ± 6.10	63.73 ± 8.35	-0.047	0.004	<0.0001	-0.046	0.004	<0.0001
Parity (n)	2.05 ± 0.99	2.01 ± 0.92	-1.225	1.867	0.512	-0.892	1.894	0.637
BMI (kg/m^2)	25.78 ± 4.60	27.14 ± 4.31	-0.088	0.010	<0.0001	-0.072	0.011	<0.0001

and birth weight[13], while non-obstetrical risk factors includes age[14,15], connective tissue disease, due to decreased ratio of collagen I to collagen III and IV[16], race[17], hysterectomy[18], and increased abdominal pressure. In addition cigarette smoking and chronic obstructive pulmonary disease (COPD) have also been suggested to play role in the development of POP[19].

Obesity might be an important aspect of pelvic organ disorders, since it has been well-documented to have a negative impact on lower urinary tract symptoms (LUTS)[20], moreover it is a well established risk factor for stress urinary incontinence (SUI)[21], and overactive bladder (OAB)[22]. The role of obesity in the development of POP, on the other hand, is till date remains to be uncertain.

Therefore our aim was to investigate obesity as a risk factor for symptomatic stage II or higher POP. Despite we found a statistically significant increase of BMI with age in the study group, we revealed no statistical difference between the POP and the control group weight, height, or BMI. In contrast to our findings, Hendrix et al.[2] found that overweight or obesity was significantly associated with greater severity prolapse in every compartment. However in that study prolapse was measured in the absence of anterior and posterior vaginal retractors or the POPQ standardization. Prolapse was categorized as either present or absent based on visualization of the external genitalia during Valsalva. Washington et al.[23] as well as Fornell et al.[24] found that being overweight or obese was strongly associated with urinary and fecal incontinence but not with symptoms of pelvic prolapse. Several studies suggest that weight loss may be an effective treatment for the management of urinary incontinence[25,26,27]. On the other hand weight loss does not appear to be significantly associated with regression of pelvic organ prolapse[3,28]. Kudish[3] suggests that damage to the pelvic floor related to weight gain might be irreversible. From our point of view, there is a second possibility to consider, namely that overweight and obesity are major risk factors for urinary and anal incontinence but not for pelvic organ prolapse.

In our current study included a relatively high number of ethnically homogenous Caucasian, Eastern-European women where we could not identify obesity as a strong risk factor for POP development, although the multivariate analysis revealed that increased body mass has an impact on the disease severity. The racial homogeneity of our study and population might the limitation of our investigation. Based on our results and clinical observations we do not believe that obesity is a key risk factor for POP. We consider that different pelvic floor disorders have different strong risk factors. As the prevalence of obesity increases, understanding how weight impacts pelvic floor disorders is imperative because body weight is a modifiable risk factor. Understanding the impact of risk factors for pelvic floor disorders is very important to facilitate patient education and counselling. Prospective research evaluating for a causal relationship between obesity and pelvic floor symptoms is essential.

ACKNOWLEDGEMENTS

We thank the medical assistants and nurses working at the Ladypower® Private Clinic, Győr, and at the University of Pecs Clinical Centre, Department of Obstetrics and Gynaecology, Pecs, Hungary for their help and dedicated contributions towards the study and our patients. This work was supported by the GINOP-2.3.2-15-2016-00021 *The use of chip-technology in increasing the effectiveness of human in vitro fertilization* and the EFOP-3.6.1.-16-2016-00004 *Comprehensive Development for Implementing Smart Specialization Strategies at the University of Pécs* grants. We are grateful for Veronika Uszkai MS, and Attila Schrempf for their help in the data collection procedure.

REFERENCES

1. Haylen BT, de Ridder D, Freeman RM et al: An International Urogynecologic Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunctions. Int Urogynecol J Pelvic Floor Dysfunct , 2010, 21: 5.
2. Hendrix SL, Clark A, Nygaard I et al: Pelvic organ prolapse in the Women's Health Initiative: gravity and gravidity. Am J Obstet Gynecol, 2008, 111, 678-85.
3. Kudish BI, Iglesa CB, Sokol RJ et al: Effect of weight change on natural history of pelvic organ prolapse. Obstet Gynecol, 2009, 113, 81-88.
4. Ogden CL, Carroll MD, Kit BK et al. Prevalence of obesity among adults: United States, 2011-2012. NCHS Data Brief. 2013, (131), 1-8.
5. Barness LA, Opitz JM, Gilbert-Barness E. Obesity: genetic, molecular, and environmental aspects. Am J Med Genet A. 2007, 143A (24), 3016-34.
6. World Health Organization. Obesity and Overweight Fact Sheet [Internet]. World Health Organization; 2013 [cited 2013 Mar 15]. Available from: http://www.who.int/mediacentre/factsheets/fs311/en/index.html.
7. Flegal KM, Carroll MD, Kit BK et al. Prevalence of obesity and trends in the distribution of body mass index among US adults, 1999-2010. JAMA. 2012, 307, 491-7.
8. Strategy for Europe on nutrition, overweight and obesity related health issues. Implementation progress report. December 2010. http://ec.europa.eu/health/nutrition_physical_activity/docs/implementation_report_en.pdf
9. Bump RC, Mattiasson A, Bo K et al. The standardization of terminology of female pelvic organ prolapsed and pelvic floor dysfunction. Am. J Obstet Gynecol 1996, 175, 291-20.
10. Pomian A, Lisik W, Kosieradzki M et al. Obesity and Pelvic Floor Disorders: A Review of the Literature. Med Sci Monit. 2016, 22, 1880-6.
11. Rortveit G, Brown JS, Thom DH et al. Symptomatic pelvic organ prolapse: prevalence and risk factors in a population-based, racially diverse cohort. Obstet Gynecol. 2007, 109 (6), 1396-403.
12. Tegerstedt G, Miedel A, Maehle-Schmidt M et al. Obstetric risk factors for symptomatic prolapse: a population-based approach. Am J Obstet Gynecol. 2006, 194 (1), 75-81.
13. Altman D, Falconer C, Cnattingius S et al. Pelvic organ prolapse surgery following hysterectomy on benign indications. Am J Obstet Gynecol. 2008, 198 (5), 572-78.
14. Smith P, Heimer G, Norgren A et al. Steroid hormone receptors in pelvic muscles and ligaments in women. Gynecol Obstet Invest. 1990, 30 (1), 27-30.
15. Smith P, Heimer G, Norgren A et al. Localization of steroid hormone receptors in the pelvic muscles. Eur J Obstet Gynecol Reprod Biol. 1993, 50 (1), 83-5.
16. Alperin M, Moalli PA. Remodeling of vaginal connective tissue in patients with prolapse. Curr Opin Obstet Gynecol. 2006, 18 (5), 544-50. Review.
17. Schaffer JI, Wai CY, Boreham MK. Etiology of pelvic organ prolapse. Clin Obstet Gynecol. 2005, 48 (3), 639-47. Review.
18. Blandon RE, Bharucha AE, Melton LJ 3rd et al. Risk factors for pelvic floor repair after hysterectomy. Obstet Gynecol. 2009, 113 (3), 601-8.
19. Olsen AL, Smith VJ, Bergstrom JO et al. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. Obstet Gynecol. 1997, 89 (4), 501-6.
20. Zhu L, Lang J, Wang H et al. The prevalence of and potential risk factors for female urinary incontinence in Beijing, China. Menopause. 2008, 15 (3), 566-9.
21. Khullar V, Sexton CC, Thompson CL et al. The relationship between BMI and urinary incontinence subgroups: results from EpiLUTS. Neurourol Urodyn. 2014, 33 (4), 392-9.

22. Aalma T, Raimondi M, Souto S et al. Correlation between body mass index and overactive bladder symptoms in premenopausal women. Rev Assoc Med Bras (1992). 2014, 60 (2), 111-7.
23. Washington BB, Erekson EA, Kassis NC et al. The association between obesity and stage II or greater prolapse. Am J Obstet Gynecol. 2010, 202 (5), 503-7.
24. Fornell EU, Wingren G, Kjolhede P. Factors associated with pelvic floor dysfunction with emphasis on urinary and fecal incontinence and genital prolapse: An epidemiological study. Acta Obstet Gynecol Scand, 2004, 83, 383-89.
25. Subak LL, Johnson C, Whitcomb E et al. Does weight loss improve incontinence in morbidly obese women? Int Urogynecol J Pelvic Floor Dysfunc 2002, 13, 40-3.
26. Auwad W, Steggles P, Bombieri L et al. Moderate weight loss in obese women with urinary incontinence: a prospective longitudinal study. Int Urogynecol J Pelvic Floor Dysfunct 2008, 19, 1251-9.
27. Bump RC, Sugerman HJ, Fantl JA et al. Obesity and lower urinary tract function in women: effect of surgically induced weight-loss. Am J Obstet Gynecol 1992, 167, 392-7.
28. Wasserberg N, Petrone P, Haney M et al. Effect of surgically induced weight loss on pelvic floor disorders in morbidly obese women. Ann Surg 2009, 249, 72-6.

Correspondence to:
Balint Dr Farkas
5 Zurna dulo - Pecs 7635 - Hungary
E-mail: dr.balint.farkas@gmail.com

Invited commentaries

The authors compared two large series of patients, with pelvic organ prolapse and without, and concluded there was little difference in outcomes. The BMI in both groups, POP or control, was slightly more than 26 Kg / m^2, up to 25 being normal. We believe the patients should have been defined as 'overweight', not 'obese'. To reach this conclusion we believe the comparison should be the presence of prolapse between a group with obesity (BMI greater than 30) and a normal group (BMI of 25), or perhaps in several subgroups according to the classification: Overweight, Obesity type I, II and III (that is morbidly obese with BMI> 40 kg / m^2). We used such a classification for incontinence when we evaluated patients before and after bariatric surgery[1]. We demonstrated that BMI > 35 kg/m^2 was strongly related to stress urinary incontinence, overactive bladder, severe fecal incontinence, and use of diapers. We endorse the authors' conclusions that obesity is an epidemic and that *"prospective research evaluating for a causal relationship between obesity and pelvic floor symptoms is essential,"* From our perspective, prospective evaluation on the impact of bariatric surgery and weight loss in POP resolution would help determine whether POP is a herniation influenced by intra abdominal pressure, or caused by loose ligaments.

REFERENCE

1. Piñango-Luna S et Al. Bariatric surgery improves pelvic floor disorders, Pelviperineology 2016; 35, 118-123.

SILVIA PIÑANGO-LUNA
General Surgeon - Surgeon Pelvic Floor . CI Service ,Hospital Pérez Carreño , IVSS . Venezuela

Obesity epidemic is worldwide affecting a consistent portion of general population, topping up 40% in US. Severe obesity is associated not only with metabolic comorbidities, such as type 2 diabetes, steatohepatitis, hypertension, dyslipidemia, obstructive sleeve apnea syndrome, but also with a significant impairment on the quality of life (QoL) as far as daily life and activities. Pelvic floor disorders directly impact on the QoL and it is well known that people with BMI above 30 kg/m^2 have a higher prevalence and incidence of fecal and urinary incontinence and sexual dysfunction. Increased intra-abdominal pressures induced by obesity, infact, strain and weaken the supporting structures of different pelvic organs, thus leading to some degree of dysfunction in 90% of patients. Severe obesity can be safely and effectively treated with bariatric surgery (BS), although the penetrance and dissemination of this latter is not yet so extensive, due to insurance coverage and affordability constraints. Although BS is primarily aimed to achieve weight loss and comorbidities resolution, the major trade-off is the amelioration of QoL. This is best perceived by the patient since the early post-operative course, when the common sensation is that of regaining a "true-life". This paper did not show a significant correlation between overweight and "symptomatic pelvic organ prolapse stage 2 or higher", the mean BMI of patients (cohort study and control group) being around 26 kg/m^2, that is in the range of overweight (25-30). On the other hand there is a strong evidence of positive associations between obesity and pelvic organ prolapse and the positive effects of weight loss surgery on pelvic floor disorders. Post BS weight loss improves pelvic floor and ultimately also sexual function, although the latter is also mediated by an increased self-esteem[1,2].

REFERENCES

1. Young N et al. Obesity: how much does it matter for pelvic organ prolapse? Int Urogynecol J 2017 (Epub ahead of print).
2. Lian W et al. Effects of bariatric surgery on pelvic floor disorders in obese women: a meta-analysis. Arch Gynecol Obstet 2017, 296 (2), 181-9.

MIRTO FOLETTO
Head of Bariatric Surgery Program Comprehensive Care and Research Obesity Center, University Hospital, Padova Italy mirto.foletto@unipd.it

Review

The role of the external anal sphincter in the physiology of the pelvic floor

MICHAEL D. LEVIN

Pediatric Surgical Center, 1st Clinical Hospital, Minsk, Belarus
State Geriatric Center, Netanya, Israel

Abstract. Objective: To clarify the physiology of the fecal retention and defecation. *Material & Method:* The comparison of the results of my own X-ray studies with published data on the anal manometry, anatomical dissection and 3D topography was produced. *Results:* Long-term retention of feces was due to tonic contraction of the internal anal sphincter (IAS) and the striated muscles of the pelvic floor including levator ani muscle (LAM), puborectalis muscle (PRM) and the external anal sphincter (EAS). The entrance into the rectum of the next fecal portion increases the rectal pressure, which leads to relaxation of the IAS and to mechanical contraction of the PRM and EAS. At this time, liquid feces and gas penetrate into the upper part of the anal canal, where they are identified. Following this, the rectum relaxes, adapting to this volume. The rectal pressure decreases, which causes contraction of the IAS and relaxation of the PRM and EAS. This anorectal inhibitory reflex can be repeated up to several times per hour. During defecation relaxation of the IAS, PRM occur, as well as deep and subcutaneous portions of the EAS. At the same time, a strong rectal peristalsis pushes the stool through the wide open anal canal. The upper part of the anal canal is opened as a result of the contraction of the LAM. The contraction of the superficial portion of the EAS leads to the opening of the distal part of the anal canal. The wide opening of the anal canal greatly reduces resistance to the stool promotion.
Conclusion: All portions of the EAS have different points of attachment and, therefore, have different functions. In fact, each of them is the separate sphincter.

Abbreviations: IAS – internal anal sphincter; EAS – external anal sphincter; PRM – puborectalis muscle; IAP– intra-abdominal pressure; LAM – levator ani muscle; TP-1 – threshold pressure of the first order, provoking of the anorectal inhibitory reflex; TP-2 - the threshold pressure of the second order, provoking the need of defecation; TP-3 - the threshold pressure of the third order, causing of the defecation reflex.

Keywords: Anorectal physiology; Defecation; Fecal retention; Hypothesis; Rectum; Anal canal

INTRODUCTION

An adequate understanding of anorectal physiology is necessary for the correct diagnosis of pathological processes and the respective correction of them[1]. To date, a large quantity of researches have accumulated in this field, but due to the fact that the authors of different techniques (anatomical, manometer, X-ray, CT, MRI and 3D-topography) do not account for the results obtained using of other techniques, there are significant discrepancies in the description of the physiology of the fecal retention and defecation.

The purpose of this research is to compare different methods to create the acceptable representation of the anatomy and physiology of the anorectal region, which does not contradict reliable scientific evidences. In order not to stray from the path of truth, it is very important to keep in mind the following axioms. 1) Every muscle has a very simple function: when it contracts, its length is shortened. Therefore, it is important to know the two places of the muscle attachment to determine of its function. This implies that the muscle fibers with various attachment places have different functions and therefore they are the different sphincters. 2) Muscle fibers during contraction use ATP, and it should relax to restore capacity to contraction. 3) There are no voids in the tissues of the pelvic floor. If the anal canal during defecation always equally and widely opened, creating a channel in the form cylinder for passage of faces irrespective of their consistency (liquid, solid or soft), it means that tissues have changed configuration[2]. Only muscles can some effect this. If this was only due to changes in the relationship between the peristaltic pressure of the rectum and the tone of the anal canal, the liquid feces (contrast material) would passe through the narrow anal canal. 4) To avoid confusion, it is necessary to adhere to the recognized anatomical designations. Thus, for example, it occurs when Wu called the anal canal of the rectum, and do not divide in the description of the deep and superficial portions of the external anal sphincter (EAS)[3]. 5) At each stage of scientific knowledge there is the gold standard, to which compare the results obtained by other methods. Wu and coworkers in the 3D-topography found no septum between the puborectalis and pubococcygeus, wich separatse these muscles from each other. However, this septum, is described in almost all textbooks[3]. Hence the anatomical dissection, rather than 3D-topography is taken as the gold standard. Applying the most modern equipment, the authors exaggerate its capabilities, leading to inappropriate conclusions.

ANALYSIS OF THE LITERATURE

Fecal retention

In healthy adults the length of the anal canal is approximately 4 cm[4]. This is the high pressure area compared with the pressure in the rectum. It is in constant contraction, with the exception of short-term opening during a bowel movement. At rest the tonic state of the internal anal sphincter (EAS) provides 45% of the total pressure in the anal canal[4]. The IAS is composed of smooth muscle fibers and is the thickened continuation of circular layer of the rectum. The caudal end of the IAS is located at a distance of 8-10 mm from the anal dimple[5]. It is absent in the contraction zone of the subcutaneous portion of the EAS. Thus, the length of the BAC in adults is about 3 cm. Outside the IAS is located a longitudinal smooth muscle layer. The puborectalis muscle (PRM), the deep and superficial portions of the EAS are located outside of longitudinal smooth muscle layer. Based on anatomical studies it was found that the striated muscle of the EAS consists of 3 parts: a subcutaneous, superficial and deep (Figure 1, B)[6,7]. Subcutaneous part is a true circular sphincter. It is separated from the superficial portion of

the fibrous tissue[3]. The superficial portion of the EAS has a U-shape. Posteriorly it is attached to the coccyx through the rising up anococcygeal ligament[8], and then it covers the back and sides of the anal canal and attached (ends) to the perineal body at a considerable distance from the pubis (Fig. 1A).

The deep part of the EAS has a small volume and is located caudal to the PRM. It is located so close to the PRM that some authors consider it to be part of the PRM[3,5].

Here is how is described a 3-D ultrasound picture of the anal canal - "The IAS is seen as a hypoechoic (dark) circular ring in these images…Surrounded by the IAS is a relatively hyperechoic ring-shaped structure of the EAS[5]. Is it that this study cannot be considered a gold standard, if anatomically (histologically) is well established that between the IAS and EAs is a longitudinal layer of smooth muscle? This example shows that modern methods of research that fascinated researchers to dissect the body without damaging it, are inferior in accuracy to anatomical dissection.

All baseline anal pressure profiles showed a peak pressure in the range of 70-80 mmHg at a level of 1.6 cm from the anal verge, which corresponds to the level of the IAS. In addition, there was a hump in the posterior pressure from 2.4 cm to 4 cm corresponding to the PRM[9].

In order to evaluate these muscles in action, the researchers provoked the rectoanal inhibitory reflex, which is caused by stretching of the rectal walls. This reflex is described manometrically by the relaxation pressure or loss of anal canal pressure during rectal balloon distention. During high definition manometry the peak of the residual pressure is at 0.9 cm in the anterior and posterior vectors and an additional hump in the posterior only vector ranging from 2.4 to 4.4 cm, corresponding to the EAS and PRM respectively[9]. The peak pressure of the IAS is seen at a level of 1.6 cm from the anal verge, which corresponds to the peak relaxation pressure. The EAS is the only muscular structure located from 0.5 cm to 1 cm from anal verge[9].

As shown earlier, the penetration of barium into the upper part of the anal canal in front of the tip of enema during barium enema is accompanied by a decrease in anal pressure and when the barium disappears from the anal canal, the pressure recovers to basal level[2].

Combining of the anatomical studies with radiographic and manometric data allows mapping the sphincters apparatus during provocation of the rectoanal inhibitory reflex (Fig. 1). Stretching of the rectal wall causes reflex relaxation of the IAS, whereby the pressure at the top of the anal canal is reduced and the liquid (barium) penetrates into the upper part of the anal canal. Simultaneously, the PRM contraction presses the posterior anal wall to the tip enema[2]. The upper part of the anal canal is shifted forward, causing a decrease of the anorectal angle. The manometric and radiographic indicators of the impact of the PRM coincide with the place and width of coverage of the anal canal (about 1.6 cm). The PRM function corresponds to the anatomical location of the loop and its attachment to the pubic bone on either side of the symphysis pubis. It follows that during the anorectal reflex the PRM not completely covers the lumen of the anal canal. A gas or liquid feces pass into the upper part of the anal canal but a formed feces remains in the rectum (Fig. 1, A).

Despite the fact that the relaxation pressure is determined significantly caudal to the PRM, i.e. virtually at the level of the subcutaneous part of the EAS (1.2 cm from the anal pit), the contrast agent does not penetrate below the PRM border (2.4 cm from the anal verge). This can be explained by the contraction of the circular muscles located caudal to

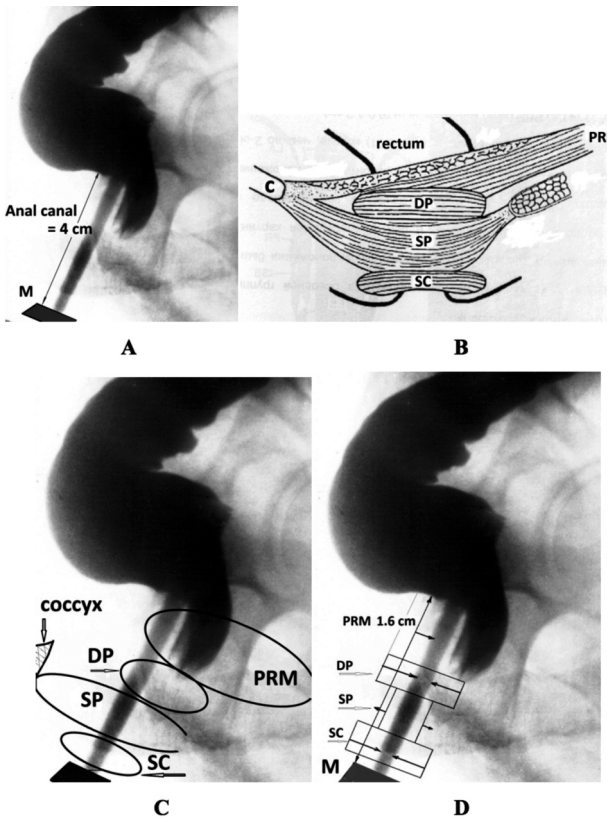


Figure 1. – The combining of the manometric study, anatomical data and X-ray imaging of the anorectal area (lateral view).
A. The contrast marker (M) is located near the anus. The barium was introduced into the rectum, and it is also defined in the tip of the enema. The distance from the rectum to the marker behind the tip is equal to the length of the anal canal (4 cm).The reflex relaxation of the IAS occurred in response to the rectal wall stretching. The barium has penetrated into the upper part of the anal canal in front of the tip only, because the posterior wall at this level is pressed against the tip by the contracted PRM.
B. Scheme of the muscle anatomy around the anal canal: PRM – puborectalis muscle; DP - deep portion of EAS; SP- superficial portion of the EAS; SC - subcutaneous portion of the EAS. From article Raizada V., Mittal R.K.[7].
C. As result of the IAS relaxation and the decreasing pressure at this level, the liquid contrast agent penetrates into the upper part of the anal canal in front of the enema tip. The barium does not penetrate caudal level of the PRM, as a result of the circular muscle contraction. The converging folds are seen over the contraction of the deep portion of the EAS.
D. At the level of the superficial portion of the EAS the peak of relaxation pressure (1.7 cm from the anal dimple) is defined. This U-shaped muscle is attached to the coccyx. During contraction it pulls back and to sides the wall of the posterior semicircular of the IAS , creating a negative pressure inside of anal canal at this level.

the PRM. The location and course of its muscle fibers correspond to the deep portion of the EAS. Although it contracts simultaneously with the PRM, the circular course of the muscle fibers and function are different from the PRM. Consequently, the deep portion of the EAS is a self-sphincter.

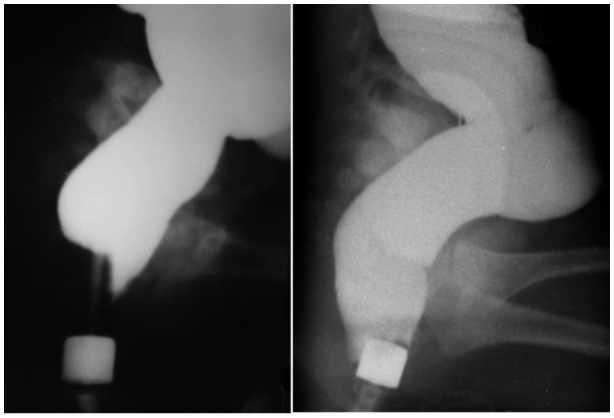
The area of the anal canal relaxation with a peak relaxation pressure between the deep and subcutaneous portions of the EAS is defined. Its location corresponds to the superficial portion of the EAS. It has a U-shaped open anteriorly. Its rear part is attached to the coccyx through the anococcygeal ligament. It adjoins the rear semicircle of the anal canal. All sources only pay attention to the fact that its two branches join the perineal body. Meanwhile, it is obvious

that superficial portion of the EAS surrounds the anal canal back and sides and adjoin to the longitudinal layer. During contraction it pulls the lower part of the anal canal back and to sides, and stretches fan-like to the anal canal wall, which may explain the increase in peak relaxation pressure. Subcutaneous portion of the EAS is separated from the superficial portion by the fibrous layer[3]. It is a typical circular sphincter. All part of EAS, together with PRM contract during the anorectal inhibitory reflex, but as a result of various shapes and places of attachment they perform different functions.

Defecation

Paired levator ani muscles (LAM) is the name of a group of muscles that form the pelvic floor. The PRM is one of them. It is hardly separated from other muscles during anatomical study. On this basis, some authors still believe that all these muscles function the same way. Since it is known that the PRM relaxes during defecation, it is assumed that the rest of the pelvic floor muscles also relax during defecation[10,11,12]. According to them, the tension causes the reflex relaxation of the PRM, IAS and EAS, which leads to the "pelvic floor descending" and to disappearance of the anorectal angle[12]. The term "descending perineum" was first proposed by Parks et al. in describing of the wide opening of the anal canal during defecography[13]. Figure 2 shows two lateral radiographs of the anorectal area in the state of barium retention (A) and during defecation (B), which clearly show the broad opening of the anal canal up to the width of the rectum due to the displacement of the posterior anal canal wall to the spine (Fig. 2).

Skeletal muscles are capable of two types contraction: tonic and mechanical. Tonic prolonged contraction of the LAM, PRM and EAS explained by the postural reflex[13,14]. Each nervous axon has a connection to the muscle fibers scattered throughout the muscle. Therefore, even a small amount of the contracted muscle fibers results in a contraction of the whole muscle. The muscle tone is dependent on the number of fibers participating in the contraction, i.e.



A **B**

Figure 2. – The lateral radiographs of children first year of life during barium enema were made. Metal marker 1.6 cm diameter is located near the anus.
A. Barium penetrated into the upper part of the anal canal in front of the enema tip as a result of the IAS relaxation. The posterior wall at this level is pressed to the enema tip by the contracted PRM. The distal part of the anal canal is blocked by the contracted PRM (anorectal inhibitory reflex).
B. During defecation the posterior wall of the anal canal sharply moved backwards. Diameter of the anal canal corresponds to the diameter of the rectum. The disappearance of the anorectal angle is the result of the opening of the anal canal.

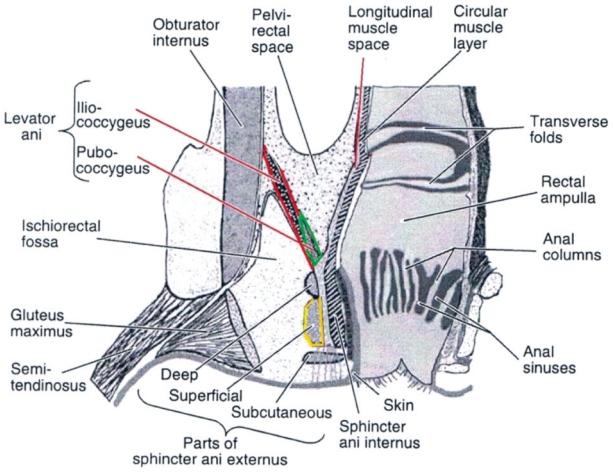


Figure 3. – The scheme of coronary section one of the pelvic sides at the level anal canal. From the article A.E.Bharucha[17].

from the percentage of axons activating muscle contraction. The prolonged, tonic contraction is due to the continuous replacement of the axons activating the different groups of muscle fibers. At different time the different groups of the muscles fibers are contracted. During the contraction of one group, other groups of fibers restore ability to contract[2, 15].

In mechanical contraction all fibers are involved, resulting in a significant shortening of the muscle. However the duration of the muscle contraction is severely limited, typically less than one minute. LAM function (pubococcygeus, iliococcygeus) during their contraction can be judged by their attachment points. It is known that these muscles on the periphery are attached to the pubic and ischial bones, and arcus tendinous, which is a thickened part of the obturator fascia. They surround the anal canal and are closely connected to the deep portion of the EAS side and the rear wall of the anal canal[16,17]. Some authors consider that these muscles are attached to the longitudinal layer of the anal canal. The longitudinal layer of the rectum, crossing anorectal compound is mixed with the fibers of the LAM[18]. In recent years the prevailing opinion is that defecation is accompanied by the LAM contraction, which leads to the disappearance of the anorectal angle and to the descending perineum[2,4,5,9,11]. These two characteristics are not related to description of physiological processes. The disappearance of the anorectal angle is a X-ray symptom. That in the lateral projection is defined as the straightening of the anorectal angle, in three-dimensional image is a wide opening of the anal canal as a result of the movement of its posterior and lateral walls to the place attachment of the peripheral ends of the LAM. The definition "descending perineum" is misleading, since it is known that during defecation pelvic floor muscles do not descend, but are raised[7]. The LAM's have a funnel shape. In the upper part, they are oriented horizontally. Dropping down they are connected to the anal canal in front at an angle of 30 ° to the horizontal line, and on the sides - 45 ° (Figure 3)[3]. Since the upper end of the LAM is fixed to the pelvis, during its contraction the muscles pull the lower end and posterolateral wall of the anal canal - up and back to the pelvis. The impression about the descending perineum is the result of the opening of the anal canal (Fig. 4).

The LAM (iliococcygeus and pubococcygeus) descend to the anal canal at an angle of 45° and to the top of the longitudinal layer of the anal canal are attached.

In recent years, most studies indicate that the main function of the LAM is the opening of the anal canal during

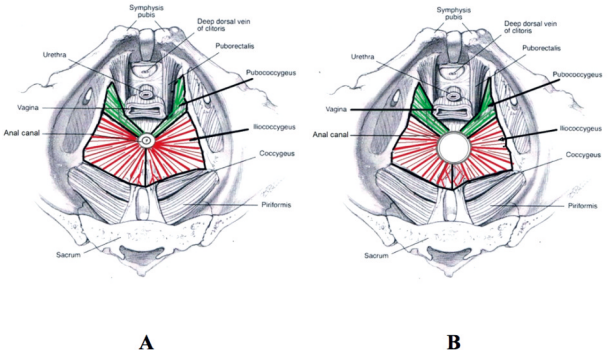


Figure 4. – Scheme cross-section at the level of the deep portion of the EAS. A scheme from the article of A.E.Bharucha was used[17].

defecation[9,17,19-21]. Scheme cross-section at the level of the deep portion of the EAS at the time of the fecal retention and bowel movements is shown in Figure 4.

Li and Guo, using CT defecography showed that "…the levator ani muscle does not lift the anus; its main function is to open the genital hiatus and the anus during defecation"[19]. Palit and co-authors came to the conclusion that plateau levators (which are connected to the posterior surface of the rectum) and longitudinal layer of the anal canal are contracted at the same time during defecation[8,11]. Petros et al. suggest that three striated muscle vectors open the anorectal angle prior to defecation, causing the anorectal luminal diameter to increase to approximately twice its resting size. If the effective diameter of the anus is doubled during defecation, the frictional resistance is reduced by a factor of 8[20,21].

The combination of X-ray pictures with the anatomical location of the muscles shows that the LAM may stretch the back and side walls only at the upper part of the anal canal with an additional force vector upward. In order to stretch the lower part of the anal canal additional force must be applied, which would have balanced the force vector directed upwards. We believe this role can perform only superficial portion of the EAS, given its location and points attachment. It has the shape of «U» and located below the LAM. Its posterior end is attached to the coccyx, and the sleeves tightly cover the lower part of the anal canal behind and on the sides, and their ends are attached to the center of the perineal body. During contraction of the superficial portion of the EAS the posterior and side walls of the anal canal are moving fan-like back and sides, counterbalancing the vector force of the LAM directed upwards. Function diagrams of the anorectal zone during the fecal retention and defecation are shown in Figure 5.

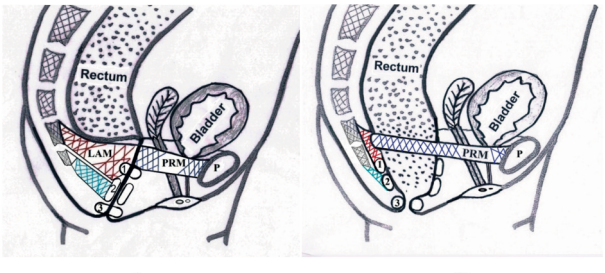


Figure 5. – Function diagrams anorectal area while fecal retention (A) and defecation (B).
LAM - red; PRM - blue; Superficial portion of the EAS - green; P - pubic bone; 1- deep portion of EAS; 2 – superficial portion; 3 – subcutaneous portion of EAS.

CONCLUSION

At rest, the IAS and all striated muscles of the pelvic floor are in a state of tonic contraction. They help to support the pelvic organs and participate in the continuous retention of feces. The pressure in an empty rectum is equal to the intra-abdominal pressure (IAP). During long-term fecal retention, while entering into the rectum of a certain volume of feces, there is a periodic increase in rectal pressure above the IAP. This pressure we called the threshold pressure of the first order (PD-1)[2]. It causes a reflex relaxation of the IAS and contraction of the EAS and PRM (anorectal inhibitory reflex). The PRM pulls forward the upper part of the anal canal. This reduces the anorectal angle. In front, inside the PRM loop the anal pressure decreases as a result of the IAS relaxation.

Between the rectum and anal canal there is a narrow opening through which the gas and liquid feces can penetrate into the upper part of the anal canal. In the mucosa at this level there are sensors that allow to distinguish the liquid from gas. In the presence of gas is enough to strain the abdominal wall to increase rectal pressure and expel gas through the lower part of the closed anal canal. Passing under pressure through a narrow channel gas causes a characteristic sound. When the liquid feces penetrate into the upper part of the anal canal the tone of the EAS increases, which leads to a contraction of the IAS and crowding out of the fluid from the anal canal into the rectum. During anorectal inhibitory reflex the formed stool remain in the rectum due to acute anorectal angle and the narrow holes between the rectum and anal canal. After a few seconds[5-12] the rectum adapts to the new volume of stool and relaxes. The rectal pressure drops up to IAP, resulting in the contraction of the IAS and relaxation of the PRM and EAS. After entering into the rectum of another portion of feces this picture (anorectal inhibitory reflex) is repeated. According to Wu this picture can be observed up to 7 times per hour[3].

During the anorectal inhibitory reflex a gas and liquid does not penetrate into the lower part of the anal canal as result of circular contraction of the deep portion of the EAS. At the same time the contraction of the superficial portion of the EAS pulls the lower part of the anal canal backward, helping to reduce anorectal angle and increases relaxation pressure in the anal canal at this level, which also contribute to the retention of feces. The contraction of the circular fibers of the subcutaneous portions of the EAS increases the fecal retention.

When the volume of stool in the rectum reaches a certain value the rectal pressure rises from the TP-1 to the threshold pressure of the second order (PD-2), in which a need for a bowel movement appears.

If this need is does not coincide with the possibility of its implementation, the rectum continues to relax, to adapt to the increasing volume of feces, but the TP-2 periodically reminds of necessity of bowel evacuation. When the need for a bowel movement coincides with the possibility of its implementation, a straining of the abdominal wall allows to increase the rectal pressure from TP-2 to TP-3. At the rectal pressure PD-3 the reflex defecation takes place: a strong peristaltic wave of the rectum expels stool through the open anal canal. It is accompanied by relaxation of the IAS, PRM, as well as the deep and subcutaneous portions of the EAS. The LAM (pubococcygeus and iliococcygeus), as well as the superficial portion of the EAS are contracted, creating a channel for facilitating the passage of stool. Circular fiber of the subcutaneous portion of the EAS located outside the IAS relax during defecation (but do not stretched), skipping the formed stool. Gas and liquid feces leave outside by a narrow stream, and soft stool passes in form a ribbon, the width of which is proportional to the density of feces.

Any of the pressure levels depend not only on the volume of feces, but also from the tone of the rectum. For example, with diarrhea, the rectal tone is higher than usual, and even small amount of feces causes a pressure rise from TP-2 up to TP-3.

Based on the combination of the results of anatomical studies, manometric data, and X-ray picture in the different phases of stool retention and during defecation, we came to the conclusion that the PRM and each of the three portions of the EAS have different functions and are actually different sphincters.

REFERENCES

1. Van Koughnett JA, da Silva G. Anorectal physiology and testing. Gastroenterol Clin North Am. 2013; 42 (4): 713-28. doi: 10.1016/j.gtc.2013.08.001. Epub 2013 Oct 10.
2. Levin MD, Troyan VV. Anatomy and physiology of anorectal zone. Hypothesis of continence and defecation. Novosti Chirurgii (Vitebsk) 2009; 2: 105-18.
3. Wu Y, Dabhoiwala NF, Hagoort J et al. Correction: 3D Topography of the Young Adult Anal Sphincter Complex Reconstructed from Undeformed Serial Anatomical Sections. PLoS One. 2015 Oct 9; 10 (10): e0140736. doi: 10.1371/journal.pone.0140736. eCollection 2015.
4. Bharucha AE, Rao SS. An update on anorectal disorders for gastroenterologists. Gastroenterology. 2014; 146 (1): 37-45.e2. doi: 10.1053/j.gastro.2013.10.062. Epub 2013 Nov 6.
5. Mittal RK, Bhargava V, Sheean G et al. Purse-string morphology of external anal sphincter revealed by novel imaging techniques. Am J Physiol Gastrointest Liver Physiol. 2014; 306 (6): G505-14. doi: 10.1152/ajpgi.00338.2013.
6. Shafik A. A new concept of the anatomy of the anal sphincter mechanism and the physiology of defecation. The external anal sphincter: a triple-loop system. Invest Urol 1975; 12: 412-419. [PubMed: 1112669].
7. Raizada V, Mittal RK. Pelvic floor anatomy and applied physiology. Gastroenterol Clin North Am. 2008 Sep; 37 (3): 493-509, vii. doi: 10.1016/j.gtc.2008.06.003.
8. Jin ZW, Hata E, Jin Y et al. The anococcygeal ligaments: Cadaveric study with application to our understanding of incontinence in the elderly. Clin Anat. 2015; 28 (8): 1039-47. doi: 10.1002/ca.22629. Epub 2015 Oct 13.
9. Cheeney G, Nguyen M, Valestin J, Rao SS. Topographic and manometric characterization of the recto-anal inhibitory reflex. Neurogastroenterol Motil. 2012; 24 (3): e147-54. doi: 10.1111/j.1365-2982.2011.01857.x. Epub 2012 Jan 11.
10. MacCrea GL, Miaskovwski C, Stotts N et al. Pathophysiology of constipation in older adult. World J Gastroenterol 2008; 14 (17): 2631-8.
11. Palit S, Lunniss PJ, Scott SM. The physiology of human defecation. Dig Dis Sci. 2012; 57 (6): 1445-64. doi: 10.1007/s10620-012-2071-1. Epub 2012 Feb 26
12. Shelton AA[1], Welto nML.The pelvic floorin health and disease. West J Med. 1997; 167 (2): 90-8.
13. Parks AG, Porter NH, Hardcastle J. The syndrome of the descending perineum. Proc R Soc Med. 1966; 59 (6): 477-82.
14. Porter NH. A physiological study of the pelvic floor in rectal prolapse. Ann R Coll Surg Engl. 1962; 31: 379-404.
15. Histology. By edition A.W. Ham and D.H. Cormack Eighth Edition. 1979. JB. Lippincoft Company.
16. Coloproctology and pelvic floor. Pathophysiology and management. MM. Henry, M. Swash. Butterworths. 1985.- Moscow, Medicina 1988. p. 155-156.
17. Bharucha AE. Pelvic floor: anatomy and function. Neurogastroenterol Motil. 2006; 18, 507-519.
18. Courtney H. Anatomy of the pelvic diaphragm and anorectal musculature as related to sphincter preservation in anorectal surgery. Am J Surg. 1950; 79 (1): 155-73, illust.
19. Li D, Guo M. Morphology of the levator ani muscle. Dis Colon Rectum. 2007; 50 (11): 1831-9.
20. Petros P, Swash M, Bush M, Fernandez M et al. Defecation 1: Testing a hypothesis for pelvic striated musclea ction to open the anorectum. Tech Coloproctol. 2012; 16 (6): 437-43.
21. Bush M, Petros P, Swash M, Fernandez M, Gunnemann A. Defecation 2: Internal anorectal resistance is a critical factor in defecatory disorders. Tech Coloproctol. 2012; 16 (6): 445-50. doi: 10.1007/s10151-012-0860-3. Epub 2012 Jul 24.

Correspondence to:

Levin M, MD, PhD, DSc, radiologist.
Amnonve-Tamar, 1/2, Netanya, 42202, Israel.
Tel: 972-53-8281393 Fax: 972-9-8630151.
nivel70@hotmail.com
http://orcid.org/0000-0001-7830-1944
http://www.anorectalmalformations.com

Editorial commentary

The great Spanish anatomist /urologist Salvador Gil-Vernet (1892-1987), stated that it was not sufficient to describe an anatomical structure. He said that an answer was required to the question of *"what is it for"*[1].

Even in the highest rating journals, the focus today seems concentrated on RCTs and Metanalyses. These are worthy but unoriginal endeavours. Innovative science asks the question "What is it for?", an important question, for without original thought, there are no RCTs and no Metanalyses. Throughout its 10 year history, Pelviperineology Journal has gone to great lengths to promote original thought. This paper by Michael Levin is one such example.

Michael Levin is a radiologist who goes beyond reading of images to ask, "what is it for". A feature of Michael's research method is the use of classic deductive logic to test his hypotheses for truth or falsity.

His reasoning on the role of the 3 external anal sphincters is a fine example of deductive logic. His emphasis on the role of internal anal sphincter (IAS) in continence control does not fit with my experience as a surgeon which considers the role of IAS is to seal not close the anus. I refer interested readers to the 2008 Musculoelastic Theory 2. Study No1 found that directional muscle forces activate anorectal continence and defecation in the female. Study No5 found only 39% of 80 fecally incontinent patients had even partial IAS damage. Four separate surgical studies (Studies 9-12), demonstrated fecal incontinence and obstructive defecation were (variously) cured by repair of incompetent pubourethral and uterosacral ligaments[2].

REFERENCES

1. Gil-Vernet JM, Salvador Gil-Vernet, a pioneer in Urological Anatomy, Chaper in De Historia Urologiae Europeaeae Vol 24 2017, Eds. Van Kerrebroecke P, Schultheiss D, EAU History Office European Association of Urology, 13-43.
2. Petros PE & Swash M A Musculoelastic Theory of Anorectal Function and Dysfunction in the Female. J Pelviperineology, 2008, 89-121.

PETER PETROS
Editor Pelviperineology
pp@kvinno.com

Original article

Efficacy of vaginal and laparoscopic sacrocolpopexy (VLSCP), a dual approach to utero-vaginal prolapse, compared with laparoscopic sacrocolpopexy (LSCP) alone

ARIEL AHARONI[1], YAAKOV MAMET[1], AND ABRAHAM AGRANAT[1]

[1] *Laniado Hospital, Natanya, Israel*

Abstract: Sacrocolpopexy is one of the most successful operations for correcting utero-vaginal prolapse. It can be done laparoscopically, but this is time-consuming and requires experienced laparoscopists. In 2011, we introduced a dual vaginal-laparoscopic technique (VLSCP), which combined the ease of vaginal suturing with the advantages of laparoscopic sacrocolpopexy (LSCP). We, now, evaluate the efficacy of this dual approach in comparison to the primary laparoscopic operation. We compared the efficacy and short-term results of 61 patients who had the dual operation to that of 28 classical LSCP patients. The study was retrospective and included analysis of patients' records.We examined 11 of the 28 LSCP patients (39%), 3-7 years after the operation, and 35 of the 61 VLSCP patients (57%), 1-5 years after the operation. The short-term results of the dual operation showed that it was faster, without compromising the wellbeing of the patients. The long-term results for the available patients showed that the subjective cure rate was 73% for the LSCP patients and 88% for the VLSCP dual operation. However, we observed some degree of vaginal prolapse in 82% of the LSCP operations, mainly cystocele or rectocele grade 1 or 2, but only 31% of the VLSCP patients had such prolapse. There were no mesh erosions or exposures in any of the groups. The dual operation combined the ease and accuracy of a vaginal operation with the benefits to the patient from a laparoscopic approach. It also enabled a convenient approach to add vaginal procedures that improved the surgical results, or complied with the patients' wishes.

Keywords: Dual-operation; Laparoscopic Sacrocolpopexy; Sacrocolpopexy; Sacrocolpouteropexy; Utero-vaginal prolapse.

INTRODUCTION

Uterine prolapse with vaginal wall prolapse has been classically treated by vaginal hysterectomy and colporrhaphy. An alternative classical approach has been a sacrocolpopexy or sacrocolpouteropexy that required the abdominal route. The success of the abdominal operations in alleviating the vaginal prolapse is mostly of longer duration with lower rate of recurrence[1,2], but an abdominal operation usually carries longer hospitalization and recovery time, and may result in more severe complications. In the last decades, it was shown that this operation can be done laparoscopically[3], but it is time consuming and requires highly experienced laparoscopists[4]. In 2010 we introduced a modification to the laparoscopic route (VLSCP), that consisted of a dual operation, vaginal and laparoscopic, and produced the benefits of a laparoscopic procedure together with the ease of a vaginal approach[5]. In the present study, we compare the efficacy of this dual approach to that obtained from the pure laparoscopic LSCP operation.

MATERIAL AND METHODS

From April 2009 to March 2016, 61 cases of severe vaginal prolapse, grade 3-4 of the POP-Q system, were treated by the dual approach, 40 with third degree and 21 with fourth degree prolapse. At first, we recruited only candidates for vaginal hysterectomy or patients who already had hysterectomy and had developed vault prolapse. In later stages, we used the dual approach also for patients who opted for uterine preservation. In all, 45 patients had presented with uterine prolapse and 16 had a previous hysterectomy and presented with vault prolapse. Of the 45 patients with uterine prolapse, 26 wanted to have vaginal hysterectomy at the time of the operation, and the other 19 opted for uterine elevation at the VLSCP. Fourteen patients were less than 50 years old, 21 were of the age-group 51 to 60, 17 were of the age-group 61 to 70 and 9 were 71 or older.

Operative Technique: The first part of the dual operation started with a vaginal approach. In cases of concomitant vaginal hysterectomy, after the uterus was removed, a 15x2 cm Y shaped polypropylene mesh was introduced. The Y shaped mesh was prepared by stitching a 5x2 cm additional mesh to the main 15x2 band, five cm from its end. The Y shaped mesh was sutured with permanent sutures to the inner surface of the anterior and posterior vaginal wall at the apex of the vagina, and the cuff was closed with absorbable sutures, leaving the mesh inside the pelvis. Patients who had a previous hysterectomy underwent a similar procedure after the opening of the Douglas' pouch. Those who preferred retaining the uterus, also, had their Douglas' cul-de-sac opened. A 15x2 cm single polypropylene tape was then sewn to the inner surface of the posterior vaginal cuff and to the posterior part of the cervix with permanent sutures. As before, the vaginal fornix was closed with absorbable sutures, leaving the tape inside the pelvis.

After the vaginal cuff was closed, the fornix (or the cervix, in cases of uterine preservation) was pushed towards the abdominal cavity to demonstrate if any part of the prolapsed vagina had remained. An existing cystocele or rectocele still present after the vaginal apex was pushed to its correct anatomical position was repaired. In cases of a wide genital hiatus a perineorrhaphy was performed and the levator-ani muscles were approximated. In three cases of VLSCP with uterine elevation, an elongated cervix was shortened. Twenty-one patients had a preoperative diagnosis of GSI, and a trans-obturator slingplasty was added.

The second part of the dual operation consisted of a laparoscopic retrieval of the free end of the mesh that was previously inserted vaginally, and then attaching it to the sacral promontory by three tuckers, after incising its peritoneal sheath. Placement of the mesh was tension free but required pushing the vaginal vault to its appropriate place when inserting the tuckers. The upper part of the mesh was then covered with peritoneum by one or two sutures.

Data from the records of the VLSCP operations were compared with those of 28 pure laparoscopic operations (LSCP) that were done during the years 2007 to 2009, by the same surgeon, using a technique described in 2004[6]. Twenty-two of the LSCP operations were performed on patients who had a previous hysterectomy. A Y shaped mesh was sutured to the upper part of the vagina after it was separated from the bladder anteriorly, and from the peritoneal

sheath posteriorly. The other six patients, who wanted to elevate their prolapsed uterus, had a one strand mesh sutured to the cervix and posterior vaginal fornix. In 5 cases (18%), a vaginal repair was added, one cystocele repair and four procedures for rectocele repair with perineorrhaphy.

All the operations, in both groups, were done by the same surgeon, and all the patients were examined 4-6 weeks after surgery for evaluation. Comparison included length of operation time, number of hospitalization days, and short-term complications. The study utilized retrospective analysis of patients' records, and therefore did not need institutional review board approval. We, also, called the patients and encouraged them to come for a follow-up examination. We managed to examine 11 of the 28 LSCP patients (39%), 3-7 years after the operation, and 35 of the 61 VLSCP patients (57%), 1-5 years after the operation.

RESULTS

The average operation time for all VLSCP cases was 84 min (54 to 122 min). When the operation included vaginal hysterectomy, 26 patients (43%), it took 103 min on average to perform. The 16 cases that had a previous hysterectomy, and presented with vault prolapse, had a mean operation time of 70 min. Altogether, 54 patients (89%) had some vaginal repair as well, including hysterectomy – 26, anterior repair – 22, posterior repair – 21, perineorrhaphy – 38, and TOT - 21.

The average operating time of the 28 LSCP cases was 92 min, although only 18% of them had vaginal repair and none had hysterectomy.

The two groups of patients experienced a recovery period like that of vaginal hysterectomy, and they were usually discharged after 2 days.

Two patients in the VLSCP group, and one who had LSCP, experienced postoperative fever. They were treated successfully by intravenous antibiotics for five days, and they recovered with no sequelae. One patient had a transient urinary retention that was relieved spontaneously after 4 days. One patient after LSCP with a retained enlarged uterus had a sudden return of the prolapse on coughing, three weeks after discharge. She was re-operated and at laparoscopy she was diagnosed with a detachment of the sacral end of the mesh. It was reinstated on the sacral promontory and was fixed by both tuckers and sutures.

For the long term results we examined the available patients and found that the subjective cure rate was 73% (8/11) for the LSCP patients and 88% (31/35) for the VLSCP dual operation. However, we observed some degree of vaginal prolapse in 82% (9/11) of the LSCP patients, mainly cystocele or rectocele grade 1 or 2, but only 31% (11/35) of the VLSCP patients had such prolapse. There were no mesh erosions or exposures in any of the groups.

DISCUSSION

We found several advantages to the dual operation: it proved to be faster than its pure laparoscopic counterpart, even though it included some cystocele or rectocele repair more often.

The reason that these additional procedures were more common in the dual approach, was probably because working vaginally, the need for vaginal wall repair was more obvious than in the preoperative assessment that characterized the pure laparoscopic operation. Once the vaginal vault was placed at its proper position, most of the vaginal prolapse was eliminated. However, due to a frequent asymmetry of the prolapsed vaginal walls, either a cystocele or a rectocele usually remained, and therefore was corrected. The pure laparoscopic approach involved less vaginal procedures, and it may imply a partial correction in some of the cases.

Furthermore, the sutures in the dual operation were placed directly, and therefore, not only faster, but also more accurately than by the laparoscopic route. They gave a better hold to the vaginal vault and, a better prolapse reduction. We think that both the exactness of the stitches' placement and the precise vaginal correction, propelled the lower incidence of residual vaginal prolapse, that was observed on follow-up. We can also speculate that the direct suturing may reduce overstretching of the vagina, and therefore have a beneficial effect on difficult defecation[7], a not uncommon consequence of these operations[8].

Our main concern at the start of the dual operation was the risk of an ascending contamination from the vagina, causing graft infection. However, under standard prophylactic antibiotics that all our patients received, IV Cephradine 1g or IV Cefazolin 2g, we had no mesh infection in any of our patients.

Lately, robotic surgery has improved the accuracy and ease of suturing, and has become widely used in prolapse operations. Nevertheless, the lengthy time for the initiation of the robotic operations, and their higher cost, still put the dual operation at an advantage.

CONCLUSION

The dual operation combines the advantages of a vaginal operation with the benefits to the patient from a laparoscopic approach.

It allows easy and accurate suturing of the mesh, a procedure that is harder, and lengthier, at laparoscopy. It, also, enables a convenient approach to add vaginal procedures that improve the surgical results, or comply with the patients' wishes. However, more cases and a longer follow-up are obviously needed to strengthen this conclusion.

REFERENCES

1. Maher C, Feiner B, Baessler K, Schmid C. Surgical management of pelvic organ prolapse in women (review). Cochrane Database Syst Rev. 2013, Apr 30, 4.
2. Barranger E, Fritel X, Pigne A. Abdominal sacrohysteropexy in young women with uterovaginal prolapse: Long-term follow-up. Am J Obstet Gynecol 2003, 189, 1245-50.
3. Higgs PJ, Chua HL, Smith AR. Long term review of laparoscopic sacrocolpopexy. BJOG. 2005 Aug, 112 (8), 1134-8.
4. Gabriel B, Nassif J, Barata S, Wattiez A. Twenty years of laparoscopic sacrocolpopexy: where are we now? Int Urogynecol J. 2011, 22, 1165-1169.
5. Aharoni A, Mamet Y, Agranat A. A Dual approach, vaginal and laparoscopic, to uterine prolapse. ICS 2011 Abstracts, Glasgow; Abstract no' 824.
6. Sundaram CP, Venkatesh R, Landman J, Klutke CG. Laparoscopic sacrocolpopexy for the correction of vaginal vault prolapse. J. Endourol 2004, 18, 620-4.
7. Petros P, Swash M. Sacrocolpopexy may cause difficult defecation by inhibiting the external opening out mechanism (let). Int Urogynecol J 2011, 22, 255.
8. Forsgren C, Zetterstrom J, Zhang A, Iliadou A, Lopez A, Altman D. Anal incontinence and bowel dysfunction after sacrocolpopexy for vaginal vault prolapse. Int Urogynecol J 2010, 21, 1079-84.

Correspondence to:
A. AHARONI
Laniado Hospital, Natanya 42150, Israel,
Tel. +972-52-8702375, Fax. +972-4-8211261
Email: ari1010@yahoo.com

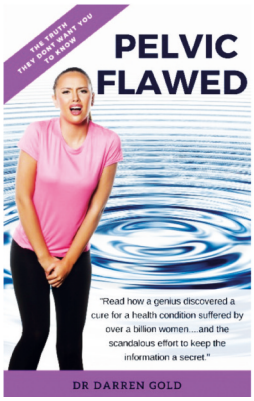
Book review

"Pelvic Flawed" by Darren Gold

SHARREN VANI BARDETTA

Macquarie University, Sydney, Australia

Keywords: Pelvic floor; Incontinence; Pelvic pain; Integral Theory; TFS.



This book, Pelvic Flawed (on Kindle, Amazon.com) is a book for women. I am not a doctor, so the perspectives of my comments are those of a woman reader. Yet the story it tells is deeply embedded in medicine and science, how major discoveries are resisted, often viciously by existing "experts". Dr Gold likens the story of Professor Petros and the Integral Theory to that of Semmelweis and Copernicus. The former was pilloried for suggesting that dirty hands were the cause of the high mortality rates in childbirth, the latter for daring to suggest that the earth circled the sun. Though technical in some parts, the book is a page-turner.

In Pelvic Flawed, Dr Darren Gold discusses the profound impact of the Integral Theory on many pelvic floor problems (including incontinence) which have not been considered curable. This impact extends from the cure of chronic pelvic pain, inability to control the bladder and bowel to Africa, where the successful application of the theory by Dr Andrew Browning is beginning to revolutionize the treatment of incontinence following successful fistula repair. This fundamental knowledge, so important to an ageing society full of incontinent women remained unknown until Professor Peter Petros' revolutionary discovery 25 years ago. It is explained clearly in the book (page 42).

Dr Gold's aim seems twofold

1. Primarily, to tell the story of a major discovery which is being suppressed by a small group of self-interested but influential doctors.

2. To educate and empower women with the knowledge to decide a course of treatment for pelvic floor problems which are curable (contrary to the current belief held by many doctors). He does this by coherently explaining the Integral Theory, a method that to date has been rejected and maligned by mainstream medicine. Yet this theory is disarmingly simple: looseness in the pelvic ligaments is the cause of symptoms and prolapses and can be cured by repair with small strips of tape. The ligaments appear to be the missing link that has eluded the profession for decades.

Dr Gold draws on examples of how its application has led to a successful surgical operation that restores the ligaments to their correct function. His inclusion of Sunny's story, written in her own words, is an excellent example of how a life of pain and suffering can be changed literally overnight by the correct application of the Integral Theory by doctors who have the necessary knowledge and skills. Sunny describes her cure as "like turning on a light switch" (127)

Initially, I was overwhelmed with the information about the muscles and ligaments including the long technical names but encouraged by Dr Gold's reminders that there was indeed a purpose to understanding how they worked, I kept reading. Surprisingly, I did understand more than I realised about the way my pelvic floor works when ligaments and muscles function normally and the multiplicity of problems which ensue should they be damaged and unable to provide the support required. His explanation about the structural importance of the uterus made clear why a hysterectomy does not cure incontinence issues permanently and should be avoided at all costs. There is no doubt that the analogies Dr Gold gives and the simple illustrations he includes to demonstrate different concepts are most effective in coherently passing on this information (122).

Dr Gold addresses the reasons why this 'tried and proven' surgical cure is not readily available to women who would benefit from this operation. His book's byline is 'the truth they don't want you to know'. Dr Gold reveals why there has been a concerted effort on the part of specific organisations and powerful members of the medical fraternity with vested interests to vilify and ostracise the inventor, Professor Peter Petros and his revolutionary operation and exposes the efforts of the TGA to ban the material required to perform the operation (92). The TGA, like every government body, relies on the advice of experts from relevant Colleges. Despite that the TFS had no safety issue, the TFS was removed from the approved list by the TGA, apparently on faulty advice from the TGA "Expert Advisory Committee on Mesh".

To substantiate his claims, Dr Gold provides relevant, comprehensive documentation and correspondence. His reader-friendly detailed explanations enable readers to grasp the most salient points of the evidence, which because of legal and medical terminology, otherwise may be difficult to understand (41).

One specific question that kept coming to mind is why doctors with all their specialised training and knowledge do not know about the Integral Theory system. However, Dr Gold explains how specialists approach their area of expertise and that unless doctors look at the body holistically and work collaboratively they may miss the correct reason for the pelvic area problem (60).

If the description of how the ligaments and muscles worked was a challenge to keep reading, the description of the actions of the government regulatory body, the TGA, was even more of a challenge. Patience in this section is most rewarding, for, on reflection, this part is the very soul of the book. It is here that the moral corruption surrounding the Integral Theory paradigm is most evident.

After reading this book I was left considering three possibilities, none of which seem acceptable; that doctors are ignorant of the cure because they do not know how the ligaments and muscles of the pelvic floor work; they know about the 'curable method' but are too busy or disinterested to be retrained, or they know that incontinence is curable but intentionally suppress this knowledge! (64)

The message from Dr Gold is very clear. Armed with this knowledge and evidence of the surgical cure for pelvic floor problems, women can now be proactive. He encourages women to overcome two important taboos: firstly, tell their doctor that there is a cure for pelvic floor problems (because the doctor may not know about it) and secondly suggest a treatment (which the doctor may not agree with). A thoroughly informative, interesting and essential read for any woman suffering incontinence problems and indeed the doctors who care for them (89).

Original article

An assessment of the functional outcome and quality of life before and after trans-obturator tape surgery for stress urinary incontinence

ANDREAS CHRYSOSTOMOU, HAYLEY JACOBSON, MARIA CHRYSOSTOMOU

University of the Witwatersrand - Charlotte Maxeke Academic Johannesburg Hospital, South Africa

Abstract: Introduction and hypothesis. The study aims to evaluate the functional outcome of Trans-Obturator Tape (TOT) in the management of female Stress Urinary Incontinence (SUI) and its impact on patients' quality of life (QOL) and symptom change by using the King's Health Questionnaire (KHQ) pre- and post-operatively. *Methods*. Seventy-six female patients with SUI underwent a TOT operation, which used the outside-in technique. A prospective cohort analysis was conducted on 63 of the women with pure SUI who completed the KHQ before and after the TOT, at a 6-24 month interval post-operatively. The study was performed at the Charlotte Maxeke Academic Johannesburg Hospital in South Africa, from 1 January 2010 to 1 June 2013. *Results*. The mean follow up was 18 months. Thirteen out of 63 patients with pure SUI, after answering positively to the presence of urgency and/or urge symptoms, were placed into a separate group, SUI with the sensation of urgency. There was a general improvement in all areas of KHQ quality of life in both groups of patients postoperatively. Improvement in QOL for SUI (n=50) for both the SUI and the sensation of urgency (n=13) groups were 80% and 92%, respectively. Improvement in stress symptoms score for the SUI group was 91%, while a 100% improvement was noted in the urgency group. There were no cases of bladder perforation, urethral injury, or post-operative urinary retention. Post-operative complications during follow-up included one sling failure, two *de novo* Detrusor Instability (DI), two incidences of groin/thigh pain, and one urinary infection necessitating intravenous treatment. *Conclusion*. The TOT outside-in procedure is a safe and effective procedure in treating SUI, and conclusively improves the quality of life for women with this condition. The King's Health Questionnaire is an easy and reliable instrument to assess symptoms of incontinence and the quality of life.

Keywords: Urinary stress Incontinence; Quality of life; Trans Obturator Tape; KHQ.

INTRODUCTION

Stress urinary incontinence (SUI) may be defined as the involuntary leakage of urine on effort, exertion or coughing without a rise in detrusor pressure[1]. It is a physiologically, emotionally, and physically devastating condition and can adversely affect a woman's quality of life. SUI is a social and hygienic problem that negatively affects multiple aspects of a woman's life, such as interpersonal relationships, social interaction, careers, health, and psychological well-being[2]. It is estimated that SUI affects up to one-third of women older than 18 years of age with a median age of 45 years[3]. Over the last twenty years, the procedure of urethral suspension using mid-urethral slings has become the most common form of surgery for the treatment of female stress urinary incontinence.

In 2001 Delorme described the Trans-Obturator Tape (TOT) as a mid-urethral sling for the surgical treatment of SUI[4]. This is a minimally invasive procedure, termed "outside-in," in which the tape is inserted underneath the middle of the urethra between the two obturator foramina. TOT has almost replaced the Tension-free Vaginal Tape (TVT), which was introduced by Ulmsten in 1995[5], as it is safer due to the minimal risk of entry into the retro-pubic space[4]. The TOT has a low risk of bladder injuries, vascular injuries and post-operative voiding difficulties[6, 7, 8, 9] as compared with TVT. Although cystoscopy is mandatory with a TVT, it is not always recommended for the TOT technique[10, 11].

The TOT approach has been found to have high success rates, with an objective and subjective cure rate of 90% and 97%, respectively, as well as a low morbidity rate[11, 12].

Quality of life (QOL), on the other hand, is more difficult to quantify, as it lacks a defined progression or biochemical measure. However, the success of a treatment cannot be determined based on the objective findings alone; the QOL of the patient in question must also be taken into account. Moreover, despite the fact that QOL is subjective, clinical parameters have shown to be in keeping with these subjective findings[2]. Since the King's Health Questionnaire (KHQ) is a well-validated, disease specific questionnaire, it was the tool utilised to measure the outcome and the post-operative QOL in the 63 patients treated with TOT surgery from January 2010 to December 2012 in the Uro-gynaecology clinic at the University of the Witwatersrand.

MATERIALS AND METHODS

The study was conducted in a tertiary uro-gynaecology unit in Johannesburg, South Africa, with the approval of the Human Research Ethics Committee of the University of the Witwatersrand. All women who underwent a TOT procedure in the unit from January 2010 to December 2012 were included in the study. These study participants were women with SUI, where the diagnosis of SUI was based on subjective complaints of involuntary leakage of urine on effort, sneezing or coughing without symptoms, suggesting overactive bladder (as recommended by ICS[1]).

Objective bedside investigations included a cough test (performed in the lithotomy or standing position with a comfortably filled bladder), residual volume, and urine dipstick to exclude infection. Uro-dynamic studies (UDS) were not systematically performed in patients with pure SUI following a history, clinical, and bedside investigations, but without exception was mandatory for those patients who were presented with overactive bladder (OAB) symptoms. The surgical technique was as described by Delorme in 2004[4].

Postoperative evaluations as per unit protocol were scheduled at 6 weeks, 6 months, 1 year, and annually thereafter. Evaluations included a cough stress test, a vaginal examination, and residual volume. If a patient presented with OAB symptoms during follow-up, UDS were performed. A 24-hour pad test was not performed. Patients unable to present at the clinic were contacted telephonically to assess subjective cure. Patients were contacted by a qualified nurse working in the uro-gynaecology clinic and asked if

symptoms were present; however, the patients were not subjected to a formal questionnaire. All patients who reported dissatisfaction with the procedure or on-going symptoms were asked to return to the uro-gynaecology clinic for further assessment.

Patients were considered to be objectively cured if they did not demonstrate SUI during the stress provocation test (cough test) and were deemed not to have urinary retention if a residual volume of less than 100 ml was recorded. Tape erosion, *de novo* Detrusor Instability (DI), groin or thigh pain were considered as a failure. Subjective success rates were assessed through the use of the KHQ before and after the TOT procedure.

A prospective cohort analysis was conducted on 63 women with pure SUI who completed the KHQ before and after the TOT procedure at 6-24 months. The study was approved by the ethics committee at the Witwatersrand University.

Inclusion criteria were pure SUI, and women with both SUI and sensation of urgency. The last group of patients were initially categorized as SUI by the unit doctors based on the initial workup (pelvic examination, demonstrating a positive cough test, and excluding urinary tract infection). However, after completion of the preoperative questionnaire on admission, these patients had significant SUI but also answered positively to both the presence of sensation of urgency and urge urinary incontinence questions. These patients were included in the study and analyzed separately because these symptoms were only elicited after answering the questionnaire. The questionnaire was done on admission so it was not feasible to perform uro dynamic studies as the patients' procedures were scheduled for the following day.

Exclusion criteria included uncomplicated mixed urinary incontinence (MUI) with a predominant stress component, urge or overactive bladder, infection (perineal skin, urethral and urinary tract), pelvic organ prolapse (stage ≥ +1 according to POP-Q classification system), pregnancy, and neurogenic bladder.

All the TOT procedures were performed by the same surgeon: the author (AC). The KHQ was repeated between 6 months and 2 years later, either at the follow-up outpatient clinic or telephonically. The patients' information was kept confidential, through the assigning of a study number to each participant. Data was analyzed after completion of the post-operative questionnaire into two groups for statistical ease and interpretation. The data sheet and the KHQ were filled out on admission of the patient before the TOT procedure. The clinical variables used in the data sheet included surgery date, age, parity, gravidity, menopausal status, height, weight, body mass index (BMI), smoking status, previous surgical history, type of incontinence, and problems after the TOT procedure.

Written or telephonic consent was obtained for each participant in the study. The primary objective was to determine the effect of urinary incontinence before and after the TOT procedure on the different aspects of a woman's QOL, as well as the subjective symptoms using the KHQ.

Information collected from the KHQ consisted of nine different domains from section 1-3. Each domain consists of questions, which are used to assess a certain aspect of QOL. Sections 1-3 have a four-point likert rating scale. The score was calculated according to the KHQ formula, with the total score being between 0 and 100; the higher the score, the worse the outcome of QOL. Section 4 assesses the impact of 10 different urinary symptoms.

The data was captured and analyzed using Excel (2010). No patient-identifying clinical variables were included. Comparisons of continuous variables were done through the use of a Student T-test. The frequencies, means, medians, and ranges were calculated for the data variables.

Analytical statistics were done using a Chi-Squared and a Fischer's exact test. Statistical significance was determined by achieving a p-value of <0.05, whereas a p-value <0.01 was considered to be highly significant.

Logistic regression models were used to determine any changes in QOL between 6 and 24 months. The data for each objective were analyzed in two different groups: SUI and SUI with urgency

RESULTS

76 patients were operated upon, in total. There were thirteen (17.1%) patients excluded from this study. Of the patients who were excluded, seven patients did not return for the follow-up visit, whilst one patient died 6 months post-operatively from pulmonary hypertension. An additional patient failed to consent to be involved in the study and four patients presented with MUI. Patients with MUI were excluded as the study was focusing on patients who presented with pure SUI.

Thus, the study included 63 patients that fulfilled the inclusion criteria. Baseline characteristics are shown on table 1

Table 1. Patient characteristics and type of SUI analyse in the study.

Patient characteristics	**N=63**
Age, mean years (sd)	57.3 (11.4)
Race, N (% of total)	
Black	18 (28.6)
White	38 (60.3)
Coloured	3 (4.7)
Indian	4 (6.3)
Parity, mean (sd)	2.9 (1.5)
Normal vaginal deliveries, mean (sd)	2.8 (1.5)
Number of Caesarean sections, mean (sd)	0.1 (0.5)
Menopause, n (%)	51 (80.9)
BMI: kg/m^2, mean (range)	30.2 (18.7-50.8)
Smoking history, n (%)	17 (27.0)
Stress UI, n (%)	50 (79.4)
Stress UI with sensation of urgency, n (%)	13 (20.7)

There were 50 (79,3 %) patients in the SUI group, and 13 (20,7%) patients in the SUI with urgency group. Concomitant surgery during TOT procedure is presented in table 2.

Table 2. Concurrent operations performed during TOT procedure.

Concomitant Surgery	**(N=63)**
Vaginal hysterectomy, n (%)	5 (7.9)
Anterior Repair, n (%)	14 (22.2)
Posterior Repair, n (%)	3 (4.8)
Posterior Intra-Vaginal Sling, n (%)	1 (1.6)

The intra and postoperative complications during follow up period are presented in table 3.

Table 3. Intra and post-operative complications encountered during the procedure and the follow-up.

Intra and Post-operative complications	**(n=63)**
Groin and Thigh pain, n (%)	2 (3.2)
Erosion, n (%)	0
de novo urgency UI, n (%)	2 (3.2)
Sling Failure, n (%)	1 (1.6)
Perforation of bladder, vagina, and urethra, n (%)	0

There were a total of five failures throughout the 24 months of follow- up period, leading to an objective success rate of 92 %. Follow up data was censored at the end of June 2013, when the last patient who underwent TOT completed the six months follow up. The follow up time varied between 6 and 30 months, with a mean follow up of 18 months.

The KHQ results classified by type of incontinence showing the mean score for the different KHQ variables before and after the TOT procedure are shown in table 5. The mean values (p= < 0.0001) for all the patients in each group under each domain.

When comparing the KHQ results, the most relatively improved variable is incontinence impact of 89%. The least improved is general health perception of 52%. The most absolute improved in post-operative success is social limitation. The X-axis corresponds to the key (KHQ variables) on the right side of the graph, while the Y-axis shows the mean score (0-100) (Fig 1)

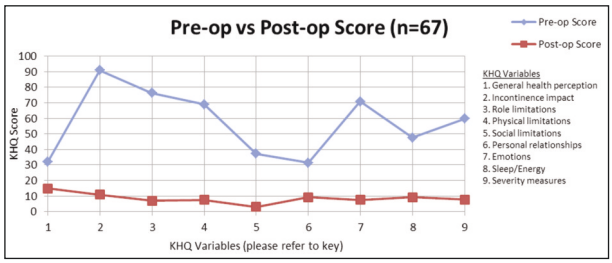


Figure 1. – Comparing the KHQ results.

There were 50 patients in the SUI group. Fig 2 measures the mean score for the patients in each KHQ variable. The relative best improvement is social limitations of 100%. The relative least improved is general health perceptions of 52%. The absolute best improvement is incontinence impact of 89%. The least improvement in absolute terms is general health perception of 15%.

There were 13 patients in the SUI and urgency group. Fig 3 measures the mean score for the patients in each KHQ variable. The relative best improvement is social limitations of 96%. The relative least improved is general health perceptions of 43%. The absolute best improvement was incontinence impact of 89%. The least improvement for absolute terms was personal relationships of 11%.

Comparative changes in each variable before and after the surgery are shown in table 5. The values given are the mean patient score for that variable. The higher the mean score for each variable, the worse the average patient level is for that variable.

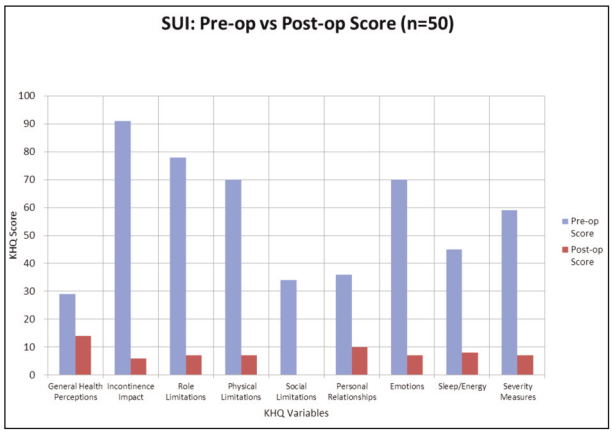


Figure 2. – Pre and post-operative change for SUI.

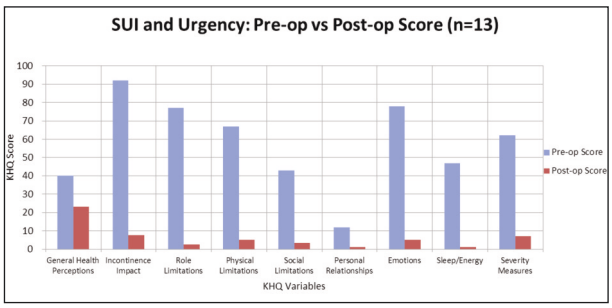


Figure 3. – Pre and post- operative change for SUI and urgency.

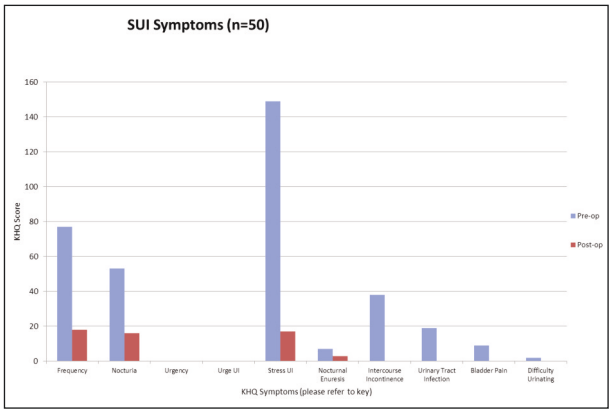


Figure 4. – Pre-operative and post-operative changes in symptoms for SUI.

TABLE 4. KHQ scores before and one year after the TOT surgery.

KHQ Variables (mean)	Pre-Operative			Post-Operative		
	SUI	SUI + Urgency	P value	SUI	SUI + Urgency	P value
General Health Perceptions	29	40	<0.0001	14	23	<0.0001
Incontinence Impact	91	92	<0.0001	6	8	<0.0001
Role Limitations	78	77	<0.0001	7	3	<0.0001
Physical Limitations	70	67	<0.0001	7	5	<0.0001
Social Limitations	34	43	<0.0001	0	3	<0.0001
Personal Relationships	36	12	<0.0001	10	1	<0.0001
Emotions	70	78	<0.0001	7	5	<0.0001
Sleep/Energy	45	47	<0.0001	8	1	<0.0001
Severity Measures	59	62	<0.0001	7	7	<0.01

Mean values (p= < 0.0001) for all the patients in each group under each KHQ symptoms.

The greatest improvement in the SUI group was in the stress symptom of 96 % (Fig 4).

In the SUI and urgency group, the relative and absolute greatest improvement was for stress symptom, which was

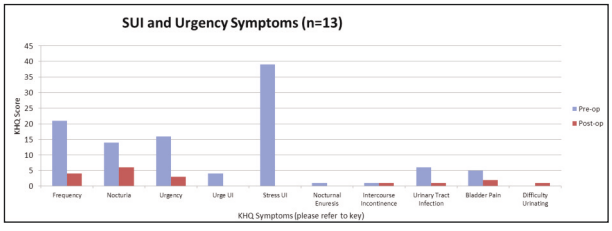


Figure 5. – Pre-operative and post-operative changes in symptoms for SUI and urgency.

TABLE 5. Pre-operative and post-operative KHQ results classified by type of incontinence showing the mean score for the different KHQ symptoms. Comparing pre-operative and post-operative changes in the symptoms.

KHQ Variables (mean)	Pre-Operative			Post-Operative		
	SUI	SUI + Urgency	P value	SUI	SUI + Urgency	P value
Frequency	77	21	<0.0001	18	4	<0.0001
Nocturia	53	14	<0.0001	16	6	<0.0001
Urgency	0	16	<0.0001	0	3	<0.0001
Urge UI	0	4	<0.0001	0	0	<0.0001
Stress UI	149	39	<0.0001	17	0	<0.0001
Nocturnal Enuresis	7	1	<0.0001	3	0	<0.0001
Intercourse Incontinence	36	1	<0.0001	8	1	<0.0001
Urinary Tract Infection	19	6	<0.0001	14	1	<0.0001
Bladder Pain	9	5	<0.0001	2	2	<0.0001
Difficulty Urinating	2	0	<0.0001	3	1	<0.0001

reduced to nil (Fig 5). There was an overall improvement in all the other symptoms, except intercourse incontinence, which indicated no change. Only two patients had urinary leakage during intercourse.

Logistic regression models were used to determine pre-operative and postoperative changes in KHQ between baseline and 12 months, as minimal change in QOL was noted between 6 and 24 months. It was found that the 6 month results correlated with the 2 year results.

DISCUSSION

Most studies that addressed the outcome of the TOT procedure focus on the objective cure rates without a real focus on the functional outcome. Therefore, the aim of this prospective study was to evaluate mainly the functional outcome of the TOT procedure in the management of female SUI and its impact on quality of life using the KHQ before and after the TOT operation.

Sixty-three patients were initially classified as having pure SUI, objectively. Thirteen of these patients (20.7 %), after answering positively to the presence of urgency and/or urge symptoms, were placed into a separate group, SUI with the sensation of urgency; these patients were initially categorized as a pure SUI by the unit doctors based on the initial workup (pelvic examination, demonstrating a positive cough test and excluding urinary tract infection). However, after the completion of the preoperative questionnaire on admission, these patients also answered positively to both the presence of sensation of urgency and urge.

A study by Dooley Y et al.[13] performed a comparison between women with MUI versus pure SUI, using two validated questionnaires. This was done in an attempt to compare the patients' history with their physical findings. The study indicated that the majority of the women who presented for surgical treatment of SUI were classified as MUI once subjective measures were used [6]. The prevalence ranged from 50% to 93%, depending on the questions used and severity selected. However, when the data was analysed, the women who presented with MUI responded similarly to the SUI group with QOL and symptom change. When using objective measures, only 8% of women were diagnosed with having MUI [6].

In our study, only 5.2% (4 out of 76 patients) were diagnosed with MUI, using objective measures. There was an increase in prevalence after completion of the KHQ to 22.3% (17 out of 76 patients). This illustrates how the definition and severity of symptoms can affect the classification and outcome of studies.

A study by Chou E et al.[14], suggests that urge incontinence may be over-diagnosed in patients with SUI who misinterpret their fear of leaking (because of SUI) for urge incontinence. This adds to the discrepancy between the subjective and objective diagnosis. Not surprisingly, the subjective classification yields a higher prevalence rate of MUI as compared to using objective measures. For this reason, thirteen patients in our study who were diagnosed as having MUI after completion of the KHQ before the TOT procedure were grouped separately and analysed as SUI with a sensation of urgency. When the data was analyzed this group (SUI with sensation of urgency) responded similarly to the SUI group with QOL and symptom change. (Fig2 and Fig3)

There was a general improvement in all areas of the KHQ quality of life in all groups of patients post-operatively (table 4). In the SUI group, the social limitations improved by 100%, and the incontinence impact improved by 89% (Fig 1). Patients in the SUI group scored better for incontinence impact. Most women in all the groups considered their general health perception to be good, but scored the worst in incontinence impact on their life pre-operatively. This shows that urinary incontinence is major impedance to good QOL. The mean operative change in the score showed an 87% improvement in the SUI group, and 89% in the SUI with a sensation of urgency group. The SUI with a sensation of urgency group had a similar response to the SUI group. The literature supports this study, showing that women with mixed symptoms reported a higher degree of effect on daily activities, social life, and mental symptoms. More women with mixed symptoms reported an insult on the overall quality of life compared to stress symptoms alone [15].

In our study, although following history and clinical examination, there were a number of patients considered as pure SUI who were found to have a sensation of urgency after completing the KHQ. These patients, following the TOT procedure for SUI, did very well. The SUI group and SUI with urgency had a reduction in the stress symptoms of 89% and 100%, respectively (Fig4 and Fig5).

In the SUI with sensation of urgency group, urge urinary incontinence disappeared while the urgency symptoms were reduced. This could suggest that urgency may be caused by an inflow of urine into the urethra, activating parasympathetic sensory nerves and causing the urgency sensation; however urine leakage is prevented by the TOT procedure.

The possible explanations of why the TOT procedure might improve the urge component is based on the fact that it may prevent urine from entering the upper posterior urethra, with an increase in intra-abdominal pressure, which prevents the reflex urgency [16, 17]. Leakage of urine into the proximal urethra may stimulate urethral afferents and facilitate voiding reflexes [18].

Taking intra- and post-operative complications into consideration, no major intra-operative complications (such as bowel, vascular, bladder, or urethral injuries) were reported in this study, confirming the results of other studies that indicate the safety of the procedure[19,20]. One sling failure with positive cough test diagnosed at the six months follow-up, was managed by reinserting a new sling.

In addition, post-operative voiding problems were found to be low in our study, which also agrees with other studies[6, 21]. *De novo* detrusor instability was noted in two patients (1.2%) during the follow-up period, and were successfully resolved with antimuscarinics. This is definitely

much lower than the rate reported with TVT[6, 8]. It is suggested that the TOT is more horizontal as compared to the U-shape of the retro-pubic slings, thereby making less contact with the urethra and so diminishing the likelihood of this complication. Urinary retention following TOT has been reported in literature as between 1.5 and 15%, respectively[9, 12]. No cases of urinary retention occurred in this series. This may be attributed to the fact that, in all cases, the catheter was clamped on the first post-operative day, and removed on the second day before discharge. This not only allowed bladder retraining, but may also have decreased the tension on the sling in the immediate post-operative period.

Six (9%) of the women had a post-operative urinary tract infection (UTI). These women presented with symptomatic dysuria but not voiding difficulties. One of them was admitted for intravenous administration of Kanamycine based on sensitivity of the culture of midstream urine. The other five patients were treated successfully with antibiotics at home. The incidence of UTI is in keeping with current literature[21] of 3.1-22%. There were two (1,2%) women who presented with groin and thigh complications; with one of the woman's groin pain resolving spontaneously at the six weeks follow-up. The other woman had unilateral groin pain affecting left groin, inner thigh, and left labia majora persisting after the six weeks follow-up, in spite of analgesia and anti-inflammatory treatment. This burning sensation was not relieved even after administration of amitriptyline. The pain and burning sensation was resolved after partial removal of the tape, and continence was preserved.

Injury to the ilioinguinal nerve and rarely the obturator nerve has been described in the literature. The ilioinguinal nerve supplies the sensory innervation to the skin over the groin, inner thigh and labia majora. The incidence of groin pain has been reported in three (1.5%) out of 204 women following TOT procedure[21]. Groin or thigh pain has been found to be more common with TVT-O inside-out procedure with reported incidence of 16-17%[22, 23]. A sub-analysis performed by Cheng Yu Long[24] found that TVT-O inside-out appears to be more painful, and the possible cause was that the exit point of the TVT-O needle is closer to the adductor muscle and the obturator neurovascular bundle compared with outside-in TOT. Cadaveric studies confirmed that tapes inserted via the Transobturator route using an outside-in technique have a lower risk of pudendal neurovascular bundle injury, as the tape is inserted further from the obturator canal and closer to inferior ischiopubic rami[25].

In twenty three (34%) of the women involved in the study, the TOT procedure was combined with an additional pelvic surgery. The results of this study are in agreement with Costa et al.[26] and demonstrate that pelvic procedures during TOT surgery do not compromise the cure rate of female SUI.

There was a general improvement in all areas of the KHQ quality of life in all groups of patients post-operatively. In the SUI group, the social limitations improved by 100%, and incontinence impact by 93%. The SUI with a sensation of urgency group had a similar response to the SUI group.

The literature states that patients may experience a deterioration of their sexual function following the mid-urethral sling procedure. This can occur as a result of the development of dyspareunia after the surgery[27] or due to decreased blood supply to the clitoris. De novo dyspareunia might be caused by the position of the tape, as the use of the tape may result in vaginal narrowing, para urethral banding or erosion[27]. The effect on clitoral blood supply after the TVT and TOT procedures was investigated by Caruso et al., with the aid of colour Doppler ultrasonography[28]. It was concluded that blood flow to the clitoris was negatively affected by TVT, but not by the TOT. Thus, the TOT was proved to be an anatomically safer approach, which does not impair the sexual function of the patient.

However, none of the sexually active patients in our study suffered from a decline in their sexual function. Additionally, there was no case of de novo dyspareunia in this study – as opposed to Elsevier et al.[29], who reported that 10% of his patients who underwent the TOT procedure reported vaginal narrowing, which caused dyspareunia.

The impact of the QOL cure rate was analysed separately from the symptoms. This study demonstrates that the QOL cure rate, as well as the subjective symptom cure rate, was defined as statistically significant, post-operatively (Table 5). The KHQ shows the negative impact of urinary incontinence in patients' QOL. There was a significant improvement in the QOL of patients that underwent the TOT outside-in surgery for female SUI, and the data obtained from the KHQ correlate with the objective cure rates

CONCLUSION

In summary, the TOT outside-in procedure is a simple, effective, safe, and minimally invasive technique for the treatment of SUI. The KHQ shows the negative impact of stress urinary incontinence in the quality of life of patients. There was a significant improvement in the quality of life of patients that underwent the TOT outside-in surgery for the treatment of their SUI; thus, there is a correlation between the subjective cure rate and the objective cure rates.

REFERENCES

1. Abrams P, Cardozo L, Fall M et al. The standardisation of terminology of lower urinary tract function: Report from the standardisation sub-committee of the International Continence Society. Neurol Urodyn 2006, 21 (2), 167-178.
2. Abrams P, Swithinbank LV. The impact of urinary incontinence on the quality of life of women. World J Urol 1999, 17, 225-229.
3. Hunskaar S, Lose G, Sykes D, Voss S. The prevalence of urinary incontinence in women in four European countries. Brit. J. Urol 2004, 93 (3), 324-330.
4. Delorme E. Transobturator urethral suspension: mini-invasive procedure in the treatment of stress urinary incontinence in women. Prog Urol 2001, 11, 1306-13.
5. Ulmsten U, Petros P. Intravaginal Slingplasty (IVS): An Ambulatory Surgical Procedure for Treatment of Female Urinary Incontinence. Scandinavian Journal of Urology and Nephrology 1995, 29 (1), 75-82.
6. Latthe P, Foon R, Toozs Hobson P. Transobturator and retropubic tape procedures in stress urinary incontinence: a systematic review and meta analysis of effectiveness and complications. Brit J Obstet. Gynaecol 2007, 114 (5), 522-531.
7. Meschia M, Pifarotti P, Bernasconi F, Guercio E et al. Tension-free vaginal tape: analysis of outcomes and complications in 404 stress incontinent women. Int. Urogynecol J 2001, 12, 24-27.
8. Nerli RB, Kumar AG, Koura A et al. Transobturator vaginal tape in comparison to tension – free vaginal tape: A prospective trial with minimum 12 months follow-up Indian J Urol 2009, 25 (3), 321-25.
9. Tamussino K, Hanzal E, Kölle D et al. Tension-free vaginal tape operation: results of the Austrian registry. Obstet Gynecol 2001, 98 (5 Part 1), 732-36.
10. Dargent D, Bretones S, George P, Mellier G. Insertion of a sub-urethral sling through the obturating membrane for treatment of female urinary incontinence. Gynécologie, obstétrique & fertilité 2002, 30 (7-8), 576-82.

11. deTayrac R, Deffieux X, Droupy S, Chauveaud-Lambling A, Calvanèse-Benamour L, Fernandez H. A prospective randomized trial comparing tension-free vaginal tape and transobturator suburethral tape for surgical treatment of stress urinary incontinence. AmJ Obstet Gynecol 2004, 190 (3), 602-608.
12. Domingo S, Alama P, Ruiz N, Lazaro G, Morell M, Pellicer A. Transobturator tape procedure outcome: a clinical and quality of life analysis of a 1-year follow-up. Int Urogynecol J 2007, 18 (8), 895-900.
13. Dooley Y, Lowenstein L, Kenton K et al. Mixed incontinence is more bothersome than pure incontinence subtypes. Int Urogynecol J 2008, 19 (10), 1359-1362.
14. Chou E, Blaivas JG, Chou LW, Flisser AJ et al. Urodynamic characteristics of mixed urinary incontinence and idiopathic urge urinary incontinence. Neurourol Urodyn 2008, 27 (5), 376-378.
15. Kim JW, Oh MM, Lee JG. Preoperative factors as predictors of outcome of midurethral sling in women with mixed urinary incontinence.Korean J Urol 2008, 49, 1112-18.
16. Koonings P, Bergman A, Ballard C. Combined detrusor instability and stress urinary incontinence: where is the primary pathology. Gynecol Obstet Invest 1998, 26 (3), 250-256.
17. Minassian V A, Stewart WF, Hirsch AG. Why do stress and urge incontinence co-occur much more often than expected? Int Urogynecol J 2008, 19 (10), 1429-1440.
18. Jung SY, Fraser MO, Ozawa H et al. Urethral afferent nerve activity affects the micturation reflux, implication for the relationship between stress incontinence and detrusor instability. J Urol 1999, 162, 204-212.
19. Chrysostomou A. The management of stress urinary incontinence using Transobturator tapes in a tertiary institution in South Africa. Pelviperineology 2012, 31, 82-85.
20. Sung V, Scleinitz M, Rardin C, Myers D. Comparison of retro pubic versus transobturator approach to midurethral sling: a systematic review and meta-analysis. Am J obstet Gynecol 2007, 197, 3-11.
21. Mellier G, Moore R, Jacquetin B A. Meta-analysis of the itraoperative safety and effectiveness of the Transobturator hammock seen in results of two prospective studies in 9 countries with 204 patients. Neurourol Urodyn 2004, 23, 556-57.
22. De Leval J. Novel surgical technique for the treatment of female stress urinary incontinence: Transobturator vaginal tape inside out. European Urology 2003, 44, 724-30.
23. Feng C, Chin H, Wang K. Transobturator vaginal tape inside out procedure for stress urinary incontinence: results of 102 patients. International Urogynecology Journal 2008, 19, 1423-27.
24. Long C, Hsu C, Wu M et al. Comparison of tension-free vaginal tape and transobturator tape procedure for the treatment of stress urinary incontinence. Curr Opin Obstet Gynecol 2009, 21 (4), 342-45.
25. Spinosa J, Dubuis P, Riederer B. Transobturator surgery for female stress incontinence: a comparative anatomical study of outside-in vs inside-out techniques. BJU international 2007, 100, 1097-1102.
26. Costa P, Grise P, Droupy S et al. Surgical treatment of female stress urinary incontinence with a Transobturator tape (TOT) Uratape; Short term results of a prospective multi-centric study. Eur Urol 2004, 46, 120-24.
27. Mazouni C, Karsenty G, Bretelle F et al. Urinary complications and sexual function aftert the TVT procedure. Acta Obstet Gynecol Scand 2004, 83 (10), 951-961.
28. Caruso S, Rugolo S, Mirabello D, Cavallaro A. Clitoral blood flow changes after surgery for stress urinary incontinence: pilot study on TVT versus the TOT procedures. Urology 2007, 70, 554-55.
29. Elsevier H W, Putter H, Delaere KP et al. Female sexual function after surgery for stress urinary incontinence: Transobturator suburethral tape vs tension-free vaginal tape obturator. J sex med 2008, 5 (2), 400-406.

There are no conflicts of interest.

Correspondence to:
Dr Andreas Chrysostomou MD, FCOG (SA), Mmed (Wits)
Department of Obstetrics and Gynaecology
Charlotte Maxeke Johannesburg Academic Hospital
PO BOX 29699 Sandringham 2131 Johannesburg
Republic of South Africa
andreas.chrysostomou@wits.ac.za +27 83 324 4122
Andreas Chrysostomou - 2 Jubilee Street Parktown - Johannesburg - South Africa

Editorial commentary

Hostile environment. In June 2014, politicians in Scotland called for mesh operations to be suspended. Across the UK, women are considering surgical treatment of stress urinary incontinence with mesh slings an operation with potential life-changing risks and are demanding it to be suspended until additional information. The Scottish parliament has petitioned a full investigation and audit to be carried out into how many women have been adversely affected by vaginal mesh implants and tapes 1. This 'anti mesh sling' atmosphere following its older sister 'anti vaginal mesh surgery' atmosphere is spreading worldwide like a fire in a field of thorns.

In this kind of environment the study by Chrysostomou et al. gains the utmost importance demonstrating once again that suburethral sling procedures (specifically, the TOT outside-in procedure) are safe and effective in treating SUI. Moreover they have conclusively demonstrated that it improves the quality of life for women with this condition. Although surgeons many times tend to focus on anatomical outcomes or objective cure rates to define surgical success, patients are more concerned with functional outcomes. While there is no doubt that urinary incontinence has a negative impact on patients' QoL, this study has demonstrated that the QoL cure rate, as well as the subjective symptom cure rate, was statistically significant, post-operatively.

REFERENCE

1. https://slingthemesh.wordpress.com/

ADI Y. WEINTRAUB
Editor Pelviperineology
Soroka University Medical Center, Beer Sheva - Department of Obstetrics and Gynecology
adiyehud@bgu.ac.il

Original Article

Questionnaire validation may not validate- a critical analysis

SILVIA PINANGO-LUNA[1], PETER PETROS[2,3]

[1] *Hospital "Dr. Miguel Pérez Carreño" Caracas, Venezuela*
[2] *University of NSW, Professorial Dept of Surgery, St Vincent's Hospital, Sydney*
[3] *University of Western Australia, Crawley, Perth WA*

Abstract: The genesis of this work came from analysis of a single patient QOL graph mainly for pain. It gave rise to 6 questions concerning the validity of the validation process using the ICIQ questionnaire as an example. The questions raised against 'validation' were: 1. The assessment was almost entirely subjective. 2. The test-re-test time frame of 2 weeks could lead to major errors. 3. The questions tested the collective memory, not variation. 4. Replacement of the physician's interaction and the considerable benefits thereof. 5. The questionnaires are reductionist, seemingly oblivious of the holistic anatomical control mechanism. 6. Validations add another layer of complexity and do not add to what can be obtained using the simple language of a questionnaire. In conclusion there seems no benefit in 'validating' what are really simple questions based on plain English. As long as the authors define what they are talking about in the methods that should suffice.

Keywords: Questionnaire validation; Art of Medicine.

BACKGROUND

From Hippocrates onwards, symptoms have been an essential element in medical diagnosis. Normally the physician elicits symptoms by listening to the patient's story or by direct questioning. Because this was said to introduce bias, patient administered questionnaires are being increasingly used to remove the bias from the physician.

The original aim of this work was to test the reproducibility of the pain symptom within an individual patient over a 3 month time period. Analysis of the graphs and the 'validated' questions themselves brought the whole concept of questionnaire validation into question.

INTRODUCTION

In urinary incontinence, wide variation in symptoms within an individual patient caused symptoms to be viewed as unreliable, thereby promoting the use of 'objective' urodynamics[1].

A later development questioned the validity of the questions themselves, leading to psychometric systems for validation of questionnaires. Psychometric validation of questionnaires involved a complex mainly subjective system involving several parameters[2], including: Face validity * Content validity* Construct validity*, Criterion validity* Test-retest for reproducibility**, statistical inner consistency (Cronbach's alpha coefficient), responsiveness*.

* physician subjective

** patient subjective

A critical analysis of the process involved in validation gave rise to 6 questions. These are detailed below.

The first question concerning 'validation'

A simple analysis of these parameters inevitably concludes that nearly all are subjective. This subjectivity raises the first question: how is a subjective 'validated questionnaire' more valid than a 'subjective' history from an experienced perceptive clinician?

A simple methodology

A 68 year old woman, parity 3, mainly with chronic pelvic pain, some nocturia and some non-stress non-urge urine loss agreed to keep a daily diary over a 3 month period to monitor her chronic pelvic pain using a 1-10 visual analogue scale (VAS), entry made immediately before retiring for the night.

Three pain charts

Three charts with no gaps are presented (Figure 1). Pain intensity was recorded on 81 consecutive days. In 12/81 days, the pain was severe, VAS 7 or above (Figure 2). The month of May had the most severe episodes, 8 with VAS>7. The outstanding feature of these graphs is the massive variations even in the space of a few days. The pain varied from VAS 8 to VAS 1, between day 16 to day 26 (May), from VAS 7 to VAS 1, between day 7 to day 10 (June), from VAS 8 and VAS 2, between day 10 to day 19 (July).

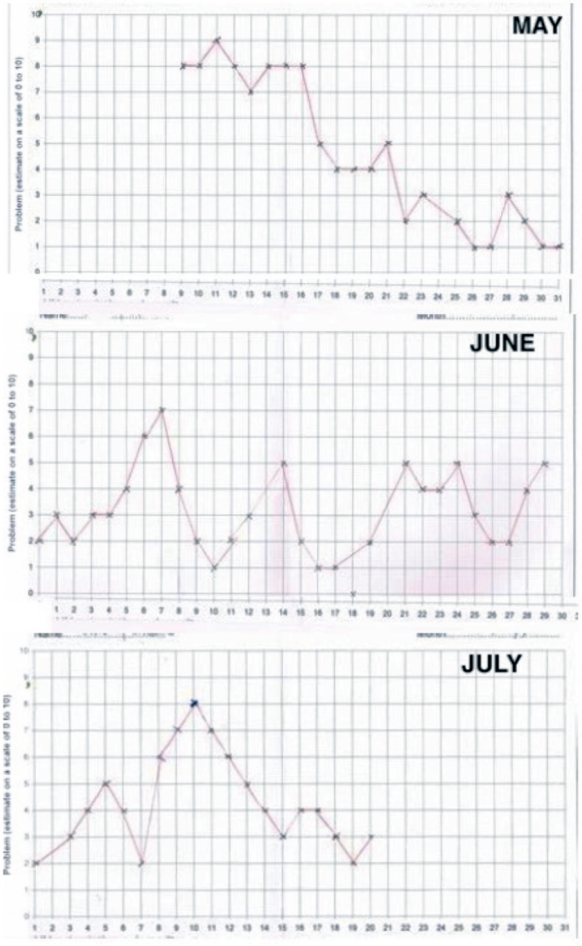


Figure 1. – Graphic display of VAS QOL scores, chronic pelvic pain.

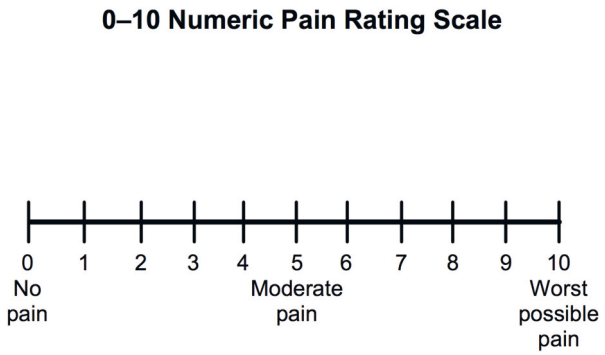


Figure 2. – Visual analogue scale 0-10 Numeric Scale.

The second question concerning 'validation'

The time for the pain to fall from severe to mild varied widely (Figure 1): 10 days in May, 3 days in June and 7 days in July. Fig1 raises the 2nd question, how valid is any 'validated questionnaire'* when it relies on a test-retest analysis which can vary so widely within 2-3 days?

* The 'scientific' basis for the recommended 7-14 day test-re-test interval is yet another subjective but 'authoritative' proclamation[3] which does not fit in any way with the graphs, (Figure 1). *From Coyne K, Kelleher C,Patient Reported Outcomes:* The ICIQ and the State of the Art[3]. *"Test-retest reliability, or reproducibility, indicates how well results can be reproduced with repeated testing. To assess test-retest reliability, the same patient completes the questionnaire more than once, at baseline and again after a period of time during which the impact of symptoms is unlikely to change (e.g., a few days or weeks). It is important to keep the test-retest period a reasonably short period of time - such as 7-14 days"*[3].

The 3rd question concerning 'validation'

'Reproducibility' may not be the parameter which the "test-retest" methodology of questionnaire 'validation' is actually testing. For example, the questions from the ICIQ questionnaire are in the present tense. They test the patient's *collective memory* of the pain. A typical question is *"To what extent does your urinary problem affect your household tasks (e.g. cleaning, shopping, etc.)?"* Another is "*Does your urinary problem affect your job, or your normal daily activities outside the home?*" and so on. These questions request a global average answer based on collective memory of individual events, recorded and averaged over a time period by the cortex. The mental process behind this question is similar to "What sort of food does your mother cook, bad, average, good?" If it is mainly 'good food', the occasional bad or average meal is discounted by the cortex. This process certainly would not vary in a two week interval. So what is really being tested by a test-retest questionnaire for this ICIQ *is the reliability of the patient's memory of the symptom, not the reproducibility of the symptom itself.*

All of which begs the 3rd question, why bother to validate ICIQ when it does not assess reproducibility?"

The 4th question concerning 'validation'

There is less provision for the doctor-patient interaction in such constructs which are essentially reductionist. What generally happens is that the physician takes the patient administered questionnaire, explains the result and prescribes some treatment or other. Inevitably, there are inroads into the "Art of Medicine" [4]. Like the function of the human body, the "Art of Medicine" is non-linear. Highly experienced clinicians read a patient's body language, sense barriers such as shyness, personality disorders, inhibitions, ask further questions and use their art to penetrate further into the cause of the problems.

The 5th question

The questions in questionnaires such as the ICIQ are reductionist. Nowhere is there any space for variation. Yet, as the VAS graph demonstrates, symptoms vary widely. How can this be? Given the pelvic structures and exponential nature of the control mechanisms for muscles, fascia, organs, ligaments, even a minor variation of anatomy, if additive, could cause sufficient laxity in the uterosacral ligaments (Figure 3), to set off a cascade of widely varied events ([4-6]). An extreme analogy is the fluttering of a butterfly causing a cyclone on the other side of the globe[6]. This gives rise to question no 5, "How can the originators of such 'validations', be so authoritatively reductionist, when the control mechanisms are holistic, exponentially determined and holistically controlled?"

The 6th question

It examines whether new constructs such as 'questionnaire validation" really add anything beyond the same 'unvalidated' questions, when both use simple language.

Karl Popper described such constructs as 'new languages'. He considered them artificial and unnecessary if they could be described in more simple terms[7].

Popper's viewpoint is that a Theory (or concept) can never be entirely validated. It can, however, be easily invalidated: one validated exception invalidates the whole concept[7]. For example if one states that all swans are white, the production of one black swan invalidates that concept. The concept of good test-retest correlations within two week intervals lie at the core of questionnaire 'validation'[2,3]. In the same way as the black swan, the VAS graph invalidates the whole test retest concept and with it, the whole process of validation.

Popper described constructs such as 'questionnaire validation' as "artificial model languages". He stated that contradictions arise when an'artificial model language' is created.

In 1980 Popper stated *"Thus the method of constructing artificial model languages is incapable of tackling the problems of the growth of our knowledge; and it is even less able*

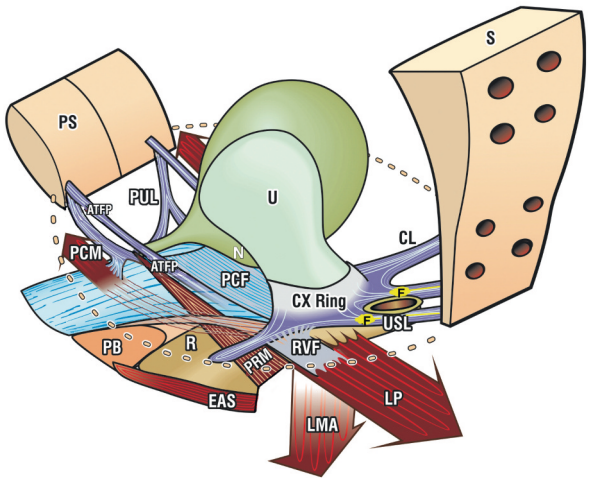


Figure 3. – Opposite directional forces (arrows) stretch CL & USL ligaments and fascia to support Frankenhauser (F) and sacral nerve plexuses . The posterior directional forces (LP/LMA) act against the cardinal (CL) and uterosacral ligaments (USL). PS = pubic symphysis; S = sacrum; PUL = pubourethral ligament; ATFP = arcus tendineus fascia pelvis; USL = uterosacral ligament; CL= cardinal ligament; PCM = pubococcygeus muscle; LP = levator plate; LMA = longitudinal muscle of the anus; PRM = puborectalis muscle; PCF = pubocervical fascia;RVF = rectovaginal fascia; PB = perineal body; EAS = external anal sphincter
Note Nerve plexuses 'F' (yellow) at the base of USLs.

to do so than the method of analysing ordinary languages, simply because these model languages are poorer than ordinary languages. It is a result of their poverty that they yield only the most crude and the most misleading model of the growth of knowledge - the model of an accumulating heap of observation statements".

Is the validated ICIQ questionnaire poorer than using simple language? Questionnaires such as ICIQ combine symptoms and give results as 'scores'. For example, the statement to an ordinary person " Your ICIQ score improved from 'x' before surgery to 'y' after surgery" is totally meaningless. A patient complains of a symptom, not a number. Furthermore, there may be differential improvement in say their urgency but not nocturia. Surely it is more informative to list each symptom and say whether it is improved (or not). This example confirms Popper's statement "*these model languages are poorer than ordinary languages. It is a result of their poverty that they yield only the most crude and the most misleading model of the growth of knowledge - the model of an accumulating heap of observation statements"*.

CONCLUSIONS

There seems no benefit in 'validating' what are really simple questions based on plain English. As long as the authors define what they are talking about in the methods that should suffice.

Declarations

Permission was obtained from the patient to anonymously publish the graphs and clinical details. No conflicts financial or otherwise.

Participation

Petros: conceptualization, analysis, diagrams writing. Pinango-Luna: analysis, writing.

REFERENCES

1. Bates P, Bradley WE, Glen E, Hansjorg M, Rowan D, Sterling A, Hald T. International Continence Society First Report on the Standardisation of Terminology of Lower Urinary Tract Function (1975).
2. Barber MD. Questionnaires for women with pelvic floor disorders. Int Urogynecol J. 2007; 18: 461+465. DOI 10.1007/s00192-006-0252-1.
3. Coyne K, Con Kelleher C Patient Reported Outcomes: The ICIQ and the State of the Art , Neurourology and Urodynamics 2010, 29, 645-651.
4. Petros PE The Art and Science of Medicine. Lancet, 2001, 358, 818-1819.
5. Petros PEP. Ch 6.1.2 The Chaos Theory Framework – its impact on the understanding of bladder control and urodynamic charting in "The Female Pelvic Floor, 3rd Ed Springer Heidelberg, pp 239-246.
6. Gleick J. "Inner Rhythms" in Chaos – Making a New Science Cardinal, Penguin, England; 1987, 275-300.
7. Popper KR. Theories. Falsifiability. The Logic of Scientific Discovery. Unwin, Hyman, London, 1980, 27-146.

Correspondence to:
Peter Petros
E-mail: pp@kvinno.com

Editorial commentary

The study of medicine, especially characterization of disease symptoms, evaluation of treatment outcomes, quality of life, and even patient satisfaction, constantly lies in the tension that exists between deduction and induction. We try to learn from the single case in order to infer the rule for many as we also try to discard information gathered from many for the single patient. While in medicine we can refer to the past decade or two as the era of evidenced-based medicine, we can witness today a transition to an era of personalized or tailored medicine. Personalized medicine is not a new concept in medicine, but rather a return to the past. We are all familiar with the typecast of the old rural doctor with the holistic approach that treats a person as a whole of body and soul, characterized by special physician-patient relations, familiarity with the patient, their family and their environment and recognition of all the physical mental and emotional factors that can promote their health.

In this article by Pinango-Luna and Petros the authors refer to this gap between deduction and induction and list and discuss the disadvantages of deduction. I completely agree with the authors that make some strong arguments in favor of the personal and direct doctor-patient contact. We must never abandon the skills of history taking and questioning so that we can obtain the whole picture of our patients' condition. In addition, the authors also argue strongly against the use of questionnaires and their validation. I don't think that validated questionnaires need to be abandoned all together, they do however need to be considered with caution.

Although studies using validated questionnaires are preferred to attain objectively obtained reproducible data, we need to be cautious in interpreting these data.

One example is the use of condition-specific questionnaires. Condition-specific questionnaires are validated to discriminate between women with and without a certain condition (i.e. pelvic pain, sexual function, quality of life, etc.), within the group of patients suffering from a broader condition (for example pelvic pain among women treated for pelvic floor dysfunction). Indeed, in some studies, questionnaires have shown responsiveness to change after surgery. After surgery, new aspects such as dyspareunia, worries about damaging the operative results, onset of new symptoms, unsatisfactory surgical results, or development of complications become relevant because of the treatment. Hence, a state following pelvic floor surgery should be regarded as a new clinical condition, necessitating a new condition-specific validated questionnaire. It may be that these questionnaires even those that are condition specific for one condition are not optimal to detect their goal after surgery because these new aspects are not represented in the questionnaire. By neglecting the negative impact that pelvic floor surgery may have on its own accord, evaluation following surgery might be too positive[1].

I believe that although interpreted with caution, validated questionnaires should be used for the study of medicine, however in no instance should they replace the doctor-patient interaction.

REFERENCE

1. 1. Weintraub AY. A validated tool would greatly enhance future research on the impact of surgery on sexual function. J Womens Health (Larchmt). 2016, 25, 327-8.

ADI Y. WEINTRAUB
Editor Pelviperineology
Soroka University Medical Center, Beer Sheva - Department of Obstetrics and Gynecology
adiyehud@bgu.ac.il

Original article

The effects of pelvic floor and transverse abdominal muscles' maximal voluntary contractions on pelvic floor ultrasound biometric parameters in women with stress urinary incontinence: preliminary results

NATALIA MARTINHO[1], SIMONE BOTELHO[1,2], ANITA NAGIB[1], JOSEANE MARQUES[1], VALÉRIA SILVA[1], RODRIGO JALES[1], ANDREA MARQUES[1], CÁSSIA JULIATO[1], PAULO PALMA[1], CÁSSIO RICCETTO[1]

[1] *Department of Surgery/Faculty of Medical Sciences/State University of Campinas (UNICAMP), Campinas/SP-Brazil*
[2] *Course of physiotherapy/Nursing school/Federal University of Alfenas (UNIFAL-MG), Alfenas/MG-Brazil*

Abstract. Aim: To verify if bladder neck position, genital hiatus area and puborectalis muscle thickness change during pelvic floor and transverse abdominal muscles' maximal voluntary contractions, compared to rest position. *Methods:* A clinical, transversal and controlled study was carried out with 31 women with stress urinary incontinence (SUI) symptoms, scored through the International Consultation on Incontinence Questionnaire Urinary Incontinence - Short Form (ICIQ UI-SF). The participants were evaluated by *GE Voluson 730 Expert®* transperineal ultrasound. The ultrasound images were collected first at rest, then during pelvic floor muscles' (PFM) maximal voluntary contraction and finally during transverse abdominal muscle's (TAM) maximal voluntary contraction. Three biometric parameters were analyzed in each situation: bladder neck position, genital hiatus area and puborectal muscle thickness. The statistical analyses were performed using Kolmogorov-Smirnov, ANOVA for repeated measures and Tukey-Kramer tests, adopting a significance level of 5%. *Results:* All biometric parameter measurements significantly changed during PFM maximal voluntary contraction compared to rest position ($p<0.05$). During TAM maximal voluntary contraction, only the puborectalis muscle thickness measurement showed a significant statistical difference compared to rest position ($p<0.05$). *Conclusion:* PFM maximal voluntary contraction significantly changed all analyzed ultrasound biometric parameters' measurements compared to rest position. In contrast, during TAM maximal voluntary contraction only the puborectalis muscle thickness significantly increased compared to rest position, without presenting any significant effects on either bladder neck position or genital hiatus area measurements.

Keywords: Pelvic floor; Physiotherapy; Stress urinary incontinence; Ultrasonography.

ABBREVIATIONS

AC	Anal canal
B	Bladder
BN	Bladder neck
Cm	Centimeter
Cm^2	Square Centimeter
ICIQ UI-SF	International Consultation on Incontinence Questionnaire Urinary Incontinence - Short Form
Kg/m^2	Kilogram per square meter
MVC	Maximal voluntary contraction
M	Mean
MHz	Mega Hertz
PFM	Pelvic floor muscles
PFM MVC	Pelvic floor muscles' maximal voluntary contraction
POP	Pelvic organ prolapse
PS	Pubic symphysis
PBR	Puborectal muscle
SD	Standard deviation
SUI	Stress urinary incontinence
TAM	Transverse abdominal muscle
TAM MVC	Transverse abdominal muscle's maximal voluntary contraction
UUI	Urgency urinary incontinence
U	Urethra
UVJ	Urethrovesical junction
V	Vagina

INTRODUCTION

A new approach for pelvic floor muscle (PFM) dysfunctions' treatment, based on deep abdominal muscle training, particularly, the transverse abdominal muscle (TAM), has been used and discussed in several recent studies[1-6]. PFM are responsible for both urethral closure and its pressure increase during a maximal voluntary contraction, supporting the pelvic organs and avoiding their descent during intra-abdominal pressure increase[7].

Due to its anatomical position, the TAM does not present a direct effect on the continence mechanisms[8]. However, some authors have mentioned that during a TAM maximal voluntary contraction a PFM co-contraction occurs because of a synergistic activity between the PFM and TAM, which has already been observed in healthy and continent women[9-14].

Thus, we hypothesized that the TAM maximal voluntary contraction could influence the pelvic floor ultrasound biometric parameters. Consequently, the aim of this study was to verify if bladder neck position, genital hiatus area and puborectalis muscle thickness change during both pelvic floor and transverse abdominal muscles' maximal voluntary contraction compared to rest position, in women with predominantly stress urinary incontinence (SUI) symptoms.

MATERIALS AND METHODS

Study design and participants

A clinical, cross sectional and controlled study was conducted after its approval by the Research Ethics Committee (CAAE: 42456114.8.0000.5404).

Initially, 39 women were recruited in the study and then eight of them were excluded for not meeting the study's eligibility criteria, resulting in a final sample of 31 women (Figure 1). All participants gave their informed and written consent according to the Helsinki declaration, prior to the initial assessment.

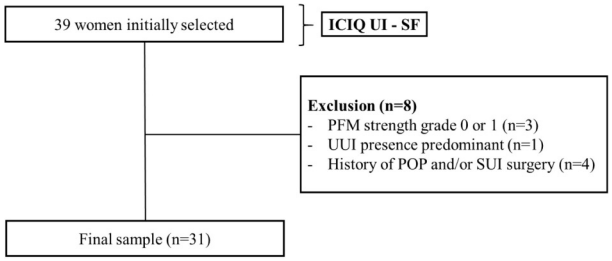


Figure 1. – Study population.
ICIQ UI – SF = International Consultation on Incontinence Questionnaire Urinary Incontinence – Short Form; PFM = pelvic floor muscles; UUI = urgency urinary incontinence; SUI = stress urinary incontinence; POP = pelvic organ prolapse.

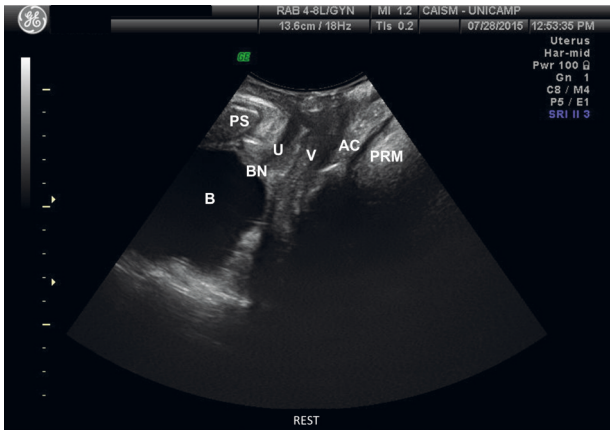


Figure 2. – Sequential representation of the structures observed in the pelvic floor muscles' ultrasound image. PS = Pubic symphysis; U = Urethra; BN = Bladder neck; B = Bladder; V = Vagina; AC = Anal canal; PRM = Puborectalis muscle.
(*Source:* Researcher's data)

Inclusion and exclusion criteria

We included 18 year or older women, who had reported predominantly SUI symptoms that were identified by means of an internationally validated questionnaire: International Consultation on Incontinence Questionnaire - Urinary Incontinence Short Form (ICIQ-UI SF), translated into Portuguese by Tamanini et al.[15]. We excluded women who had current urinary tract infection, myopathy, neurological abnormalities, diseases with a collagen alteration, cognitive and physical disorders that would hinder their participation in the evaluation, both SUI or/and pelvic organ prolapse surgery history, any pelvic organ prolapse exceeding the vaginal opening, PFM strength grade either zero or one according to the *Modified Oxford Grading Scale*[9] inability to contract the TAM and previously performed pelvic floor and/or transverse abdominal training supervised by health professionals.

Outcome measurements

First, one of the researchers investigated the participants' personal, demographic and clinical data, verifying whether they were eligible to participate in the research. A second researcher, a physical therapist specialized in woman health and in female PFM assessment, carried out the physical examination. This same examiner was trained by a physician, specialist in gynecological ultrasound and member of the research group, in order to carry out the ultrasound exams.

In the beginning, the participants' ability to perform a correct PFM contraction was verified by digital palpation. We also verified their ability to perform correct TAM contractions using ultrasound. To do this, the linear SP 6-12 MHz transducer was positioned at the point where the abdominal lateral wall is intercepted by the umbilical line, asking the participant to contract the lower abdominal part without performing any articular movements or any other muscle contractions[8,17]. Contractions were standardized in order to be carried out during the expiratory phase, correcting both inspiratory apnea or Valsalva maneuver situations.

3D / 4D Transperineal ultrasound GE Voluson 730 Expert (GE Medical Systems Kretz-Technik GmbH and Co. OHG, Zipf, Austria) ultrasound device and the *RAB4-8L / obstetric* convex transducer were used to obtain the 3D / 4D ultrasound images, where the image acquisition angle was set at 85º.

With the participant in supine position, with her knees bent, hips and feet flat on the table, the researcher placed the transducer, covered by a condom and gel, in contact with her vaginal introitus and between the major labia, without making too much pressure. The transducer axis was positioned on the mid-sagittal plane, allowing the sequential views of the following structures: the pubic symphysis, urethra, bladder neck, bladder, vagina, anal canal and, posteriorly, the puborectalis muscle, in Figure 2.

A first image, at rest, was recorded and stored into the device. Then, and always in this order, the participant was asked to conduct a PFM maximal voluntary contraction, followed by a TAM maximal voluntary contraction. Each maneuver was maintained for about 10 seconds in order that it would be possible to capture the 3D / 4D ultrasound real-time image.

Data processing and analysis

The ultrasound images were initially stored into the device, and then transferred to a notebook, to be able to analyze them afterwards through *4D View software* (*GE Healthcare Medical System*). In each image, three parameters were analyzed:

– *Urethrovesical junction's (UVJ) position:* Measured from the bladder neck to the lower margin of the pubic symphysis, after drawing a reference line, on the pubic symphysis axis (x axis) and another line, perpendicular to this at the intersection of the posterior inferior margin of the pubic symphysis (y axis)[18];

– *Genital hiatus area:* Bounded by the puborectal muscle's dorsal part and pubic symphysis[19];

– *Puborectalis muscle thickness*: The thickness of the puborectalis was measured each side (left and right), near the rectum, at 3 and 9 o'clock positions[20].

The UVJ positioning was analyzed on the mid-sagittal plane, while the genital hiatus area and the puborectalis muscle thickness were analyzed after 3D / 4D-volume design, on the axial plane at the minimum hiatal dimension level, shown between the pubic symphysis hyperechogenic front edge and the rear part of the rectum[19].

Statistical analysis

Data normality was analyzed using the Kolmogorov-Smirnov test. ANOVA for repeated measures test was used for investigate the biometric parameters' differences among the three proposed situations, followed by Tukey-Kramer post-test to investigate these parameters' differences between the rest and maximal voluntary contractions' situations.

The statistical analysis was carried out using GraphPad INSTAT 3.0 software, adopting a 5% significance level.

RESULTS

The group was considered homogeneous for demographic and clinical variables. Most participants were white (74.2%), married (64.5%), completed primary school (48.4%) and had no labor activity (61.3%). The participants' average age was 51.6 (± 8.2) years and their body mass index was 24.6 (± 5.5) kg / m^2. Their ICIQ-UI SF questionnaire's mean score was 15 (± 3.6) points and PFM average strength grade was equal to 2.5 (± 0.7) according to the *Modified Oxford Scale*.

All analyzed ultrasound parameters presented significantly different measurements between rest and PFM maximal voluntary contraction situation. Only the puborectal muscle thickness showed a statistically significant difference in the measurements between rest and the TAM maximal voluntary contraction (Table 1).

DISCUSSION

Arnold Kegel, a gynecologist, was the first to introduce the isolated PFM contraction exercises to treat urogynecological dysfunctions, including female urinary incontinence. Currently, globalized body interventions focusing on the abdominopelvic enclosure muscles[1-6] are being associated with Kegel's exercises, in order to strengthen PFM and improve the urogynecologic symptoms.

Considering studies on the co-activation between PFM and TAM[9-14], some authors[3,5] suggest that training TAM contractions must be encouraged before activities that promote intra-abdominal pressure increase and for women who do not present PFM awareness and perception. Currently, there seems to be a growing number of physiotherapists who are replacing PFM contractions by TAM contractions, as a treatment of female PFM dysfunctions[8]. However, there has not been any consensus yet on the effectiveness of trainings that use, exclusively, TAM contractions in order to increase PFM strength and treat urinary incontinence[21].

There is evidence that the PFM co-contraction occurs from the TAM contraction in continent women[9,11,12], but in incontinent women, this co-contraction seems to have been lost or changed[17,22,23].

Recent studies[24] have used ultrasound to evaluate the PFM contraction effect on the abdominal muscles, verifying that the TAM presents an increased thickness as a response to PFM contraction. However, this study has not evaluated the pelvic floor biometric parameters, to verify how they would respond during TAM contractions.

The effect of TAM maximal voluntary contraction on both PFM and the anatomical structures involving urinary continence mechanisms is not clear yet. Some authors argue that the thickness of TAM directly correlates with the PFM electromyographic activity[24] and that an isolated contraction of the TAM causes the elevation of the bladder neck in women without pelvic floor dysfunction[13]. On the other hand, other authors[8] believe that the PFM contraction obtained from a TAM contraction is significantly smaller and does not generate any significant changes in the genital hiatus area when compared to a direct PFM contraction, in women with pelvic organ prolapse.

The preliminary results of our study showed that the bladder neck position, genital hiatus area and puborectalis muscle thickness showed a significant difference between rest and PFM maximal voluntary contraction. In contrast, during the TAM maximal voluntary contraction, only the puborectalis muscle thickness presented a significant difference when compared to its value at rest. The other evaluated ultrasound parameters (bladder neck position and genital hiatus area), in spite of having changes during the TAM maximal voluntary contraction, did not result in significant changes when compared to their values at rest.

Based on these results, we can assume that puborectalis muscle thickness increasing during the TAM maximal voluntary contraction reinforces the theory that there is a synergic and functional relationship between the PFM and TAM[9-12].

In contrast, the TAM maximal voluntary contraction was not able to generate an effective PFM co-contraction so that it could significantly reduce the genital hiatus area and elevate the UVJ positioning, corroborating with the study of Bø et al[8].

This is a considerably important factor, since the genital hiatus area reduction can serve as a parameter to assess the efficacy of a PFM contraction once that this reduction occurs due to the shortening of their muscle fibers[19]. Similarly, the TAM maximal voluntary contraction was also not effective in raising the UVJ positioning, which is an important process for maintaining urinary continence[13]. Other authors[23,25] reported that incontinent women have a likely uncoordinated action between PFM and TAM, which generates an increase in intra-abdominal pressure and consequent urinary loss.

These preliminary results, indicated that is necessary to continue the research to clarify whether TAM voluntary contraction has an effect on the bladder neck position and genital hiatus area in women with SUI, which allows promoting evidence-based clinical practice.

As limitations of this study, we can mention the contraction time required for capturing the image and form the 3D / 4D volume in real time. Ten seconds, becomes too long, considering that incontinent women usually have low PFM

TABLE 1. PFM ultrasound biometric parameters during pelvic floor and transverse abdominal muscles' maximal voluntary contractions, compared to rest position.

	Rest M (SD)	PFM MVCM (SD)	TAM MVC M (SD)	Comparison of all situations[2]	Comparison of each situation with rest[2]
Urethrovesical junction position (cm)	2.7 (0.3)	3.0 (0.4)	2.8 (0.3)	**p=0.0001***	Rest x PFM MVC **p<0.001***Rest x TAM MVC p>0.05
Genital hiatus area (cm^2)	13.8 (3.2)	10.5 (2.5)	12.7 (3.4)	**p<0.0001***	Rest x PFM MVC **p<0.001***Rest x TAM MVC p>0.05
Puborectalis muscle thickness (cm)	0.7 (0.2)	0.9 (0.1)	0.8 (0.2)	**p<0.0001***	Rest x PFM MVC **p<0.001***Rest x TAM MVC p**<0,05****

Data presented as mean (M) and standard deviation (SD). PFM MVC = Pelvic floor muscles' maximal voluntary contraction; TAM MVC = Transverse abdominal muscle's maximal voluntary contraction; PFM = Pelvic floor muscles; TAM = Transverse abdominal muscle; cm = centimeter; cm^2 = square centimeter. [1]ANOVA for repeated measures. [2]Tukey-Kramer post test. *p<0.001. **p<0.05.

sustaining capacity. Faced with this issue, all the collections that would be incompatible should be excluded, although we have not had any such cases so far.

PFM and TAM assessments were not simultaneously performed as well, due to the used method's limitation. However, prior to evaluation, we confirmed the correct contraction of the TAM through ultrasound. Thus, we are sure that all participants were able to perform the appropriate contraction for both assessed muscles.

We stress the need for new studies that compare the effect of TAM contraction on both continent and incontinent women's pelvic floor biometric parameters. Furthermore, we suggest conducting randomized clinical trials evaluating the TAM contraction effect on the PFM biometric parameters in women with SUI, after conducting a TAM training protocol.

In conclusion, we verified that the PFM maximal voluntary contraction significantly changed all analyzed ultrasound parameters, compared with its measurements at rest. In contrast, during TAM maximal voluntary contraction, only the puborectalis muscle thickness increased significantly, compared to its size at rest, without presenting any significant effects on the bladder neck position and genital hiatus area.

ACKNOWLEDGEMENTS AND DISCLOSURES

This research was funded by Fundação de Amparo à Pesquisa do Estado de São Paulo - FAPESP (process number: 2015/22521-8, approved on: 2016).

REFERENCES

1. Culligan PJ, Scherer J, Dyer K et al. A randomized clinical trial comparing pelvic floor muscle training to a Pilates exercise program for improving pelvic muscle strength. International Urogynecologycal Journal 2010; 21: 401-8.
2. Stupp L, Resende AP, Petricelli CD et al. Pelvic floor muscle and transversus abdominis activation in abdominal hypopressive technique through surface electromyography. Neurourology and Urodynamics 2011; 30: 1518-21.
3. Talsz H, Kalchschmid E, Kofler M et al. Effects of multidimensional pelvic floor muscle training in healthy young women. Archives of Gynecology and Obstetrics 2012; 285 (3): 709-15.
4. Marques J, Botelho S, Pereira LC et al. Pelvic floor muscles training program increases muscular contractility during first pregnancy and postpartum: eletromyographic study. Neurourology and Urodynamics 2013; 32 (7); 998-1003.
5. Junginger B, Seibt E, Baessler K. Bladder-neck effective, integrative pelvic floor rehabilitation program: follow-up investigation. European Journal of Obstetrics and Gynecology and Reproductive Biology 2014; 174: 150-53.
6. Martinho NM, Silva VR, Marques J et al. The effects of training by virtual reality or gym ball on pelvic floor muscle strength in postmenopausal women: a randomized controlled trial. Brazilian Journal of Physical Therapy 2016: *in press*.
7. Ashton-Miller JA, DeLancey JOL. Functional anatomy of the pelvic floor. Annals of the New York Academy of Sciences 2007; 1101: 266-96.
8. Bø K, Braekken IH, Majida M et al. Constriction of the levator hiatus during instruction of pelvic floor or transversus abdominis contraction: a 4D ultrasound study. International Urogynecological Journal of Pelvic Floor Dysfunction 2009;20(1):27-32.
9. Sapsford R, Hodges PW, Richardson CA et al. Co-activation of the abdominal and pelvic floor muscles during voluntary exercises. Neurourology and Urodynamics 2001; 20 (1): 31-42.
10. Sapsford RR, Hodges PW. Contraction of the pelvic floor muscles during abdominal maneuvers. Archives of Physical Medicine and Rehabilitation 2001; 82 (8): 1081-8.
11. Neumann P, Gill V. Pelvic floor and abdominal muscle interaction: EMG activity and intra-abdominal pressure. International Urogynecological Journal 2002; 13: 125-32.
12. Madill SJ, McLean L. Relationship between abdominal and pelvic floor muscle activation and intravaginal pressure during pelvic floor muscle contractions in healthy continent women. Neurourology and Urodynamics 2006; 25: 722-30.
13. Junginger B, Baessler K, Sapsford R et al. Effect of abdominal and pelvic floor tasks on muscle activity, abdominal pressure and bladder neck. International Urogynecological Journal 2010; 21 (1): 69-77.
14. Pereira LC, Botelho S, Marques J. et al. Are Transversus Abdominis/Oblique Internal and Pelvic Floor Muscles Coactivated During Pregnancy and Postpartum? Neurourology and Urodynamics 2013; 32 (5): 416-19.
15. Tamanini JTN, Dambros M, D'Ancona CAL, Palma P, Rodrigues Neto N Jr. Validation of the "International Consultation on Incontinence Questionnaire – Short Form" (ICIQ-SF) for portuguese. Revista de Saúde Pública 2004; 38 (3): 1-6.
16. Laycock J.; Jerwood D. Pelvic floor muscle assessment: The PERFECT scheme. Phisyotherapy 2001; 87 (12): 631-42.
17. Bo K, Sherburn M, Allen T. Transabdominal ultrasound measurement of pelvic floor muscle activity when activated directly or via a transversus abdominis muscle contraction. Neuroutology and Urodynamics 2003; 22: 582-88.
18. Schaer GN, Koechli OR, Schuessler B, Haller U. Perineal ultrasound for evaluating the bladder neck in urinary stress incontinence. Obstetrics and Gynecology 1995; 85 (2): 220-4.
19. Dietz HP, Shek C, Clarke B. Biometry of the pubovisceral muscle and levator hiatus by three-dimensional pelvic floor ultrasound. Ultrasound in Obstetrics and Gynecology 2005; 25 (6): 580-5.
20. Albrich SB, Laterza RM, Skala C, Salvatore S, Koelbl H, Naumann G. Impact of mode of delivery on levator morphology: a prospective observational study with three-dimensional ultrasound early in the postpartum period. An International Journal of Obstetrics and Gynaecology 2012; 119 (1): 51-60.
21. Bø K, Herbert RD. There is not yet strong evidence that exercise regimens other than pelvic floor muscle training can reduce stress urinary incontinence in women: a systematic review. Journal of Physiotherapy 2013; 59 (3) :159-68.
22. Bø K, Mørkved S, Frawley H, Sherburn M. Evidence for Benefit of Transversus Abdominis Training Alone or in Combination With Pelvic Floor Muscle Training to Treat Female Urinary Incontinence: A systematic Review. Neurourology and Urodynamics 2009; 28: 368-373.
23. Smith MD, Coppieters MW, Hodges PW. Postural response of the pelvic floor and abdominal muscles in women with and without incontinence. Neurourology and Urodynamics 2007; 26: 377-84.
24. Tajiri K, Huo M, Maruyama H. Effects of Co-contraction of Both Transverse Abdominal Muscle and Pelvic Floor Muscle Exercises for Stress Urinary Incontinence: A Randomized Controlled Trial. Journal of Physical Therapy Sciences 2014; 26: 1161-63.
25. Thompson J, O'Sullivan P. Levator plate movement during voluntary pelvic floor muscle contraction in subjects with incontinence and prolapse: A crosssectional study and review. International Urogynecological Journal of Pelvic Floor Dysfunction 2003; 14: 84-8.

Correspondence to:
Simone Botelho
Curso de Fisioterapia – Escola de Enfermagem, Universidade Federal de Alfenas - UNIFAL/MG Av. Jovino Fernandes Sales, 2600 Santa Clara - Alfenas/MG – Brasil. Prédio B, Sala 101-K - Alfenas 37130000 Minas Gerais – Brazil
CEP: 37130-000 - Telephone: (+55) 35-3292-2377
www.unifal-mg.edu.br - simone.botelho@unifal-mg.edu.br

InGYNious

Single incision pelvic floor repair with an ultralight mesh.

Maximise patient comfort and minimise pain while ensuring firm suspension to the sacrospinous ligament and full, 3-level support.

It's InGYNious. Why settle for anything less?

A.M.I.
Agency for Medical Innovations

INNOVA medica SPA

Viale Europa 78 20090 Cusago
tel. 029039201 fax 0290394211
www.innovamedica.com
info@innovamedica.com

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