Vol. 31 - N. 3
September 2012

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

ANNOUNCEMENT

Pelviperineology is open access in the web. In 2011 **www.pelviperineology.org** and **www.pelviperineologia.it** have been visited over 117.000 times. Some printed copies of the journal are distributed free by sponsors. If you wish to receive all issues of the printed journal, unless this is provided by your scientific society, send your name and full postal address to **subscriptions@pelviperineology.org**, and pay a 30,00 € yearly fee to the **Integrated Pelvis Group** via Paypal account (see the instructions in the website **www.pelviperineology.org**).

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

Why?

PSYLLOGEL® fibra

In case of...

... Constipation, Hemorrhoids, Pelvic floor diseases.

The most natural way to promote, restore and maintain **regularity**.

Psyllium is the strongest natural dietary fiber for promoting regularity and supporting benefits overall health. Psyllium has low fermentation; this gel provides lubrication that facilitates propulsion of colon contents and produces a stool that is bulkier and more moist.

AVAILABLE IN THE TASTES:

Red orange | Strawberry | Lemon tea | Cocoa | Vanilla

PSYLLOGEL® fibra
The leader in **psyllium fiber 99% purity**.

Informations reserved to the doctors and pharmacists
IN PHARMACY

NATHURA®
Nutrizione Scientifica

NATHURA SRL - Tel. +39 0522 865464 - www.nathura.com - nathura@nathura.com
UNI EN ISO 9001:2008 QUALITY MANAGEMENT SYSTEM CERTIFIED BY CERTIQUALITY

Vol. 31
N. 3
September 2012

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)
(the former Australasian Association of Vaginal and Incontinence Surgeons)
International Pelvic Floor Dysfunction Society
Pelvic Reconstructive Surgery and Incontinence Association (Turkey)
Perhimpunan Disfungsi Dasar Panggul Wanita Indonesia
Romanian Uro-Gyn Society

Editorial Office: Enrico Belluco
c/o Clinica Chirurgica 2 University of Padova, 35128, Padova, Italy
e-mail: **editor@pelviperineology.org**
Quarterly journal of scientific information registered at the Tribunale di Padova, Italy n. 741 dated 23-10-1982 and 26-05-2004
Editorial Director: Giuseppe Dodi
Printer "Tipografia Veneta" Via E. Dalla Costa, 6 - 35129 Padova - e-mail: info@tipografiaveneta.it

A.M.I.®
Agency for Medical Innovations

HAVE A HEART FOR YOUR PATIENTS

Free them from piles with a virtually pain-free procedure! Regardless of what grade, A.M.I. HAL-RAR is the safe, gentle and effective way to treat their haemorrhoidal disease.

And now the new RAR FlexiProbe makes your life even easier. To find out more, mail us at info@ami.at or contact your local A.M.I. distributor.

With the new RAR Flexi Probe

www.ami.at

Editorial

FIGO Working Group on Pelvic Floor Medicine and Reconstructive Surgery

On January 26-28, 2012 the members of the FIGO Working Group on Pelvic Floor Medicine and Reconstructive Surgery met in Rome. The Working Group was founded during the FIGO Congress in Kuala Lumpur, Malaysia in 2006 with the acceptance of FIGO Executive Board.

At present there are more than 100 international and national societies and foundations that participate in the proposals of development of this multidisciplinary area of medicine. That is why the members of the FIGO Working Group are international opinion leaders independently of the society they belong to and whose fundamental objective is to offer FIGO proposals and opinions validated by the meta-analysis of international bibliography through the recommendation criteria that arise from the evidence to which the agreed experience of its participants is added.

From the beginning three initial subgroups were programmed:

Subgroup 1* – *"Educational Program on Pelvic Floor Medicine and Reconstructive Surgery"
Subgroup 2* – *Pelvic Floor Dysfunction Classification
Subgroup 3* – *Pelvic Organ Prolapse Surgery in Women

These subgroups are in charge of designing proposals oriented towards physicians who are in postgraduate training (residences or other modalities). In second place, to give adequate information that would allow the obstetrician and gynecologist have access to necessary and updated knowledge of this area for their daily practice.

Finally, to emphasize on the educational objectives proposed by the devoted professionals in this area.

Upon these bases "The FIGO guidelines for training residents and fellows in Urogynecology, female urology, and female pelvic medicine and reconstructive surgery" were published in 2009 in the International Journal of Gynecology and Obstetrics" and an Action Plan was developed whose results were presented and agreed in the meeting that the FIGO Working Group had in January 26-28, 2012 in Rome at the Università Cattolica del Sacro Cuore - Policlinico Universitario "Agostino Gemelli" thanks to the support given by Professor Giovanni Scambia and Professor Mauro Cervigni. In this last meeting the outcomes of the development of the different subgroups were defined and agreed. These outcomes will be presented in at the FIGO Congress that will be held in Rome on October 7 – 12, 2012.

I highly appreciate the attendance and active participation of Drs Mauro Cervigni, Mohamed Hefni, Masayasu Koyama, Stelios Doumouchtsis, Teresa Mascarenhas, Ruwan Fernando, Elisabetta Costantini, Filippo La Torre, Alex Digesu, Steven Swift, Gabriele Falconi, Ali Abdel Raheem, Stefano Salvatore, Adolf Lukanovic, Martin Jomaa, Giuliano Zanni, Jittima Manonai, Biagio Adile, Bruce Farnsworth and Helio Retto that made possible the consolidation of the conclusions of the Action Plan.

Oscar Contreras Ortiz, MD., FACOG
Consultant Head Professor
Faculty of Medicine University of Buenos Aires, Argentina
IUGA Past President
IPFDS Past President
ACOG Argentine Section Chairman
FIGO Working Group Chairman

ISPP

www.pelviperineology.com

ISPP INTERNATIONAL PELVIPERINEOLOGY CONFERENCE

YOKOHAMA SYMPOSIA, YOKOHAMA, JAPAN, OCTOBER 22-25, 2012

The International Pelviperineology Society (ISPP), formerly AAVIS is pleased to announce that this year our Annual Scientific meeting and International Pelviperineology Conference will be held in Yokohama, Japan.

The program will include a variety of international speakers together with specialized workshops and symposia focusing on various topics in pelvic medicine relevant to urologists, gynaecologists and colorectal surgeons. There will be live surgery demonstrations at Shonan Kamakura General Hospital.

Further information and online registration will soon be available from the ISPP Website at **www.pelviperineology.com** or by contacting Bruce Farnsworth by email drbruce505@gmail.com. We look forward to welcome you to Yokohama in October. Join us for a memorable medical and social experience.

Dr Bruce Farnsworth
Dr Hiromi Inoue
ISPP 2012 Conference Organising Committee

Invitation

ISPP Annual Scientific Meeting and International Pelviperineology Conference

22nd-25th October 2012 Yokohama Japan

The ISPP Organising Committee is pleased to invite you to the first International Conference to be held in Asia. ISPP and its' predecessor AAVIS have held very successful annual scientific meetings since our first one held on the Gold Coast in 1999. Now the ISPP is a truly international multidisciplinary society with valued contributions from urologists, gynaecologists and colorectal surgeons as well as nurses, pelvic therapists, pain therapists and physiotherapists. This year the meeting is in the fascinating city of Yokohama where our Japanese colleagues are doing their best to ensure a stimulating medical and social experience.

This year an impressive Australasian and international faculty will present a number of papers on pelvic medicine and surgery. There will be special workshops and symposia on a number of topics, and delegates will be able to participate in pre and post conference tours. The conference dinner will be onboard a floating restaurant ship cruising the Yokohama harbor. Live surgery will be performed at the Shonan Kamakura General Hospital. One of the highlights of the meeting will be a hands-on ultrasound training workshop conducted by the leading European ultrasound experts Drs Giulio Santoro and Pawel Wieczorek. There will also be a WIPS Pelvic Surgery workshop conducted by Associate Professor Richard Reid, Professor Carl Zimmerman and their associates.

Yokohama is only 30 minutes from Tokyo and is easily accessed directly from Narita Airport. Narita has direct flights daily from Australia, Europe and North America. From Narita you can transfer directly to Yokohama by the YCat bus which travels from the Airport terminals directly to central Yokohama. You can also catch the train from Narita to Yokohama via Tokyo.

In Yokohama the conference venue and hotels are only a short taxi ride from either the YCat terminal or the railway station. The ISPP 2012 Conference venue is the Yokohama Symposia. This is a purpose-built conference centre on the waterfront in Yokohama adjacent to Yamashita Park within walking distance of several hotels and easy access to Yokohama bus and rail connections.

A number of workshops and symposia have been organized as part of the program. These options can be selected when making your online booking. Registration for the workshops and symposia is only available to conference registrants. Please book early to secure your place as space is limited and some sessions will be limited as to the number of attendees.

BRUCE FARNSWORTH

link for the program of the Congress: **http://bit.ly/RSwftk**

Original article

Laparoscopic chordofixation: a new technique for vaginal vault suspension

MIKLOS KOPPAN[1,3], ANDREAS HACKETHAL[1], ION-ANDREI MÜLLER-FUNOGEA[2], JOZSEF BODIS[3], HANS-RUDOLF TINNEBERG[1]

[1]*Department of Obstetrics and Gynaecology, Justus-Liebig-University Giessen, Giessen, Germany*
[2]*Departement of Obstetrics and Gynecology, Regional Hospital Aachen, Germany*
[3]*Department of Obstetrics and Gynaecology, University of Pécs, Pécs, Hungary*

Abstract. Objective: The aim of this study was to assess the surgical feasibility, safety and clinical/anatomical outcomes of vaginal vault suspension applying a new method at the time of laparoscopic hysterectomy. This technique was based on the theory that the use of the obliterated umbilical artery as an anchoring structure provides a safe, anatomically correct and flexible suspension to the vaginal cuff. *Methods:* Twentyfive patients during an 8-month period with a benign disease, in two cases with coexisting pelvic floor disorder, underwent total laparoscopic hysterectomy completed by a bilateral suspension of the vaginal vault to the proximal segment of the obliterated umbilical artery (chorda). Patients were examined at 6 weeks after the operation with site-specific analysis of vaginal cuff anatomy and interviewed by a questoinnaire focusing on pre- and postoperative complaints. The overall follow-up lasted 8 months. *Results:* There were no intra- and postoperative complications. Six weeks after the operation all patients were without complaints. The length, the position and the axis of the vaginal cuff was found to be excellent in all cases, yet, the fixed vaginal cuff was found to be flexible. In the two cases when surgery was performed for patients with moderate apical prolapse no prolapse of the vaginal vault could be detected at six weeks and in one case 5 month following the operation. *Conclusion:* Vaginal vault suspension through the chorda of the umbilical artery is easily performed via laparoscope and is associated with excellent clinical and anatomical outcomes in short-term follow-up.

Key words: Apical Prolapse; Laparoscopic Vaginal Vault Suspension.

INTRODUCTION

The exact incidence of vaginal vault prolapse is not known but has been estimated to occur in 0.1–45% of patients who have undergone hysterectomy[1,2]. Loss of pelvic support with resultant pelvic organ prolapse results from impairment and/or attenuation of any part of the pelvic support system. There are multiple risk factors known to increase a woman's risk for the development of pelvic organ prolapse. These risk factors can be categorized as predisposing, inciting, promoting, and decompensating events. Among the inciting events we may find prior surgery such as hysterectomy[3]. Support for the vaginal apex is provided by the fibers of the paracolpium comprising the cardinal and uterosacral ligaments (Level I)[4]. In contrast, support for the midportion of the vagina derived from the lateral attachments to the arcus tendineus fasciae pelvis and superior fascia of the levator ani muscles (Level II)[5]. However, some suggest that anterior wall support defects are often a result of coincident apical prolapse[6]. This suggests that in cases when patients have both cystocele and apical prolapse, surgery to address the apical defect may obviate additional surgery to repair the cystocele.

Apical support defects may occur because of the compromise of the cardinal uterosacral ligament complex or failure to reapproximate the superior aspects of the pubocervical and rectovaginal fascia at the time of hysterectomy[7]. The key anatomical structure for the adequate suspension of the apical vagina and the cervix of the uterus is the pericervical ring with the ligamentous condensations of the endopelvic fascia attached to it[8]. During hysterectomy, this ring might be directly, or, by impairing the blood supply to it, indirectly damaged. This damage may lead to weakening of the fascia and, thus, might later result in apical prolapse. That is why a proper suspension of the apex of the vagina at the time of hysterectomy is important. Beyond that, when hysterectomy is performed for prolapse, hysterectomy alone, or with colporrhaphy, is insufficient; a specific vault suspension procedure must be performed in addition to the hysterectomy[9]. As early as 1929, in his description of hysterectomy techniques, Dr Richardson emphasized the importance of proper identification and use of the uterosacral ligaments during vaginal cuff closure at the time of hysterectomy to ''guarantee'' the prevention of subsequent pelvic organ prolapsed[10]. Studies suggest that apical vault repair should be used routinely along with laparoscopic hysterectomy[11]. Based on above principles we have designed a new laparoscopic vault suspension technique that is simple to perform, uses no foreign material, appears to be safe and provides excellent support to the apical vagina with proper position, orientation and axis of the vaginal cuff. The procedure uses the obliterated umbilical artery as an anchoring structure to suspend the vaginal cuff.

MATERIALS AND METHODS

Patients

Altogether 25 patients admitted between December 1, 2009 and August 1, 2010 for hysterectomy with or without adnexectomy due to benign uterine disease were randomly selected preoperatively. After thorough preoperative counseling patients gave written consent to the procedure.

Evaluation of pelvic floor integrity prior and after the operation

We used the standardized pelvic organ prolapse quantification (POP-Q) exam to quantify, describe, and stage pelvic support[12].

Surgical technique

All laparoscopic hysterectomies were performed using the intrafascial technique similar to the one described recently by Hohl and Hauser[13]. Minor differences in our hysterectomy procedure are the use of Mangeshikar uterusmanipulator (Bissinger Medizintechnik GmbH, Teningen, Germany), the application of only two secondary 5-mm ports (one on each side) for the surgical instruments, the use of EnSeal Advanced Bipolar Device (Ethicon Endo-Surgery, Inc., Cincinnati, OH, USA) for temperature con-

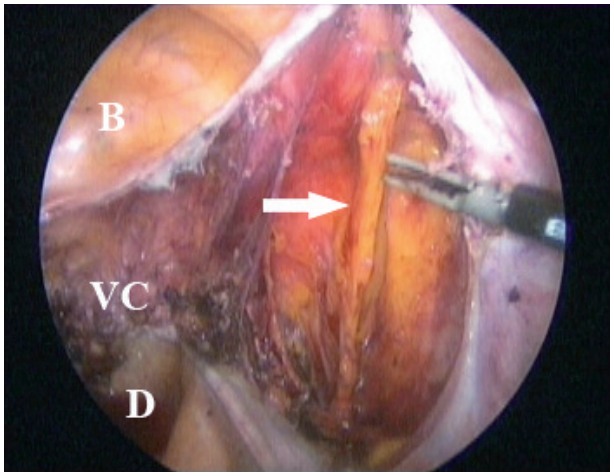

Figure 1. – The exposed chorda of the right side in the retroperitoneum at the level of resection (arrow). B: urinary bladder; VC: vaginal cuff (sutured); D: Douglas pouch.

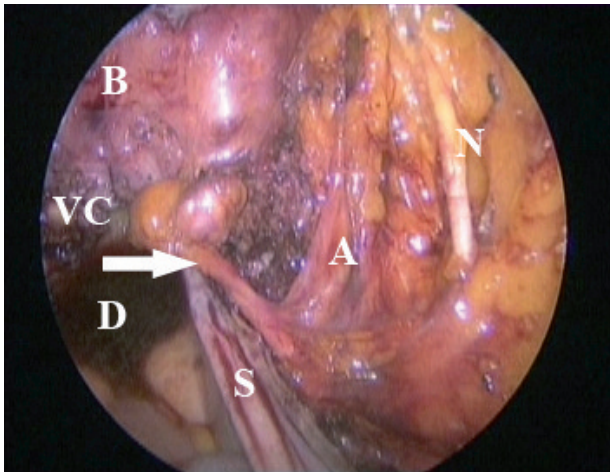

Figure 2. – The chorda of the right side (arrow) sutured to the vaginal cuff (VC). B: urinary bladder; D: Douglas pouch; S: sacrouterine fold; A: superior vesical artery; N: obturator nerve.

trolled vessel sealing and tissue cutting. At the end of hysterectomy we apply one running suture using 1–0 polydiaxonon (PDS, Ethicon, Inc. Somerville, New Jersey, USA), incorporating cardinal and sacrouterine ligaments as well as the endopelvic fascia posteriorly and anteriorly to close the vagina knotted intracorporally. At this point, the fixation of the vaginal vault starts with the preparation of the obliterated umbilical arteries (chordae). The procedure described below is performed on both sides.

Step 1. *The localization of the chorda* on the anterior abdominal wall is simple, grabbing the medial umbilical fold and tracing it back proximal shortly above the point where it crosses the pelvic brim anteriorly. In obese patients gentle movements with a blunt grasper on the abdominal wall in a horizontal way may help identify the fold and the chorda in it.

Step 2. *Preparation of the chorda* with opening the retroperitoneum next to it using EnSeal, then cutting the chorda just a few centimeters above the pelvic brim (Figure 1). Thus we ensure that ample length of the obliterated (ligamentous) vessel will be available for proper fixation, in order not to cause overstretch of the vaginal membrane. We recommend to leave some extra fat tissue of the abdominal/pelvic wall on the chorda thus making the anchoring structure bulkier. During the preparation one should pay attention to the preservation of the most distal branch of the umbilical artery that is the superior vesical artery, so blood supply to the bladder is not affected. This is better ensured by keeping bulkier fat tissue on the chorda. Also, anchorage of the chorda on the vaginal vault provides a firmer bridge if the anchoring structure is bulkier. The pulsation of the superior vesical can later be visually verified at the end of the fixation procedure.

Step 3. *Determining the suture points of the chorda* by approximating it to the lateral edge of the vaginal vault. If the patient has previously had a prolapse, the vault should be elevated by a manipulator to develop a normal anatomical rectouterine pouch. The basic rule is not to overstretch the vagina.

Step 4. *Placing the sutures* using nonabsorbable, braided, 2-0 Ethibond Excel Polyester surgical suture (Ethicon, Inc. Somerville, New Jersey, USA). First we place the suture in the chorda at the point what we consider to be the optimal point for fixation without overstretch. Then we continue placing the suture into the lateral edge of the vaginal cuff and the paracolpium between the cardinal and sacrouterine ligaments. The suture is knotted intracorporally. If proper fixation has been done, a deep cul-de-sac is clearly visible (Figure 2).

Step 5. *Checking the ureters and the pulsation of the superior vesical artery* is optional. We performed that during our first few operations and found that both ureters were moving free under the fixed chorda without obliteration. The pulsation of the preserved superior vesical arteries were also clearly seen. In doubt these can be ensured by blunt dissection of the retroperitoneum below the newly placed chorda (for the ureters) and a gentle dissection alongside the chorda finding the superior vesical artery that forms a "Y" shape together with the chorda from which it is now given off laterally.

The peritoneum remains open. Hemostasis is checked and a thorough lavage using warm ringer lactate is done.

Evaluation and follow-up

In follow-ups primary gynecological care providers of patients have been involved. We constructed a detailed questionnaire for the primary gynecological care taker colleagues to standardize the long-term postoperative follow-up of patients. This questionnaire focuses on the pre- and postoperative conditions of patients regarding the presence of prolapse, problems with urinary and/or fecal continence, difficulties with emptying the bladder, pain in conjunction with or independent of sexual intercourse.

RESULTS

Until date the longest follow-up period has been eight months.

Intraoperative or short term post-operative complications

So far we have not encountered any intraoperative complication, including ureteral injury or serious bleeding from the adjacent branches of the internal iliac artery.

Anatomical outcome

At follow-up examinations 6 weeks after the operation all patients were without complaints. The anatomical outcome concerning the length, the position and the axis of the vaginal cuff was found to be excellent in all cases, using the POP-Q prolapse evaluation method. On the other hand, the fixed vaginal cuff was found to be flexible, that is believed to be enough to accommodate physical wear during intercourse. When surgery was performed for patients with moderate apical prolapse (POP-Q Stage II., 2 cases), no prolapse could be detected at 6 weeks.

Later post-operative complaints

We have no data about complaints or complications such as pain, apical prolapse, pain during intercourse, problems with voiding or defecating. One of our major concern was a later bleeding from the internal iliac vessel due to an abrupt damage during intercourse but this has not been encountered, either. Similarly, no data about fistulas or delayed postoperative recovery for any reason are known. In one of the two cases when Stage II prolapse was present prior the operation, the later follow-up examination has not been possible but in the other case, at 5 month following surgery, no apical prolapse, but cystocele and rectocele was recorded.

DISCUSSION

Our experience suggests an improved outcome of pelvic floor anatomy by applying chordofixation at the time of hysterectomy. However, due to the limited number of cases and follow-up period, we have not been able to draw firm, long-term conclusions. The treatment and prevention of vaginal vault prolapse is challenging, as best shown by the fact, that more than 40 different techniques exist to treat this pathology[14]. Moreover, controversy exists over the choice of vaginal procedure as well as the relative merits of vaginal versus abdominal suspension procedures.

The primary indication for sacrospinous ligament fixation was to correct total procidentia or post-hysterectomy vaginal vault prolapse with an associated weak or atrophied cardinal-uterosacral ligament complex[14]. There is controversy about whether it should be used as a prophylactic measure after vaginal hysterectomy[15,16]. When performed for correction, the objective cure rate ranged from 8% to 94%[14]. Complications may include hemorrhage with a transfusion rate of 2%, perforation of the bladder, rectum, and small bowel (0.8%), ureteral kinking and micturition problems (2.9%), vaginal adhesions and rectovaginal fistulas (0.5%), and nerve damage to the femoral, peroneal, or sciatic nerves (1.8%)[17]. Gluteal pain may resolve within 6 weeks, but patients may require reoperation[14]. Also, vaginal narrowing and shortening may occur. Sexual dysfunction has also been reported in up to 13% of the patients[18,17]. When performed unilaterally, normal vaginal axis is not established.

Another approach is the suspension of the vaginal vault to the uterosacral ligaments[19]. It can be used prophylactically at hysterectomy or for treatment of vault prolapse[20]. It's main advantages are a normal resultant vaginal axis and avoidance of suturing near neural or vascular structures. However, when performed in a patient with lax uterosacrals (and resultant prolapse), the anatomical outcome is highly questionable. Furthermore, intraoperative ureteral injury has been reported as high as 11%[21].

Bilateral fixation of the vaginal apex to the iliococcygeus fascia was first described in 1963[22]. A potential benefit is the absence of vulnerable structures in the area. The success rate ranges from 81%[23] to more than 90%[24-26].

An abdominal approach, using autologous, allograft, or synthetic material, is indicated after failed vaginal repair, when concomitant abdominal surgery is required, or when the surgeon is not familiar with the vaginal route[27]. In an extensive review[28], the success rate ranged from 58% to 100%. The overall rate of mesh erosion was 3.4%. Although mesh erosion can frequently be managed by vaginal excision of all or part of the mesh, laparotomy or laparoscopy is occasionally required[29]. Some concern has also been raised about the durability of allograft fascia[30].

Beyond vaginal and abdominal routes, laparoscopic approaches have also developed with the first one reported in 1992[31]. The uterosacral suspension was first reported by Miklos and colleagues using a combined vaginal and laparoscopic approach[32]. The full laparoscopic procedure was reported in 2001[33]. The laparoscopic sacral colpopexy evolved from the classical open procedure using graft material attached to the anterior and posterior vaginal walls and to the presacral ligament. There has been one cohort study to compare laparoscopic sacral colpopexy with the open procedure[34]. In the laparoscopic group the mean operating time was longer, blood loss was lower, and hospital stay appeared to be shorter.

The large number of operative techniques demonstrates the lack of one univocally successful operative procedure. The disadvantage of the vaginal routes comprises relatively lower success rates, less visualization, higher incidence of injury to adjacent organs or bleeding. Furthermore, unilateral operations establish distorted vaginal anatomy. The abdominal routes might be considered obsolete unless there is a need for concomitant abdominal surgery. All techniques that use the sacrouterine and/or cardinal ligament complex to restore anatomy, might face the challenge of restoring anatomy using the already lax tissues. Laparoscopic sacral colpopexy uses foreign material that can be a source of later erosion or *de novo* dyspareunia. Moreover, a recent safety communication of the U.S. Department of Food and Drug Administration[35] has shown, that no evidence exists to prove any added benefit of transvaginal apical repair with mesh compared to traditional surgery without mesh. Also, the FDA review advocated, that most cases of POP can be treated successfully without mesh.

Our technique of chordofixation uses no foreign material, thus no later erosion can be expected. Also, the procedure is extremely cost-effective. So far no *de novo* dyspareunia has been encountered. It is probable, that the obliterated umbilical artery maintains its basically vessel-type flexibility, that synthetic meshes never possess. Furthermore, this anatomical structure bears no signs of wear or tear over the years or due to a multiparous status. Thus, it can be safely used even in patients presenting with prolapse. In addition, based on the course of the vessel and its relation to the apex of the vaginal cuff, proper axis, length and orientation of the vagina is ensured. The procedure is easy to perform, requires no extra surgical skills and it is not time consuming. The technique is extremely safe, puts no extra risk to the bladder, ureters, the rectum or great vessels, mainly because of the ease of the preparation and the anatomical location of the chorda. Based on our experience, we highly recommend this method be applied routinely in all laparoscopic hysterectomies as a preventive measure. However, in order to elucidate its long term efficacy, prospective studies are necessary. Beyond that, we believe, that our procedure should also be offered as a curative method for patients presenting with vaginal vault prolapse. For that, prospective studies concerning efficacy and safety must be designed.

REFERENCES

1. Cruikshank SH. Sacrospinous fixation – should this be performed at the time of vaginal hysterectomy? *Am J Obstet Gynecol* 1991; 164:1072–1076.
2. Karram M, Goldwasser S, Kleeman S, et al. High uterosacral vaginal vault suspension with fascial reconstruction for vaginal repair of enterocele and vaginal vault prolapse. *Am J Obstet Gynecol* 2001; 185:1339–1342.
3. Bump RC, Norton PA. Epidemiology and natural history of pelvic floor dysfunction. *Obstet Gynecol Clin North Am* 1998;25:723–746.
4. Shippey SH, et al. Anatomic outcomes of abdominal sacrocolpopexy with or without paravaginal repair. *Int Urogynecol J* (2010) 21:279–283.

5. DeLancey JO. Anatomic aspects of vaginal eversion after hysterectomy. *Am J Obstet Gynecol* 1992; 166:1717–1724
6. Lowder JL, Park AJ, Ellison R, Ghetti C, Moalli P, Zyczynski H et al (2008) The role of apical vaginal support in the appearance of anterior and posterior vaginal prolapse. *Obstet Gynecol* 111:152–157
7. Richardson AC: The anatomic defects in rectocele and enterocele. *J Pelvic Surg* 1995; 1:214-221.
8. Siddighi S, Hardesty JS: Anatomy relevant to female reconstructive pelvic surgery: Part II. In: Urogynecology and female pelvic reconstructive surgery: just the facts. 2006; p. 5-12. The McGraw-Hill Companies, Inc., New York, NY, USA.
9. Weber AM, Richter HE: Pelvic organ prolapse. *Obstet Gynecol* 2005; 106:615-634.
10. Richardson EH. A simplified technique for abdominal panhysterectomy. *Surg Gyneco Obstet* 1929;48:248–252
11. Ross JW. Apical vault repair, the cornerstone or pelvic vault reconstruction. *Int Urogynecol J Pelvic Floor Dysfunct* 1997; 8(3):146-52.
12. Bump RC, Mattiasson A, Bo K, et al. The standardization of terminology of female pelvic organ prolapse and pelvic fl oor dysfunction. *Am J Obstet Gynecol* 1996; 175:13.
13. Hohl MK, Hauser N: Safe total intrafascial laparoscopic (TAIL™) hysterectomy: a prospective cohort study. *Gynecol Surg* 2010; 7:231-239.
14. Sze EH, Karram MM: Transvaginal repair of vault prolapse: A review. *Obstet Gynecol* 1997; 89:466-475.
15. Cruikshank SH, Cox DW: Sacrospinous ligament fixation at the time of transvaginal hysterectomy. *Am J Obstet Gynecol* 1990; 162:1611-1615. discussion 1615-1619
16. Colombo M, Milani R: Sacrospinous ligament fixation and modified McCall culdoplasty during vaginal hysterectomy for advanced uterovaginal prolapse. *Am J Obstet Gynecol* 1998; 179:13-20.
17. Beer M, Kuhn A: Surgical techniques for vault prolapse: A review of the literature. *Eur J Obstet Gynecol Reprod Biol* 2005; 119:144-155.
18. Holley RL, Varner RE, Gleason BP, et al: Sexual function after sacrospinous ligament fixation for vaginal vault prolapse. *J Reprod Med* 1996; 41:355-358.
19. McCall ML: Posterior culdoplasty; surgical correction of enterocele during vaginal hysterectomy; a preliminary report. *Obstet Gynecol* 1957; 10:595-602.
20. Shull BL, Bachofen C, Coates KW, et al: A transvaginal approach to repair of apical and other associated sites of pelvic organ prolapse with uterosacral ligaments. *Am J Obstet Gynecol* 2000; 183:1365-1373.discussion 1373-1374.
21. Barber MD, Visco AG, Weidner AC, et al: Bilateral uterosacral ligament vaginal vault suspension with site-specific endopelvic fascia defect repair for treatment of pelvic organ prolapse. Am *J Obstet Gynecol* 2000; 183:1402-1410.discussion 1410-1411.
22. Inmon WB: Pelvic relaxation and repair including prolapse of vagina following hysterectomy. *South Med J* 1963; 565:77-82.
23. Shull BL: Clinical evaluation of women with pelvic support defects. *Clin Obstet Gynecol* 1993; 36:939-951.
24. Meeks GR, Washburne JF, McGehee RP, et al: Repair of vaginal vault prolapse by suspension of the vagina to iliococcygeus (prespinous) fascia. *Am J Obstet Gynecol* 1994; 171:1444-1452.discussion 1452-1454
25. Peters 3rd WA, Christenson ML: Fixation of the vaginal apex to the coccygeus fascia during repair of vaginal vault eversion with enterocele. *Am J Obstet Gynecol* 1995; 172:1894-1900. discussion 1900-1902.
26. Koyama M, Yoshida S, Koyama S, et al: Surgical reinforcement of support for the vagina in pelvic organ prolapse: Concurrent iliococcygeus fascia colpopexy (Inmon technique). *Int Urogynecol J Pelvic Floor Dysfunct* 2005; 16:197-202.
27. Kobashi KC, Leach GE: Pelvic prolapse. *J Urol* 2000; 164:1879-1890.
28. Nygaard IE, McCreery R, Brubaker L, et al: Abdominal sacrocolpopexy: A comprehensive review. *Obstet Gynecol* 2004; 104:805-823
29. Begley JS, Kupferman SP, Kuznetsov DD, et al: Incidence and management of abdominal sacrocolpopexy mesh erosions. *Am J Obstet Gynecol* 2005; 192:1956-1962.
30. FitzGerald MP, Edwards SR, Fenner D: Medium-term follow-up on use of freeze-dried, irradiated donor fascia for sacrocolpopexy and sling procedures. *Int Urogynecol J Pelvic Floor Dysfunct* 2004; 15:238-242
31. Ostrzenski A: Laser video-laparoscopic colpopexy. *Ginekol Pol* 1992; 63:317-323.
32. Miklos JR, Kohli N, Lucente V, et al: Site-specific fascial defects in the diagnosis and surgical management of enterocele. *Am J Obstet Gynecol* 1998; 179:1418-1422.
33. Carter JE, Winter M, Mendehlsohn S, et al: Vaginal vault suspension and enterocele repair by Richardson-Saye laparoscopic technique: Description of training technique and results. *JSLS* 2001; 5:29-36.
34. Paraiso MF, Walters MD, Rackley RR, et al: Laparoscopic and abdominal sacral colpopexies: A comparative cohort study. *Am J Obstet Gynecol* 2005; 192:1752-1758.
35. U.S. Food and Drug Administration. FDA Safety Communication: Update on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse. July 13, 2011. (http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm.

Correspondence to:

MIKLOS KOPPAN, MD, PhD
Department of Obstetrics and Gynaecology
Faculty of Medicine, University of Pécs
Édesanyák Str. 17.
7624 Pécs, Hungary
Tel.: +36 72 536 000
Email: mkoppan@gmail.com

Focus

The development of laparoscopy and its application to pelvic floor repair

ELVIS I. SEMAN, MARC J.N.C. KEIRSE

Department of Obstetrics, Gynecology and Reproductive Medicine, Flinders Medical Centre and Flinders University, Adelaide, South Australia, Australia

Abstract: We present a brief overview of how laparoscopy evolved from a purely diagnostic to a therapeutic procedure. Emphasis is given to the many innovative developments that led to its application to correct pelvic floor dysfunction with its range of anterior, apical and posterior defects. It may serve to reflect on how current methods and techniques can still be improved to deal with pelvic problems that are likely to become more prevalent as our population ages.

Key words: History; Laparoscopy; Laser; Pelvic Floor Repair; Operative laparoscopy; Videolaparoscopy.

INTRODUCTION

Although attempts to visualize the viscera "per vias naturales" date back to Hippocratic times,[1] recorded attempts to do so transabdominally, named ventroscopy by von Ott in 1901, coelioscopy by Kelling in 1902, and laparoscopy by Jacobeus in 1911, only started in the last century.[2] Innovative as these approaches were, it took a great deal of ingenuity from several people to develop the instruments and techniques that have given laparoscopy the diagnostic and therapeutic scope that it has today.

In this paper we briefly mention these early developments before tracing the innovations that led to the use of laparoscopy for the treatment of pelvic organ prolapse, an approach that might seem to be counter-intuitive at first sight.

The ebb and flow of early laparoscopy

Much of the early developments in laparoscopy as they relate to gynaecology have been well documented[1-4] and the main innovations made in the first half of the last century are briefly summarized in Table 1. They came somewhat to a standstill in the 1940s, as culdoscopy (endoscopy via the posterior vaginal fornix) surged in popularity, especially in the USA where it found a great advocate in Te Linde.[2] Pelvic organ visualization with the culdoscope was limited, though, until Decker described the knee-shoulder position in 1946. [2]

After World War Two, resurgence in gynaecological laparoscopy was led by Frangenheim in Germany and Palmer in France, from where it spread to the English-speaking world. Its resurgence was facilitated by important innovations. In 1943, Fourestier and colleagues, in Paris, had introduced the cold light source, which overcame the need for and dangers of a hot light bulb at the end of the scope.[2] In 1953, Hopkins introduced the rod lens system which improved visual clarity, the angle of vision, and the depth of field.[2] In the early 1950s, Frangenheim designed laparoscopic instruments and made the first purpose-built CO_2 insufflator.[4] He also popularized tubal cautery, as did Palmer, who wrote extensively on gynaecologic laparoscopy and described the use of the Palmer forceps, which is still in use today. Steptoe wrote the first English monograph on laparoscopy in 1967.[5]

Monopolar, bipolar and beyond

Monopolar diathermy was introduced in the early 1950s for tubal sterilisation.[3] Strangely enough, complications from burns did not lead to safer alternatives for many years. They only came with the development of bipolar coagulation by Frangenheim in Germany [4]and Rioux and Cloutier in Canada[6] and with the introduction of the even safer thermocoagulation by Semm in Germany.[7] Eventually, mechanical occlusion methods emerged for tubal sterilisation which totally eliminated electrosurgical risks. The best-known of these is the Filshie clip, first reported in 1981 and still in use today.[8]

In the meantime, thermocoagulation and the development of the endosuture developed in 1977, led Semm to develop new instruments and techniques which widened the range of operative procedures.[9] These now included ablation of endometriosis, adhesiolysis, adnexectomy, myomectomy, ovarian cystectomy, and salpingotomy for ectopic pregnancy as well as appendicectomy.[9]

The veni, vidi, vici of videolaparoscopy

In the mid-1980s, the development of the modern chip camera and closed circuit television allowed through-the-lens viewing to be replaced by video monitoring. These advances came to fruition in the practice of videolaparoscopy, which was popularized by Nezhat[10] and rapidly replaced naked eye laparoscopy by the early 1990s.

Videolaparoscopy avoided the operator's back-breaking posture of lateral flexion that was needed to peer down the laparoscope and which inevitably limited the duration of laparoscopic procedures. It had other major advantages. The camera could be held by an assistant permitting the surgeon to operate with both hands, an essential prerequisite for the development of laparoscopic suturing and prolapse repair. Everyone in the operating theatre could view the procedure facilitating a team approach and better teaching. Surgery could be recorded on video tape and used as a permanent record. New techniques could easily be shown to colleagues. This helped to spawn the formation of multiple societies of gynaecological endoscopy around the world, including the Australian Gynaecological Endoscopy Society (AGES) in 1990.

Videolaparoscopy also had many advantages over laparotomy. It magnified pelvic and abdominal anatomy enabling microsurgical procedures. The pneumoperitoneum improved microvascular haemostasis, giving a dryer and cleaner operating field. Surgical access and visualization were better in areas that were difficult to reach with open surgery, such as the pouch of Douglas and the posterior leaf of the broad ligament. For the patients, operative laparoscopy gave a better cosmetic result, less postoperative pain, a shorter convalescence, and it caused fewer adhesions than open surgery.

Rise and fall of laser laparoscopy

In 1973, Kaplan introduced the carbon dioxide (CO_2) laser into gynaecology for the treatment of cervical dysplasia.[11] By 1979, Bruhat in France had applied the CO_2 laser to laparoscopic surgery.[2] The term videolaseroscopy was coined by Nezhat and referred to laser laparoscopy with video monitoring .[10] Nezhat and Daniell[12] popularized it in the English-speaking world. In the mid-1980s, the CO_2 laser became widely adopted following a common pattern from treating dysplasia of the lower genital tract to laser laparoscopy. The adaptation of the CO_2 laser to laparoscopy required several innovations in equipment and operating technique: an articulated optical arm to deliver the laser beam from its generator to the operating laparoscope or laser probe; a laser hand piece that was leak-proof and accepted CO_2 to keep the lens free of debris; the addition of a helium-neon sighting laser to add a coloured light to the invisible CO_2 beam; the development of a smoke evacuation system whilst simultaneously maintaining the pneumoperitoneum; and the use of an instrument or fluid to absorb stray energy. Laser laparoscopy was used to vaporize endometriosis, separate pelvic adhesions, and treat tubal pregnancy by linear salpingotomy.[2]

In the 1970s and 1980s, microsurgical instruments were adapted to laparoscopy and used to perform benign adnexal surgery with diathermy or endocoagulation as energy sources.[2] These electrosurgical instruments were easier to use and less expensive than laser laparoscopy. Their uptake was so rapid that laser laparoscopy was superseded within a decade of its development. It earned laser the reputation of being 'technology in search of work.'

Learning from ectopic pregnancies

During the 1980s early diagnosis of tubal ectopic pregnancy was greatly facilitated by sensitive and rapid assays for human chorionic gonadotrophin and improvements in the availability and quality of gynaecological ultrasound. Developments in laparoscopic techniques followed pace and resulted in open salpingectomy and salpingotomy being replaced by their laparoscopic equivalents. These included use of the Endoloop® (Ethicon, Endo-Surgery, Inc.), a precursor to the development of slip knots which are now commonly used in laparoscopic prolapse surgery. The application of laser laparoscopy and electrosurgery to the treatment of ectopic pregnancy taught gynaecologists many important lessons that were relevant to laparoscopic pelvic floor repair later on. Perhaps the key lesson was that minimally-invasive surgery should strive to be technically and technologically simple and inexpensive.

This was best exemplified in the Triton (Microfrance), an instrument designed for the treatment of ectopic pregnancy by salpingostomy. The 7 mm wide shaft of the Triton incorporated three elements: a retractable monopolar needle for salpingostomy, an irrigation channel to loosen the ectopic by aqua-dissection, and a suction channel to extract it. At one French centre, the average time taken to remove an ectopic with the Triton was an impressive 8 minutes.[13]

The emergence of new procedures

The 1980s heralded the arrival of several advanced laparoscopic procedures. Starting from laparoscopically directed appendicectomy and laparoscopic cholecystectomy the range of procedures in general surgery rapidly expanded to include hernia repair, vagotomy, and bowel resection.

In gynaecology, the treatment of endometriosis progressed from coagulation to excision and, in 1989, Reich and colleagues in the USA published their landmark paper on laparoscopic hysterectomy.[14] In the same year Reich presented the technique at the first world congress of gynaecologic endoscopy in France. Despite creating a sense of incredulity in the audience, his technique was adopted rapidly and the first such procedure was performed in our unit in 1991.

TABLE 1. – Main laparoscopic innovations in the first half of the 20th century.[1-4] .

Year	Principal innovator	Innovation
1912	Jacobeus	first laparoscopy in humans
1912	Nordentoeft	trocar laparoscope
1924	Zollikofer	CO_2 insuffflator
1933	Fervers	first operative laparocopy (adhesiolysis)
1934	Ruddock	first laparoscopic female sterilisation
1937	Hope	diagnosis of ectopic pregnancy by laparoscopy
1938	Veress	Veress needle
1943	Fourestier	cold light source

A plethora of techniques for laparoscopic hysterectomy ensued around the globe leading Garry, Reich and Liu to formulate a simple classification system.[15] This categorized procedures as laparoscopically assisted vaginal hysterectomy (LAVH) if the uterine vessels were ligated vaginally, laparoscopic hysterectomy (LH) if they were secured laparoscopically, laparoscopic supracervical or subtotal hysterectomy (LSH) if the cervix was preserved, and total laparoscopic hysterectomy (TLH) if the entire procedure, including vault closure, was done laparoscopically.

The transition from the hybrid procedure of laparoscopically assisted vaginal hysterectomy to the pure total laparoscopic hysterectomy was greatly facilitated by the development of vaginal fornix presenters and safer energy sources, such as the harmonic scalpel,[16] which had less lateral thermal spread than diathermy. The prime Australian example of a vaginal fornix presenter is the tube developed by McCartney.[17] This simplified the colpotomy procedure, reduced the risk of injury to surrounding structures, and preserved the pneumoperitoneum during colpotomy, specimen removal and vault closure. McCartney's tube was later used to facilitate excision of the enterocoele sac during laparoscopic pelvic floor repair.

The impact of laparoscopic hysterectomy on gynaecological surgery was far-reaching. Reich's main aim of reducing the proportion of hysterectomies that required open surgery was never fully achieved. However, laparoscopically assisted vaginal hysterectomy had the spin-off of improving vaginal operating skills and total laparoscopic hysterectomy became important for acquiring laparoscopic skills in pelvic dissection, haemostasis and suturing, all of which were essential prerequisites for laparoscopic pelvic floor repair.

Laparoscopic suturing widens the surgical spectrum

Significant advances in laparoscopic suturing occurred during the last three decades of the 20th century. In the 1990s these facilitated the development of techniques for pelvic floor repair, total laparoscopic hysterectomy and the treatment of operative complications, such as bowel and urinary tract injury. These techniques maintained the pneumoperitoneum by the development of novel suturing equipment and ports, direct and indirect (back-loading) methods of needle and suture introduction, and various knot-tying techniques. The latter included intracorporeal knot tying, the use of extracorporeal slip knots, and extracorporeal knot tying using knot pushers.[18]

The first report of laparoscopic pelvic floor repair came from an Italian group in 1986 which published on laparoscopic uterosacral hysteropexy.[19] In 1991, Vancaillie and

Schuessler reported laparoscopic bladder neck suspension.[20] Anatomically, the technique described was closer to a Marshall Marchetti Kranz procedure than to a Burch colposuspension. The treatment of vaginal vault prolapse by laparoscopic sacral colpopexy was first performed by Wattiez et al. in 1991.[21] In 1996, Ostrzenski published on laparoscopic colposuspension for the treatment of total vaginal prolapse,[22] and a year later Richardson, Saye and Miklos reported the first laparoscopic repair of paravaginal defects.[23] In 1997, Rosen and Lam[24] described a suturing technique for enterocoele repair which was widely adopted in Australasia.

A new century of continence surgery and pelvic floor repair

In the current millennium, there has been a strong trend to abandon Burch colposuspension in favour of synthetic mid-urethral slings for the treatment of urodynamic stress incontinence from urethral hypermobility.[25] There is also a tendency, albeit less pronounced, to replace traditional vaginal and laparoscopic repair by transvaginal pelvic floor repair augmented by grafts or mesh, especially for recurrent prolapse.[26, 27] In units with a laparoscopic interest, mesh sacral colpopexy is emerging as the most popular laparoscopic prolapse repair procedure.[28] These trends have been facilitated by improvements in laparoscopic suturing instruments, suture materials, and screw applicators, as well as the development of a variety of tapes, meshes, grafts and mesh-kits specifically designed for incontinence and prolapse surgery.

Currently, the laparoscopic pelvic floor surgeon has a wide range of procedures and techniques to choose from.[29] In the anterior compartment laparoscopic paravaginal repair is a good native tissue alternative to colporrhaphy for primary cystocoele repair.[30] Apical support failure is effectively addressed by laparoscopic uterosacral suspension with or without uterine preservation.[31] Combined apical and posterior defects can be treated by laparoscopic supralevator repair or mesh sacral colpopexy. [32]

Living through history

In our hospital, which opened in 1976, developments have followed trends seen elsewhere. In the first decade, the range of procedures was limited to diagnostic laparoscopy, ovarian cyst aspiration, diathermy of endometriosis, and tubal sterilization using fallope rings or Filshie clips. By the late 1980s, clinical trials were conducted on the treatment of unruptured tubal ectopic pregnancy using intralesional methotrexate and laser salpingostomy.[33, 34] By the mid-1990s, virtually all benign adnexal surgery was performed laparoscopically with simple instruments and electrosurgery. At the same time, laparoscopic hysterectomy and Burch colposuspension were introduced.[35, 36] By the late 1990s, total laparoscopic hysterectomy had replaced laparoscopically assisted vaginal hysterectomy and laparoscopic entry techniques were expanded.[37, 38] Concurrently, improvements in suturing instruments, extracorporeal knottying and growing experience resulted in shorter operating times, lower rates of accidental injury and fewer conversions to open surgery. Dedicated endogynaecology and urogynaecology units were established, which offer one year fellowships and yearly organize a two-day training course on laparoscopic suturing and ad hoc advanced skills symposia to learn from developments, evidence and experiences elsewhere.

From the past to the future

The prehistory of endoscopy took about 20 centuries characterised mainly by an absence of noteworthy developments. Its proper history took only one century, but it was exciting and eventful, shaped by many people with vision and ideas who laid the foundations of where we stand today. What was considered key-hole surgery at one time no longer requires an eye glued to the lens. Everyone can view and learn from what is seen through the key-hole. Inevitably, the better everything can be seen by different eyes, the more likely this will inspire a continuation of innovative thoughts that have shaped laparoscopic surgery thus far. A reassessment of pelvic floor surgery 10 years on may look very different from what it is today. We must always strive to ensure, though, that what is new is also better.

REFERENCES

1. Sutton CJG. Foreword. Baillière's Clin Obstet Gynaecol 1989; 3: ix-xi.
2. Gordon AG, Magos AL. The development of laparoscopic surgery. Baillière's Clin Obstet Gynaecol 1989; 3: 429-450.
3. Filshie GM. Laparoscopic female sterilization. Baillière's Clin Obstet Gynaecol 1989; 3: 609-624.
4. Frangenheim H. History of endoscopy. In: Gordon AG, Lewis BV (eds). Gynaecological Endoscopy. London: Chapman and Hall, 1988; 1-5.
5. Steptoe PC. Laparoscopy and Gynaecology. London: Livingstone, 1967.
6. Rioux JE, Cloutier D. Bipolar cautery for sterilization by laparoscopy. J Reprod Med 1974; 13: 6-10.
7. Semm K. Thermal coagulation for sterilization. Endoscopy 1973; 5: 218.
8. Filshie GM, Casey D, Pogmore JR, Dutton AG, Symonds EM, Peake AB. The titanium/silicone rubber clip for female sterilization. Br J Obstet Gynaecol 1981; 88: 655-662.
9. Semm K. Operative manual for endoscopic abdominal surgery. Chicago: Year Book.1987.
10. Nezhat C, Crowgey SR, Garrison CP. Surgical treatment of endometriosis via laser laparoscopy. Fertil Steril 1986; 45: 778-783.
11. Kaplan I, Goldman JM, Ger R. The treatment of erosions of the uterine cervix by CO2 laser. Obstet Gynecol 1973; 41: 795-796.
12. Daniell JF, Brown DH. Carbon dioxide laser laparoscopy: initial experience in experimental animals and humans. Obstet Gynecol 1982; 59: 761-764.
13. Pouly JL, Manhes H, Mage G, Canis M, Bruhat MA. Conservative laparoscopic treatment of 321 ectopic pregnancies. Fertil Steril 1986; 46: 1093-1097.
14. Reich H, De Caprio J, Mc Glynn F. Laparoscopic hysterectomy. J Gynecol Surg 1989; 5: 213-216.
15. Garry R, Reich H, Liu CY. Laparoscopic hysterectomy: definitions and indications. Gynecol Endosc 1994; 3: 1-3.
16. Miller CE, Amaral JF. Harmonic scalpel-pros and cons! Fertil Steril 1994; 62: 1094-1095.
17. McCartney AJ, Obermair A. Total laparoscopic hysterectomy with a transvaginal tube. J Am Assoc Gynecol Laparosc 2004; 11: 79-82.
18. Reich H, Clarke HC FM, Sekel L. A simple method for ligating in operative laparoscopy with straight and curved needles. Obstet Gynecol 1992; 79: 143-147.
19. Rapisarda V, Carnino F, Schiavina F, Quattrocchio D. [Laparoscopic hysteropexy]. Minerva Ginecol 1986, 38: 773-776.
20. Vancaillie TG, Schuessler W. Laparoscopic bladder neck suspension. J Laparoendosc Surg 1991; 1: 169-173.
21. Wattiez A, Boughizane S, Alexandre F, Canis M, Mage G, Pouly JL, Bruhat MA. Laparoscopic procedures for stress incontinence and prolapse. Curr Opin Obstet Gynecol 1995; 7: 317-321.
22. Ostrzenski A. Laparoscopic colposuspension for total vaginal prolapse. Int J Gynaecol Obstet 1996; 55: 147-152.
23. Richardson AC, Saye WB, Miklos JR. Repairing paravaginal defects laparoscopically. Contemp Obstet Gynecol 1997; 42: 125-130.
24. Rosen D, Lam A. A new laparoscopic approach for enterocoele repair. Gynecol Endosc 1997; 6: 211-217.

25. Lee J, Dwyer PL. Surgery for stress urinary incontinence in Australia – Medicare data for 1994-2009. Aust N Z J Obstet Gynaecol 2010; 50: 543-549.
26. Vanspauwen R, Seman E, Dwyer P. Survey of current management of prolapse in Australia and New Zealand. Aust N Z J Obstet Gynaecol 2010; 50: 262-267.
27. Armitage S, Seman EI, Keirse MJNC. Use of Surgisis for treatment of anterior and posterior vaginal prolapse. Obstet Gynecol Int (in press).
28. Gabriel B, Nassif J, Barata S, Wattiez A. Twenty years of laparoscopic sacrocolpopexy: Where are we now? Int Urogynecol J 2011; 22: 1165-1169.
29. Seman EI, Cook JR, O'Shea RT. Two-year experience with laparoscopic pelvic floor repair. J Am Assoc Gynecol Laparosc 2003; 10: 38-45.
30. Behnia-Willison F, Seman EI, Cook JR, O'Shea RT, Keirse MJNC. Laparoscopic paravaginal repair of anterior compartment prolapse. J Minim Invasive Gynecol 2007; 14: 475-480.
31. Bedford N, Seman EI, O'Shea RT, Keirse MJNC. Effect of uterine preservation on the outcome of laparoscopic uterosacral suspension. Int Urogynecol J (submitted).
32. Seman EI, Bedford N, O'Shea RT, Keirse MJNC. Laparoscopic supralevator repair for combined apical and posterior compartment prolapse. J Minim Invasive Gynecol (in press).
33. Thompson GR, O'Shea RT, Seman E. Methotrexate injection of tubal ectopic pregnancy. A logical evolution? Med J Aust 1991; 154: 469-471.
34. O'Shea RT, Thompson GR. CO_2 Laser laparoscopic salpingotomy for treatment of tubal ectopic pregnancies potential limitations. Aust N Z J Obstet Gynaecol 1994; 30 4: 361-363.
35. Seman E, O'Shea RT. Laparoscopic Burch colposuspension—a new approach for stress incontinence. Med J Aust 1994; 160: 42.
36. O'Shea R, Petrucco O, Gordon S, Seman E. Adelaide laparoscopic hysterectomy audit (1991-1998): realistic complication rates! Gynaecol Endosc 2000; 9: 369-371.
37. Cook JR, O'Shea RT, Seman EI. Laparovaginal hysterectomy: a decade of evolution. Aust N Z J Obstet Gynaecol 2004; 44: 111-116.
38. Gordon S, Maher P, Seman E. Open laparoscopy utilising either a 5mm or 10mm standard intra-umbilical trocar. Gynaecol Endosc 2001; 10: 249-252.

Correspondence to:
ELVIS I SEMAN
Department of Obstetrics and Gynecology,
Flinders Medical Centre,
Bedford Park, SA 5042, Australia
Tel: +61-8-8204 4471
Fax: +61-8-8204 5454
E-mail: elvis.seman@flinders.edu.au

Review

Male incontinence and trans-obturator approach: where we are

SALVATORE SIRACUSANO

Department of Urology, University of Trieste, Italy

Abstract: Surgery is the mainstay for treating postprostatectomy stress urinary incontinence. Although the artificial urinary sphincter (AUS) remains a gold standard treatment option, a decade worth of innovations have expanded the role of male sling surgery. The sling appears to have a low risk of infection, erosion, and urethral atrophy. Recent changes in male sling surgery may improve efficacy in men with moderate or mild incontinence. Transobturator slings are currently promoted for the treatment of stress urinary incontinence (SUI) after radical prostatectomy (RP), but data on the outcome remain still limited.

Key words: Male; Suburethral sling; Postoperative male incontinence; Transobturator male sling.

INTRODUCTION

Although surgical techniques for radical prostatectomy have been refined significantly during the last 20 years, a significant number of patients still suffer from persisting post-prostatectomy stress urinary incontinence.[1,2] Post-prostatectomy urinary incontinence is a disorder that often has an important impact on the quality of life of those who suffer from it. The artificial urinary sphincter has become the gold standard for the treatment of this disorder but it is expensive and associated with mechanical failure. Despite the success of the artificial urinary sphincter there has been a renewed interest in male slings.

Current male sling devices are based on the early concepts described by Berry,[3] Kaufman,[4] and Kishev[5] in the 1960s early 1970s. Most notable were Kaufman procedures which included a crural crossover[6] and then modified to use a synthetic mesh tape that brings crural together in midline[4] by a silicone gel device attached to the corpora cavernosa that compresses the ventral urethra. Based on the Kaufman principles, Clemens[7] reported a bulbourethral sling procedure in 64 men with severe PPI with a series of tetraflurolethylene bolsters placed beneath the bulbar urethra, through which a suture is passed and then transferred suprapubically using Stamey needle lateral to the urethra and bladder neck, in this way providing the compression of the bulbar urethra. At a mean follow-up of 18 months, 56% of patients became dry and 8% improved significantly. However, despite the encouraging results, sling revision was required in 21% of patients and bolster removal was necessary secondary to infection in 6%. Moreover, 52% of patients had perineal numbness or pain with 26% rating this problem as moderate or severe. This discomfort is most likely due to the high pressure entrapment of pudendal nerve branches during blind suprapubic suture or passage.

Therefore, in order to avoid discomfort, some special sling systems have been realized to make this surgical approach procedure even less invasive and safer.

All currently marketed slings for a minimally invasive treatment of male incontinence induce compression or suspension of the bulbar urethra as recently described by Gozzi and co-workers.[8] At present a long term follow-up of these procedures is lacking even if EAU guidelines assign a Grade of recommendation C with level of evidence 3.[1]

In this overview we report the results of transobturator non-adjustable and readjustable sling systems through a review of the literature using MEDLINE and PubMed database for original articles published using the terms "postoperative male incontinence, transobturator male sling and male sling from 2002 to 2011. Most relevant current publications and data were evaluated.

METHODS

Non-adjustable slings

a) Outside in

AdVance

Different compressive sling systems were evaluated for many years and Advance is the first sling with a functional therapeutic approach. This new sling merely repositioned the lax and descended supporting structures of the sphincter to the former preoperative position.[8] The retrourethral transobturator sling offers a noncompressive functional therapeutic approach. It exerts its function on the membranous urethra by fixing it into the normal anatomic position, thus allowing the function of the sphincter and has been shown to be not efficacious in patients with intrinsic sphincter deficiency. [8] The urodynamic studies show an increase of the membranous urethral length and an improvement of the urethral closure pressure without obstruction.[8]

The surgical procedure

The AdVance system is an outside-in trans-obturator sling. A midline perineal incision is made, exposing the bulbospongiosus muscle, which is then split centrally and retracted laterally. The dissection is extended to the perineal body. After exposure of the urethral bulb, blunt-finger dissection is used to identify the space between the corpora cavernosa laterally and the corpus spongiosum medially. A small skin incision is made in the leg fold on the lateral side of the scrotum, 1 cm below and lateral to the insertion of the adductor longus tendon at the medial border of the obturator foramen. The index finger of the surgeon is then placed between the urethral bulb medially and the proximal corpus cavernosum laterally, just inside the bulbospongiosus muscle. The helical curved introducer needle is placed over the skin incision and mild force is used to perforate the subcutaneous tissue and obturator fascia, maintaining a constant axis of rotation at 45°. The needle is passed towards the tip of the finger and the tape is then positioned through both obturator fossae. With 2 absorbable sutures the middle part of the polypropylene tape is then fixed distally onto the bulb and proximally onto the perineal body. The tape is then pulled at both ends to its final position, and the ends are cut at skin level.[8-10]

Outcomes

Short-term results of this technique have shown to be effective in 70% of patients as reported in Tab.1 at median follow-up of 29 months.

The first results were reported by Rehder and confirmed by Gozzi, who showed cure and improvement rates of 52% and 38% respectively with low morbidity after 6 months

follow-up.[8,12] These results were confirmed in a large prospective single-armed study by Bauer[13] who reported a cure rate of 51.4% (defined as 0 pads or security pad), an improved rate of 25.7% and a failure rate of 22.9% in 70 men followed for 12 months. Improvement was defined as one or two wet pads a day or a reduction in pad use by 50%. HRQL measures were significantly improved at 6 months, but these improvements were not sustained at 12 months. There was no difference in outcome according to severity of preoperative post-prostatectomy urinary incontinence (PPUI). Men with severe PPUI fared as well as those with milder forms, although this definition is based on pad usage rather than urodynamic data, which were not included in the study.

Cornel[14] reported efficacy of the AdVance sling in 36 men with PPUI, with unimpressive results: the cure rate (0 pad use and <20 g urine loss/day) was only 9% at 12 months, with improvement in 45.5%. There was no effect on cure of PPUI in 36.5% of men.

Gill in a retrospective chart review and phone interview of 35 men treated with placement of the AdVance sling[15] showed satisfactory results, although there are obvious study limitations. The success rate was 51.4% while the objective success, defined as cure or improvement (0 pads or 1-2 pads/day), occurred in 60% of men. The mean pad use was significantly decreased, from 3.7 to 1.4 pads/day, with a pad-free rate of 28.5% at 9 months.

In a prospective evaluation conducted by Cornu on 136 patients with a median follow-up of 21 months, an overall success rate of 62% is reported.[16]

The urodynamic changes observed by Davies in 13 patients after AdVance sling surgery with a show a significant improvement in the 24-h pad test (779.3 vs 67.6 g) at 6 months.[17]

In most series, urinary retention is rare, and usually transient. Cornel[14] had one of 36 men with transient retention, while Gill[18] had three men with retention and two who needed to catheterize for 3 and 6 months. By contrast, Bauer,[19] in a paper specifically examining complications of AdVance sling surgery, reported a postoperative retention rate of 21.3%. All but one man had returned to normal voiding at 3 months. This study of 230 men described also a need to remove the sling in 0.9% and one case requiring sling division due to obstruction. In the Cornel[14] study, 17% of men had severe postoperative pain that settled at 3 months, but otherwise pain is rarely reported. Recently Hanhan[20] and Rehder[21] reported interesting results at 2 and 3 year follow-up respectively. In particular Hahan showed a success of 53.6% in 66 patients concluding that the majority of them reported an improvement in post-prostatectomy incontinence but with a decrease of the benefit with time. However these results were not confirmed by Rehder in a multicentric study describing a success of 76.6% at 12 months that was mantained at 3 year at 75.7%. This trend reported by Rehder was also described by Bauer with a success rate of 75.4% in 137 patients at median follow-up of 27 months.[22]

Trans-obturator slings (TOMS)

In 2006 Grise developed a new transobturator bulbar male sling[23] that works by compressing the urethra in a more distally position than AdVance sling.

The surgical procedure

The surgical technique was performed under spinal or general anesthesia, the patients were placed in the lithotomy position and a 6 cm median vertical perineal incision below the inferior border of the pubic symphysis was carried out in order to expose the bulbospongiosus muscle, then to expose the perineal aponeurosis at the top of the triangular space delimited laterally by each ischiocavernous muscle and medial to the bulbospongiosus. A short 2 mm incision through the pelvic fascia afforded access to the obturator muscle just under the ischiopubic ramus bone. A stab incision was made at the top of the thigh, 4 cm from the median line and 4 cm below the major adductor longus muscle. The transobturator puncture was an outside inside with a Hemet needle. The end point of the puncture was the opening in the pelvic fascia. After sling attachment to the needle, it was pulled back in order to correctly implant the sling. The same procedure was repeated on the other side. The sling was sutured to the bulbospongiosus muscle with non-absorbable sutures. The graft was then constructed as a circle around the inferior pubic branch on each side and was self-anchoring with the necessary compression of the urethra.

Table 1. – Outcomes of AdVance trans-obturator sling systems.

Author	N° of Patients	Mean follow-up	Cure,	improved
Bauer et al. (2009)	70	12	51.4%	25.7%
Cornu et al. (2009)	102	13	62.7%	17.6%
Rehder et al. (2009)	20	24,3	65.0%	20.0%
Bauer et al. (2010)	126	27,2	51.6%	23.8%
Rehder et al. (2010)	118	12	73.7%	16.9%
Cornel et al. (2010)	35	12	9.0%	45.5%
Cornu et al. (2010)	136	21	62.0%	16.0%
Gill et al. (2010)	35	2.9	60.0%	-

Outcomes

Grise reported at three months and at 12 months follow-up a reduction of pad use in 30% of cases within a concomitant improvement of QoL. [24]

b) Inside-out

de Leval sling

In 2008 de Leval reported on a new transobturator polypropylene sling, [25] with two arms passed inside out through the obturator foramen, pulled for compressing the urethral bulb, and tied to each other across the midline. Conceptually this approach was designed to minimize the risk of pelvic space penetration and urethra perforation by the trocars and mesh arms, lessen the possibility of urethra erosion by using a large mesh entirely covering the bulbospongiosus muscle and by avoiding fixation of the mesh to the urethra with suture material and sustain sling tension by tying up the mesh arms to prevent mesh slippage.

The surgical procedure

A 6-cm sagittal skin incision is made at the median raphe of the perineum ending 2 cm above the anal margin. Transection of the subcutaneous fat and Colles superficial perineal fascia allows access to the bulbospongiosus muscle, which is freed ventrally to the pubic symphysis and dorsally to the central body of the perineum. Further dissection is conducted laterally to expose the ischiocavernous muscles. Together with the transverse muscles, the bulbospongious and ischiocavernous muscles delineate, on either side of the urethral bulb, a triangular space. The inferior layer of the median perineal aponeurosis, which is located in depth of this space, is carefully dissected. Starting with the right side, the bulbar urethra is reflected on the left side using a retractor, thus providing access to the median perineal plane. Scissors are used to open up the inferior layer of the median perineal aponeurosis in the anterior portion of the triangular space, just lateral to the bulb. The guide is inserted through the scissors-initiated dissection path with a 45° angle rela-

tive to the urethral sagittal plane to come into contact with the upper part of the ischiopubic branch. The guide is introduced further and perforates the right internus obturator muscle and obturator membrane. The distal linear segment of the passer is slipped along the gutter of the guide so as to pass through the obturator membrane.

The tape was then clipped to the extremity of the needle and was pulled out laterally outside the skin. This procedure was then repeated on the other side, and the central part of the mesh was fixed by a resorbable suture to the ventral part of the urethra.

Outcomes

In 2008 de Leval showed, at 24 months mean follow-up, cure and improvement rates of 49% and 35%, respectively. The failure rate was of 16%. No sling infection, persistent pain, bladder, urethra, bowel, or nerve complications were encountered. [25] Recently the same author published the midterm results on 173 consecutive patients. [26] After a median follow-up of 24 months 49% were cured, 35% improved and 16% not improved. The QoL was enhanced and 72% of patients were moderately to completely satisfied with the procedure.

Adjustable slings

ArgusT

ArgusT is readjustable suburethral sling devices which permit an effective regulation of the sling tension not only during surgery but also in the first postoperative days. This possibility of suburethral pressure control should represent the main advantage of this procedure in order to cure incontinence avoiding urinary retention.

The Argus® system is composed of a radiopaque cushioned system with silicone foam for soft bulbar urethral compression, two silicone columns formed by multiple conical elements, which are attached to the pad and allow system readjustment, and two radiopaque silicone washers which allow regulation of the sling tension.

The surgical procedure

A 7 cm vertical perineal incision is made in order to open the interbulbar urethral cavernous space until it reaches the inside edge of the ischial pubic branch of the pubic bone, and the helicoid needles are inserted from outside inward. The point of the skin puncture is established at the intersection of a line beginning with the pubic insertion at the adductor muscle, crossing 3 cm below the inguinal plies (this point corresponds to the middle portion of the obturator orifice) where a 3 cm vertical incision is made until it reaches the facial tissue separating the fat tissue. Using the index finger, the crochet tip of the needle is retrieved from behind the ischial pubic bone, where the same finger simultaneously protects the urethra by pushing it to the other side. The pelvic floor is perforated and the cone column snapped into place and spread out bilaterally.

The symmetric adjustment of the washers with the positioner will be controlled by measuring the adjustment retrograde pressure with a water column connected to the Foley catheter, which will be located in the navicular fossa. The objective is to achieve urethral wall cooptation and stop the drip, indicating that a retrograde LPP of 45 cmH2O has been achieved.

Outcomes

In patients with mild to moderate incontinence, dry rates of up to 70% was achieved after a median follow-up of 6 months in 37 patients. [27] In this study Romano reported a 73% cure rate and 13.5% of improvement. The treatment failed in five patients (13.5%).

ATOMS

This sling was developed in 2005 [28] and introduced in Europe in 2008 to be implanted for the first time in March 2009. The advantages of this device are the postoperative adjustment without surgical reintervention and the low possibility of dislocation.

The ATOMS system consists of a mesh implant with an integrated adjustable cushion, protection sheet and titanium pot for adjustment of cushion volume. The silicon cushion is located in the middle of the mesh type and filled via the port and catheter intraoperatively and postoperatively. The adjustment is performed by puncturing the port percutaneously and is possible at any time in an outpatient setting to counteract continued incontinence or urinary retention.

The surgical procedure

It is performed under spinal or general anesthesia with the patient in lithotomy position. A medial vertical perineal incision is made to exposure the bulbospongious muscle. A space is created between the bulbospongious and ischiocavernous muscle. The system is implanted using an outside-in technique whereby the obturator foramen is passed subcutaneously with an helical tunneller. The mesh arms are drawn back to the central part of the cushion and sutured, thereby anchoring the device to the inferior pubic branch like a backpack.

Outcomes

At present are available only results in the short-term as reported by Seweryn. [29] At mean follow-up of 16.9 months the overall success rate was 84.2 %. Of these cases 60.5% were considered dry and 23.7% improved. In 15.8% of the patients the treatment was considered failed.

CONCLUSION

Advances in surgical management of incontinence have led to new alternatives in the management of post-prostatectomy incontinence. It is generally accepted that patients with mild to moderate incontinence are appropriate candidates for a male sling and probably patients with severe incontinence should be treated with AUS although there is not a specific recommendation in this context.

Although there was a lack of prospective randomized studies concerning the different anti-incontinence surgical procedures, the AUS represented the gold standard by which other surgical managements were compared (Grade 2. Level of recommendation B). However, technical problems related to the AUS management are the long-term complications as well as expensiveness.

In this way sling procedures are quicker and less invasive than AUS. In particular the use of a trans-obturator approach seems to be safer and easier than the retropubic approach with a lower incidence of intraoperative complications. At present we have long term results for transobturator sling AdVance only. The use of new trans-obturator sling models is still under clinical investigation and further clinical experience are is needed to compare the trans-obturator approach with the retropubic approach.

REFERENCES

1. Schroder A., Abrams P., Andersson K.E., et al. Guidelines on urinary incontinence. In: Arnheim A.G., editor. EAU guidelines. Arnheim, the Netherlands: European Association of Urology; 2010; p. 11-28.
2. Shamliyan T.A., Wyman J.F., Ping R., Wilt T.J., Kane R.L. Male urinary incontinence: prevalence, risk factors, and preventive interventions. Rev Urol 2009; 11: 145-65.

3. Berry J.L. New procedure for correction of urinary incontinence. A preliminary report. J Urol 1961; 85: 771-775.
4. Kaufman J.J. Urethral compression operations for the treatment of postprostatectomy incontinence. J. Urol. 1973; 110: 93-96.
5. Kishev S.V. Suprapubic wad suspension. Combined perineal-abdominal approach for correction of postprostatectomy urinary incontinence. Urology 1978; 11: 28-32
6. Kaufman J.J. Surgical treatment of post-prostatectomy incontinence: Use of the penile crura to compress the bulbous urethra. J Urol 1972; 107: 293-7.
7. Clemens J.Q., Bushman W., Schaeffer A.J. Questionnaire based results of the bulbourethral sling procedure. J Urol 1999; 162: 1972-6.
8. Rehder P., Gozzi C.: Transobturator sling suspension for male urinary incontinence including post-radical prostatectomy. Eur Urol 2007; 52: 860-7.
9. Rehder P., Freiin von Gleissenthall G., Pichler R., Glodny B. The treatment of postprostatectomy incontinence with the retroluminal transobturator repositioning sling (Advance1): lessons learnt from accumulative experience. Arch Esp Urol 2009; 62: 860-70.
10. Rehder P., Mitterberger M.J., Pichler R., Kerschbaumer A., Glodny B. The 1 year outcome of the transobturator retroluminal repositioning sling in the treatment of male stress urinary incontinence. BJU Int 2010; 106: 1668-72.
11. de Leval J., Waltregny D. The inside-out trans-obturator sling: A novel surgical technique for the treatment of male urinary incontinence. Eur Urol. 2008; 54: 1051-65.
12. Gozzi C., Becker A.J., Bauer R., Bastian P.J. Early results of trans-obturator sling suspension for male urinary incontinence following radical prostatectomy. Eur Urol. 2008; 54: 960-1.
13. Bauer R.M., Soljanik I., Fullhase C, et al. Results of the AdVance transobturator male sling after radical prostatectomy and adjuvant radiotherapy. Urology 2011; 77: 474-9.
14. Cornel E.B., Elzevier H.W., Putter H. Can advance transobturator sling suspension cure male urinary postoperative stress incontinence? J Urol. 2010; 183: 1459-63.
15. Gill B.C., Swartz M.A., Klein J.B., Rackley R.R., Montague D.K., Vasavada S.P., Angermeier K.W. Patient perceived effectiveness of a new male sling as treatment for post-prostatectomy incontinence. J Urol. 2010; 183: 247-52.
16. Cornu J.N., Sebe P., Ciofu C., Peyrat L., Cussenot O., Haab F. Mid-term evaluation of the transobturator male sling for post-prostatectomy incontinence: focus on prognostic factors. BJU Int. In press. DOI:10.1111/j.1464-410X.2010.09765.x.
17. Davies T.O., Bepple J.L., McCammon K.A. Urodynamic changes and initial results of the AdVance male sling. Urology 2009; 74: 354-7.
18. Gill B.C., Swartz M.A., Klein J.B., et al. Patient perceived effectiveness of a new male sling as treatment for postprostatectomy incontinence. J Urol 2010; 183: 247-252.
19. Bauer R.M., Mayer M.E., May F., et al. Complications of the AdVance transobturator male sling in the treatment of male stress urinary incontinence. Urology 2010; 75: 1494-8.
20. Hanhan Li, Bradley C.G., Nowacki A.S. et al. Therapeutic durability of male transobturator sling: midterm patient reported outcomes. J Urol. 2012; 187: 1331-1335.
21. Rehder P., Haab F., Cornu J.N. et al. Treatment of postprostatectomy male urinary incontinence with the transobturator retroluminal repositioning sling suspension: 3 year follow-up. Eur urol 2012; 62: 140-145.
22. Bauer R.M., Solljanik I., Fullhase C. et Al. Mid-term results for the retroluminar transobturator sling suspension for stress urinary incontinence after prostatectomy. BJU 2010; 108: 94-98.
23. Grise P. Incontinence after prostatectomy, the transobturator I-Stop male sling as a new treatment option. In: European Renal and Genito-Urinary disease. 2006; Issue II: 69-70.
24. Grise P., Geraud M., Lienhart J. et Al. Transobturator Male Sling TOMS for the treatment of stress post-prostatectomy incontinence, initial experience and results with one year's experience. International Braz J Urol 2009, 35: 706-15.
25. de Leval J., Waltregny D. The inside-out transobturator sling: a novel surgical technique for the treatment of male urinary incontinence. Eur Urol 2008; 54: 1051-65.
26. Leruth J., Waltregny D., de Leval J. The inside-out transobturator male sling for the surgical tratment of stress urinary incontinence after radical prostatectomy: midterm results of a single prospective study. Eur Urol 2012; 61: 608-15.
27. Romano S., Hubner W., Trigo Rocha F. et al. 24th EAU Congress 2009 Stockholm.
28. Bauer W., Karik M. and Schramek P. The self-anchoring transobturator male sling to treat stress urinary incontinence in men: a new sling, a surgical approach and anatomical findings in a cadaveric study. 2005; BJU 95: 1364.
29. Seweryn J., Bauer W., Ponholzer A. et al. Initial experience and results with a new adjustable transobturator male system for the treatment of stress urinary incontinence. J Urol 2012; 187: 956-61.

Correspondence to:
SALVATORE SIRACUSANO
Dept. of Urology
Trieste University
Via Strada di Fiume 447
34100 Trieste, Italy
siracus@units.it

Original article

The management of stress urinary incontinence using transobturator tapes in a tertiary hospital in South Africa

ANDREAS CHRYSOSTOMOU

Department of Obstetrics and Gynaecology, University of Witwatersrand Charlotte Maxeke Johannesburg Academic Hospital

Abstract: Introduction and objectives: The aim of this case series was to assess the safety and efficacy of the TOT in treating SUI, as well as the intra- and postoperative complications and their management. Methods: Five different macroporous tapes were inserted by a single operator. Patients were assessed by history, positive cough test and intra- and postoperative complications; objective, subjective success rates have been recorded. Results: 120 patients with SUI were included. Intraoperative complications included 2 bladder and 2 vaginal perforations, which were diagnosed and managed intra-operatively. The follow up was between 3 and 63 months. Both objective and subjective cure rates of 94.5% were recorded. Positive results persist over a period of 5 years. Mesh erosion was noted in 1 case, 3 procedure failures and one de novo Detrusor Instability (DI) were found during the follow up period. Conclusion: TOT outside-in is a safe and effective procedure for SUI with low complications.

Key words: Complications; Outside-in Transobturator tape (TOT); Urinary stress incontinence; Urodynamic studies.

INTRODUCTION

Stress Urinary Incontinence (SUI) is defined as the involuntary leakage of urine on effort, exertion or coughing without a rise in detrusor pressure.[1] It is estimated to affect up to one-third of women older than 18 years, with a median age of 45 years.[2] The Tension-free vaginal tape (TVT) is a standard, minimally invasive procedure used to treat SUI, introduced by Ulmsten in 1995.[3] In spite of its proven efficacy of subjective and objective SUI cure of 90% at the 11-year follow up[4] TVT, has been found to be associated with intra and post operative complications such as urethral, bladder, bowel perforations, major blood vessel injuries as well as post operative voiding difficulties, de novo urgency and Urge Incontinence (UI).[5-9] In 2001, Delorme described the Transobturator tape (TOT)[10] as a mid urethral sling for the surgical treatment of SUI. This minimally invasive procedure, termed "outside-in"- in which the tape is inserted in an almost horizontal plane underneath the middle of the urethra, between the two obturator foramina- has almost replaced the TVT. The TOT technique has been safer, due to avoidance of entry into the retro-pubic space.[10] A modified technique ("inside-out") of TVT-O was introduced by de Laval in 2003.[11]

The Transobturator passage of the tape ensures that the retro-pubic space is not entered. Therefore this approach has a low risk of bladder injuries, vascular injuries and post-operative voiding difficulties.[5,12,13] The risks of complications seen with the retro-pubic approach (TVT) are avoided. Although cystoscopy is mandatory with a TVT, with the TOT technique it is not always recommended.[14,15]

The Transobturator (TOT) approach was found to have high success rates with an objective and subjective cure rate of 90% and 97% respectively and low morbidity.[15,16] The objectives of this case series were to assess the safety and efficacy of the TOT in the treatment of stress urinary incontinence in our hospital and to assess intra and postoperative complications associated with the TOT procedure and their management.

MATERIAL AND METHODS

Between April 2005 and April 2010, 114 female patients were diagnosed with SUI and were included in the study; two were included with mixed urinary incontinence (MUI) and four patients with overflow incontinence who agreed to Intermittent Self-Catheterization (ISC). All underwent TOT (outside-in) operations. The diagnosis of SUI was based on subjective complaints of involuntary leakage on effort, sneezing or coughing, without overactive bladder symptoms (as recommended by ICS).[1] Objective bedside investigations included a cough test, residual volume and urine dipstick to exclude infection.

Uro-dynamic studies were not systematically performed due to lack of availability 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 2001.[10]

The Key Procedure Steps Are As Follows:

1. Place the patient in dorsal lithotomy position with the buttocks over the edge of the table and the hips flexed at 120º.
2. Insert a bladder catheter (Foley size 12-14) to empty the bladder and identify the urethra during the procedure.
3. Mark the tunneler insertion point through the obturator foramen on the lateral margin of the inferior ischiopubic ramus. The insertion point is not fixed as it depends on the depth of the lateral vaginal fornix, and must be at least 1cm above the horizontal line at the level of the urethra meatus and below the horizontal line at the level of clitoris.
4. Make a vaginal incision about 2cm long at the junction of the middle and lower third of the urethra (wide enough to insert a finger). Grasp each side of the incision with Allis' forceps and pull laterally to open a window. Separate the vaginal epithelium from the underlying periurethral fascia, using sharp and digital dissection in the direction of the inferior pubic ramus. If the index finger is in the incision, and the thumb is at the nearest point of the genito-crural fold, one may determine the entry point.
5. The incision that is made at this point should be big enough to fit the tunneler that will be used (3-5 mm).
6. Introduce the tip of the tunneler into the obturator skin incision. Pass the tunneler through the obturator membrane and muscle, keeping it close to ischiopubic ramus directed towards the meatus urethra. The tip of the tunneler should make contact with the finger inside the vagina incision. The tip of the tunneler must be brought out into the vaginal incision. With the tunneler in the in-

cision, the lateral vaginal fornix must be checked for perforation.
7. The tape must be inserted through the eye of the tunneler, pulled through the dissection and out of the obturator incision by reversing the tunneler.
8. This must be repeated on the other side of the patient, ensuring that the tape is not twisted and lies flat under the urethra. Once the positioning of the tape is confirmed, the vagina is close with bio-absorbable suture.
9. The lateral ends of the tape should be cut off and the inner thigh skin incisions are closed with an absorbable suture bilaterally.
10. A local modification included hospital stay for the patient, clamping the catheter the following day and removal on the second postoperative day. If residual volume was <100 ml, the patient was discharged.

Postoperative pain was assessed by Visual Analog Scale (VAS), which was simply and easily comprehended by the patient and the length of the postoperative hospital stay was recorded.

Postoperative evaluations were scheduled for 1 week, 6 weeks, 6 months, 1 year and yearly thereafter. Evaluations included: a cough stress test, a vaginal examination and residual volume. If a patient presented with Overactive Bladder (OAB) symptoms, Uro-Dynamic Studies (UDS) were performed. A 24 hour pad test was not performed. Patients were considered objectively cured if they had no stress urinary incontinence during the stress provocation test (Cough test) and did not have urinary retention if a residual volume of less than 100 ml was recorded. Subjective success rates were measured as the patients' satisfaction with the procedure during the follow-up. Cure rate of SUI was defined as a disappearance of subjective and objective leakage.

Descriptive statistics were performed showing the frequencies and percentage for categorical variables and the means, standard deviations and ranges for continuous variables. Inferential statistics were performed on some variables. The student's t-test was performed for differences in means on Gaussian distributed data, to determine the differences between operation times for those who had TOT alone and those who had additional operation. Spearman's correlation was also used to determine the relationship between duration of operation and days stayed in hospital. The maintenance of continence was shown using the Kaplan Meier curve. Statistical significance was ascertained at the 5% level hence a p-value of less than 0.05 rendered statistical significance. The analysis was performed using STATA 10.1.[17]

TABLE 1. – Patient Characteristics: Patients may have more than one previous operation.

Age (years)	mean	54.7 (±12.96)
	range	(29-87 years)
Parity	mean	2.6 (P1-P6)
Previous operations:		
Anterior repair		14
Posterior repair		9
Total abdominal hysterectomy		18
Vaginal Hysterectomy		10
PIVS		1
Concurrent operations during TOT procedures (n=22)		
Posterior IVS		3
Vaginal hysterectomy		3
LAVH		3
Anterior repair		2
Posterior repair		4
Laparoscopic sterilization		2
Removal of IUCD		1
Removal of Labial cyst		1
Laparoscopy cystectomy		2
Fento's procedure		1

RESULTS

Procedures were performed under spinal anesthesia in 98 cases and general anesthesia in 22. All the TOT's were performed at the Charlotte Maxeche Johannesburg Academic Hospital, and all cases were done by the same surgeon, the author. One hundred and twenty women underwent a TOT procedure during the study period, of which twenty two were associated with another surgical procedure. Patient's characteristics, previous operations and concurrent operations during TOT procedures have been summarized in table 1. The mean patient age was 54.7(±12.6) years. Pure stress urinary incontinence was found in 114 patients out of 120 patients. Two patients with mixed urinary incontinence and 4 patients with overflow incontinence who agreed to Intermittent Self Catheterization (ISC) were included in this study. Five different types of slings were used during the study period and are shown in table 2. All the cases were successfully completed. Intra-operative complications are presented in table 3.

The average operating time was 30 minutes (25-40). Some of the women had to undergo additional operations and this on average doubled the operating time e.g. the operating time for TOT had a mean of 21.2 minutes (SD±0.7). An additional operation increased the mean time of surgery to 40.3 (SD±2.8). Student's t-test showed a p-value<0.0001. This increase in time of operation lead to the statistically significant increase in the stay in hospital (Spearman's rho= 0.4323, p-value<0.0001).

The postoperative complications during the follow up period are presented in table 4. The postoperative hospital stay and pain (assessed by Visual Analogue Scale) are presented in table 5. The follow up period after TOT range from 3 to 63 months, and the condition appears in the parous women with average age of 42 years, with the majority of the women having either two or three children (Figure 1).

There were a total of five failures through out the 63 months of follow-up with a success rate of 94.5%. The x-axis shows the number at risk per each time point and the cases in brackets per each interval (Figure 2).

Follow-up data was censored at the end of July 2010 when the last patient who underwent TOT completed 3 months follow-up. At the last follow-up (range 3 to 63 months), 5 cases were considered treatment failure (according to the definition of stress specific cure).

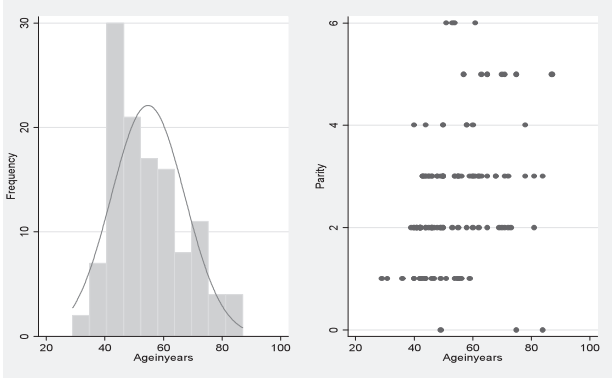

Figure 1. – Histogram of the Ages and the parity distribution across the ages.

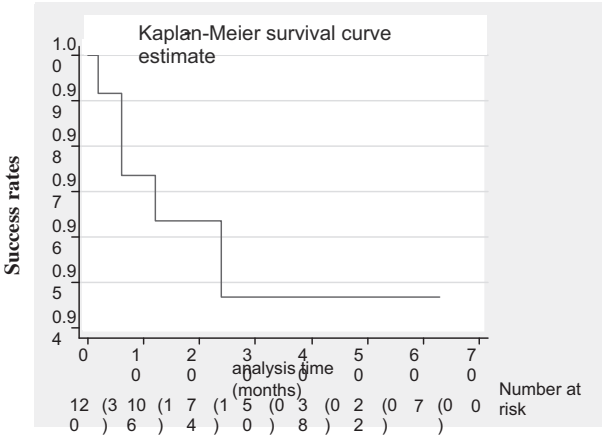

Figure 2. – Kaplan Meier survival curve for the development of any urinary incontinence after surgery.

DISCUSSION

The results from this study show that the TOT is a simple, effective and safe procedure for treating SUI. The cure rate of SUI, defined as the disappearance of subjective and objective SUI, was 94,5% during the follow up period. Success rates are similar to other reported series of retro-pubic or Transobturator mid urethral slings.[4,15,16,18] Routine uro-dynamic studies (UDS) were not performed to confirm the diagnosis of SUI in 114 patients with strongly suggestive SUI prior to surgery. Although this may be considered by some, as a weakness of this study, there is available evidence to demonstrate that cough test is useful and reliable tool in the diagnosis of SUI,[19] especially in countries with limited resources and in absence of symptoms indicating an Overactive Bladder (OAB). It is recommended that women with clearly defined clinical diagnosis of SUI do not need routinely UDS prior to surgical intervention.[20] We limit UDS to the patients with the history of OAB symptoms, those with RV > 100ml in absence of cystocele. This is supported by the literature that show that there is a little reason to delay surgery prior to treatment. Important issues also include cost, discomfort, constraint to the patient and lack of reproducibility.[21] A recent systematic review has shown there is no evidence that performing uro-dynamics does improve the outcome of anti-incontinence surgery.[22]

In our setting with limited resources, clinical assessment alone has place, as we have to treat the patient not the urodynamic findings. All cases were successfully completed. There has been a reported decreased risk of intra-operative complications with TOT as compared to TVT and particularly bladder perforation.[5,12,13] In our study, bladder perforation occurred in two patients, (1.6%) and this is in agreement with other reported rates of 0 –1.5%. [5,7,13,15,23] In the two patients in this study with bladder perforations, both had had a previous anterior repair, and both perforations were created at the time of vaginal dissections, not during tunneler insertion. In both patients, bladder perforation was diagnosed immediately, repaired in two layers and the procedure completed. Post-operative urethral catheterization was left in-situ for 10 days. Abdel-Fatah et al[24] reported 4 cases of urethral and bladder perforation in their series of 389 cases comparing TOT to TVT-O. He stated that all occurred in TOT "outside in" group, and no cases of bladder perforation ensued in the TVT-O "inside out" group. However, three of the perforations occurred during the dissections following vaginal incision, and only one bladder perforation during the insertion of the tape. If the correct technique is applied the risk of bladder perforation with the tunneler is minimal. Bladder injury during the insertion of the tunneler as seen in TVT should be distinguished from the bladder injuries during the creation of the par urethral tunnel as seen in transobturator techniques (TOT, TVT – O). It is evident from the literature that both Transobturator tape techniques are associated with lower risk of bladder perforation as compared to the retro-pubic techniques.[5,13,25] To be engaged in comparisons between TOT vs TVT-O undermine the transobturator technique of treating SUI and should be avoided. Because bladder perforation is one of the most common intraoperative complications of retro-pubic midurethral slings, cystoscopy is considered mandatory, whereas the use of cystoscopy with the Transobturator approach is not always recommended.[14,15]

Cystoscopy can be considered in women who have concomitant vaginal surgery or where the TOT procedure is considered difficult. Two bladder perforations repaired and two concomitant anterior repairs were performed in this study without cystoscopy. Instead a catheterization of a methylene blue test was performed demonstrating no leakage. Two vaginal perforations were diagnosed during the insertion of the tunneler. These were corrected by repositioning and re-passing of the tunneler and the tape, without complications. This complication can be avoided if the dissection is carried out away from the anterior vaginal wall as far as the iscio-public rami on each side. There was no bleeding in our series as opposed to others[13,25] who report bleeding in excess of 200 ml in 3. 3% and 5. 2% respectively in their series.

No major intraoperative complications such as bowel and vessel injuries were reported in this study, confirming the results of other studies that indicates the safety of this procedure. A recent report of the Austrian registry with data on 2,543 operations including 11 different tape systems, reported no bowel or major vessel injuries and low rates of intraoperative complications.[13]

Post-operative voiding problems found to be low (0.8%) in our study, in agreement with other studies.[5,23] De novo de-

Table 2. – Different TOTs used in the study.

IVS-O	Tyco	98	(81, 6%)
Aris	Mentor-Porges	16	(13, 3%)
Monarc	AMS	2	(1, 6%)
Obtryx	Boston Scientific	2	(1, 6%)
Intramesh	Cousin	2	(1, 6%)

Table 3. – Intra-Operative Complications.

Bladder perforation	2	(1,6%)
Vaginal perforation	2	(1, 6%)
Bleeding > 100 ml	0	
Urethral perforation	0	
Others	0	

Table 4. – Complications during follow-up.

Tape erosion	1	(0.8%)
Sling failure	3	(2.4%)
De novo UI	1	(0.8%)

Table 5. – Hospital Stay and Pain as Assessed by V.A.S.

Postoperative pain as assessed by VAS	Day 1: 2.9 (0-5) Day 2: 1.06 (0-3)
Postoperative Hospital stay (days)	2.1 (2-3 days)

trusor instability was noted in one patient and was treated successfully with antimuscarinics. This is definitely much lower than the rate reported with TVT.[5,7] It is suggested that the TOT is more horizontal as compared to the U-shape of retro-pubic slings, thereby making less contact with the urethra and so diminishing the likelyhood of this complication. Some expressed concern that the more horizontal axis of the TOT may translate into lower cure rates of SUI. The results of this study do not support such concerns.

Three failures with positive cough test were diagnosed at six months, one year and two years of follow up. All were managed by reinserting a new sling.

One patient in this series had sling erosion at the six-month follow up. Excision of the exposed portion of the sling was performed, followed by local application of estrogen vaginal cream for six weeks. Complete healing was achieved in 6 weeks follow up. Sling erosions may be secondary to surgical technique used and may relate to the sling material used. The low rates of erosion in this study is due to the fact that all 5 slings used were polypropylene Type 1 meshes (macro porous, monofilament), and the technique was correct. The strength of this study lies on the fact that the same surgeon performed all the TOT's (AC).

Urinary retention following TOT have been reported in the literature as between 1,5 to 15% respectively.[16,18] 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 postoperative day, and removed on the second day before discharge. This not only allows bladder retraining but may also decrease tension of the sling in the immediate postoperative period.

Postoperative groin or thigh complications with TOT that were found in other studies[5,25] did not occur in this study. This study supports the evidence that such a complication is uncommon with TOT outside-in. Groin or thigh pain has been found to be more common with TVT-O inside out procedures with a reported incidence of 16%-17%.[11,26] A sub-analysis performed by Cheng Yu Long[12] found that TVT-O appear 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. Cadaver studies show that tapes inserted via the transobturator route using an 'outside in' technique have a lower risk of pudendal neurovascular bundle injury as the tape may be placed further from the obturator canal and closer ischiopubic ramus[27] Tapes placed with the "inside out" technique were found further from the ischiopubic ramus and closer to the obturator canal.[28]

Two patients with UDS demonstrated mixed UI were cured after TOT, thus keeping with the results of others that show 91% improvement with MUI where the stress was the most bothering symptom.[29] This study is in agreement with other epidemiological studies that show that SUI occurs more often in perimenopausal/postmenopausal women. The mean age of TOT in our study was 55,3 years (31-84 years).[30]

CONCLUSIONS

In summary, the TOT outside-in is a simple, effective, safe and minimally invasive procedure for treating SUI. It is associated with a low rate of complications and high success rate over a 5 year follow up period. The technique was found to be easier to teach registrars, offering them a good understanding of anatomical landmarks that are required to perform the procedure.

CONFLICT OF INTEREST

There are no conflicts of interest.

ACKNOWLEDGEMENT

I would like to thank Eustasius Musenge, School of Public Health, Faculty of Health Sciences, University of the Witwatersrand, for the help in the statistical analysis, interpretation and data entry, as well as Dr William Edridge for assisting with the editorial process.

REFERENCES

1. Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, van Kerrebroeck P, Victor A, Wein A. The standardisation of terminology of lower urinary tract function: Report from the standardisation sub-committee of the International Continence Society. Neurourology and Urodynamics 2002; 21:167-178.
2. Hunskaar S, Lose G, Sykes D, Voss S. The prevalence of urinary incontinence in women in four European countries. BJU International 2004; 93:324-330.
3. Ulmsten U, Petros P. Intravaginal Slingplasty (IVS): An Ambulatory Surgical Procedure for Treatment of Female Urinary Incontinence. Scandinavian Journal of Urology and Nephrology 1995; 29:75-82.
4. Nilsson C, Palva K, Rezapour M, Falconer C. Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence. International Urogynecology Journal 2008; 19:1043-1047.
5. 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. BJOG: An International Journal of Obstetrics & Gynaecology 2007; 114:522-531.
6. Meschia M, Pifarotti P, Bernasconi F, Guercio E, Maffiolini M, Magatti F, Spreafico L. Tension-free vaginal tape: analysis of outcomes and complications in 404 stress incontinent women. International Urogynecology Journal 2001; 12:24-27.
7. Novara G, Galfano A, Boscolo-Berto R, Secco S, Cavalleri S, Ficarra V, Artibani W. Complication Rates of Tension-Free Midurethral Slings in the Treatment of Female Stress Urinary Incontinence: A Systematic Review and Meta-Analysis of Randomized Controlled Trials Comparing Tension-Free Midurethral Tapes to Other Surgical Procedures and Different Devices. European Urology 2008; 53:288-309.
8. Zilbert A, Farrell S. External iliac artery laceration during tension-free vaginal tape procedure. International Urogynecology Journal 2001; 12:141-143.
9. Huffaker R, Yandell P, Shull B. Tension-free vaginal tape bowel perforation. International Urogynecology Journal 2010; 21:251-253.
10. Delorme E. Transobturator urethral suspension: mini-invasive procedure in the treatment of stress urinary incontinence in women. Progrès en urologie: journal de l'Association française d'urologie et de la Société française d'urologie 2001; 11:1306.
11. De Leval J. Novel surgical technique for the treatment of female stress urinary incontinence: transobturator vaginal tape inside-out. European Urology 2003; 44:724-730.
12. Long C, Hsu C, Wu M, Liu C, Wang T, Tsai E. Comparison of tension-free vaginal tape and transobturator tape procedure for the treatment of stress urinary incontinence. Current Opinion in Obstetrics and Gynecology 2009; 21:342.
13. Tamussino K., Hanzal E, Kölle D, Ralph G, Riss P. Tension-free vaginal tape operation: results of the Austrian registry. Obstetrics & Gynecology 2001; 98(5 Part 1):732.
14. 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; 30:576-582.
15. 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 in-

continence. American journal of obstetrics and gynecology 2004; 190:602-608.
16. 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. International Urogynecology Journal 2007; 18:895-900.
17. StataCorp L: Stata statistical software: Release 10. College Station, TX: Stata Corporation 2007.
18. Deval B, Ferchaux J, Berry R, Gambino S, Ciofu C, Rafii A, Haab F. Objective and subjective cure rates after trans-obturator tape (OBTAPE®) treatment of female urinary incontinence. European Urology 2006; 49:373-377.
19. Ghoniem G, Stanford E, Kenton K, Achtari C, Goldberg R, Mascarenhas T, Parekh M, Tamussino K, Tosson S, Lose G. Evaluation and outcome measures in the treatment of female urinary stress incontinence: International Urogynecological Association (IUGA) guidelines for research and clinical practice. International Urogynecology Journal 2008; 19:5-33.
20. NICE: Urinary Incontinence. The Management of Urinary Incontinence in Women. In: NICE Clinical Guidline 2006; 40:13.
21. Gupta A, Defreitas G, Lemack G. The reproducibility of urodynamic findings in healthy female volunteers: Results of repeated studies in the same setting and after short term follow up. Neurourology and Urodynamics 2004; 23:311-316.
22. Glazener C, Lapitan M. Urodynamic investigations for management of urinary incontinence in adults. Cochrane database of systematic reviews (Online) 2002.
23. Sung V, Schleinitz M, Rardin C, Ward R, Myers D. Comparison of retropubic versus transobturator approach to midurethral slings: a systematic review and meta-analysis. American journal of obstetrics and gynecology 2007; 197:3.
24. Abdel Fattah M, Ramsay I, Pringle S. Lower urinary tract injuries after transobturator tape insertion by different routes: a large retrospective study. BJOG: An International Journal of Obstetrics & Gynaecology 2006; 113:1377-1381.
25. Isabelle K, Sandrine J, Michel B, Jean-Bernard D, Patrick D. Complications associated with transobturator sling procedures: analysis of 233 consecutive cases with a 27 months follow-up. BMC Women's Health 2009; 9.
26. Feng C, Chin H, Wang K. Transobturator vaginal tape inside out procedure for stress urinary incontinence: results of 102 patients. International Urogynecology Journal 2008; 19:1423-1427.
27. 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.
28. Zahn C, Siddique S, Hernandez S, Lockrow E. Anatomic comparison of two transobturator tape procedures. Obstetrics & Gynecology 2007; 109:701.
29. Hockey J: Mixed urinary incontinence: continuing to confound? Current Opinion in Obstetrics and Gynecology 2007; 19:521.
30. Shah A, Kohli N, Rajan S, Hoyte L: The age distribution, rates, and types of surgery for stress urinary incontinence in the USA. International Urogynecology Journal 2008; 19:89-96.

Correspondence to:
ANDREAS CHRYSOSTOMOU
Department of Obstetrics and Gynaecology
Charlotte Maxeke Johannesburg Academic Hospital
PO BOX 29699 Sandringham 2131
Johannesburg
Republic of South Africa

Original article

Abdominal rectopexy for rectal prolapse. Meta-analysis of literature

FEDERICA CADEDDU, PIERPAOLO SILERI, MICHELE GRANDE, ELISABETTA DE LUCA, LUANA FRANCESCHILLI, CAROLINA ILARIA CIANGOLA, GIOVANNI MILITO

Department of Surgery, University Hospital Tor Vergata, Rome, Italy

Abstract. Objective: Laparoscopic rectopexy to treat full-thickness rectal prolapse has proven short-term benefits, but there are little long-term follow-up and functional outcome data available. Using meta-analytical techniques, this study was designed to evaluate long term results of open and laparoscopic abdominal procedures to treat full-thickness rectal prolapse in adults. *Methods:* A literature review was performed using the National Library of Medicine's Pubmed Database; all articles reporting on abdominal rectopexy with a follow up longer than 16 months were considered. The primary end point was recurrence of rectal prolapse and the secondary end points were incontinence and constipation improvement. A random effect model was used to aggregate the studies reporting these outcomes, and heterogeneity was assessed. *Results:* Eight comparative studies, consisting of a total of 467 patients (275 open and 192 laparoscopic) were included. Analysis of data suggested that there is no significant difference in recurrence, incontinence and constipation improvement between laparoscopic abdominal rectopexy and open abdominal rectopexy. *Conclusions:* Laparoscopic abdominal rectopexy is a safe and feasible procedure, which may compare equally with the open technique with regards to recurrence, incontinence and constipation. However large-scale randomized trials, with comparative, strong methodology are still needed to find out outcome measures accurately.

Key words: Rectal Prolapse; Rectopexy; Follow up; Outcomes; Literature Review.

INTRODUCTION

Rectal prolapse, is defined as a protrusion of the rectum beyond the anus. Full-thickness rectal prolapse should be distinguished from mucosal prolapse in which there is protrusion of only the rectal or anal mucosa.[1,2]

Aetiological factors include lax and anatomic condition of the muscles of the pelvic floor and anal canal, abnormally deep pouch of Douglas, weakness of both internal and external sphincters, lack of normal mesorectum and finally weakness of lateral ligaments.[1-3]

Constipation is associated with prolapse in 30% to 70% of patients, with chronic straining, sensation of anorectal blockade, need of digital evacuation. In addition 60% of patients have coexisting incontinence due to the stretching of the anal sphincters caused by the prolapse and due to the impaired rectal compliance.

Regardless of the therapy chosen, matching the surgical selection, i.e. physical examination, defecatory history, endoscopy, manometry and colonic transit studies, is essential for the correct management of the patients.[3,4]

A complete colonoscopy is useful to test for organic colonic pathologies anorectal manometry and defecating proctography to confirm rectal prolapse and to test for outlet dysfunction or associated rectocele. A colonic transit study can be helpful for those patients who give a history of severe constipation and in whom the surgeon may be considering a resection-rectopexy.[3,4]

Regarding the treatment, patients who gain no relief from dietary modification and biofeedback therapy should be offered surgery.

Surgical therapy is aimed to correcting the prolapse, restore the continence and prevent constipation or impaired evacuation with acceptable mortality and recurrence rates.5-7 There are many procedures described for the treatment of rectal prolapse, that can be divided into abdominal or perineal approaches. The perineal approaches have been reserved to the frail and elderly patients, given that general anesthesia and laparotomy can be avoided; whereas the abdominal approaches are thought to provide a more effective repair with a lower recurrence rate.[7-9] More recently, laparoscopic surgery has emerged as an effective tool for the treatment of rectal prolapse because no specimen is removed and no anastomosis is required. Previous trials have suggested that laparoscopic surgery has many short term advantages over open surgery, including less pain and scarring, shorter hospital stay and faster recovery.[7-9]

In this prospective study we presented our experience with patients presenting with rectal prolapse surgically treated with ventral rectopexy with biomesh. In addition a review of literature was performed to point out the surgical strategies and outcomes for the treatment of rectal prolapse.

ABDOMINAL APPROACHES

Many transabdominal techniques have been proposed for rectal prolapse. These procedures require fixation of the rectum to the sacrum, by either a suture or mesh. An anterior resection or sigmoid colectomy is often added to the procedure.[1,9]

Suture rectopexy consists of rectum fixation to presacral fascia by interrupted sutures. In the Wells procedure after the rectal mobilisation a mesh is inserted between the sacrum and the rectum and fixed to sacral promontory and lateral rectal wall. The Ripstein procedure is an anterior 360º rectopexy. The Orr-Loygue rectopexy consists of anterolateral rectum fixation with double mesh.[1,9]

The addition of sigmoid resection to rectopexy (Frykman Goldberg procedure) combines the advantages of mobilisation of the rectum, sigmoid resection and rectum fixation. Most series used resection plus suture rectopexy. Besides this, few authors performed resection plus posterior mesh rectopexy.[5]

Regarding the results of Wells procedure in literature, mortality rates ranged from 0% to 3% and recurrence rates were reported between 0% and 6%. Improvement in continence occurred up to 75%, but there was a variable response of constipation. Regarding the results of resection and rectopexy in literature, mortality rate ranges between 0% and 6.7% with an associated recurrence rate of 0%-5%. There was an overall improvement both in continence and in constipation. Discussion about the mesh fixation, i.e. posterior or anterior approach, is still ongoing; in addition, the optimal material or suture to be used for fixation is still unclear.[1,5-9]

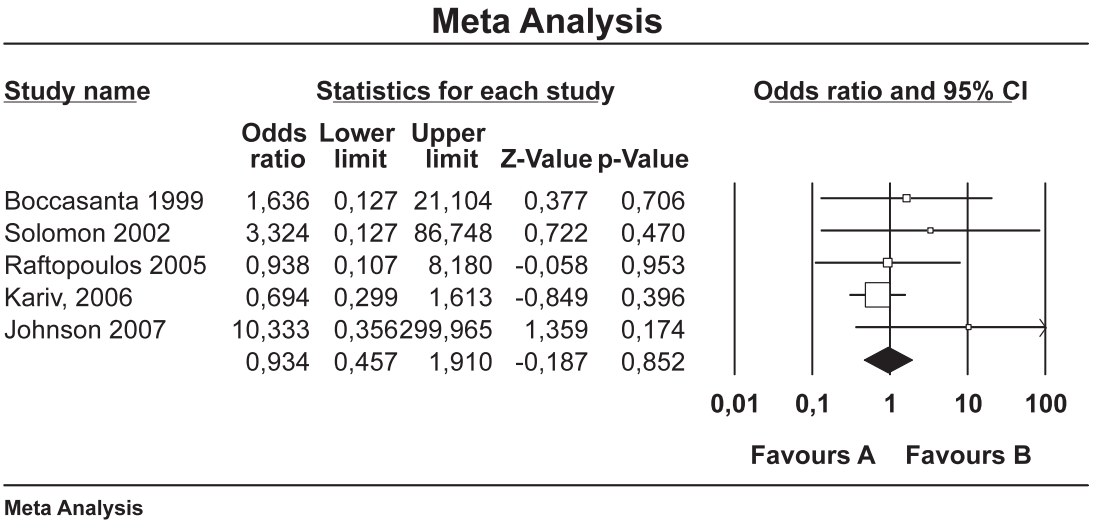

Figure 1 – Meta-analysis of trials comparing open and laparoscopic approach. Forest plot of recurrence. Random model. Salked 2004 and Baker 1999 have been excluded because of lack of data.

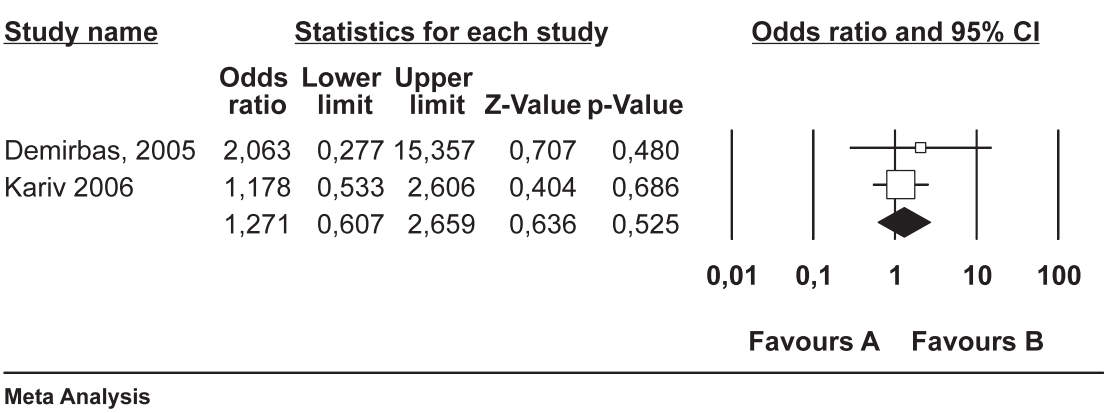

Figure 2 – Meta-analysis of trials comparing open and laparoscopic approach. Forest plot of incontinence Random model. Salked 2004, Baker 1997, Boccasanta 1999, have been excluded because of lack of data. Johnson 2007, Solomon 2002 reported data in a way not suitable for meta-analysis.

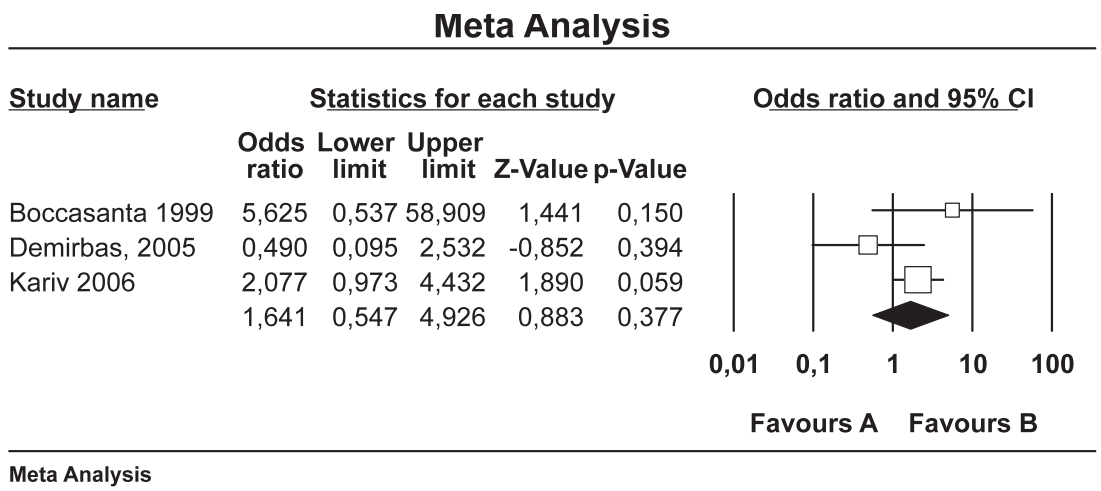

Figure 3 – Meta-analysis of trials comparing open and laparoscopic approach. Forest plot of constipation. Random model. Salked 2004, Baker 1999, Raftopoulos 2005, have been excluded because of lack of data. Johnson 2007, Solomon 2002 reported data in a way not suitable for meta-analysis.

Besides this, constipation is a major functional problem for patients with rectal prolapse with conflicting results and worsening of constipation reported up to 40% of patients. The only theme that seems clear from literature is that postoperative constipation after rectopexy is not completely understood. Actually, the constipation may be obstructive (bowel intussusception into the rectum, enterocele, puborectalis dissynergia) or secondary to colonic dysmotility. Besides, postoperative constipation may be due to colonic dysmotility from denervation, division of the lateral rectal ligaments, and sigmoid kinking secondary to rectal mobilization. Several authors suggested to preserve lateral ligament in order to improve both constipation and continence. The left colon and rectum receive retrograde innervations through the lateral ligaments; thus, lateral ligament division during rectopexy has been suggested to denervate the rectum, causing postoperative constipation. Accordingly, Nelson and coworkers in a recent Cochrane review on 12 trials and 380 patients, reported that division, rather than preservation, of the lateral ligaments was associated with less recurrent prolapse but higher post-operative constipation rate.

The abdominal operations for rectal prolapse can all be performed laparoscopically. Laparoscopic rectopexy gained rapidly popularity given that it's simple, easy to perform and has several short term advantages, including less pain and scarring, decrease rate of wound hernias and bowel obstruction, shorter hospital stay and a more rapid recovery. Regarding the results reported in literature the mortality was 0% with recurrence rates up to 4% the effect on continence and constipation depends on the type of operation performed.[9-12.]

LAPAROSCOPIC VERSUS OPEN SURGERY: META-ANALISYS OF LITERATURE

Recently, we meta-analysed the trials comparing laparoscopic versus open abdominal rectopexy (suture and mesh rectopexy with or without resection) with a focus on long term results.

In the meta-analysis, both randomized and nonrandomized trials comparing open and laparoscopic rectopexy with a follow up longer than 16 months have been included. Any technique for abdominal repair of rectal prolapse has been considered i.e. resection and rectopexy either with suture or mesh.

Seventeen trials on open and laparoscopic rectopexy, including more than 1000 patients, were obtained from the database. Eight comparative studies,13-20 published between 1997 and 2007, matched the inclusion criteria, comparing laparoscopic and open rectopexy, with a follow up longer than 16 months.

The quality of the included studies was assessed on study design, allocation concealment and blinding of participants both investigators and observers for randomized trials, mean outcome measures, statistical examination, length of follow up. These trials included three retrospective, four prospective nonrandomized and one prospective randomized blinded study.

A total of 467 patients, of which 275 (58.8 percent) underwent open rectopexy and 192 (41.2 percent) laparoscopic rectopexy, were included in the final analysis. The largest study was based on 172 patients the smallest on 18 patients. The year of study, number of patients and study design, are demonstrated in table 1.

Incidence of recurrence, incontinence improvement and constipation improvement after the intervention and length of follow up.[61-68]

Figure 1 demonstrates the outcome for meta-analysis for recurrence. All the studies except for Baker19 et al and Salked et al20 reported the incidence of recurrence and there was significant heterogeneity among trials ($Q = 4.99$, $p < 0.05$).

The median follow-up time of the studies ranged from 16 to 49 months. Meta-analysis showed no significant difference in the recurrence rate between open rectopexy and laparoscopic rectopexy (OR, 0.934; 95 percent CI, 0.457-1.910; Z value = -0.187; P = 0.852) using random effect model.

Figure 2 demonstrates the outcome of meta-analysis for incontinence. Baker et al.[19], Boccasanta et al.[18] and Salked et al.[20] did not reported the incidence of patients with continence improvement after the intervention. Jonhson and Solomon reported grouped data not suitable for meta-analysis.

The two remaining studies were compared. There was no significant heterogeneity among trials ($Q < 1$, $p > 0.05$).

The median follow-up time of the studies was 59 and 24 months. Meta-analysis showed no statistical significant difference regarding incontinence between open rectopexy and laparoscopic rectopexy (OR, 1.271; 95 percent CI,

TABLE 1. – Results of OPEN versus LAPAROSCOPIC APPROACH.

Trial	Year	Study type	Type PTS	N PTS	Continence improvement N	Constipation improvement N	Recurrence N (%)	Follow-up (months)
JOHNSON[13]	200	Prosp	OPEN	5	GD	GD	1/5	17*
	7	NR	LPS	15	GD	GD	0	
KARIV[14]	200	Prosp	OPEN	86	19/56	30/56	11/86	59*
	6	NR	LPS	86	17/56	20/56	15/86	
DEMIRBAS[15]	200	Prosp	OPEN	17	3/11	411	0	36
	5	NR	LPS	23	2/13	7/13	0	16
RAFTOPOULOS[16]	200	Retrosp	OPEN	105	NS	NS	9/105	49
	5	Retrosp	LPS	11	NS	NS	1/11	
SOLOMON[17]	200	Prosp	OPEN	19			1/19	23**
	2	RB	LPS	20			0	
BOCCASANTA[18]	199	Prosp	OPEN	13	NS	5/13	2/13	37*
	2	NR	LPS	10		1/10	1/10	26
BAKER[19]	199	Retrosp	OPEN	10	NS	NS	NS	27*
	7		LPS	8				26
SALKED[20]	200	Retrosp	OPEN	20	NS	NS	NS	NS
	7	Cohort	LPS	19				

NS: not stated; Retrospec: retrospective; Prosp: prospective; NR: not randomized; LPS: laparoscopic; GD: Grouped Data; RB: Randomied Blinded; *: mean values; **: median values

0.607-2.659; Z value = 0.636; P = 0.525) using random effect modelling.

Figure 3 demonstrates the outcome of meta-analysis for constipation. Baker et al.[19] and Salked et al.[20] did not reported the incidence of patients with constipation improvement after the intervention. Jonhson[13] and Solomon[17] reported grouped data not suitable for meta-analysis. The three remaining studies were compared.

There was significant heterogeneity among trials (Q = 4.32, p < 0.05). The median follow-up time for the studies ranged between 24 and 59 months. Meta-analysis showed no statistical significance regarding constipation between open and laparoscopic rectopexy (OR, 1.641; 95 percent CI, 0.547-4.926; Z value = 0.833; P = 0.377) using random effect modelling.

Finally, although multiple studies have small sample size, graphic exploration of the results with funnel plots of the primary and secondary outcomes did not demonstrate any evidence of publication bias.

DISCUSSION

The management of rectal prolapse is still a challenge with no clear predominant treatment of choice. Although short term results are in favour of laparoscopic surgery, relatively little is known regarding comparison of the long-term functional results between either laparoscopic and open surgery or different surgical techniques.21-28 In this large study, we meta-analyzed the long-term functional outcomes of open and laparoscopic procedures to treat rectal prolapse considering both comparative and noncomparative trials with a follow up longer than 16 months.

Three meta-analysis of comparative studies open versus laparoscopic surgery for rectal prolapse have been published in literature.[6,27,28] The results of these meta-analysis suggested that although the operative time is greater, laparoscopic surgery has many short term advantages over open surgery, including less pain and scarring, shorter hospital stay and faster recovery. There was no difference in recurrence rates or morbidity (the primary outcomes) between the two techniques.[6,21-28]

Recurrence after surgery for rectal prolapse is a key measure of successful long term outcome.6 The rate of recurrence varies in literature according to the type of repair, the length of follow up and the definition of relapse. Most studies showed that the recurrence rates for rectal prolapse after either laparoscopic or open surgery are lower than 10% and similar.[21-28] Accordingly, our meta-analysis of studies, comparing open and laparoscopic procedures, showed no statistically significant difference in recurrence between the two approaches ($P = 0.852$).

Constipation is a major functional problem for patients with rectal prolapse with conflicting results both for open and laparoscopic procedures.[6] The only theme that seems clear from literature is that postoperative constipation after rectopexy is not completely understood and previous comparisons between laparoscopic and open surgery failed to reveal significant long-term functional differences between the two groups.[6,21-28]

Actually, the constipation may be obstructive (bowel intussusception into the rectum, enterocele, puborectalis dissynergia) or secondary to colonic dysmotility. Besides, postoperative constipation may be due to colonic dysmotility from denervation, division of the lateral rectal ligaments, and sigmoid kinking secondary to rectal mobilization.[62,70] Accordingly, Nelson and coworkers in a recent Cochrane review on 12 trials and 380 patients, reported that division, rather than preservation, of the lateral ligaments was associated with less recurrent prolapse but higher postoperative constipation rate6. Furthermore, rectal resection was associated to rectopexy according to the theory that removal of the redundant sigmoid colon could result in less kinking at the rectosigmoid angle and thus improvement of transit into the rectum.[5,6] Other advantages include avoiding torsion or volvulus of the redundant sigmoid colon and achieving a straighter course and less mobility of the left colon.

Nonetheless, in literature, the addition of sigmoid resection is associated with variable results in terms of postoperative constipation.[5,6,23] The procedure seems well suited to patients with a long redundant sigmoid and a long history of constipation.[24]

Besides, according to the previous meta-analyses,[6,27,28] our quantitative analysis of trials comparing laparoscopic and open surgery failed to reveal significant constipation differences between the two groups ($P = 0.377$).

Different mechanisms of fecal incontinence in patients with rectal prolapse have been claimed: pudendal nerve neuropathy, direct sphincter trauma from the rectal intussusception, chronic stimulation of the rectoanal inhibitory reflex, and impaired rectal sensation. Continence is restored after surgery for a high percentage of patients with rectal prolapse.[26] In our quantitative analysis most of the studies reported an improvement in continence after the operation that was statistically significant after laparoscopic surgery and open mesh rectopexies. Finally, according to previous results[6,27,28] no difference was obtained in continence from the meta-analysis of trials comparing open and laparoscopic surgery.

CONCLUSIONS

In summary, predicting which patient, presenting with rectal prolapse and obstructed defecation, will benefit from surgical intervention remains a challenge. Surgery should be considered only when conservative therapy fails and a careful patient selection is crucial to obtain a satisfactory outcome. As stated by Nelson in the recent Cochrane database System review on rectal prolapse, it is impossible to identify a gold standard of treatment.[6]

Ventral rectopexy using biological mesh for internal rectal prolapse has come out as safe and effective procedure in ameliorating symptoms of obstructed defecation and faecal incontinence. Laparoscopic ventral rectopexy allows for reduced hospital stay and convalescence and should be considered the gold standard in colorectal centres.

REFERENCES

1. Jacobs LK, Lin YJ, Orkin BA. The best operation for rectal prolapse. Surg Clin North Am. 1997; 77:49-70.
2. Felt-Bersma RJ, Cuesta MA. Rectal prolapse, rectal intussusception, rectocele and solitary ulcer syndrome. Gastroenterol Clin North Am. 2001; 30:199-222.
3. Roig JV, Buch E, Alós R, et al. Anorectal function in patients with complete rectal prolapse: differences between continent and incontinent individuals. Rev Esp Enferm Dig 1998; 90:794-805.
4. Brodén B, Snellman B. Procidentia of the rectum: studies with cineradiography. Dis Colon Rectum 1968; 11:330-347.
5. Kuijpers HC. Treatment of complete rectal prolapse: to narrow, to wrap, to suspend, to fix, to encircle, to plicate or to resect? World J Surg 1992; 16:826-830.
6. Tou S, Brown SR, Malik AI, Nelson RL. Surgery for complete rectal prolapse in adults. Cochrane Database of Systematic Reviews 2008, Issue 4. Art. No.: CD001758.
7. Yakut M, Kaymakciioglu N, Simsek A, et al. Surgical treatment of rectal prolapse: a retrospective analysis of 94 cases. Int Surg 1998; 83:53-55.

8. Kim DS et al. Complete rectal prolapse: Evolution of management and results. Dis Colon Rectum 1999; 42: 460-466.
9. Corman ML () Chapter 17: Rectal Prolapse, Solitary Rectal Ulcer, Syndrome of the Descending Perineum, and Rectocele. In Colon and Rectal Surgery, edn 5 2005; 499-554 (Ed. Corman ML) Philadelphia, PA: Lippincott Williams and Wilkins.
10. Johnson E, Stangeland A, Johannessen HO, Carlsen E () Resection rectopexy for external rectal prolapse reduces constipation and anal incontinence. Scand J Surg 2007; 96:56-61
11. D'Hoore A, Cadoni R, Penninckx F. Long-term outcome of laparoscopic ventral rectopexy for total rectal prolapse. Br J Surg 2004; 91:1500-1505.
12. Slawik S, Soulsby R, Carter H, Payne H, Dixon AR. Laparoscopic ventral rectopexy, posterior colporrhaphy and vaginal sacrocolpopexy for the treatment of recto-genital prolapse and mechanical outlet obstruction. Colorectal Dis 2008;10:138-43.
13. D'Hoore A, Penninckx F. Laparoscopic ventral recto(colpo)-pexy for rectal prolapse: Surgical technique and outcome for 109 patients. Surgical Endoscopy 2006; 20: 1919-23.
14. Kariv Y, Delaney CP, Casillas S, et al. Long-term outcome after laparoscopic and open surgery for rectal prolapse: a case-control study. Surg Endosc 2006; 20:35-42.
15. Demirbas S, Akin ML, Kalemoglu M, Ogun I, Celenk T. Comparison of laparoscopic and open surgery for total rectal prolapse. Surg Today 2005; 35:446-452.
16. Raftopoulos Y, Senagore AJ, Di Giuro G, Bergamaschi R. Recurrence rates after abdominal surgery for complete rectal prolapse: a multicenter pooled analysis of 643 individual patient data. Dis Colon Rectum 2005; 48:1200-6.
17. Solomon M et al. Randomized clinical trial of laparoscopic versus open abdominal rectopexy for rectal prolapse. Br J Surg 2002; 89: 35-39.
18. Boccasanta P, Venturi M, Reitano MC, et al. Laparotomic vs laparoscopic rectopexy in complete rectal prolapse. Dig Surg 1999; 16:415-419.
19. Baker R, Senagore AJ, Luchtefeld MA. Laparoscopic assisted vs open resection: rectopexy offers excellent results. Dis Colon Rectum 1995; 38:199-201.
20. Salkeld G, Bagia M, Solomon M. Economic impact of laparoscopic versus open abdominal rectopexy. Br J Surg 2004; 91:1188-91.
21. Demirbas S, Akin ML, Kalemoglu M, Ogun I, Celenk T. Comparison of laparoscopic and open surgery for total rectal prolapse. Surg Today 2005; 35:446-52.
22. Lechaux D, Trebuchet G, Siproudhis L, Campion JP Laparoscopic rectopexy for full-thickness rectal prolapse: a single-institution retrospective study evaluating surgical outcome. Surg Endosc 2005; 19:514-8.
23. Rose J et al. Laparoscopic treatment of rectal prolapse: experience gained in a prospective multicenter study. Lang Arch Surg 2002; 387:130-137.
24. Metcalf AM, Loening-Baucke V. Anorectal function and defecation dynamics in patients with rectal prolapse. Am J Surg 1988;155: 206-210.
25. Byrne CM, Smith SR, Solomon MJ, Young JM, Eyers AA, Young CJ. Long-term functional outcomes after laparoscopic and open rectopexy for the treatment of rectal prolapsed. Dis Colon Rectum 2008; 51:1597-604.
26. Madiba TE, Baig MK, Wexner S. Surgical management of rectal prolapse. Arch Surg 2005; 140:63-73.
27. Sajid M, Siddiqui M, Baig M. Open Versus Laparoscopic Repair Of Full Thickness Rectal Prolapse: A Re-Meta-Analysis Colorectal Dis 2009 Apr 13.
28. Purkayastha S, Tekkis P, Athanasiou T, et al. A comparison of open vs. laparoscopic abdominal rectopexy for full-thickness rectal prolapse: a metaanalysis. Dis Colon Rectum 2005; 48:1930-40.

Correspondence to:
FEDERICA CADEDDU
Department of Surgery, University Hospital Tor Vergata
Viale Oxford, 81 - 00133 Rome, Italy.
Phone +39.06.20902976
Fax +39.06.20902976
E-mail fede.cadeddu@libero.it

Original article

Transurethral bulking agent injection in female stress urinary incontinence: long term results using Opsys®

MIGUEL ANGEL ZANGONE[1], TOMÁS OLMEDO[2], MAURICIO OLEA[2]

[1]*Hospital Bernardino Rivadavia, Buenos Aires, Argentina*
[2]*Hospital San José - Urology Unit and Urology Department of Hospital Clínico of the University of Chile, Santiago, Chile*

Abstract. *Objective*: assessment the long term clinical effectiveness of the Opsys® bulking agent used as injectable therapy in the treatment of female stress urinary incontinence (SUI). *Patients and Method*: a total of 38 women with SUI were prospectively included in this non-randomized, open, multicenter study after having signed an informed consent form. The subjects' mean age was 62.6 years, and the mean body mass index (BMI) was 31.8 kg/m^2. One woman was lost to follow-up 12 months postoperatively. The preoperative evaluation included a physical examination, a 24-hour pad weight test (PWT), a Q-Tip test, Valsalva leak point pressure (VLPP) with urodynamic studies and the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF[1]). Patients were followed-up for a total of 60 months, and these results were compared to those obtained at 12 months. Thirty-three patients (86.8%) underwent a single implant procedure, the remaining five cases (13.2%) received a second implantation. *Results*: Sixty months after surgery, the 24-hour PWT showed 46% of patients being dry, 27% improved, and 27% failed producing a 73% cure rate (dry+improved). The ICIQ-SF at 60 months showed a mean value of 10.1 (SD=6.2) compared to the preoperative mean value of 18.0 (SD=2.4). Nine patients (23.7%) presented with *de novo* urge incontinence, and 7 (18.4%) had transient urinary retention. Urinary tract infections (UTI) were confirmed in 3 cases (7.4%) and dysuria in 4 (10.5%). *Conclusions*: Opsys can be offered as a minimally invasive procedure with durable clinical results.

Key words: SUI; Heterologous material; Bulking agent; Biocompatible: Polyacrylate polyalcohol.

Acronyms: BMI: Body Mass Index; ICIQ-SF: International Consultation on Incontinence Questionnaire – Short Form; ISD: Intrinsic Sphincter Deficiency; PWT: Pad Weight Test; SUI: Stress Urinary Index; VLPP: Valsalva Leak Point Pressure.

INTRODUCTION

The main objective of this work has been to assess long term clinical effectiveness of the Opsys bulking agent as an injectable therapy used in the treatment of SUI. It is important to initially comment that ISD is a relevant component in SUI, and, thus, its assessment is highly valuable. SUI due to ISD is defined as the presence of a urethral sphincter mechanism that fails to maintain sufficient resistance for urinary continence either at rest or in the presence of minimal physical exertion.[1] Surgical treatment of SUI is generally prescribed after conservative treatments, such as biofeedback and drugs, have failed. These surgical procedures can be divided into three groups: suburethral slings, colposuspension procedures and periurethral injections. The sling is currently considered as the "gold standard" for SUI treatment.[2]

For the past twenty years, the trend has been to develop less invasive procedures with similar cure rates when compared to sling placement or Burch techniques but with the advantage of reducing morbidity, hospitalization and convalescence before returning to normal activities.[3] Transurethral injections via urethroscopy have the significant advantage of being less invasive and easily performed when compared to slings or Burch techniques.[4] The injection of bulking agents through urethroscopy has been studied and utilized for more than 65 years[5] during which time a variety of different substances have been tried. In the last decades, different substances have been tested including autologous fat,[6] polytetrafluoroethylene paste,[7] bovine collagen, silicon elastomer,[8] dextranomer copolymers (DiHA), polyvinyl alcohol foam, calcium hydroxyapatite (CaHA), myoblasts (stem cells)[9] and chondrocytes.

Patient selection is a critical factor in determining objective and subjective success of transurethral bulking agents. The advantages of such a procedure are clear, but not all women are equally suitable for this treatment. This therapy is indicated for women who want or need a less-invasive procedure, who may be an anesthetic risk, who may have had a previous sling procedure failure, for those patients with multiple co-morbidities or for young women who may want to achieve future pregnancies.[10]

PATIENTS AND METHODS

Results were collected from an open, single-arm, non-randomized, multicentric study. A total of 38 female patients with SUI who had ISD as the main component of incontinence and had completed a 60 month follow-up were included in this study. One patient was lost to follow-up 12 months postoperatively. The mean age of the patients was 62.6 [42-92] years, and the mean BMI was 31.8 [22-49] kg/m^2. 80% of the patients enrolled in the study were postmenopausal, and 6/38 subjects had an initial diagnosis of mixed incontinence. Although incontinence was due predominantly to ISD, 4/38 were treated with antimuscarinics before undergoing the Opsys procedure. Other baseline information is summarized in Table 1.

The bulking agent substance used in this study is made of a polyacrylate polyalcohol copolymer, which is a non-absorbable biomaterial[11] also used in children to treat vesicourethral reflux conditions.[12,13] The macroparticles of Opsys have an average diameter of 300 μm, and they are hydrated in a 40% glycerol solution. This combination leads to a substance which can be manually injected easily through small needles (21-gauge). The biocompatibility and non-migration characteristics as well as long-term bulking stability in the implant site of the substance have been proven by both *in-vivo* and *in-vitro* studies.[11]

Preoperatively, patients were questioned using the ICIQ-SF and were objectively evaluated through the 24-hour PWT.[14] Urodynamics was verified by a complete physical examination which involved: cystometry with measurement of leakage pressure, profilometry with evaluation of urethrovesical differential pressure in active phase, maximum pressure of urethral closing in active/passive phase and functional length. Valsalva leak point pressure (VLPP) was measured in each patient after the bladder was filled with 200 mL

TABLE 1. – Baseline characteristics of patients and preoperative assessments.

Characteristic	N	Mean	SD	Min-Max	% (N/N_{TOTAL})
Women recruited	38	-	-	-	100.0
Age - years	-	62.6	10.1	42-92	-
Body Mass Index - kg/m^2	-	37.6	8.5	22-55	-
Parity	-	2.4	1.1	1-6	-
Menopausal	31	-	-	-	79.5
Type of Urinary Incontinence					
Mixed Incontinence	6	-	-	-	15.8
ISD Incontinence	32	-	-	-	84.2
VLPP - cmH_2O	-	46.8	11.0	27-65	-
Cases treated with antimuscarinics	4	-	-	-	10.5
Previous anti-incontinence surgery	4	-	-	-	10.5
Burch	1	-	-	-	2.6
Sling	3	-	-	-	7.9
ICIQ-SF	-	18.0	2.4	11-21	-
Maximum Flow - mL/s	-	25.5	2.9	20-30	-
Urine leakage - g/day	-	108.6	69.5	34-300	-

of saline solution. Patients were diagnosed with SUI due to ISD when VLPP was lower than or equal to 60 cmH_2O and primary urethral hypermobility was discarded (Q-tip>30°).

Opsys implantation was performed transurethrally under direct vision using a rigid cytoscope with 30º angle optics. General anaesthesia was the most commonly used technique (38.5%) followed by neuroleptoanaesthesia (30.8%), spinal (23.1%) and peridural (7.7%). Transurethral injection sites were identified at the 2-, 6-, and 10-o'clock positions (injecting ≥ 1 mL, ≥ 2 mL and ≥ 1 mL respectively) one centimeter from the bladder neck in the submucosal region of the proximal urethra. Figure 1a and Figure 1b show the cystoscopic image of the urethral lumen before and after the bulking agent was injected.

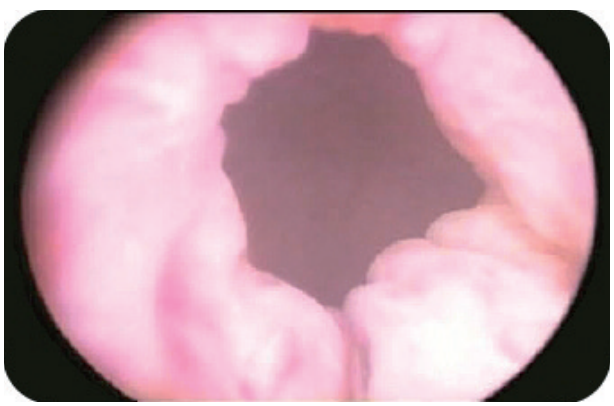

Figure 1. – *1a* Cystoscopic image before the bulking agent was implanted.

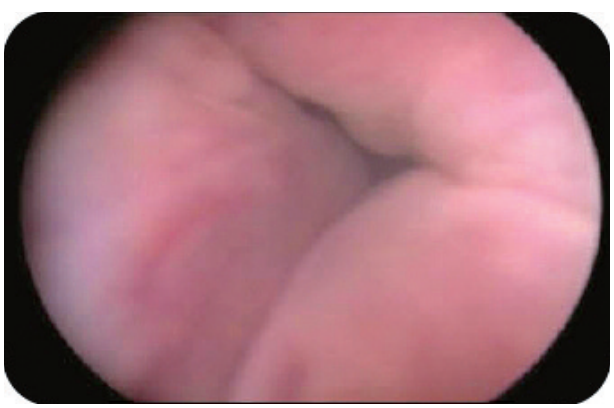

Figure 1. – *1b* Cystoscopic image after the bulking agent implantation.

Postoperative follow-up of patients was performed at a physician's office repeating both the questionnaire (ICIQ-SF) and 24-hour PWT at 3, 6, 12, and 60-months. Patients were considered objectively dry when the post-operative 24-hour PWT resulted in less than 1.3 g of urine loss.[14] If the loss represented a reduction of more than 50% from the initial preoperative measurement, the patients were classified as improved.[15] Patients were considered as having failed if they did not meet either of the previous criteria.

A re-implantation procedure was offered 90 days post-procedure to those patients who did not get a positive result and it was performed upon patient's consent.

A comparison between the 60-month and 12-month data was done using a paired-samples Student t-test in IBM SPSS Statistics 17 with a significance level of 0.05.

RESULTS

Thirty-three on 38 patients (86.8%) underwent a single implant procedure. The median volume of injected material was 4.8 mL. Sixty months postoperatively, 46.0% of the patients were completely dry, and 27.0% met the criteria to be considered improved. These numbers indicate a 73% cure rate (dry+improved) and a 27% failure rate based on the

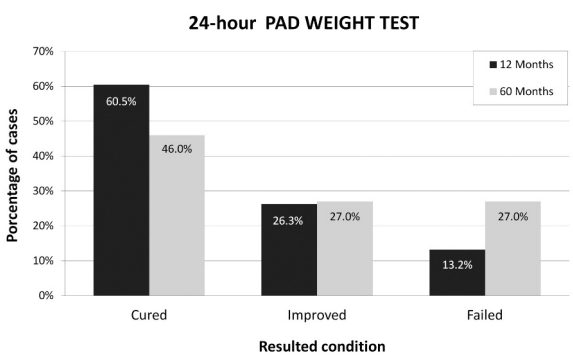

Figure 2. – Mean values of cured/improved/failed rates obtained from the 24-hour Pad Weight Test.

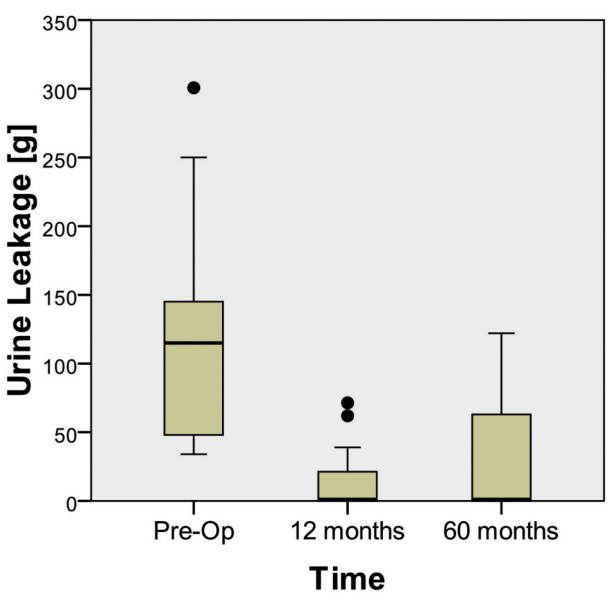

Figure 3. – Urine leakage measured with the 24-hour Pad Weight Test.

Table 2. – Complications.

Adverse event	N	%
Urinary tract infection	3	7.9
Urinary retention	7	18.4
De novo urge incontinence*	9	23.7
Dysuria	4	10.5

*At 12 months, only 2 (5.3%) of these women had presented with this condition. The other 7 (18.4%) reported their first symptoms 60 months postoperatively.

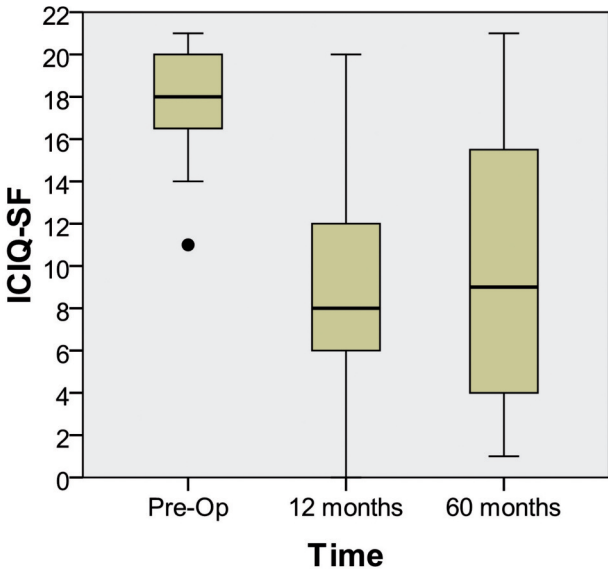

Figure 4. – Results obtained for the ICIQ-SF.

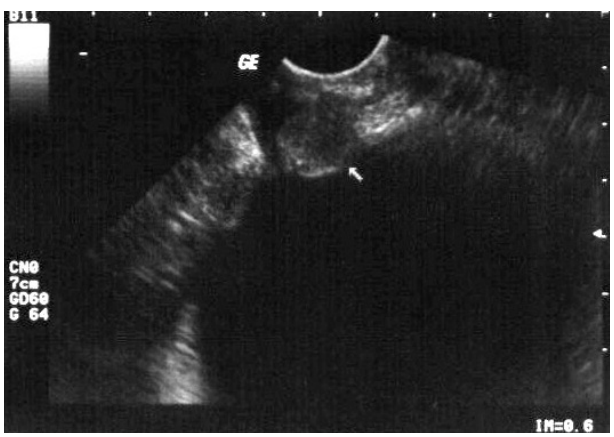

Figure 5. – Patient's transvaginal ultrasound performed 3 months after implant procedure. The image clearly shows the presence of the implanted substance (arrow), which confirmed the permanence of the resulting bulk.

objective measurement of a 24-hour PWT. Figure 2 shows these results in terms of percentage rates, and they are paired to the results obtained at 12 months. The paired-samples Student t-test did not show a statistically significant difference between these measurements (*p=0.209 two-tailed test*). Figure 3 shows the comparison of urine leakage in grams. Five patients (13.2%) underwent a re-implantation procedure 90 days after the surgery. Among these 5 patients, 2 became dry, 1 improved her condition, and the other 2 patients remained incontinent.

The ICIQ-SF at 60 months resulted in a mean value of 10.1 (SD=6.2) compared to the original mean value of 18.0 (SD=2.4). The mean value registered for the 12-month follow-up was 8.4 (SD=5.5). These follow-up differences were found not to be statistically significant (*p=0.593 two-tailed test*) indicating stability in patient perception of the implantation outcomes. Figure 4 shows the results of ICIQ-SF arranged in a box plot graph. The median value for 12 months and 60 months were 8 and 9 respectively (pre-operative median value was 18).

Complications are summarized in Table 2. Two patients (5.3%) presented with *de novo* urge incontinence at 12 months. The number of patients with *de novo* urge incontinence increased up to 9 (23.7%) after the 60-month follow-up. Seven patients (18.4%) had urinary retention in the first 48 hours, and intermittent sterile catheterization had to be performed during that time to resolve this complication. Three cases of urinary tract infections were reported; all were resolved with antibiotics. Dysuria was identified in 4 patients (10.5%).

DISCUSSION

The goal of SUI treatment is to increase urethral resistance to achieve continence during intra-abdominal pressure variation. This is obtained through coaptation or narrowing of the urethral lumen and by increasing urethral closure pressure.[16] The gold standard treatment in this type of pathology is sling implantation with success rates over 70%.[17,18] However, patient demands for less invasive procedures and decreased morbidity postoperatively have resulted in renewed interest in bulking agent treatments. A variety of both absorbable and non-absorbable bulking agents have been tested throughout the years. The published success rates range from as low as 7% to 83%. The latter success rate of 83% was observed in absorbable substances with a short term follow up, the values of which significantly decreased within 9 to 19 months after the substance was initially injected.[19]

In our study, an objective dry/improvement rate of 73% was measured 60 months after the implantation of Opsys. When compared to the 12-month results, no significant statistical difference was found. Other authors have published subjective success rates at 60 months with silicone elastomer macroparticles from 29%[20] to 80%.[21] The latter rate corresponds to a study with a re-injection rate of 38%. In this study with Opsys, a second procedure was performed in 5 (13.2%) patients compared to reported rates up to 49%[22] for silicon elastomer and reaching a 35% with a polyacrylamide substance.[23]

Radiographic imaging and ultrasonagraphy are common techniques used to verify the presence of a bulking site formed by different transurethral injectable substances. Opsys is not radiopaque, but it can be seen via ultrasound after the first 3 months post-injection. The image of Figure 5, taken 3 months after the implantation, shows the presence of the heterologous material in the perivesical, suburethral region. This photo was obtained by using transvaginal ultrasound performed with a 7 MHz transducer. The use of ultrasound imaging can be used before executing a second injection in order to verify the presence of the bulking agent at the initial sites and the appropriateness of their positions.

Sixty months postoperatively, an anticipated loss of efficacy in some subjects was noted for this bulking agent treatment. One factor which might be partially responsible for this loss of continence was the appearance of an important number of *de novo* urge incontinence cases. In fact, only 2 cases (5.3%) of *de novo* urge incontinence were registered at the 12-month follow-up, while 7 (18.4%) were registered at the 60-month follow-up for a total of 9 (23.7%) cases of patients with urge incontinence (Table 2). When using a silicone elastomer bulking agent, a 4.9% incidence of *de novo* urge incontinence was registered at 12 months,[8] and 50% incidence was found in a 60-month, follow-up study.[20] The dif-

ference in the number of new urge incontinence cases may be supported by epidemiological evidence which highlights the correlation of urge incontinence prevalence with age. Our study population presented a preoperative mean age of 62.6 years, and with the additional 60-month follow-up, the average age became 67.6 years. According to the NOBLE Study (National Overactive Bladder Evaluation), the prevalence of urge incontinence for 45-64 year old U.S. women was approximately 13%; this prevalence increases to 19% for women within an age range of 65-74 years.[24] Several other studies[25] support this correlation of urge incontinence with age although the rates may differ depending on the study design and the definition of overactive bladder symptoms. When evaluating the signs and symptoms of the study patients who presented with urge incontinence at their last follow-up, it was concluded that there was strong evidence that these symptoms could represent an additional, independent condition that had no relationship to the pathophysiology of the patient's original SUI condition or to the therapeutic application of the bulking agent. Women are more likely to suffer from other systemic pathologies as they age which negatively impact the inhibitory influence of the supraconal levels of the central nervous system over the spinal cord cone (medullary micturition center, S2/S3). This loss of inhibition would not be directly associated to the vesicourethral anatomic alteration due to an injectable substance even when these conditions produce the same symptomatology as the primary condition (SUI) as the involuntary loss of urine.

Based on this study's results, the authors believe that Opsys can be used as a minimally invasive transurethral bulking procedure with durable clinical results and no serious adverse events. Additionally, another important point to be considered when reviewing our results is the low re-injection rate registered in this study which makes Opsys a robust option as a single injection treatment.

ACKNOWLEDGEMENTS

GRANTS OR FINANCIAL SUPPORT: Promedon S.A. has funded the investigation. The authors have not reported any financial relationship with Promedon S.A. or other conflicts of interest.

REFERENCES

1. Agency for Health Care Policy and Research. Urinary incontinence in adults: clinical practice guideline. AHCPR Publication Nº 92-0038. Rockville, Maryland: Agency for Health Care Policy and Research, Public Health and Human Services, 1992.
2. Bemelmans B.L.H., Chapple C.R. Are slings now the gold standard treatment for the management of female urinary stress incontinence and if so which technique? Curr Opin Urol, 2003; 13: 303-7.
3. Balmforth E., Cardozo L.; Trends towards less invasive treatment of female stress urinary incontinence, Urology, 2003; 62 (Suppll 4A): 52-60.
4. Maman J.T.N., D'Ancona C.A.L., Tadini V., Netto N.R.; Macroplastique implantation system for the treatment of female stress urinary incontinence; J Urol; 2003; 169: 2229-2233.
5. Benshushan A., Brzezinski A., Shoshani O., Rojansky N.; Periurethral injection for the treatment of urinary incontinence; Obstet Gynecol Surv, 1998; 53: 383-8.
6. Nilsson C.G., Kuuva N., Falconer C., et al; Long-term results of tension free vaginal tape (TVT) procedure for surgical treatment of female stress urinary incontinence; Int Urogynecol J Pelvic Floor Dysfunct 2001; 12 (Suppl): 5-8.
7. Palma P.C.R., Riccetto C.L.Z.; Injeçoes periuretais no tratamento da incontinência urinária de esforço. In: Aplicações Clínicas da Urodiâmica; Ed 3. São Paulo: Atheneu, 2001; 167-74.
8. Ghoniem G., Corcos J., Comiter C., Bernhard P., Westney O., Herschorn S.; Cross-Linked Polydemethylsiloxane injection for female stress urinary incontinence: Results of a multicentric, randomized, controlled, single-blind study. J Urol 2009; 181: 204-10.
9. Radley S.C., Chapple C.R., Mitsogiannis I.C., Glass K.S.; Transurethral implantation of macroplastique for the treatment of female stress urinary incontinence secondary to urethral sphincter deficiency; Eur Urol 2001; 39: 383-9.
10. Ramsden M., Williams E., Siegel S.; Female Stress Urinary Incontinence: Office based Urethral Bulking Agent Procedure; Urol Nurs 2010; 30: 297-305.
11. Ormaechea M., et al, VANTRIS®, a biocompatible, synthetic, non-biodegradable, bulking substance, easy to inject. Evaluation of local reaction, localized migration and long-distance migration; Ach Esp Urol 2008; 61: 263-8.
12. Ormaechea M., Ruiz E., Denes E., Gimenes F., Dénes F., Moldes J., Amarante A., Pioner G., Dekemacher S., de Badiola F.; New tissue bulking agent (polyacrylate polyalcohol) for treating vesicourethral reflux: Preliminary results in children. J Urol 2010; 183: 714-17.
13. Chertin B., Arafeh W.A., Zeldin A., Kocherov S.; Preliminary data on endoscopic treatment of vesicoureteric reflux with polyacrylate polyalcohol copolymer (Vantris): Surgical outcome following single injection; J Pediatr Urol 2011; 7: 654-7.
14. Tubaro A., et al. Imaging and other investigations, Chapter in Incontinence 4th Ed. Abrams P., Cardozo L., Khoury S., Wein A. (Eds.). Health Publications Ltd, 2009. Committee 7B: 541-630.
15. Clinical investigations of devices indicated for the treatment of urinary incontinence - Guidance for industry and FDA staff. Document issued on March 8, 2011. US Department of Health and Human Services Food and Drug Administration, Center for Devices and Radiological Health.
16. Haab F., Zimmern P.E., Leach G.E.; Female stress urinary incontinence due to intrinsic sphincteric deficiency: recognition and management; J Urol 1996; 156: 3-17.
17. Bergman A., Elia G.; Three surgical procedures for genuine stress incontinence: five years follow-up of a prospective randomized study; Am J Obstet Gynecol 1995; 173: 66-71.
18. McGuire E.J., Bennett C.J., Konnak J.A., Sonda L.P., Savastano J.A.; Experience with pubovaginal slings for urinary incontinence at the University of Michigan; J Urol 1987; 138: 525-6.
19. Appell R.A.; Periuretral injection in urogynecologic surgery: The masters techniques in gynecologic surgery; 2nd ed. Edited by W. G. Hurt. Philadelphia: Lippincott Williams & Wilkins, 2000, p. 149.
20. Maher C.F., O'Reilly B.A., Dwyer P.L., Carey M.P., Cornish A., Schulter P.; Pubovaginal sling versus transurethral Macroplastique for stress urinary incontinence and intrinsic sphincter deficiency: a prospective randomised controlled trial; BJOG 2005; 112: 797-801.
21. Tamanini J.T.N., D'Ancona C.A.R.L., Netto N.R.; Macroplastique implantation sistem for female stress urinary incontinence: Long-Term Follow-Up; J Endourol 2006; 20: 1082-6.
22. Ghoniem G., Corcos J., Comiter C., Westney L., Herschorn S.; Durability of urethral bulking agent injection for female stress urinary incontinence: 2-year multicenter study results; J Urol 2010; 183: 1444-9.
23. Lose G., Sorensen H.C., Axelsen S.M., Falconer C., Lobodasch K., Safwat T.; An open multicenter study of polyacrylamide hydrogel (Bulkamid®) for female stress and mixed urinary incontinence; Int Urogynecol J 2010; 21: 1471-77.
24. Stewart W.F., Van Rooyen J.B., Cundiff G.W., Abrams P., Herzog A.R., Corey R., hunt T.L., Wein A.J.; Prevalence and burden of overactive bladder in the United States; World J Urol 2003; 20: 327-36.
25. Shamliyan T., Wyman J., Bliss D.Z., Kane R.L., Wilt T.J.; Prevention of fecal and urinary incontinence in adults; Evidence Report/Techonology Assessment N° 161 (Prepared by the Minnesota Evidence-based Practice Center). AHRQ (Agency for Healthcare Research and Quality), 2007. Publication N° 08-E003. Rockville, MD.

Correspondence to:
MIGUEL ANGEL ZANGONE
Av. Las Heras 2670.
Buenos Aires (C1425ASQ) Argentina
E-mail: miguelzangone@gmail.com

Letter to the Editor

Tailored treatment for obstructed defecation

Dear Professor Dodi,

I read the editorial LANGUAGE AND COMMUNICATION published in Pelviperineology 2011;30:101-103 By Dodi, Stocco and Petros, titled " Why is it so difficult to define constipation?" The authors should be commended for their provocative efforts to clarify this difficult subject.

There are two terms: *the placebo effect*, mentioned by the authors, and the *honeymoon period*, proposed by James Church at the Cleveland Clinic, i.e. the short interval of time during which the patients tries to please the surgeon meeting his expectations after the treatment.

Both of them seem to demonstrate that the psychological dynamics (not only of the patient, but also between the patient and the doctor) may play a major role in influencing the outcome of a surgical procedure.

Therefore *success* and *failure* of any operation may well depend upon factors which are unlikely to be categorized and may present with a broad spectrum, such as *lifestyle*, *character* and *personality*, difficult to be scheduled and interpreted.

If one agrees on that, it is not surprising why it is extremely difficult carry out a prospective randomized trial on *obstructed defecation*, comparing, for instance, different operations such as retrograde enema, internal Delorme, Starr or Transtar, resection rectopexy, entero-rectocele repair, Express and ventral rectopexy, and looking for the "gold standard"

The reason being that so many factors which cannot be categorized are also involved, such as anxiety and depression or rectal hyposensation or slow bowel transit due to a previous sexual arrassement, or even the abuse of chocolate and glycerine suppositories, which are know to alter the viscoelastic properties of the stool and their evacuation.

The number of potential bias is unlikely to be taken under control by the researcher and therefore the results of the study may be misleading.

As an example, only a small proportion of the Starr-Transtar studies take under account the psychological pattern of the patient candidate to surgery,[1] despite we know that two-thirds of the subjects suffering from obstructed defecation have either anxiety or depression.[2]

When facing with such a complex and wide range of variables, the average surgeon tends to consider as a goal of his treatment something which may be easily evaluated by means of simple tests, such as defecography, i.e. the restoration of the normal anatomy.

Unfortunately restoring the anatomy does not mean restoring function, as nearly half of the patients who had their rectocele repaired and disappeared at defecograpfhy, are still severely constipated.[3]

That is why is a nonsense to perform a Starr to *all* or *most* of the patients with constipation and just rectal intussusception-rectocele diagnosed at x-ray: half of them will still be constipated after 18 months.[4] I strongly suspect that the same concept is true for other manual operations.

The authors of this stimulating Editorial are in favour of the *holistic approach* and so am I. We should take under consideration both the mind and the body when evaluating our patients, as they are a unique entity.

Also, we should bear in mind the concept of obstructed defecation as a kind of an *iceberg syndrome*: all these patients have *at least two occult underlying lesions*, mainly functional.[2] If neglected, they are likely to cause symptoms' recurrence.

In conclusion, I take the liberty to suggest that less time and energy might be dedicated to comparative studies aimed at establishing *which is the best operation* for these complex patients.

A wise and evidence-based eclecticism is preferable and each specialist should be able to perform more than one procedure and select it on the basis of three criteria:

a. the *patient* (man, woman, young, elderly, fit, fragile)

b. the *targeted* lesion (e.g. dealing with a rectocele the rectovaginal septum should be reinforced, in case of pudendal neuropathy better not to fire staples close to the puborectalis muscle)

c. the *associated occult* lesions (e.g. anismus and rectal hyposensation have to be corrected with bio-feedback and depression with psychotherapy).

In two words, what I suggest for obstructed defecation is not the "gold-standard", but the "*tailored treatment*", like the one widely accepted for rectal external prolapse.

REFERENCES

1. Pescatori M. Prevention and treatment of complications in proctological surgery. Foreword by S Goldberg. Chapter 8: Obstructed defecation and related diseases. Springer-Verlag 2012, pp.135-163.
2. Pescatori M, Spyrou M, Pulvirenti d'Urso A. A prospective evaluation of occult disorders in obstructed defecation using the "Iceberg diagram". Colorect Dis 2006;8: 785-789.
3. Vermeulen J, Lange JF, Sikkenk AC, van der Haarst E. Anterolateral rectopexy for corrections of rectoceles leads to good anatomical but poor functional results. Tech Coloproctol 2005; 9:35-41.
4. Gagliardi G, Pescatori M, Altomare DF et al. Italian Society of Colo-Rectal Surgery (SICCR) Results, outcome predictors, and complications after stapled transanal rectal resection for obstructed defecation. Dis Colon Rectum 2008; 51:186-195.

Correspondence to:
MARIO PESCATORI
FRCS (Hon), EBSQ
ucpclub@virgilio.it

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


DISPOSABLE
HYGIENIC
EASY TO HANDLE
SIMPLE TO USE
DO YOU NEED ANY MORE?
A COMPLETE PROGRAM
OF SYSTEMS AND INSTRUMENTS
FOR THE ADVANCED TECHNIQUES
IN COLOPROCTOLOGY
AND FOR PELVIC FLOOR DISEASES
sapimed S.p.A.
Alessandria - Italy
Tel. +39-0131-348109
Fax +39-0131-348383
info@sapimed.com
www.sapimed.com