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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 Digese, 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, M.D., 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

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.
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](http://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
Laparoscopic chordofixation: a new technique for vaginal vault suspension

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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: Twenty-five patients during an 8-month period with a benign disease, in two cases with coexisting pelvic floor disorders, 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 questionnaire 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 months 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. 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. Support for the vaginal apex is provided by the fibers of the paracolpium comprising the cardinal and uterosacral ligaments (Level I). 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). However, some suggest that anterior wall support defects are often a result of coincident apical prolapse. 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. 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. 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. 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. Studies suggest that apical vault repair should be used routinely along with laparoscopic hysterectomy. 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.

Surgical technique

All laparoscopic hysterectomies were performed using the intrafascial technique similar to the one described recently by Hohl and Hauser. Minor differences in our hysterectomy procedure are the use of Mangeshikar uteromana-
ligaments. The suture is knotted intracorporally. If proper and the paracolpium between the cardinal and sacrouterine placing the suture into the lateral edge of the vaginal cuff point for fixation without overstretch. Then we continue the chorda at the point what we consider to be the optimal Somerville, New Jersey, USA). First we place the suture in 2-0 Ethibond Excel Polyester surgical suture (Ethicon, Inc. the vagina.

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 abdomi nal/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 artery 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 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 concerns 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. 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 procidencia or post-hysterectomy vaginal vault prolapse with an associated weak or atrophied cardinal-uterosacral ligament complex. There is controversy about whether it should be used as a prophylactic measure after vaginal hysterectomy. When performed for correction, the objective cure rate ranged from 8% to 94%. Complications may include hemorrhage with a transfusion rate of 2%, perforation of the bladder, rectum, and small bowel (0.8%), ureteral kinking and muciturition problems (2.9%), vaginal adhesions and rectovaginal fistulas (0.5%), and nerve damage to the femoral, peroneal, or sciatic nerves (1.8%). Gluteal pain may resolve within 6 weeks, but patients may require reoperation. Also, vaginal narrowing and shortening may occur. Sexual dysfunction has also been reported in up to 13% of the patients.

When performed unilaterally, normal vaginal axis is not established. Another approach is the suspension of the vaginal vault to the uterosacral ligaments. It can be used prophylactically at hysterectomy or for treatment of vault prolapse. It's main advantages are a normal resultant vaginal axis and avoidance of suturing near neural or vascular structures. The technique is extremely safe, puts no extra risk to the vagina is ensured. The procedure is easy to perform, requires no extra surgical skills and it is not time consuming.

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

An abdominal approach, using autologus, 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. In an extensive review, 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. Some concern has also been raised about the durability of allograft fascia.

Beyond vaginal and abdominal routes, laparoscopic approaches have also developed with the first one reported in 1992. The uterosacral suspension was first reported by Miklos and colleagues using a combined vaginal and laparoscopic approach. The full laparoscopic procedure was reported in 2001.

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.

REFERENCES


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The development of laparoscopy and its application to pelvic floor repair

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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, 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. 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 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. Pelvic organ visualization with the culdoscope was limited, though, until Decker described the knee-shoulder position in 1946.

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 a hot light bulb at the end of the scope. In 1953, Hopkins introduced the rod lens system which improved visual clarity, the angle of vision, and the depth of field. In the early 1950s, Frangenheim designed laparoscopic instruments and made the first purpose-built CO₂ insufflator. 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.

Monopolar, bipolar and beyond

Monopolar diathermy was introduced in the early 1950s for tubal sterilisation. 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, and Rioux and Cloutier in Canada, and with the introduction of the more safer thermocoagulation by Semm in Germany. 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.

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. These now included ablation of endometriosis, adhesiolyis, adnexectomy, myomectomy, ovarian cystectomy, and salpingectomy for ectopic pregnancy as well as appendectomy.

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 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 (CO₂) laser into gynaecology for the treatment of cervical dysplasia. By 1979, Bruhat in France had applied the CO₂ laser to laparoscopic surgery. The term videozoscopy was coined by Nezhat and referred to laser laparoscopy with video monitoring. Nezhat and Daniell popularized it in the English-speaking world. In the mid-1980s, the CO₂ laser became widely adopted following a common pattern from treating dysplasia of the lower genital tract to laser laparoscopy. The adoption of the CO₂ laser to laparoscopic surgery required several innovations in equipment and operating technique: an articulated optical arm to deliver the laser beam from its generator to the operating laparoscope; a laser hand piece that was leak-proof and accepted CO₂ to keep the lens free of debris; the addition of a helium-neon sighting laser to add a coloured light to the invisible CO₂ 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.

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. These surgical instruments were easier to use and less expensive than laser laparoscopy. Their uptake was rapid and 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. 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 aque-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.

The emergence of new procedures

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

A plethora of techniques for laparoscopic hysterectomy ensued around the globe leading Garry, Reich and Liu to formulate a simple classification system. 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, which had less lateral thermal spread than diathermy. The prime Australian example of a vaginal fornix presenter is the tube developed by McCartney. 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 enterocele 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.

The first report of laparoscopic pelvic floor repair came from an Italian group in 1986 which published on laparoscopic uterosacral hysteropexy. In 1991, Vancaille and...
Schuessler reported laparoscopic bladder neck suspension.  
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 Wattez et al. in 1991. In 1996, Ostrzenski published on laparoscopic colposuspension for the treatment of total vaginal prolapse and a year later Richardson, Saye and Miklos reported the first laparoscopic repair of paravaginal defects. In 1997, Rosen and Lani 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. 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. In units with a laparoscopic interest, mesh sacral colpopexy is emerging as the most popular laparoscopic prolapse repair procedure. 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. In the anterior compartment laparoscopic paravaginal repair is a good native tissue alternative to colpoprhaphy for primary cystocele repair. Apical support failure is effectively addressed by laparoscopic uterosacral suspension with or without uterine preservation. Combined apical and posterior defects can be treated by laparoscopic supravaginal repair or mesh sacral colpopexy.

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 intraluminal methotrexate and laser salpingostomy. 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. By the late 1990s, total laparoscopic hysterectomy had replaced laparoscopically assisted vaginal hysterectomy and laparoscopic entry techniques were expanded. Concurrently, improvements in suturing instruments, extracorporeal knotting and growing experience resulted in shorter operating times, lower rates of accidental injury and fewer conversions to open surgery. Dedicated laparoscopy 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


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Male incontinence and trans-obturator approach: where we are

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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 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\(^7\) by a silicone gel device attached to the corpora cavernosa that compresses the ventral urethra. Based on the Kaufman principles, Clemens\(^8\) reported a bulbourethral sling procedure in 64 men with severe PPI with a series of tetrafurolethylene bolsters placed beneath the bulbar urethra, through which a suture is passed and then transferred subcutaneously 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.\(^9\) 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.\(^1\) The urodynamic studies show an increase of the membranous urethral length and an improvement of the urethral closure pressure without obstruction.\(^1\)

The surgical procedure

The AdVance system is an outside-in trans-obturator sling. A midline perineal incision is made, exposing the bulbospongious 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 bulbospongious 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.\(^9,10\)

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. These results were confirmed in a large prospective single-armed study by Bauer 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 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 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. 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.

In most series, urinary retention is rare, and usually transient. Cornel had one of 36 men with transient retention, while Gill had three men with retention and two who needed to catheterize for 3 and 6 months. By contrast, Bauer, 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 Cornell study, 17% of men had severe postoperative pain that settled at 3 months but otherwise pain is rarely reported. Recently Hanhan and Rehder 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 maintained 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.

Trans-obturator slings (TOMS)

In 2006 Grise developed a new transobturator bulbar male sling 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 bulbospongious muscle, then to expose the perineal aponeurosis at the top of the triangular space delimited laterally by each ischiocavernous muscle and medially to the bulbospongious. 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 suture was sutured to the bulbospongious 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.

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.

b) Inside-out De Leval sling

In 2008 de Leval reported on a new transobturator polypropylene sling, 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 bulbospongious 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. Transsection of the subcutaneous fat and Colles superficial perineal fascia allows access to the bulbospongious 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-
Male incontinence:---  18/09/12  12:55  Pagina 80

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. Recently the same author published the midterm results on 173 consecutive patients. 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 adjustable 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 aductor 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. In this study Romano reported a 73% cure rate and 13.5% of improvement. The treatment failed in five patients (13.5%).

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.

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Male incontinence and trans-obturator approach: where we are


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

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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 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).5,8 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 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- has almost replaced the TVT. The TOT technique has been safer, due to avoidance of entry into the retro-pubic space.
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-uralis 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 tunnel-
er, pulled through the dissection and out of the obtura-
tor 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 con-
firmed, the vagina is close with bio-absorbable suture.
9. The lateral ends of the tape should be cut off and the in-
ner 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' sat-
isfaction 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 differ-
ences in means on Gaussian distributed data, to determine
variables. Inferential statistics were performed on some
the means, standard deviations and ranges for continuous
frequencies and percentage for categorical variables and

The following is a sample of the text in the document:

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

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RESULTS

Procedures were performed under spinal anesthesia in 98
cases and general anesthesia in 22. All the TOT’s were per-
formed 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 opera-
dations during TOT procedures have been summarized in
table 1. The mean patient age was 54.7 (±2.6) 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 op-
treating 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-val-
ue<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 pe-
period are presented in table 4. The postoperative hospital
stay and pain (assessed by Visual Analog Scale) are pre-

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 (accord-
ing to the definition of stress specific cure).

**Figure 1.** – Histogram of the Ages and the parity distribution
across the ages.
The management:---  20/09/12  08:58  Pagina 84

correct technique is applied the risk of bladder perforation during the insertion of the tape. If the dissections following vaginal incision, and only one group. However, three of the perforations occurred during the procedure completed. Post-operative urethral catheterization was left in-situ for 10 days. Abdel-Fatah et al 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 during tunneler insertion. In both patients, bladder perforation was diagnosed immediately, repaired in two layers and demonstrated no leakage. The mean estimated blood loss was 60 ml in one case, and 30 ml in the other. In our series, in agreement with other studies, no cases of major intraoperative complications were reported. The only complication noted was a minor bladder perforation in one patient, which was repaired at the time of surgery. The patient made an uneventful recovery and was discharged home on the same day. Postoperative voiding problems found to be low (0.8%) in our study, in agreement with other studies. De novo de-

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. Routine urodynamic 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, 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. 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. A recent systematic review has shown that there is evidence that performing uro-dynamics does improve the outcome of anti-incontinence surgery.

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. In our study, bladder perforation occurred in two patients, (1.6%) and this is in agreement with other reported rates of 0-1.5%. In the two patients in this study with bladder perforations, both 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 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. 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.

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 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 vesicle 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 vesicle injuries and low rates of intraoperative complications.

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

Table 2. – Different TOTs used in the study.

<table>
<thead>
<tr>
<th>TOT</th>
<th>Cases (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVS-O</td>
<td>98 (81.6%)</td>
</tr>
<tr>
<td>Aris</td>
<td>16 (13.3%)</td>
</tr>
<tr>
<td>Monarc</td>
<td>2 (1.6%)</td>
</tr>
<tr>
<td>Obtryx</td>
<td>2 (1.6%)</td>
</tr>
<tr>
<td>Intramesh</td>
<td>2 (1.6%)</td>
</tr>
</tbody>
</table>

Table 3. – Intra-Operative Complications.

<table>
<thead>
<tr>
<th>Complication</th>
<th>Cases (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bladder perforation</td>
<td>2 (1.6%)</td>
</tr>
<tr>
<td>Vaginal perforation</td>
<td>2 (1.6%)</td>
</tr>
<tr>
<td>Bleeding &gt; 100 ml</td>
<td>0</td>
</tr>
<tr>
<td>Urethral perforation</td>
<td>0</td>
</tr>
<tr>
<td>Others</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 4. – Complications during follow-up.

<table>
<thead>
<tr>
<th>Complication</th>
<th>Cases (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tape erosion</td>
<td>1 (0.8%)</td>
</tr>
<tr>
<td>Sling failure</td>
<td>3 (2.4%)</td>
</tr>
<tr>
<td>De novo UI</td>
<td>1 (0.8%)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Measure</th>
<th>Day 1</th>
<th>Day 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postoperative pain as</td>
<td>2.90</td>
<td>1.06</td>
</tr>
<tr>
<td>assessed by VAS</td>
<td>(0-5)</td>
<td>(0-3)</td>
</tr>
<tr>
<td>Postoperative Hospital</td>
<td>2.1</td>
<td>(2-3)</td>
</tr>
<tr>
<td>stay (days)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
trusor instability was noted in one patient and was treated successfully with antimuscarinics. This is definitely much lower than the rate reported with TVT.\textsuperscript{3,5} 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 likelihood 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.\textsuperscript{2,4} 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\textsuperscript{2,3} 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%.\textsuperscript{11,26} A sub-analysis performed by Cheng Yu Long\textsuperscript{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. Cadaveric 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.\textsuperscript{20}

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.\textsuperscript{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).\textsuperscript{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 Museenge, 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

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Abdominal rectopexy for rectal prolapse.

Meta-analysis of literature

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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 (235 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 abdominal or perineal approaches. The perineal approaches treatment of rectal prolapse, that can be divided into ab-

store 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 abdominal or perineal approaches. The perineal approaches treatment of rectal prolapse, that can be divided into ab-

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 ante-

rior resection or sigmoid colectomy is often added to the procedure.13 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 Hipkman procedure is an anterior 360º rectopexy. The Orr-Loygue rectopexy consists of anteriolateral rectum fixation with double mesh.14 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.3,4 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 conti-

nence occurred up to 75%, but there was a variable re-

sponse 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
Federica Cadeddu, Pierpaolo Sileri, Michele Grande, Elisabetta De Luca, Luana Franceschilli et al.

**Meta Analysis**

<table>
<thead>
<tr>
<th>Study name</th>
<th>Odds ratio Lower limit</th>
<th>Odds ratio Upper limit</th>
<th>Z-Value p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boccasanta 1999</td>
<td>1.636 0.127 21.104 0.377</td>
<td>0.706 0.127 21.104 0.377</td>
<td></td>
</tr>
<tr>
<td>Solomon 2002</td>
<td>3.324 0.127 86.748 0.722</td>
<td>0.470 0.127 86.748 0.722</td>
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</tr>
<tr>
<td>Raftopoulos 2005</td>
<td>0.938 0.107 8.180 0.058</td>
<td>0.953 0.107 8.180 0.058</td>
<td></td>
</tr>
<tr>
<td>Kariv, 2006</td>
<td>0.694 0.299 1.613 0.849</td>
<td>0.396 0.299 1.613 0.849</td>
<td></td>
</tr>
<tr>
<td>Johnson 2007</td>
<td>10.333 0.356299,965 1.359</td>
<td>0.174 0.356299,965 1.359</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.934 0.457 1.910 0.187</td>
<td>0.852 0.457 1.910 0.187</td>
<td></td>
</tr>
</tbody>
</table>

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.

**Meta Analysis**

<table>
<thead>
<tr>
<th>Study name</th>
<th>Odds ratio Lower limit</th>
<th>Odds ratio Upper limit</th>
<th>Z-Value p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demirbas, 2005</td>
<td>2.063 0.277 15.357 0.707</td>
<td>0.480 0.277 15.357 0.707</td>
<td></td>
</tr>
<tr>
<td>Kariv, 2006</td>
<td>1.178 0.533 2.606 0.404</td>
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</tr>
<tr>
<td></td>
<td>1.271 0.607 2.659 0.636</td>
<td>0.525 0.607 2.659 0.636</td>
<td></td>
</tr>
</tbody>
</table>

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.

**Meta Analysis**

<table>
<thead>
<tr>
<th>Study name</th>
<th>Odds ratio Lower limit</th>
<th>Odds ratio Upper limit</th>
<th>Z-Value p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boccasanta 1999</td>
<td>5.625 0.537 58.909 1.441</td>
<td>0.150 0.537 58.909 1.441</td>
<td></td>
</tr>
<tr>
<td>Demirbas, 2005</td>
<td>0.490 0.095 2.532 -0.852</td>
<td>0.394 0.095 2.532 -0.852</td>
<td></td>
</tr>
<tr>
<td>Kariv, 2006</td>
<td>2.077 0.973 4.432 1.890</td>
<td>0.059 0.973 4.432 1.890</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1.641 0.547 4.926 0.883</td>
<td>0.377 0.547 4.926 0.883</td>
<td></td>
</tr>
</tbody>
</table>

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 continence depends on the type of operation performed.9-12

LAPAROSCOPIC VERSUS OPEN SURGERY: META-ANALYSIS 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 non-randomized 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 for meta-analysis for incontinence. Baker et al.19, Boccasanta et al.18 and Salked et al.20 did not reported the incidence of incontinence and there was significant heterogeneity among trials (Q = 4.99, 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.

<table>
<thead>
<tr>
<th>Trial</th>
<th>Year</th>
<th>Study type</th>
<th>Type</th>
<th>N PTS</th>
<th>Continence improvement</th>
<th>Constipation improvement</th>
<th>Recurrence N (%)</th>
<th>Follow-up (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>JOHNSON13</td>
<td>200</td>
<td>Prosp</td>
<td>OPEN</td>
<td>5</td>
<td>GD</td>
<td>GD</td>
<td>1/5</td>
<td>17*</td>
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<tr>
<td></td>
<td>7</td>
<td>NR</td>
<td>LPS</td>
<td>15</td>
<td>GD</td>
<td>GD</td>
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</tr>
<tr>
<td>KARIV14</td>
<td>200</td>
<td>Prosp</td>
<td>OPEN</td>
<td>86</td>
<td>19/56</td>
<td>30/56</td>
<td>11/86</td>
<td>59*</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>NR</td>
<td>LPS</td>
<td>86</td>
<td>17/56</td>
<td>20/56</td>
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<tr>
<td>DEMIRBAS15</td>
<td>200</td>
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<td>3/11</td>
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<tr>
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<td>LPS</td>
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<td>2/13</td>
<td>7/13</td>
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<td>16</td>
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<tr>
<td>RAFTOPOULOS16</td>
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<td>Retrop</td>
<td>OPEN</td>
<td>105</td>
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<td>NS</td>
<td>9/105</td>
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<td>5</td>
<td>Retrop</td>
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<td>11</td>
<td>NS</td>
<td>NS</td>
<td>1/11</td>
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<td>SOLOMON17</td>
<td>200</td>
<td>Prosp</td>
<td>OPEN</td>
<td>19</td>
<td>NS</td>
<td>NS</td>
<td>1/19</td>
<td>23**</td>
</tr>
<tr>
<td></td>
<td>2</td>
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<td>LPS</td>
<td>20</td>
<td>NS</td>
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<tr>
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<td>199</td>
<td>Prosp</td>
<td>OPEN</td>
<td>13</td>
<td>NS</td>
<td>5/13</td>
<td>2/13</td>
<td>37*</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>NR</td>
<td>LPS</td>
<td>10</td>
<td>1/10</td>
<td>1/10</td>
<td>2/10</td>
<td>26</td>
</tr>
<tr>
<td>BAKER19</td>
<td>199</td>
<td>Retrop</td>
<td>OPEN</td>
<td>10</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
<td>27*</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>Retrop</td>
<td>LPS</td>
<td>8</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
<td>26</td>
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<tr>
<td>SALKED20</td>
<td>200</td>
<td>Retrop</td>
<td>LPS</td>
<td>20</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
</tbody>
</table>

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

Abdominal rectopexy for the treatment of rectal prolapse. Meta-analysis of literature

Abdominal rectopexy for: --- 13/09/12 09:33 Pagina 89
Federica Cadeddu, Pierpaolo Sileri, Michele Grande, Elisabetta De Luca, Luana Franceschilli et al.

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.\(^\text{21-28}\) 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.\(^\text{6,27-28}\) 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.\(^\text{6,21-28}\)

Recurrence after surgery for rectal prolapse is a key measure of successful long term outcome.\(^\text{6}\) 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.\(^\text{21-28}\) 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.\(^\text{6}\) 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.\(^\text{6,21-28}\)

Actually, the constipation may be obstructive (bowel intussusception into the rectum, enterocoele, suprarectal dysmotility) 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.\(^\text{6,5,20}\) 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 rates.\(^\text{6}\) 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.\(^\text{5,6}\) 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.\(^\text{6,25}\) The procedure seems well suited to patients with a long redundant sigmoid and a long history of constipation.\(^\text{24}\)

Besides, according to the previous meta-analyses,\(^\text{6,27-28}\) 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.\(^\text{20}\) 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,\(^\text{6,27-28}\) 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.\(^\text{6}\) Ventral rectopexy using biological mesh for internal rectal prolapse has come out as a safe and effective procedure in alleviating 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.

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Abdominal rectopexy for the treatment of rectal prolapse. Meta-analysis of literature


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

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¹Hospital Bernardino Rivadavia, Buenos Aires, Argentina
²Hospital 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/m². 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 Valsalva leak point pressure (VLPP), a Q-Tip test, 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 years⁵ 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.¹⁰

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, multicenter 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/m². 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 antimuscarnics 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 biomaterial¹¹ also used in children to treat vesicourethral reflux conditions.¹²¹³ 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.¹⁴

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 urethrovessical 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.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>Min-Max</th>
<th>% (N/N TOTAL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women recruited</td>
<td>38</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>100.0</td>
</tr>
<tr>
<td>Age - years</td>
<td>-</td>
<td>62.6</td>
<td>10.1</td>
<td>42-92</td>
<td>-</td>
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<tr>
<td>Body Mass Index - kg/m²</td>
<td>-</td>
<td>37.6</td>
<td>8.5</td>
<td>22-55</td>
<td>-</td>
</tr>
<tr>
<td>Pariy</td>
<td>-</td>
<td>2.4</td>
<td>1.1</td>
<td>1-6</td>
<td>-</td>
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<tr>
<td>Menopausal</td>
<td>31</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>79.5</td>
</tr>
<tr>
<td>Type of Urinary Incontinence</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mixed Incontinence</td>
<td>6</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>15.8</td>
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<tr>
<td>ISD Incontinence</td>
<td>32</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td>VLPP - cmH₂O</td>
<td>-</td>
<td>46.8</td>
<td>11.0</td>
<td>27-65</td>
<td>-</td>
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<tr>
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<td>4</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>10.5</td>
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<tr>
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<td>-</td>
<td>-</td>
<td>10.5</td>
</tr>
<tr>
<td>Burch</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>2.6</td>
</tr>
<tr>
<td>Sling</td>
<td>3</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>7.9</td>
</tr>
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<td>-</td>
<td>18.0</td>
<td>2.4</td>
<td>11-21</td>
<td>-</td>
</tr>
<tr>
<td>Maximum Flow - mL/s</td>
<td>-</td>
<td>25.5</td>
<td>2.9</td>
<td>20-30</td>
<td>-</td>
</tr>
<tr>
<td>Urine leakage - g/day</td>
<td>-</td>
<td>108.6</td>
<td>69.5</td>
<td>34-300</td>
<td>-</td>
</tr>
</tbody>
</table>

of saline solution. Patients were diagnosed with SUI due to ISD when VLPP was lower than or equal to 60 cmH₂O and primary urethral hypermobility was discarded (Q-tip>30°).

Opsys implantation was performed transurethrally under direct vision using a rigid cystoscope 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.

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. If the loss represented a reduction of more than 50% from the initial preoperative measurement, the patients were classified as improved. 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...
TABLE 2. – Complications.

<table>
<thead>
<tr>
<th>Adverse event</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
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<td>Urinary tract infection</td>
<td>3</td>
<td>7.9</td>
</tr>
<tr>
<td>Urinary retention</td>
<td>7</td>
<td>18.4</td>
</tr>
<tr>
<td>De novo urge incontinence*</td>
<td>9</td>
<td>23.7</td>
</tr>
<tr>
<td>Dysuria</td>
<td>4</td>
<td>10.5</td>
</tr>
</tbody>
</table>

*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. The gold standard treatment in this type of pathology is sling implantation with success rates over 70%. 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.

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% to 80%. 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% for silicon elastomer and reaching a 35% with a polyacrylamide substance.

Radiographic imaging and ultrasonography 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, and 50% incidence was found in a 60-month follow-up study.
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 studies25 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 supracaecal 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.

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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 patient 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, despite we know that two-thirds of the subjects suffering from obstructed defecation have either anxiety or depression.

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 defecography, are still severely constipated.

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. 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. 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


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ucpclub@virgilio.it

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