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PELVIPERINEOLOGY

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EDITORIAL

Dear Colleagues,

I have been appointed as editor-in-chief of the Journal of Pelviperineology. I took over this task from our previous editor-in-chief, Prof. Dr. Jacob Bornstein. I am grateful to him for his invaluable contribution to the journal. Likewise, I would like to extend my respects to Prof. Dr. Giuseppe Dodi, who had been the editor-in-chief of our journal for many years.

My main goal is to put our journal among the respected medical journals of the world; to turn it into a scientific publication on the management of pelvic floor disorders and cosmetic gynecology. Undoubtedly, this aim can only be possible if you and your close circle send qualified reviews, research articles, meta-analyses, case reports to our journal.

I look forward to your contributions to our journal and wish you a pleasant reading.

Stay healthy.

Prof. Dr. Ahmet Akın SİVASLIOĞLU

Editor-in-chief

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The multidisciplinary approach to pelvic floor diseases: an Italian survey

Luigi LOSACCO[1], Alfredo ANNICCHIARICO[2], Nicola NARDELLI[3], Fabio GAJ[4], Roberta DIMALIO[5], Claudia MENCONI[6], Jacopo MARTELLUCCI[7]

[1]UO General Surgery, Rovigo Hospital, Rovigo, Italy
[2]Department of Medicine and Surgery, University of Parma, Parma, Italy
[3]Coloproctology Clinic, Taranto, Italy
[4]Department of General Surgery, Surgical Specialties and Organ Transplantation "Paride Stefanini", Azienda Policlinico Umberto I, Sapienza University of Rome, Italy
[5]UO General Surgery, Teramo Hospital, Teramo, Italy
[6]Proctology and Pelvic Floor Clinical Centre, Cisanello University Hospital, Pisa, Italy
[7]Department of Emergency Surgery, Pelvic Floor Center, Careggi University Hospital, Florence, Italy

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ABSTRACT

Objectives: Pelvic floor disorders (PFD) consist in a series of anatomic-functional disfunctions involving different professional profiles and often requiring a multidisciplinary approach. The purpose of this survey is to identify how PFD are managed in Italian centers and what is the degree of integration between the various specialists involved.

Materials and Methods: This survey was a retrospective, observational, multicenter census, among all colorectal surgeons and proctologists affiliated with the Italian Society of Colorectal Surgery (SICCR) who were contacted by email and invited to answer to a 12-item questionnaire on a voluntary basis.

Results: Thirty-seven surgeons from all over Italy answered to the survey. Only 14 (37.8%) stated that a dedicated pelvic floor center consisting of urologist, gynecologist and colorectal surgeon/proctologist was available in their hospital. Eighteen surgeons declared the availability of a pelvic rehabilitation center and the most performed rehabilitation modalities are biofeedback (BF) + electrostimulation (ES) + physiokinesitherapy (PFK). In 22 (59.4%) centers the complex surgical procedures can be performed simultaneously by the various specialists of the team even if only in half of these centers this occurs in a systematic manner and in dedicated operating sessions.

Conclusion: The multidisciplinary center of the pelvic floor represents the apex of a hierarchical organization for more complex cases in which the pelvic disease is thoroughly analyzed in a multidisciplinary way, with a full availability of diagnostic investigations and in which a series of standard and innovative treatments could be offered.

Keywords: Pelvic floor disease; multidisciplinary approach; multidisciplinary pelvic center; survey; SICCR

Address for Correspondence: Jacopo Martellucci, Department of Emergency Surgery, Pelvic Floor Center, Careggi University Hospital, Florence, Italy
E-mail: jamjac64@hotmail.com **ORCID ID:** orcid.org/0000-0002-7437-9098
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INTRODUCTION

Pelvic floor disorders (PFD) consist in a series of anatomic-functional pathologies that involve not only different medical figures such as urologists, gynecologists, proctologists, general surgeons, but also other professional profiles such as nurses, physiotherapists or obstetricians. More than in other specialties, for general surgeons, pelvic floor represents a sort of grey zone, in which a multidisciplinary approach could not be avoided. The figure of the colo-proctologist, especially in Italy, arises from an extension and a sub-specialization of general surgery and dedicated experts in this field are few. Although pelvic floor disorders, especially functional ones, have a multidisciplinary etiopathogenesis, in most Italian centers all functional disorders of the pelvic floor are treated by different specialists without coordination and cooperation between the various professional figures. The purpose of this survey is to identify how PFD are managed in Italian centers and what is the degree of integration between the various specialists involved.

MATERIALS AND METHODS

The survey was a retrospective, observational, multicenter census, analyzing the presence and organization of Italian pelvic floor centers, the level of collaboration of the various specialists (general surgeon, gynecologist, and urologist), the presence of a dedicated rehabilitation center, the number and type of procedures that are carried out in multidisciplinary team. All colorectal surgeons and proctologists affiliated with the Italian Society of Colorectal Surgery (SICCR) were contacted by email and invited to answer to a 12-item questionnaire (Table 1) on a voluntary basis.

A reminder was e-mailed two, three, and four weeks after the initial mailing to non-responders. Because of the retrospective nature of the survey, and for the lack of use of patient data, approval by an ethics committee was not required.

Results of the survey were reported according to the Checklist for Reporting Results of Internet ESurveys (CHERRIES) guidelines.[1]

RESULTS

Thirty-seven surgeons from all over Italy answered to the survey, most of these operating in northern Italy. Only 14/37 (37.8%) stated that, in their hospital, a dedicated pelvic floor center consisting of urologist, gynecologist and colorectal surgeon/proctologist is available. Only one center has been present with this modality of organization since before 2000 and four since before 2010 while most of the others were established from 2010 onwards (Figure 1).

Clinical evaluation: All centers provide access through an initial coloproctological or urogynecological/urological evalulation. Only five Italian regions recognize a dedicated code that refers to the pelvic specialist visit (different from that of the normal surgical, uro-ginecological, urological or colo-proctological visit). A simultaneous multidisciplinary evaluation is available in 20/37 (54%) centers.

Diagnostic tools: Anorectal manometry and/or urodynamic studies are available in 67% of cases, while radiological studies (defecography, magnetic resonance, pelvic floor ultrasound, etc.) are available in 87% of centers. In 10/37 (27%) pelvic floor centers there is a neurologist or neurophysiopathologist for neurophysiologic studies.

Rehabilitative programs: In the survey 48.6% (18/37) of surgeons declared the availability of a pelvic rehabilitation program in their center, in 5/32 cases the rehabilitation center was defined with limited availability and in 7/32 of the cases the surgeon or the structure entrusted to a rehabilitation center external to the structure. In the 30 rehabilitation centers reported and evaluated, the most performed rehabilitation modalities are biofeedback (BF) + electrostimulation (ES) + physiokinesitherapy (PFK) (17/37), BF + ES (9/37), and PFK only (4/37). In only 12/37 (32.4%) the multidisciplinary team gives indications on the type of rehabilitation treatment. Out of 37 surgeons interviewed, 5 (13.5%) always use rehabilitation programs, 14/37 (37.8%) use rehabilitation programs in 20%–60% of patients and 15/37 (40.5%) use rehabilitation in less than 20% of cases. In 9/37 (24.3%) centers, posterior tibial nerve stimulation is regularly performed.

Surgery: In 11/37 (29.7%) centers, colorectal surgeons/proctologists perform regularly sacral neuromodulation. In the case of diseases that require a multidisciplinary surgical approach, in 22/37 (59.4%) centers the surgical procedure can be performed simultaneously by the various specialists of the team even if only in half of these centers this occurs in a systematic manner and in dedicated operating sessions while in the other half of this collaboration occurs only if planned. The most frequently performed combined procedures are summarized in Table 2. The most reported combined procedure is a laparoscopic approach (2 or 3 compartments) with or without perineal surgical time, followed by a combined middle and posterior compartments treatment. Anterior/posterior compartments combined surgery is less frequently reported.

In 4/37 (10.8%) centers a multidisciplinary pelvic-integrated care pathways are available. Finally, the surgeons were interviewed on the average annual number of pathology-related procedures performed in their own center to extrapolate an overall number of the most frequently performed. Regarding anal fistulas, seton

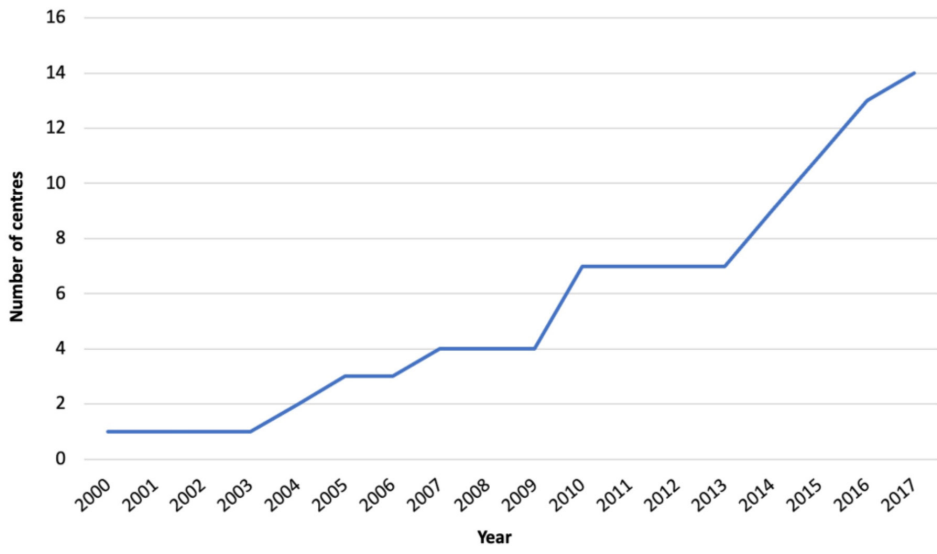

Figure 1. The number of centers dedicated to pelvic floor disorders over the years.

positioning and subsequent fistulotomy are the most performed procedures (47%) followed by flap (17%), ligation intersphincteric fistula tract (LIFT) (7%), video assisted anal fistula treatment (VAAFT) (6%), plug placement (5%) and fistula laser closure (FiLac) (4%). The Milligan–Morgan procedure is the most widely used for haemorrhoidal disease (60%), followed by stapler haemorrodopexy (21%), transanal hemorrhoidal dearterialization (THD) (9%) or other hemorroidopexy techniques (8%). The most performed procedures for internal rectal prolapse/obstructed defecation syndrome are stapled transanal rectal resection (STARR) (60%), Delorme procedure (18%) and ventral rectopexy (17%). For external rectal prolapse Altemeir procedure (44%) and ventral rectopexy (38%) are the most commonly performed.

DISCUSSION

PFD consist of a spectrum of symptoms that includes urinary incontinence, sexual disorders, pelvic organ prolapse (POP) and gastrointestinal disorders. Increased weight, menopause, previous hysterectomies, vaginal deliveries, smoking, and alterations of connective tissue represent the main risk factors for the development of PFDs. PFDs are very common, and it is estimated that at least 25% of women experience at least one symptom during their lifetime. Incidence increases also with age and more than 40% of women after 40 years may present with urinary incontinence.[2,3] POP, described as a descent of the anterior or posterior vaginal wall, or descent of the uterus (or the vaginal vault after hysterectomy),[4] is seen in up to 30%–76% of women presenting for routine gynecologic care[5] with 3%–6% of those with descent beyond the vaginal opening.[6] During their lifetime 12%–19% of women will develop POP and more than 300,000 surgeries are performed for this disorder every year in the United States (US) alone.[7,8] The complete rectal prolapse, characterized by the circumferential, full-thickness intussusception of the rectal wall which protrudes outside the anal canal, along with the incomplete one, that is a telescoping of the rectum on itself without expression through the anal verge, are part of the disorders resulting from pelvic floor weakness and often occurs in conjunction with one or more of the other disorders in the spectrum. Rectal prolapse has an incidence of 2.5 cases per 100,000 people,[9] it can also arise in pediatric age,[10] but in adults it generally occurs in the fifth decade and in 80%–90% of cases in women.[11,12] Pelvic floor disorders are an extremely age-related disease but despite the average age increase of the population, it is estimated that in the next 30 years, the growth in demand for services for the treatment of female pelvic floor disorders will increase twice as much at the rate of growth of the same population.[13] A recent study by Kirby et al.[14] predicted that in the US between 2010 and 2030 the demand for treatment of PFDs will increase by 35%. Pelvic floor weakness, which is one of the main etiopathogenetic causes of pelvic floor disorders, implies that these disorders are rarely isolated but often associated with each other and could require a surgical solution which involves the experience and skill of different pelvic floor clinicians. Symptoms of obstructed defecation (OD) and abnormalities of the posterior compartment such as rectal prolapse, rectocele and enterocele are, in fact, highly prevalent also in uro-gynecological patients;[15] according to Li et al.[16] 50% of patients with stress urinary incontinence and 80% of patients with uterovaginal prolapse also experienced symptoms of OD. As early as 1994 Virtanen et al.[17] showed that

Table 1. Questionnaire for the 37 surgeons who took part in the survey

Is there a multidisciplinary pelvic surgical clinic (consisting of urologist, gynecologist and general surgeon/proctologist) in the hospital where you work?	**No**		**Yes**	
	23		14	
If yes, from what year?	**Before 2010**		**In/After 2010**	
	4		10	
Does your hospital have a dedicated performance code for pelvic multidisciplinary examination?	**No**		**Yes**	
	32		5	
Does your work environment have a rehabilitation center?	**No**	**Partially**	**External**	**Yes**
	7	5	7	18
If so, what kind of rehabilitation does it perform?	**PFK**	**BF + ES**	**PKT + BF + ES**	
	4	9	17	
Are reservations and the type of rehabilitation treatment set by the multidisciplinary team?	**No**		**Yes**	
	25		12	
In what percentage do you use rehabilitation?	**<20%**	**20%–60%**	**Always**	
	15	14	5	
Is posterior tibial nerve stimulation performed in your hospital?	**No**		**Yes**	
	28		9	
Do the patients who undergo rehabilitation repeat the follow-up visit again with the multidisciplinary team after treatment?	**No**		**Yes**	
	17		20	
Does your center make use of the collaboration of an osteopath?	**No**		**Yes**	
	33		4	
Does your facility provide a pelvic neurofunctional study with a dedicated neurologist?	**No**		**Yes**	
	27		10	
Is sacral neuromodulation performed in your hospital?	**No**		**Yes**	
	11		26	
In pathologies that require a multidisciplinary surgical approach, is any surgical procedure performed simultaneously by the specialists who make up the team?	**No**		**Yes**	
	15		22	
If yes, how often?	**Sporadically**		**Sistematically**	
	11		11	
Does your facility use a pelvic-integrated care pathways filed in medical direction?	**No**		**Yes**	
	33		4	

PFK: physiokinesitherapy; BF: biofeedback; ES: electric stimulation

Table 2. Combined multidisciplinary procedures in the various centers per year

Combined multidisciplinary procedures	Number of centers carrying out the procedure (%)	Total number of procedures in all the centers per year
Anterior compartment + posterior compartment	11/37 (29.7%)	79
Middle compartment + posterior compartment	13/37 (35.1%)	108
Laparoscopic assistance to perineal surgery of at least 2 of the 3 pelvic compartments	11/37 (29.7%)	104
Urethral hypermobility + posterior compartment	9/37 (24.3%)	53
Pelvic reconstruction combined with using mesh	9/37 (24.3%)	65
Laparoscopic surgery of at least 2 of the 3 pelvic compartments without perineal approach	12/37 (32.4%)	127

a unicompartment approach could worsen, or even provoke, symptoms in the untreated compartments and subsequently, a long-term analysis highlighted how the efficacy of 10-year STARR for ODS is lower than in the short term, probably due to multicompartmental prolapses if not adequately diagnosed and treated.[18] The simultaneous or sequential evaluation by a urologist, gynecologist and colorectal surgeon is often mandatory and it may facilitate the stepwise approach and allows the patient to feel more confident about the standard of care. Despite this, this type of integration is rarely applied.[19] This survey shows that systematic cooperation between the various professional figures is actually present in only five of the 37 centers interviewed. From this it follows that in 40.5% of the centers interviewed (15/37), even in the case of pathology that would require a contemporary multidisciplinary approach, the treatment takes place in a deferred and sequential manner. Moreover, a simultaneous multidisciplinary evaluation is available in 20/37 (54%) centers. This point is essential, since the possibility of interaction and cooperation between the professionals involved in the pathway is essential to ensure optimal management of complex pelvic floor problems, as well as representing the most essential significance of the pelvic floor center itself. In fact, the relevancy of the interaction among different team specialists, as a central index of the existing cooperation, by means of a routinary decision making debate to be implemented before any treatment choice, is the key to ensuring optimal service for patients.

The coordination between the various specialists, in addition to raising the level of quality of care, could allow to carry out combined procedures with enormous benefit for the patient. A recent 10-year retrospective cohort of study proved that combined rectal and urogynecological surgery is well tolerated, associated with low morbidity, and more effectively treats a distressing and debilitating condition vs separate surgery for rectal and pelvic organ prolapse.[20] A fundamental point of strength of a multidisciplinary center of the pelvic floor is also the possibility to perform an adequate rehabilitation therapy. It is now well established that the rehabilitation of the pelvic floor plays a crucial role in the dysfunctions of this district as it prevents, assists, or integrates surgical therapy. The literature is now uniform on the usefulness of pelvic floor muscle rehabilitation (PFMR), BF and ES in dealing with numerous dysfunctions such as stress urinary incontinence,[21] hyperactive bladder,[21,22] pelvic organ prolapse,[23,24] dyspareunia and vaginismus,[25-27] chronic pelvic pain,[28,29] vulvodynia,[30,31] levator ani syndrome,[32,33] anal incontinence,[34-36] low anterior resection syndrome[37-40] and dyssynergic defecation.[34,41-43] Another advanced rehabilitation technique, in most advanced centers, is represented by tibial nerve stimulation (TNS). TNS is a non-invasive nerve stimulation technique that is widely used in the context of urge urinary incontinence and overactive bladder, but which has also proved effective in anorectal disorders such as constipation due to slow transit, fecal incontinence, and enhanced postoperative recovery after colorectal surgery.[44-49]

PFMR, BF, ES, TNS and SNM, as well as the presence of an integrated activity between doctor, nurse, midwife and physiotherapist, are the basic services that a pelvic floor center, in which urological, gynecological and proctological dysfunctions converge, should offer. This makes the problem of the Italian centers even more evident as just over half of the centers interviewed (18/37) have a pelvic floor rehabilitation center available, seven centers use reference structures outside and five centers declared to have a rehabilitation center that is available only for some kind of treatments. This could raise from the fact that some realities performed a rehabilitation exclusively dedicated to pre- and post-partum training (middle compartment), but which does not treat disorders of the anterior and posterior compartment. A direct consequence of this situation is that in only five centers the rehabilitation programs are used consistently and systematically.

Of the 37 surgeons interviewed, only 30% perform sacral neuromodulation (SNM) in their center. SNM is a low-invasive surgical procedure and represents an effective treatment of several urinary and pelvic floor disorders including overactive bladder, urgency urinary incontinence, urinary retention, fecal incontinence, pelvic chronic pain and irritable bowel syndrome.[50-53]

CONCLUSION

The multidisciplinary center of the pelvic floor could be conceived as the apex of a hierarchical organization for more complex cases in which the problem is thoroughly analyzed in a multidisciplinary way, with a full availability of diagnostic investigations and in which a series of standard and innovative treatments could be offered (Figure 2). However, multidisciplinary collaboration, as well as diagnostic technologies, rehabilitation programs, or the possibility of combined surgery are not always available in all pelvic floor centers in Italy.

More precise criteria should be identified for the definition and recognition of a pelvic floor center, as well as the creation of a territorial network, based on the interaction of structures with a diversified level of assistance.

Pelvic floor diseases are extremely rooted in the population and are often typical of the elderly, often hospitalized or non-self-sufficient, in whom intensive and multidisciplinary treatment would not help in most cases. This type of patient should be

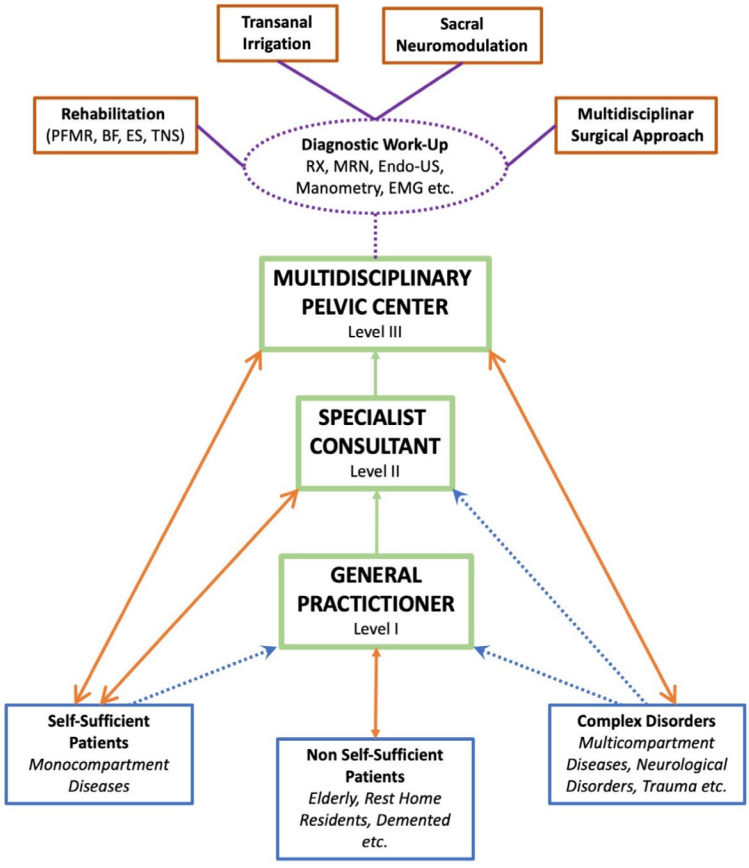

Figure 2. Hierarchical organization of pelvic floor disorders' management.
The blue dashed one-way arrows indicate the practitioner or center that patients are going to. The continuous orange bi-directional arrows also indicate the possible management of the disorder.

PFMR: pelvic floor muscle rehabilitation; BF: biofeedback; ES: electrical stimulation; TNS: tibial nerve stimulation

managed by the general practitioner (Level I) who, if necessary, could refer to the specialist (Level II) for more complex cases. Isolated pathologies of the pelvic floor (monocompartment disorders) could be managed by the specialist who in case of complex dysfunctions could refer to a referral pelvic center (Level III).

ETHICS

Ethics Committee Approval: Because of the retrospective nature of the survey, and for the lack of use of patient data, approval by an ethics committee was not required.

Informed Consent: Retrospective study.

Peer-review: Both internally and externally peer-reviewed.

Contributions

Concept: L.L., A.A., N.N., F.G., R.D., C.M., J.M.; Design: L.L.; Data Collection and/or Processing: A.A.; Revision: M.J.; Writing: L.L., A.A., N.N., F.G., R.D., C.M., J.M.

DISCLOSURES

Conflict of Interest: No conflict of interest was declared by the authors.

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Integral Theory Diagnostic System artificial intelligence "Wayfinding" software helps unravel the complexity of multiple symptom causation prior to ligament surgery

Peter PETROS

University of Western Australia School of Mechanical and Mathematical Engineering, Perth WA, Australia

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ABSTRACT

Background: A principal reason for developing diagnostic software is to reduce diagnostic error and facilitate a more accurate diagnosis. The National Academies of Sciences, Engineering, and Medicine publication "*Improving Diagnosis in Health Care*", has three main themes: reduce diagnostic errors, patient involvement and how to address "the increasing complexity of health care".

Aim: To describe in principle a computerized decision-tree software Integral Theory Diagnostic System (ITDS).

Materials and Methods: A node system of individual symptoms guided placement into three zones of ligament damage, anterior, middle, posterior. Percentage probabilities guided diagnosis. The system was tested against a Bayesian Network method

Results: The ITDS works well as a diagnostic aid. The diagnosis of zone of damage is displayed pictorially, with deepening colours of red indicating probability of damage. A separate button describes the iteration to the diagnosis. The Bayesian method was tested only in a fairly small number of women, it was found to be equivalent or even superior to that made by the expert.

Conclusion: The Integral Theory is holistic and its control non-linear. The contribution of the six main ligaments to pathogenesis and particular symptom causation may vary from patient to patient. A more developed version of the ITDS would be very helpful in assisting a more accurate diagnosis and reducing diagnostic error.

Keywords: Artificial intelligence; software; ITDS Integral Theory Diagnostic System; Bayesian Network

INTRODUCTION

The National Academies of Sciences, Engineering, and Medicine publication *"Improving Diagnosis in Health Care"*,[1] has three main themes: ("to err is human"), diagnostic errors which "continue to harm an unacceptable number of patients", patient involvement in their problem and "the increasing complexity of health care". The artificial intelligence ITDS* "Wayfinding" diagnostic software (pictorially summarized by Figure 1), addresses these three interdependent themes with relevance to the female pelvic floor.

Address for Correspondence: Peter Petros, University of Western Australia School of Mechanical and Mathematical Engineering, Perth WA, Australia
E-mail: pp@kvinno.com **ORCID ID:** orcid.org/0000-0002-9611-3258
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*Integral Theory Diagnostic System

The Integral Theory System (ITS)[2] is the basis of the midurethral sling, the gold standard operation for cure of stress urinary incontinence (SUI).[3] Since 1990, the ITS has evolved into a practical management system for the female pelvic floor.[2] The ITS is based on ligament pathogenesis: prolapse/bladder/bowel/pain dysfunctions, are related, mainly caused by connective tissue (collagen) damage to ligaments or related fascia, Figure 1, improved or cured by ligament repair thereof.[2] High cure rates for pelvic symptoms in the three zones of vagina, Figure 1, can be achieved by suspensory ligament repair, native tissue plication,[4] or slings.[3,5] However, singular ligament weakness may cause multiple symptoms, Figure 1. For example, urgency and frequency may be caused by ligament weakness in all three zones, Figure 1: anterior (pubourethral "PUL"); middle (cardinal "CL"); posterior (uterosacral "USL"). Therefore, accurate diagnosis is required to decide which ligament(s) to repair.

This research letter demonstrates how the Integral Theory Diagnostic System (ITDS) Artificial intelligence "Wayfinding" software and future developments applying a Bayesian Network system may help to unravel the diagnostic complexity of multiple symptom causation, Figure 1, prior to ligament surgery.

MATERIALS AND METHODS

The ITDS software is based on a decision tree approach, Figure 1. Input data include answers to a self-administered patient questionnaire, clinical tests during routine examinations and "simulated operations": supporting specific ligaments e.g., pubourethral "PUL" and observing control of stress urinary incontinence "SUI" (see video https://youtu.be/0UZuJtajCQU).

During ITDS development, a human expert trained in ITS supplied a diagnosis for each patient: inferring laxity defects in a combination of anterior, middle and posterior zones of the pelvic floor. To limit computational complexity, parameters with continuous values were mapped to discrete ranges.

Network nodes correspond to questionnaire items, specific clinical tests, physician observations during routine examinations: SUI, deficient emptying problems, urge, frequency, pelvic pain, bowel problems, previous surgery, Figure 1. Nodes were assigned approximate diagnostic probabilities

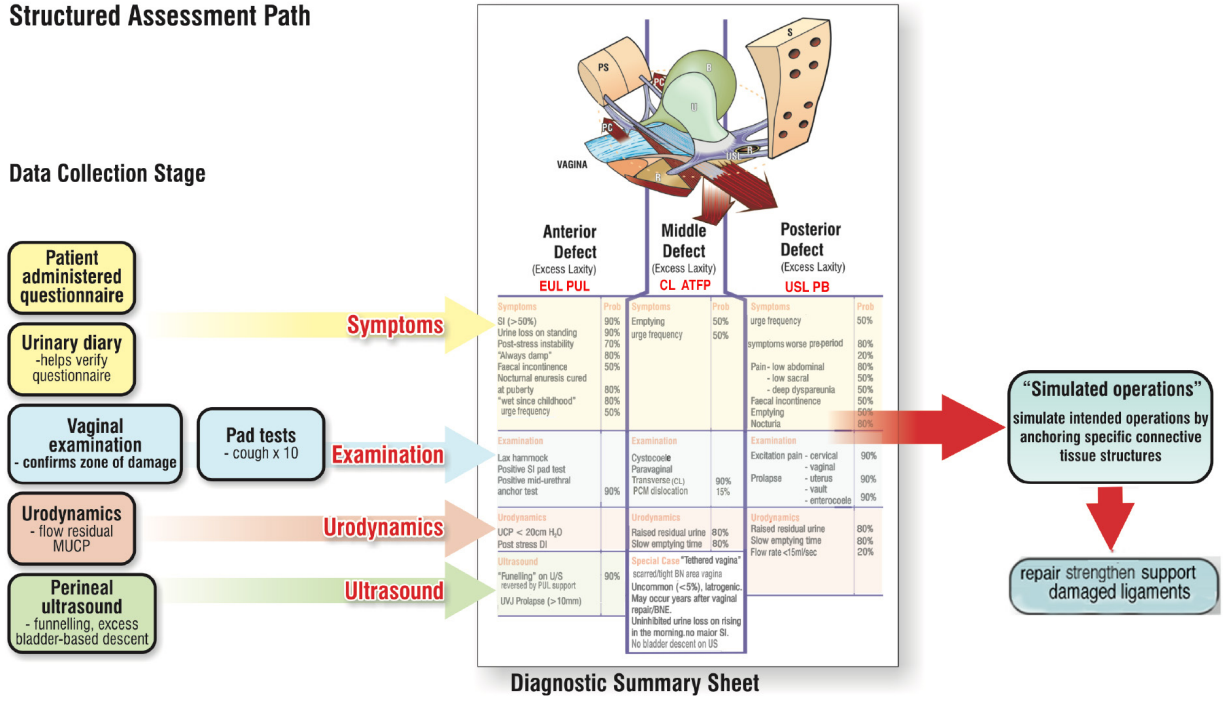

Figure 1. The ITDS diagnostic decision tree.
On the left are the six separate diagnostic "nodes" which are assessed and graded by the ITDS and Bayesian software. Both can reach a diagnosis using only the questionnaire and vaginal examination nodes.
The diagnostic Summary Sheet (middle section, Figure 1) assigns specific elements of each node into the three anatomical zones of ligament damage, anterior, (EUL, PUL), middle (CL ATFP), posterior (USL PB), with probabilities for each element. "Simulated operations" use a finger, hemostat, speculum or even pessary to mechanically support specific ligaments to reduce the symptom, e.g., SUI, urge, pain to confirm ligament pathogenesis prior to performing surgery.

ITDS: Integral Theory Diagnostic System; EUL: external urethral ligament; PUL: pubourethral ligament; CL: cardinal ligament; ATFP: arcus tendinous fascia pelvis; USL: uterosacral ligament; PB: perineal body; SUI: stress urinary incontinence

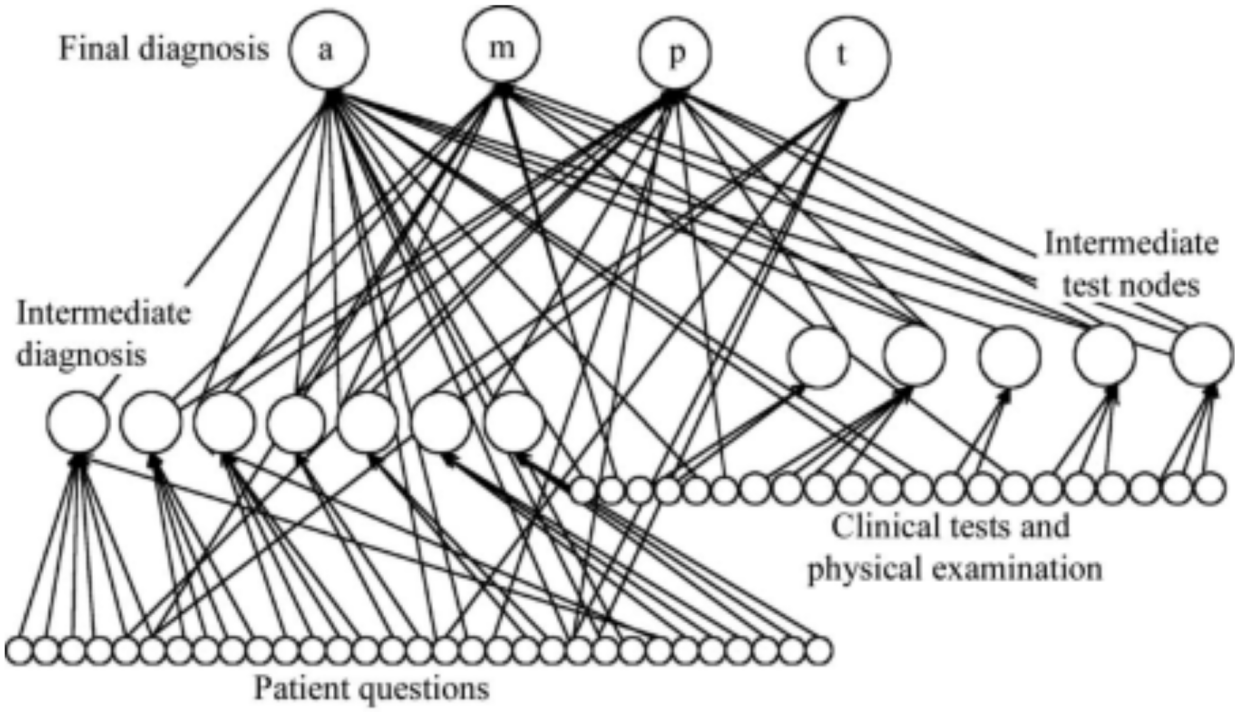

Figure 2. Bayesian Network output nodes (top row) predicting the likelihood of defects in the anterior (a), middle (m), or posterior (p) zones, or a diagnosis of tethered vagina syndrome (t). Intermediate diagnosis and test, and patient questions and clinical test nodes are as shown.

from the human expert. All nodes, Figure 1, were computed to diagnose ligament specific pathogenesis in the three zones.

The Bayesian Network connected nodes to all four final diagnoses. Matlab and BN Toolbox were used to build and train the Bayesian networks. The toolbox has facilities that enable model specification, inference and learning. Computational complexity was alleviated by using a technique called divorcing. Intermediate nodes were introduced, Figure 2, representing simplifying assumptions.

RESULTS

The ITDS decision tree approach is summarized in Figure 1. Inputs with estimated probabilities compute zone of ligament damage which needs repair: anterior, middle, posterior, pictorially displayed.

In both Bayesian Decision Tree approaches, results for accuracy, sensitivity and specificity ranged from 90% to 100% for each diagnosis. Initial assessments indicated superiority of the Bayesian Network approach.

DISCUSSION

Both software models addressed "Wayfinding" criteria[6] and the Academy's three principal themes:[1] reducing diagnostic error, patient participation (self-administered questionnaire/clinical tests), simplifying the "increasing complexity of health care". Figure 1.[1]

The Decision Tree approach, Figure 1, is a working model. While attaining reasonable levels of accuracy, it did not address the interconnectedness of the diagnoses. In the Decision Tree method, the classifier had to be executed four separate times, once for each diagnosis. The Bayesian Network approach is still experimental. Its advantage is it addresses the defects concurrently and can train the diagnostic process. Further development is required.

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ETHICS

Ethics Committee Approval: Since this article is a modelling study, it is not necessary.

Informed Consent: Since this article is a modelling study, it is not necessary.

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DISCLOSURES

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ORIGINAL ARTICLE

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An effective method of teaching cystoscopy to obstetrics and gynecology specialists

Bertan AKAR[1], Ali SARIBACAK[2], Yasin CEYLAN[3], Eray ÇALIŞKAN[4]

[1]Department of Obstetrics and Gynecology, İstinye University School of Medicine, Private Kocaeli Hospital, Kocaeli, Turkey
[2]Department of Urology, Private Konak Hospital, Kocaeli, Turkey
[3]Department of Obstetrics and Gynecology, University of Health Sciences Turkey, Bağcılar Training and Research Hospital, İstanbul, Turkey
[4]Department of Obstetrics and Gynecology, Okan University School of Medicine, İstanbul, Turkey

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ABSTRACT

Objectives: In this study, it was aimed to evaluate the knowledge and skills of gynecologists and obstetricians about cystoscopy theoretically and practically during the two-day urogynecology course.

Materials and Methods: Thirty-eight gynecologists and obstetricians aged 29–55 were simultaneously enrolled in cystoscopy training and evaluation in the urogynecology course, which includes theoretical, fresh cadaver and live surgery training stages. In addition, a theoretical evaluation was made with quizzes before and after fresh cadaver training. Finally, 6 months after the training, all trainees were called by phone and detailed information about their surgical experiences was obtained after the course.

Results: After the cadaver training, it was observed that the time and motion scores and instrument handling scores of the trainees increased significantly on the patients.

Conclusion: With surgical courses and simulations, the use of cystoscopy should be increased in the diagnosis and management of complications in urogynecological surgical procedures during and after the residency training of gynecologists and obstetricians.

Keywords: Cystoscopy; cadaver course; urogynecology course

INTRODUCTION

The clinical increase in endoscopic surgical procedures has necessitated training in these procedures for both surgeons and resident trainees. Many studies have been performed to examine the effectiveness of different training modalities. These modalities include anatomic models, virtual reality endoscopic video simulators, cadaver training courses and animal training courses. Although significant progress has been made in all of these surgical training models, human cadaver remains the gold standard for specific surgical training. Cadaveric tissue provides superior surgical training, so it is important to increase the availability of cadavers for training.[1]

Address for Correspondence: Yasin Ceylan, Department of Obstetrics and Gynecology, University of Health Sciences Turkey, Bağcılar Training and Research Hospital, İstanbul, Turkey
E-mail: md.yasinceylan@yahoo.com **ORCID ID:** orcid.org/0000-0001-5517-8461
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Cadaver dissection is highly effective in the perceived effectiveness in understanding the classification and interrelation of different body parts, the integration of anatomy theory and practice, touch-mediated perception, three-dimensional perspectives of structures, and the application of practical skills.[2]

Cystoscopy is used by urologists, urogynecologists, and gynecologists. Lower urinary tract damage occurs in approximately one percent of all pelvic surgeries in women.[3] However, after hysterectomy, this number rises to two percent.[4] Urogynecological operations carry the risk of ureter and bladder injuries and require cystoscopy information for diagnosis.

Intraoperative detection and recognition of urinary tract injuries is very important for patients and gynecologist because of less morbidity.[5] In a recent meta-analysis showed that proportion of ureteric and bladder injuries detected intraoperatively without routine cystoscopy is approximately 18% and 79% respectively. However, with routine cystoscopy this proportion increases to approximately 95%.[6] Also, hospitalizations from delayed diagnosis result in 1.72 times greater cost to the health system than those with intraoperative detection of injury.[7]

It is logical that the gynecologists need to improve the identifications of these injuries. Lower urinary tract injuries are hard to identify without expertise in cystoscopy.

Despite a three months of urology education during residency program most obstetrics and gynecology specialist in Turkey do not perform cystoscopy by themselves. Many of them do not have enough experience to confidently identify lower urinary tract injury and differentiate normal from abnormal findings. The aim of this study is to investigate the efficacy of fresh cadaver course for gynecologists to adapt and apply cystoscopy.

MATERIALS AND METHODS

After institutional review board approval 38 obstetrics and gynecology specialists were enrolled in the study. This study was planted in an urogynecology course and contain a two days theoretical education, fresh cadaver application of cystoscopy and performing of cystoscopy during hands on urogynecological surgeries.

On theoretical season a 40-minute presentation was given by the primary investigator. It reviewed the cystoscopy instrumentation, indications, procedural details, normal and anormal findings and also how to manage the lower urinary tract injuries.

Every trainee had access fresh-frozen cadavers with intact urethra and bladder. Each trainee had a chance to work with a well-experienced urologist and perform a pre-determined series of cystoscopy skills one to one. These skills contained assembly of the cystoscope, additional equipment, proper set up, proper bladder and urethra observation, identification of abnormalities. At the end of the cadaver training all trainees were tested by a single physician blindly. They were scored using a modified Technical Skills checklist and global rating scale.[8,9] Also, pre- and post- cadaver education quiz assessed theoretical knowledge.

During live surgeries every trainee was asked to perform cystoscopy with a well experienced physician after urogynecology operations. They were also scored after live cystoscopy. Trainees were expected to find and locate a sign (needle) in the bladder during cystoscopy on cadaver not on live surgeries. So technical skills checklist scores were calculated over 35 on cadaver and over 30 on live surgeries. At the 6th month of education every trainee were called and interviewed about the progress they got after the education. Paired samples t-test and Pearson's correlation analysis was used to evaluate the data.

RESULTS

The mean age of the surgeons was 37.6±6.6 years. They were working as specialist for 7.3±5.9 years. Twenty out of 38 (52.6%) had never practiced cystoscopy. The demographic characteristics of the participants and their surgical application histories are given in Table 1. The quiz scores improved after cadaver education (4.8±1.3 to 6.8±0.39, $p<0.001$). Global rating scale scoring were similar both during cadaver and live surgery performance (25.9±3.9 vs 26.4±3.8, $p=0.29$). Previous hysteroscopy (r=0.48, $p=0.002$) and cystoscopy experience (r=0.44, $p=0.006$) were positively correlated with global rating scale score. Task points improved during live surgery compared to cadaver application (76±14 vs. 70±12 points, $p<0.001$).

After the cadaver training, it was observed that the time and motion scores and instrument handling scores of the trainees increased significantly on the patients. In addition, it was observed that the knowledge of instruments score increased with the positive effect of the course. Another striking positive effect of the course on the trainees was that the rate of help needed in the procedures performed on the patients decreased. Flow of operation score, knowledge of specific procedure score and overall performance score were found to be higher in transactions with cadavers (Table 2).

Thanks to the cadaver course, the trainees learned the anatomical structures better and they were able to complete the cystoscopy procedure in a shorter and safer manner (Table 3).

DISCUSSION

Cystoscopy simulation should be routinely placed in the curriculum to maximize the quality of training in the training of gynecologists and obstetricians. However, it should be known

Table 1. Trainee characteristics (n=38)				
Sex (n)	**Male**	18		
	Female	20		
Age, (year)	37.6±6.6 (29–55)			
Years of practice beyond training	7.3±5.9 (1–24)			
Practice patterns before course (n)	**Never experienced n (%)**	**Performed under guidance n (%)**	**Performed independently n (%)**	**Expert n (%)**
Cystoscopy, (n=38)	20 (52.6)	11 (28.9)	7 (18.4)	-
Hysteroscopy, (n=38)	-	9 (23.7)	24 (63.2)	5 (13.2)
Laparoscopy, (n=38)	-	11 (28.9)	22 (57.9)	5 (13.2)
n: number of the trainees				

Table 2. Global scores			
Global domain	**Mean rating score on cadavres (SD)**	**Mean rating score on patients (SD)**	**p-value**
Time and motion	3.2±0.7	3.7±0.6	<0.001
Instrument handling	3.4±0.7	3.8±0.6	<0.001
Knowledge of instruments	3.6±0.7	3.8±0.8	0.01
Flow of operation	3.9±0.6	3.8±0.7	0.2
Use of assistance	3.8±0.8	3.7±0.8	0.1
Knowledge of specific procedure	3.7±0.7	3.6±0.6	0.6
Overall performance	4±0.6	3.9±0.7	0.1
Total global rating score (over 35)	25.9±3.9	26.4±3.8	0.29
SD: standard deviation; n: number			

that simulation should be used as an auxiliary instrument rather than a replacement for clinical training.[10] The first assistants see the anatomical structure in the real body, but without blood and safely on the cadaver. They can then use the information in surgical procedures of living bodies. During the learning period, it may be advisable to use surgical steps to determine the lack of training. The aim of this study is to investigate the efficacy of fresh cadaver course for gynecologists to adapt and apply cystoscopy. We carried out theoretical and fresh cadaver trainings by accepting them as the pioneer and complement of clinical training. We think that these simulations and applications on cadavers will be able to bypass the early steps in the training of trainees more quickly.

Increasing cystoscopy skills and a more comprehensive cystoscopy examination by gynecologists is important, as identification of lower urinary tract injuries, complications, and urinary pathologies allows earlier diagnosis, improved treatment modalities, and a better understanding of pelvic floor anatomy. In addition, the need for cystoscopy with increasing surgical interventions for mid-urethral sling surgery and pelvic organ prolapse repair will continue to be an important component of gynecology and obstetrics residency training in the coming years.[11] Our aim of organizing this course is to help gynecologists and obstetricians learn the anatomical structures on the cadaver better and increase their manual skills, shortening the time of cystoscopy and increasing its quality.

In the study by Bowling et al.[11], they stated that the ability of assistants to bring together the cystoscopy and perform cystourethroscopy improved significantly after the bladder model didactic application. In our study, it was observed that the ability of the trainees to recognize, put together and use the cystoscope developed significantly at the end of the course.

Table 3. Practice time and task scores and duration on cadavers and patients	
Evaluated variable	**Results**
Practice time on cadavres (min)	76.3±21.9 (48–144)
Task application score on cadavre (over 100)	70.3±12.6 (45–94)
Cystoscopy time on patients (min)	65.8±11 (48–88)
Cystoscopy task completion time on patients (min)	19±3.7 (6–24)
Task application score on patients (over 100)	77.5±10.9 (48–96)

Brehmer and Swartz[12] reported in their study that repeated training on a bench-top simulator for semi-rigid ureteroscopy significantly improved established performance and made trainees feel more comfortable with instruments and procedures. In our study, it was observed that the trainees felt more comfortable in the cystoscopy procedure performed on the cadaver together with the theoretical training later in the course, which increased the overall performance and the flow rate of the procedure. They were also found to be more successful in performing specific procedures on cadavers.

CONCLUSION

The American College of Obstetricians and Gynecologists (ACOG) has advised to train all gynecologist and obstetrician residents in cystoscopy, but not all gynecology and obstetrics residency programs formally teach cystoscopy to their residents. In addition to the new ACOG recommendations, there is a growing body of evidence suggesting that cystoscopy should not only be performed during routine hysterectomy but is also cost-effective when rates of ureteral injury are exceeded. 1.5% for abdominal approaches and 2.0% for vaginal or laparoscopic approaches. Because of new suggestions and increasing demand for routine cystoscopy in gynecology and obstetrics field, teaching the basics of cystoscopy should be considered firmly.[11,13]

Our aim is to reach more trainees in the following course programs and make cystoscopy a surgical procedure that gynecologists and obstetricians can routinely perform.

ETHICS

Ethics Committee Approval: Since this is a cadaver study, approval by an ethics committee was not required.

Informed Consent: Informed consents were obtained from each patient.

Peer-review: Externally peer-reviewed.

Contributions

Concept: Y.C.; Design: B.A., A.S., Y.C., E.Ç.; Data Collection and/or Processing: Y.C.; Analysis and/or Interpretation: A.S.; Project Development: E.Ç.; Writing/Editing: B.A., E.Ç.

DISCLOSURES

Conflict of Interest: No conflict of interest was declared by the authors.

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Comparison of obstetric outcomes and morbidity in nulliparous pregnant women who received antenatal and intrapartum perineal massage

Sevil KİREMİTLİ, Tunay KİREMİTLİ, Paşa ULUĞ, Nesrin YILMAZ

Department of Obstetrics and Gynaecology, Erzincan Binali Yildirim University Medical Faculty, Erzincan, Turkey

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ABSTRACT

Objectives: We aimed to compare antepartum and intrapartum perineal massage in nulliparous patients to a control group in terms of "reducing the episiotomy necessity, duration of the second stage of labor, obstetric outcomes, and perineal injury"; and aimed to see if these two massages were superior to each other.

Materials and Methods: One hundred and seventy-three nulliparous pregnant women who delivered at 37–42 weeks of gestation were included in the study. Of these pregnants, 55 were in the antenatal massage group (AG), 59 were in the intrapartum massage group (IG), and 59 were in the control group (CG). Among these groups, demographic data of the patients, whether vacuum was applied during delivery, duration of the second stage of labor, whether episiotomy was performed, the degree-of-perineal injury, if any, and 1st and 5th minute Apgar scores were compared.

Results: 14 (25.5%) patients in AG, 11 (18.6%) patients in IG, and 5 (8.6%) patients in CG were delivered without performing episiotomy (p=0.04). The rate of having an intact perineum (no perineal laceration) was statistically significantly higher in AG (eight in AG, three in IG, two in CG) (p=0.03). Third degree perineal laceration was less common in both AG and IG compared to CG. However, there was a statistically significant difference only between AG and CG (p=0.04).

Conclusion: Antenatal perineal massage is effective in reducing the episiotomy necessity and the duration of the second stage of labor compared to the control group, but no significant difference was found with intrapartum perineal massage. So, we recommend starting intrapartum perineal massage in patients who have not started in the antenatal period.

Keywords: Antenatal perineal massage; episiotomy; intrapartum perineal massage; perineal laceration; perineal massage

Address for Correspondence: Tunay Kiremitli, Department of Obstetrics and Gynaecology, Erzincan Binali Yildirim University Medical Faculty, Erzincan, Turkey
E-mail: tkiremitli@hotmail.com **ORCID ID:** orcid.org/0000-0002-4531-827X
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INTRODUCTION

Although the incidence of third and fourth degree perineal lacerations has been reported as 0.5%–10% in vaginal delivery, it is known that 30%–80% of the patients have different degrees of lacerations. These lacerations are more common especially in nulliparous pregnant women.[1,2]

Episiotomy has been a routine component of vaginal deliveries for many years to reduce anal sphincter injury, uncontrolled perineal lacerations, the risk of operative delivery, and birth trauma to the fetus.[3] However, in recent years, it has been reported that routine episiotomy is not protective for perineal lacerations, and contrary to expectations, it has negative effects on perineal trauma and postpartum recovery time.[4]

American College of Obstetricians and Gynecologists (ACOG) and Royal College of Obstetricians and Gynaecologists (RCOG) do not recommend routine episiotomy in vaginal deliveries. Today, it is recommended to abandon routine episiotomy and to apply limited episiotomy only in cases where the fetus must be delivered quickly, in operative vaginal deliveries and in cases of shoulder dystocia.[5,6]

There are studies reporting that techniques such as "warm application to the perineum, perineal massage, pelvic floor muscle exercises, use of massage and dilatation devices, application of hyalurinidase to the perineum and passing the labor stages in water" are used to reduce the episiotomy necessity and the possibility of perineal trauma.[7-9]

The effectiveness of perineal massage in reducing the perineal trauma, the episiotomy necessity and the length of the second stage of labor is being investigated in several research.[10-12]

In researches, perineal massage timing has been reported as antepartum or intrapartum periods. Antepartum perineal massage describes the daily perineal massage starting 4–6 weeks before the expected delivery time, while intrapartum perineal massage describes the intermittent perineal massage during the second stage of labor at a cervical opening of 4 cm and above.[11,13] The effect of perineal massage on perineal trauma and obstetric outcomes is controversial. To the best of our knowledge, there is no study in the literature comparing perineal massage performed during the intrapartum or antepartum period in terms of birth complications and perinatal outcomes. We aimed to compare antepartum and intrapartum perineal massage in nulliparous patients to a control group in terms of "reducing the episiotomy necessity, duration of the second stage of labor, obstetric outcomes, and perineal injury"; and aimed to see if these two massages were superior to each other.

MATERIALS AND METHODS

This study was conducted following the principles of the Declaration of Helsinki. This randomized controlled trial began on August 1, 2021 and was finished on January 20, 2022. Nulliparous pregnant women aged 20–35 years and delivered at 37–42 weeks of gestation were included in the study. In the antenatal massage group (AG), 82 patients who applied to the pregnant outpatient clinic in the third trimester and agreed to perform perineal massage for 10 minutes a day after 34 weeks of gestation until delivery were included. Perineal massage was described as applying olive oil to the hands and vagina to facilitate the movement of the hands, and placing one or two fingers (preferably the index and middle fingers) 3–4 cm inside the vagina and stretching them towards the rectum in a U shape from 3 o'clock to 9 o'clock. The first perineal massage was taught to the patient by the midwife or doctor. They were asked to perform perineal massage for 10 minutes a day until delivery. Twenty-seven patients were excluded from the study: 14 pregnant women could not do perineal massage regularly, two pregnant women had preterm births, five pregnant women did not deliver in our hospital, and six pregnant women delivered by cesarean section. Sixty-two nulliparous pregnant women admitted to the delivery room for vaginal delivery were included in the intrapartum massage group (IG). Massage was started when the cervical opening, which is considered as the active phase of labor for pregnant women, was at least 4 cm.[14] After the patients were placed in the lithotomy position, the massage was performed by applying olive oil to the practitioner's two fingers and the patient's vagina in the interval where there was no contraction. After placing the fingers in the vagina up to the second node, a "U" shaped stretching movement was performed from 3 to 9 o'clock level. Massage was performed a total of four times, the last of which was in full cervical dilatation. The total duration of the four was 10 minutes. Three patients who required cesarean section during labor were excluded from the study. In the control group (CG), 59 patients who were not performed perineal massage during the antepartum or intrapartum period were included. Patients who agreed to have regular perineal massage after 34 weeks of gestation were included in the AG. To ensure randomization for IG and C, patients with an even last digit of the protocol number were included in IG, and patients with odd numbers were included in CG. Demographic data of the patients, obstetric histories, vacuum application during delivery, duration of the second stage of labor, whether episiotomy performed, the degree of perineal injury, if any, and 1st and 5th minute apgar scores after delivery were recorded. The second stage of labor, the time from full cervical dilation to the completion of fetal delivery, was recorded in minutes.

The degree of laceration in the classification of perineal injury;

First Degree: superficial injury to the vaginal mucosa that may involve the perineal skin.

Second Degree: first-degree laceration involving the vaginal mucosa and perineal body.

Third Degree: second-degree laceration with the involvement of the anal sphincter. This is further classified into three sub-categories:

A: Less than 50% of the anal sphincter is torn.

B: Greater than 50% of the anal sphincter is torn.

C: External and internal anal sphincters are torn.

Fourth Degree: third-degree laceration involving the rectal mucosa.

Severe perineal lacerations, which include third- and fourth-degree lacerations, are referred to as obstetric anal sphincter injuries (OASIS).[15]

Statistical Analysis

IBM SPSS ver for data analysis, 21 (IBM Corp., Armonk, N.Y., USA) was used. The conformity of the data to the normal distribution was tested with the Shapiro–Wilk test. Kruskal–Wallis and One-Way ANOVA tests were performed for non-parametric and parametric data, respectively. Tukey test was used for ANOVA test, Mann–Whitney U test with Bonferroni correction was used for Kruskal–Wallis and Bonferroni test was used for chi-square in multiple comparisons. Descriptive statistics of continuous variables were presented as mean ± standard deviation, median (minimum-maximum) value, and categorical variables as number (%). A *p*-value <0.05 was considered statistically significant.

RESULTS

A total of 173 patients, 55 of whom were in AG, 59 in IG, and 59 in CG, were included in our study. Demographic data of the patients are presented in Table 1.

14 (25.5%) patients in AG, 11 (18.6%) patients in IG, and 5 (8.6%) patients in CG were delivered without episiotomy. The rate of episiotomy was found to be higher in CG compared to AG and IG (statistically significant between AG and CG, p=0.01). Perineal laceration was not observed in 8 (14.4%) of 14 deliveries without episiotomy in AG, while first degree laceration was observed in five and second degree laceration in one patient. On the other hand, perineal laceration was not observed in 3 (5.1%) patients on IG, first degree laceration was observed in 3 (5.1%) and second degree lacerations were observed in 5 (8.5%) patients. On CG, 2 (3.4%) patients had no perineal injury, 1 (1.7%) had first degree laceration, and 3 (5.1%) had second degree laceration. The rate of having an intact perineum (no perineal laceration) was statistically significantly higher in AG (p=0.04 and p=0.03) (Table 2).

When we compared the groups among third-degree perineal lacerations, third degree laceration was observed in 1 (1.8%) patient in AG, in 3 (5.1%) patients in IG, and in seven patients (11.9%) in CG. Third degree perineal laceration was the lowest in AG and this difference was statistically significant compared to CG (p=0.03) (Table 2). Fourth degree perineal injury was not observed in any of the three groups.

Prenatal hemoglobin values were 11.8±1.2 g/l, 11.8±1.1 g/l and 11.7±1.3 g/l in the groups, respectively (p=0.7). Postpartum hemoglobin values were 10.7±1.7 g/l, 10.9±1.3 g/l and 10.1±1.1 g/l, respectively, the difference was statistically significant (p=0.03).

In addition, no statistically significant difference was found between the groups at birth week, birth weight, number of patients receiving labor induction, and 1st and 5th minute apgar scores of the fetus (p>0.05) (Table 3).

DISCUSSION

In this study, in which we compared the results of perineal massage performed in the antenatal or intrapartum period on obstetric and perinatal outcomes, we found that perineal massage performed in both periods (compared to the control

Table 1. Demographic data of the patients

	AG (n=55)	IG (n=59)	CG (n=59)	*p*-value
Age	25.9±4.1	25.2±3.9	24.8±3.6	0.3*
Weight	74.4±9	73.3±8.4	75.9±10	0.07*
Height	1.65±0.4	1.63±0.5	1.66±0.4	0.3*
Weight gained during pregnancy	12 (4–24)	12 (7–25)	13 (5–21)	0.6**
Gravidy	1 (1–3)	1 (1–4)	1 (1–3)	0.9**

*One-Way ANOVA test was used; **The−Kruskal Wallis test was used.
AG: antenatal massage group; IG: intrapartum massage group; CG: control group; n: number

group) was effective in reducing the rate of episiotomy and the duration of the second stage of labor. In terms of the absence of laceration in the perineum, massage performed during the antenatal period was found to be more effective than the massage performed during the intrapartum period. According to our study results, we think that perineal massage may have an important role in today's world, where routine episiotomy was abandoned and birth as close to natural is aimed with minimal trauma. This study is valuable in that there is no study in the literature comparing massage performed in these two different periods.

In a meta-analysis, it was reported that perineal massage performed in the antanatal period reduced the incidence of episiotomy, and had a protective effect especially against third and fourth degree perineal lacerations.[10] According to the results of the Cochrane systematic review, which included 2,497 women, in which perineal massage performed during the antenatal period was examined, it was reported that perineal massage provided a reduction in episiotomy requirement, perineal traumas and postpartum perineal pain, but differently, it was emphasized that the protective effect of perineal massage was not observed in third and fourth degree lacerations.[11] On the contrary, in their case-control study, Mei-dan et al.[16] found no significant difference in episiotomy rates between women who received and did not receive perineal massage during the antenatal period. In studies investigating the effectiveness of intrapartum perineal massage, the results of the study are also controversial. Karaçam et al.[17] found that the rate of episiotomy in women who received intrapartum perineal massage was lower than the control group. However, another study investigating the effect of perineal massage in the second stage of labor did not observe a difference in the rate of episiotomy between the massage and control groups.[18] In another study, although intrapartum perineal massage reduced the rate of episiotomy, no protective effect was found in terms of perineal lacerations.[19] In our study, we concluded that perineal massage performed both in the antanatal and intrapartum periods reduced the rate of episiotomy (only antenatal perineal massage is statistically significant compared to control patients, although intrapartum perineal massage reduces the episiotomy rate, it is not statistically significant), and perineal massage performed at two different times was not superior to each other. It has been reported that in the area where perineal massage was performed, an increase in muscle strength, elongation in muscle length and release of endorphins that help control pain increase.[20] We also think that this stretching exercises performed to the perineum reduce the episiotomy necessity due to the increase in muscle strength and muscle elasticity. It is noteworthy that perineal massage started in the intrapartum period has no significant difference with the one started in the antepartum period in reducing the rate of episiotomy. Based on this result, it may be important to performing perineal massage to patients in labor in order to reduce the routine episiotomy by healthcare professionals who manage labor. Perineal massage performed in the antenatal period seems to be more effective than the intrapartum massage in terms of no laceration (intact perineum). We think that this

Table 2. Variables related to labor and outcomes

	AG (n=55)	IG (n=59)	CG (n=59)	p^1	p^2	p^3
Episiotomy**	41 (74.5%)	48 (81.4%)	54 (91.5%)	0.3	**0.01**	0.06
Induction of labor, n (%)**	12 (23.6%)	9 (22%)	11 (20.3%)	0.5	**0.5**	0.8
No laseration**	8 (14.4%)	3 (5.1%)	2 (3.4%)	**0.04**	**0.03**	0.5
Third degree laceration**	1 (1.8%)	3 (5.1%)	7 (11.9%)	0.6	**0.03**	0.1
Vacuum/forceps**	1 (1.8%)	2 (3.4%)	4 (6.8%)	0.6	0.3	0.6
Stage 2 of labor (min)*	30.1±14.8	28.9±15	36.8±14.4	0.9	**0.04**	**0.01**

Significant values are shown in bold.
*Chi-square test was used; ** One-Way ANOVA test was used.
p^1: AG-IG; p^2: AG-CG; p^3: IG-CG; AG: antenatal massage group; IG: intrapartum massage group; CG: control group; n: number

Table 3. Perinatal outcomes

	AG	IG	CG	*p*-value
Birth weight	3282±375	3310±391	3344±400	0.6
Birth week	39.2±1.2	39.1±1.1	39.3±1.1	0.08
1st min Apgar	7.7±1.3	7.4±1.6	7.2±1.6	0.2
5th min Apgar	8.9±1.2	8.8±1.4	8.8±1.2	0.9

AG: antenatal massage group; IG:intrapartum massage group; CG: control group; n: number

result is due to a more significant increase in skin and muscle elasticity with longer massage. In addition, daily massage after the third trimester of pregnancy can be effective in overcoming the fear of vaginal birth and examination, increasing the motivation of vaginal birth and increasing the self-confidence of the patients.

Although there are studies reporting that perineal massage has no effect on the duration of the second stage of labor,[8,21] a meta-analysis concluded that antenatal massage is effective in shortening the duration of the second stage of labor.[10] Akhlaghi et al.[22] also reported that perineal massage performed during the intrapartum period was effective in shortening the second stage of labor. Similarly, in our study, we observed that massage performed both in the antenatal period and in the intrapartum period shortened the second stage of labor compared to the control group. In addition, we did not observe any difference in the effectiveness of massages performed at two different times in shortening the duration of the second stage of labor. It is known that the blood supply and oxygenation increase in the perineal massage area, the resulting pain decreases, and the massage helps in pain control by stimulating the release of endorphins.[23] It has also been reported that massage can stimulate the release of oxytocin.[24] This may be associated with the shortening of the second stage of labor.

Abdelhakim et al.[10] emphasized that antenatal perineal massage caused an amelioration in the apgar score of the fetus. In another study, it was reported that perineal massage performed during the antenatal period did not change the rate of birth asphyxia, the rate of hospitalization in the neonatal ıntensive care unit, the 1st and 5th minute apgar scores, and the rates of using vacuum/forceps.[25] Aquino et al.[26] also observed no difference in the apgar score of patients who was performed intrapartum perineal massage. In our study, we observed that perineal massage performed both in the antenatal and intrapartum periods reduced the rate of episiotomy and shortened the second stage of labor, but it was not superior to the control group in terms of vacuum application and 1st and 5th minute apgar scores. Studies with a larger number of patients may be more effective in demonstrating perinatal outcomes.

CONCLUSION

As a result, in this study, which compared the effectiveness of antenatal and intrapartum perineal massage, which we have not encountered before in the literature; we observed that perineal massage, which is simple, easy to apply, less time consuming, inexpensive and has no negative consequences for the newborn, is similarly effective in shortening the rate of episiotomy and the duration of the second stage of labor. Antenatal massage was found to be more effective in terms of intact perineum (no laceration). Based on these findings, it seems more appropriate to recommend regular perineal massage applications to be started in the antenatal period in nullipare pregnants. However, we recommend starting intrapartum perineal massage in patients who have not started in the antenatal period. As stated in the literature, reducing the rate of episiotomy and perineal lacerations are used as a quality measure of health,[27] and perineal massage is also effective on this.

ETHICS

Ethics Committee Approval: This study was approved by Erzincan Binali Yıldırım University Clinical Researches Ethics Committee (decision no: 11/17 and date: 25/10/2021).

Informed Consent: It was obtained.

Peer-review: Externally peer-reviewed.

Contributions

Concept: T.K., S.K.; Design: T.K., S.K.; Data Collection and/or Processing: S.K., N.Y.; Analysis and/or Interpretation: T.K., N.Y.; Drafting: S.K.; Critical Revisions: P.U.; Writing: T.K.

DISCLOSURES

Conflict of Interest: No conflict of interest was declared by the authors.

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ORIGINAL ARTICLE

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Female genital aesthetic surgery: comparison of cadaver and live surgery training models

Bertan AKAR[1], Yasin CEYLAN[2], Aşkı ELLİBEŞ KAYA[3], Eray ÇALIŞKAN[4]

[1]Department of Obstetrics and Gynecology, İstinye University School of Medicine, Private Kocaeli Hospital, Kocaeli, Turkey
[2]Department of Obstetrics and Gynecology, University of Health Sciences Turkey, Bağcılar Training and Research Hospital, İstanbul, Turkey
[3]Private Doctor, Department of Obstetrics and Gynecology, Samsun, Turkey
[4]Department of Obstetrics and Gynecology, Okan University School of Medicine, İstanbul, Turkey

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ABSTRACT

Objective: In this study, it was aimed to search the efficiency of fresh cadaver course and live surgical operations for female genital aesthetic surgery application.

Materials and Methods: Seventy-three obstetrics and gynecology specialists underwent a two-day course about genital cosmetic surgery that includes theoretical lectures, fresh cadavers and live surgeries. These surgeons divided into two group. First group trained on cadavers (n=33), second group was involved in live surgeries (n=40). Skills in genital cosmetic surgery, applied procedures, number of participating colleagues in a procedure, ability to learn and motivations to take the course were compared before and after the training course. At the 6th month of education every trainee were called and interviewed about the progress they got after the education.

Results: After the fresh cadaver and live surgery training, numbers of trainees who performed genital cosmetic procedures (GCP) before the course and 6 months after the course were compared. A meaningful increase on numbers of trainees after the course who performed all GCP applications was observed. According to the statistics of participants, it was observed that a live surgical course is more beneficial than a cadaver course. Numbers of trainees who performed genital aesthetic surgery before and 6 months after the course were compared. A meaningful raise was observed in the statistics of trainees' numbers who performed all surgical applications apart from anterior and posterior compartment repair.

Conclusion: Fresh cadaver and live surgical courses have positive effects in the long term for the surgeons who have lack of surgical confidence and skills.

Keywords: Female genital aesthetic surgery; fresh cadaver courses; genital cosmetic procedures; live surgical courses

Address for Correspondence: Yasin Ceylan, Department of Obstetrics and Gynecology, University of Health Sciences Turkey, Bağcılar Training and Research Hospital, İstanbul, Turkey
E-mail: md.yasinceylan@yahoo.com **ORCID ID:** orcid.org/0000-0001-5517-8461
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Introduction

Female genital cosmetic surgery (FGCS) includes procedures to augment reduce or reconstruct various anatomic structures in an attempt to cumulatively improve cosmetic appearance of external genitalia. Patient satisfaction could be achieved by reasonably preferring a combination of surgical and non-invasive procedures. Labioplasty application rates increased 44% in 2013 and is reported to be the fourth most common cosmetic surgical procedure in USA after liposuction, breast augmentation and rhinoplasty.[1] Admission of vulvoplasty rate in women without any medical necessity increased 140% in Australia between 2001 and 2013.[2] Most of the procedures performed without a medical necessity aims to improve vaginal laxity, sexual functions, sexual satisfaction of both partners and to alleviate discomfort in dressing or when participating in sports. FGCS, also known as vulvoplasty, describes a group of cosmetic surgical procedures applied without medical indications that change structure and appearance of healthy external genitalia.[3] These procedures could be more specifically described as labioplasty, hymenoplasty, vaginoplasty, mons pubis liposuction, labia majora lipid injection, vaginal "rejuvenation" or laser "rejuvenation", G spot enhancement and orgasm-shot.[3]

There is growing interest and demand for female genital cosmetic applications in both patients and surgeons. Although surgical and non-invasive procedures of female genitalia fall under the field of gynecology, plastic surgeons and even dermatologists showing increasing interest to these procedures. Contemporarily, training for these cosmetic procedures in obstetrics and gynecology (obs/gyn) residency is far from being sufficient. Therefore, independent surgery workshops and training programs, specifically targeting female genital cosmetic procedures, has been developed. These training programs include anatomic models, virtual reality video simulators, cadaver courses, practices on animal subjects, live surgeries besides theoretical lectures. In spite of the improvements in surgical training models, human cadaver remains to be gold standard in specific surgical training. Cadaver tissue provides unsurpassed surgical experience; therefore, it is crucial to increase the availability of cadavers.

This study aims to evaluate the effectiveness of fresh cadaver courses and live surgeries for FGCS training.

MATERIALS AND METHODS

Seventy-three obs/gyn specialists underwent a two-day course about genital cosmetic surgery that includes theoretical lectures, fresh cadavers and live surgeries. These surgeons divided into two group. First group trained on cadavers (n=33); second group was involved in live surgeries (n=40). Skills in genital cosmetic surgery, applied procedures, number of participating colleagues in a procedure, ability to learn and motivations to take the course were compared before and after the training course.

At the 6th month of education every trainee were called and interviewed about the progress they got after the education.

RESULTS

Mean age of trainees in Group 1 and Group 2 were 39.1±7.9 and 37.4±6.4 respectively. Group 1 includes 12 group two includes 30 women trainees. Mean working experience in Group 1 was 9.1±8.5 years and 7.2±5.9 years in Group 2. Number of monthly applied genital cosmetic examinations were found higher in Group 2 (7.3±9.1) and genital cosmetic surgeries were found higher in Group 1 (2.9±2.9). Motivations in taking the course, developing in practice and financial interests were similar between two groups, however concerns about malpractice was found higher in group 2 (6.9±2) (Table 1).

Table 1. Distrubution of selective variable in the two groups

Variable	Group 1 (cadaveric model group) (n=33)	Group 2 (live surgery model group) (n=40)	*p*-value
Age	39.1±±7.6	37.4±6.4±6.4	0.28
Gender (female; n, %)	12 (36%)	30 (75%)	0.001
Period of expertise (year)	9.1±8.5±8.5	7.2±±5.9	0.25
Genital aesthetic examination (in one month)	5.7±5.1±5.1	7.3±9.1±9.1	0.31
Genital aesthetic surgery (in one mount)	2.9±2.9±2.9	2.2±2.7±2.7	0.31
Course motivation reason of professional development (VAS)	9.1±1.5±1.5	9.1±1.4±1.4	0.82
Course motivation reason of earn money (VAS)	6.8±2.8±2.8	7.1±2.6±2.6	0.66
Course motivation reason of avoiding malpractice (VAS)	5.9±2.5±2.5	6.9±2±2	0.06

VAS: Visual Analogue Scale; n: number

Number of trainees applying genital cosmetic procedures (GCP) before and 6 months after the course were compared by questionnaire. Significantly higher number of trainees were found to perform all genital cosmetic procedures after the course. Number of trainees performing all types of genital cosmetic procedures before the course was lower in Group 2 in comparison to Group 1, however increase in number of surgeons performing all types of genital procedures after the course was greater in Group 2 (Table 2). Information obtained from participants revealed that live surgeries were more efficient than cadaver courses.

Number of trainees performing genital aesthetic surgeries (GAS) before and 6 months after the course were compared with questionnaires (Table 3). No significant difference was found in number of trainees performing genital aesthetic surgeries except labia major plasty and perinal body repair in Group 1. However, significantly increased number of trainees are found to perform all types of genital aesthetic surgeries except anterior and posterior compartment repairs in Group 2, 6 months after the course. Application of specific procedures was prominently increased 6 months after the course in Group 2. Increase in professional confidence in Group 2 trainees was reflected as growing number of procedures performed after the course.

Applicability of all types of GCP was found lower than applicability of all types of GAS procedures both before and after the course.

DISCUSSION

Safely improving patient outcomes and providing high standards of training for colleagues are foremost components of professional ethics of a surgeon. Rapid technological advances in medicine permits surgeons to perform procedures on virtual models, cadavers or animal subjects and provide training for colleagues accordingly. This training models allow the trainee to learn and practice surgical techniques step by step in a safe and comfortable environment, leads to an increase in professional confidence ensued by fewer mistakes. Moreover, simulations allow surgeons to accurately assess their surgical skills.[4] Enhanced reality focused training seems advantageous for both trainee and the instructor. Although cadaver practice is a traditional method, it still remains to be gold standard before attempting live surgeries. Practices on cadavers are of great importance before independently performing surgeries. Cadaver courses are approved training method in neurosurgery, plastic surgery, orthopedics, general surgery, urology, cardiovascular surgery and other fields to convey skills and information.[5] This is a unique study about applicability of FGCS and non-invasive procedures on fresh cadavers and live surgeries, involving transfer of knowledge and skills to trainees by professional instructors. Furthermore, our data indicate that training by live surgeries in accompany of an experienced team is more effective than cadaver courses.

Ahmed et al.[6] described a series of 81 urology residents that underwent surgical training course on cadavers. In their study they concluded human cadavers are the best simulation-based training models and provide supreme improvement in surgical skills that could be conducted to operating room. Sharma et al.[7] reported favorable effects of cadaver courses targeting specific procedures on improving surgical skills and professional confidence. Kim et al.[8] reported first applications of advanced surgeries in cadaver courses that improves anatomical knowledge and allows trainees to independently perform surgeries. Jansen et al.[9] showed the applicability of both basic and advanced procedures on cadavers and demonstrated the contribution of cadaver courses on comprehending specific procedures. Tasks of transferring skills and identifying new surgical technics could

Table 2. Adaption and application of genital cosmetic prosedures in the two groups

Variables	Group 1: Cadaveric model (n=33)			Group 2: Live surgery model (n=40)			*p*-values pre-course between groups	*p*-values post-course between groups
	Pre-course (n, %)	Post-course (n, %)	*p*-values within group	Pre-course (n, %)	Post-course (n, %)	*p*-values within group		
G-spot augmentasyon	2 (6.1)	12 (36)	0.006	1 (2.5)	20 (50)	<0.001 0.001	0.44	0.24
Hyaluronic asid vulvar rejuvenation	9 (27)	15 (45)	0.003	2 (5)	21 (52.5)	<0.001 0.001	0.008	0.54
Vulvar lipo-filling	6 (18.2)	12 (36.4)	0.03	1 (2.5)	10 (25)	0.004	0.02	0.29
Laser whitening	12 (36.4)	21 (63.6)	0.004	5 (12.5)	21 (52.5)	<0.001 0.001	0.01	0.33
Laser vaginal tightening	15 (45.5)	21 (63.6)	0.03	6 (15)	20 (50)	<0.001 0.001	0.004	0.24

n: number

Table 3. Adaptiaon and aplication of cosmetic genital surgeries

Variables	Cadaveric model (n=33)			Live surgery model (n=40)			*p*-values pre-course between groups	*p*-values post-course between groups
	Pre-course (n, %)	Post-course (n, %)	*p*-values within group	Pre-course (n, %)	Post-course (n, %)	*p*-values within group		
Labia minora reduction	30 (90.9)	33 (100)	0.9	27 (67.5)	33 (82.5)	0.03	0.01	0.01
Labia majora plasty	15 (45.5)	24 (72.7)	0.004	4 (10)	22 (55)	<0.001 0.001	0.001	0.11
Hudoplasty	15 (45.5)	15 (45.5)	1	7 (17.5)	20 (50)	<0.001 0.001	0.01	0.69
Surgical vaginal tightening	33 (100)	33 (100)	1	27 (67.5)	33 (82.5)	0.03	<0.001	0.01
Episiotomy scar revision	30 (90)	33 (100)	0.9	23 (57.5)	33 (82.5)	0.006	0.001	0.29
Perineal body repair	18 (54.5)	24 (72.7)	0.03	14 (35)	22 (55)	0.008	0.09	0.11
Anterior compartment repair	33 (100)	33 (100)	1	40 (100)	40 (100)	1	1	1
Posterior compartment repair	33 (100)	33 (100)	1	40 (100)	40 (100)	1	1	1

n: number

be accomplished by using cadavers. Many advances in female genital cosmetic surgery were transferred to trainees in this course. A noteworthy result of our study shows trainees in both groups were performing basic procedures like anterior and posterior compartment repair before the course however application of specific procedures like labia major plasty, clitoral hood plasty and perineal body repair increases over 50% after the course. This showed cadaver courses and more importantly live surgeries are effective in improving surgical skills besides indicating the lack of experience involving FGCS gained in residency trainings of obs/gyn specialists. Therefore, showed that cadaver courses and live surgeries accompanied by experienced instructors should be incorporated into regular residency training.

One of the basic issues that a surgeon should learn is management of complications. Cadaver courses could imitate complications by simulations and allows trainee to gain experience and improve skills safely. Mismanagement of any possible complications in genital cosmetic surgery may lead a surgeon to lose his confidence ensuing avoidance of performing surgeries of similar types. In our courses, possible complications and their managements were explained to trainees on cadaver courses that increased their professional confidence. Multidisciplinary participation in live surgeries and exclusive training also contributed to increased awareness of complications in trainees.

Practical cadaver courses should be incorporated into residency and post-residency educations to obtain surgical skills experience and professional confidence before applying procedures on real patients. Anastakis et al.[10] described cadaver models as gold standard for technical skills training. Cadaver model provides a safe environment to trainees to make mistakes and practice procedures. Cadaver courses could be useful for a wide spectrum of surgeons from a junior resident to an experienced surgeon that practices new techniques. In this study we evaluated surgical skills of trainees before and 6-month after the course, besides the effects of cadaver training models and live surgeries on training of female genital cosmetic procedures. We have the opportunity to demonstrate that our course increased professional confidence of trainees. Questionnaires indicated an increase in trainees' professional confidence and surgical skills by showing an increase in number of procedures performed 6 months after course.

Growing demand and popularity of FGCS warrants incorporation of surgical and non-invasive genital cosmetic procedures into routine residency training. In addition to this we expect fresh cadaver and live surgery courses to have favorable long-term effects on professional confidence and surgical skills of surgeons without adequate training and experience in genital cosmetic surgery.

ETHICS

Ethics Committee Approval: Since this is a cadaver study, approval by an ethics committee was not required.

Informed Consent: Informed consents were obtained from each patient.

Peer-review: Externally peer-reviewed.

Contributions

Concept: B.A., Y.C., A.E.K., E.Ç.; Desgin: B.A., Y.C., A.E.K., E.Ç.; Data Collection and/or Processing: Y.C.; Analysis and/or Interpretation: A.E.K.; Project Development: E.Ç.; Writing: B.A., E.Ç.

DISCLOSURES

Conflict of Interest: No conflict of interest was declared by the authors.

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Is a softly knitted polypropylene tape a better choice than a laser cut polypropylene tape for the treatment of female urinary stress incontinence?

Yanina TROZKY HEFETZ[1], Menahem NEUMAN[2], Jacob BORNSTEIN[3]

[1]Bar Ilan University Medical School of Medicine, Safed, Israel
[2]Department of Urogynecology Ben Gurion University, Beersheba, Israel
[3]Department of Obstetrics and Gynecology, Bar Ilan University Galilee Medical Center and Faculty of Medicine, Safed, Israel

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ABSTRACT

Objectives: Urinary stress incontinence (USI) is a discomforting condition that negatively affects the quality of life of many female individuals and frequently treated by surgical intervention. The incontinence curative operations revolutionized at 1995, with the introduction of the first retro-pubic sub-mid urethral synthetic slings, intra-vaginal sling-plasty (IVS) and tension free vaginal tape (TVT), by Ulmsten and Petros. This was later proposed to be done trans-obturator (TOT), for avoiding operative bladder injuries such as perforation (5.5% were attributed to the older technique and 0.3% to TOT) according to Cochrane review in 2009. Among other peri-operative untoward outcomes attributed to the commonly used anti-incontinence TOT are the dyspareunia, thigh and groin pain. This current study aims to compare TVT-Abbrevo procedure (12 cm polypropylene laser cut tape) to Serasis procedure (softly knitted monofilament non-absorbable polypropylene) for the cure of USI. The purpose of this study is to evaluate the feasibility, the safety, the cure rate, and postoperative pain of both procedures, as well as digital ability to palpate the implanted tapes and on physical examination. We assume that production of pain during palpation of the tape might predict dyspareunia in our patients.

Materials and Methods: This is a two arm, prospective and randomized comparative study. Ninety-nine women were recruited for the study and followed for one year after the surgery. Data was collected from the patient's medical charts and, in addition, the patients were interviewed by using three different questionnaires [Pain Questionnaire (Pain Q), Urinary Distress Inventory - Short Form (UDI-6), Incontinence Impact Questionnaire - Short Form (IIQ-7)] at different time intervals. In addition, physical examinations were performed before and after the operations.

Results: Cure rates at three months and one-year post surgery were similar between both groups based on questionnaires and physical exams. A trend of higher palpation score was documented with TVT-Abbrevo group vs. Serasis group (5.6% vs. 0.0%, p=NS) one-year post surgery. Replies to the pain questionnaire showed no significant difference between the two groups. Surgery characteristics-needle passing in the tissue was more difficult in Serasis group (23.4% vs. 0.0%, p=NS) than in TVT- Abbrevo group, however, blood loss was more prominent in TVT-

Address for Correspondence: Menahem Neuman, Department of Urogynecology Ben Gurion University, Beersheba, Israel
E-mail: menahem.neuman@gmail.com **ORCID ID:** orcid.org/0000-0003-0934-4240
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Abbrevo group (1- sided *p*-value 0.046). One procedure failed in TVT-Abbrevo and Serasis groups meaning inadequate improvement, leakage persisted one year after the surgery.

Conclusion: Based on the results, Serasis softly knitted polypropylene tape might be a better choice than TVT-Abbrevo laser cut polypropylene for the treatment of female USI due to less unfavorable outcomes.

Keywords: Serasis; TVT-Abbrevo; USI; pain; groin; thigh; dyspareunia; safety

Introduction

The International Uro-gynecological Association (IUGA) and International Continence Society (ICS) defined urinary stress incontinence (USI) as urine loss condition with sudden pressure on the bladder or urethra during effort, physical exertion such as sports activities, or while sneezing or coughing.[1] USI is not a life-threatening condition, yet, if left untreated, it might have a significant negative impact on quality of life of many patients. According to epidemiologic studies woman's age, multi-parity and menopausal status are all risk factors for USI.[1,2] Treatment options offer changes in life style, and nonsurgical modalities such as pelvic floor muscle training which can be useful in mitigating discomforting symptoms. However, upon failure of conservative treatment, surgery will be recommended for women who are unsuccessful in coping with USI.[3]

Intravaginal sling-plasty retro-pubic surgical procedure was reported by Ulf Ulmsten and Peter Petrous at 1995 for treating urinary stress incontinence[4]. Soon after, a study was done on this new procedure now called TVT, which was concluded to be a safe and an efficient ambulatory procedure.[4-6] This led to a major change with the uro-gynecologic operation preferences, that was previously based mainly on open retro-pubic operations. Trans-obturator sub mid urethral tape procedures (TOT) for treating female urinary stress incontinence were reported thereafter, first by Delorme,[7] then by De Leval.[8] The TOT procedures were designed in order to minimize the incidence of urinary tract injuries, urinary outlet obstruction, bowl penetration and intra-operative bleeding.[9,10] The TOT procedures' efficacy was claimed to be non-inferior to the TVT, therefore became greatly adopted by uro-gynecologists world-wide.[9] The proximity of the TOT needle to the obturator vessels and nerves, might explain the incidental post-operative thigh pain.[10]

Despite the fact that TOT is reported to have a low complication rates, there are still complaints on post-operative thigh and groin pain as well as dyspareunia.[11] A study on a mini TVT, using a single incision sling that does not pass through the obturator membrane, found reduced post-operative pelvic and thigh pain, yet many surgeons are reluctant to use mini TVT implants because of the expected reduced cure rates. Dyspareunia, occurred with TVT, TOT and mini TVT procedures causing concern with sexually active patients.[11] Thigh and groin pains are complications caused by trans-obturator passage of the sling close to the obturator nerve. The typical TOT post-operative pain is at the thigh, uni or bilateral, yet it was described even at the lumbar spine or hip regions. This might have been due to patient's hips position during operation, but more likely to intra-operative obturator nerve injury or post-operative neuralgia, due to a direct pressure or tape foreign body reaction.[9] Jean de Leval, Alexandre Thomas and David Waltregny proposed a modified TOT[9], the TVT-Abbrevo (Ethicon J&J Somerville, NJ, USA). The polypropylene tape's length was reduced to 12 cm. The TVT-Abbrevo was developed in order to avoid extensive tape trans-obturator traumatic passage, thus reducing the amount of mesh in the aponeurotic tissues, and this way to reduce the postoperative pain in the thigh and groin areas.[9] The post TVT Obturator thigh pain might be due to nerve injury or compression, or might it be due to irritation of the adductor muscle components. Anyhow, this thigh pain was shown to be significantly reduced with the Flam modification.11

Their results showed that the group that underwent modified TVT-Abbrevo procedure experienced less pain on day 0 than the TVT-Obturator group but not thereafter.[9,12] In addition to thigh and groin pain, Sue Ross, in his clinical study was concerned to find that a significant number of women in TOT group (80%) had a palpable polypropylene tape at vaginal examination one year after the surgery vs. TVT group (27%).[13] These findings are rather concerning because risk factors for unfavorable outcomes of tape surgeries such as dyspareunia, erosions are not completely understood.[13,14]

The Serasis (Serag-Wiessner, Naila, Germany) is composed of soft knitted sling implant, potentially able to reduce the occurrence and severity of post-operative pain. The ratio is that the tape softness will reduce tissue trauma when the tape is introduced through the obturator plat and maybe less fibrotic tissue reaction as well. There are no comparative studies performed on effectiveness of Serasis tape implantation as an anti-USI procedure, neither a comparison to other polypropylene tapes.

In this prospective study we compared the Serasis to the TVT-Abbrevo, for the treatment of USI. Firstly, we evaluated feasibility, the safety and the effectiveness of both procedures including the post-operative immediate and long-term pain levels as well as the dyspareunia developed after the insertion of the devices.

Secondly, we evaluated differences in the ability to palpate the Serasis and TVT-Abbrevo tapes and possibly produce local pain at vaginal examination in both groups one-year post surgery. We focused our attention on rigidity of the Serasis tape, a soft knitted sling, versus the common polypropylene tape, which is provided with the TVT-Abbrevo. Previous studies showed that the TVT-Abbrevo caused less immediate post-operative thigh and groin pain. There was no pain found in the long term.[12,15] This current study hypothesis is that being gently knitted, the Serasis tape, would be superior to the TVT-Abbrevo tape, in terms of post-operative pain levels and severity. We think that Serasis might be an effective solution for the above stated post-operative complications due to its softer monofilament non-absorbable polypropylene tape.

We presumed that the objective and subjective cure rates may be around 85% in Serasis group and in TVT-Abbrevo group. Early postoperative pain levels, caused probably by operative trauma, will be the same in Serasis and TVT-Abbrevo groups of patients. Finally, the long term post-operative pain levels, dyspareunia and ability to palpate the implanted tape at vaginal examination will be reduced with the Serasis patients' group in comparison to the TVT-Abbrevo groups of patients. The significance of this study is that the effectiveness, immediate and long term post-operative outcomes and vaginal tape palpability and exposure can improve the choice of the tape.

MATERIALS AND METHODS

Study Design

This is a two arm, prospective and randomized comparative study.

The enrolled patients were given detailed, explanation regarding the study. Patients signed an informed consent and got randomized onto one of the two study groups, to have either Serasis or TVT-Abbrevo.

The operations were performed under general anesthesia and the patients were discharged 8 hours after surgery.

The operations were performed according with previously medially deviated trans-obturator needle passage. The TVT-Obturator Flam which is a medial deviation of the de-Leval surgical needle pass. The needle is inserted perpendicularly through the medial section of the structures.[15]

Data such as history of health was extracted from patient's medical folders that were created by the researchers for this particular study, collected on interviews by using three questionnaires [Pain Questionnaire (Pain Q), Urinary Distress Inventory - Short Form (UDI-6), Incontinence Impact Questionnaire - Short Form (IIQ-7)] and physical exams.

Validation of the urogenital distress inventory (UDI-6) and incontinence impact questionnaire (IIQ-7) standardized questionnaires that are composed of multiple-choice questions ordered based on the severity of the condition. For example, UDI 6- Frequent urination? 0- not at all, 1- a little bit, 2- moderately, 3- greatly.

Chronbach's Alpha was calculated 1 month and 3 months after the surgery for both questionnaires. UDI-6=0.628, IIQ-7=0.802 and UDI-6=0.535 and IIQ-7=0.879. Pain questionnaire was written by the researchers. Chronbach's Alpha was calculated for pain questionnaire before release from the hospital 0.734 and after the release 0.665.

Study's detailed steps:

Pre-operation: interview + physical exam + (Pain Q, UDI-6, IIQ-7).

Intra-operative estimate of feasibility and safety: needle passage ease and adjustment using (modified visual analog scale (VAS) system: 0- not at all, 1- slightly, 2- moderately, 3- greatly), estimate blood loss (cc).

Before discharge from the hospital: chart data download, interview + physical exam+ pain questionnaire.

Early postoperative follow up: interview and a pain questionnaire by telephone on the 1st post-operative day.

1 month follow up: interview + physical exam + Pain Q, UDI-6, IIQ-7 questionnaires, palpability score was determined at physical exam.

3 months follow up: interviewed by telephone + Pain Q, UDI-6, IIQ-7 questionnaires

12 months follow up: interview + Pain Q, UDI-6, IIQ-7 questionnaires, physical exam including objective palpability score determination.

Data was collected, reviewed and investigated by the researchers.

Subjects

Inclusion criteria: Women suffering from urinary incontinence during physical exertion proved by clinical examination such as supine cough stress test. This study enrolled 99 patients, 52 women to TVT-Abbrevo group and 47 to the Serasis group. Sample size was calculated according to the difference in pain levels between women in TVT-Abbreveo and Sersis groups. The difference of 50% in pain levels between the two groups was considered as a significant difference (for example, 1.2±2 on 0 to 3 scale, 3=great pain).[15] Based on the Independent sample t-test, 2-sided hypothesis, 5% significance for approximately 40 patients in each group, the power is 96%. With intention to use a parametric test as Mann–Whitney according to the A.R.E rule, it is required at least 46 patients in each group to achieve the same

power of 96%. The sample size analysis was calculated with the IBM SamplePower software (Endicott, New York, United States), version 1.2.

The exclusion criterion:

Women younger than 30 and older than 80 years old.

Women who had previous surgical procedures involving the pelvic floor, either for the treatment of USI or for pelvic organ prolapse (POP).

Women who suffered from advanced POP [POP-Quantification System (POP-Q) stage more than 2].

Patients who had absent or incomplete medical records regarding their history of health.

Women who refused to participate with the study.

Women who were not able to give informed consent or participate with this randomized research study for any other reason.

Variables

Demographic data was collected such as age, background illness, etc.

Preoperative/intraoperative/postoperative data collection: medical records created by the researchers for this particular study which included health background, demographic data and personal information such as contact numbers, and other relevant information. Questionnaires on quality of life (IIQ-7), urogenital distress (UDI-6) and sexual functioning, surgical procedure that was undertaken, clinical postoperative analysis, pain levels and other intra and post-operative complications were evaluated using VAS.

Pain location, severity, onset and duration were determined at thorough examination by the main researcher. The ability to identify the implant upon digital vaginal palpation (VAS)-zero "not at all" palpable and three "greatly/very" palpable.

The primary outcome measures were the cure or failure of the operation, as well as any adverse effects such as dyspareunia or pain. This was based upon interview and questionnaires. The second outcome measure was the ability to palpate on the polypropylene tape at vaginal examination.

Statistical Analysis

Quantitative data is presented using mean and standard deviation, median and ranges, while qualitative data is presented using frequencies and percentages. Comparison of quantity data between the groups was examined by comparisons tests: Independent sample t-test or Mann–Whitney U test (if the normality assumption was violated). Qualitative data was compared among/between groups using chi-square test or Fisher's exact test (if expectancy <5). Changes over time were examined. Quantity data was compared by Wilcoxon signed ranks test, as appropriate. Ordinal data was compared by Freidman test (comparison test of a rank variable between different time points. Sometimes it is also used for the purpose of comparing quantitative data between different time points when the assumptions that are required for parameter tests in this case do not exist.) or Wilcoxon signed ranks test.

Estimation of feasibility and safety of the procedures: blood loss (cc)-estimated clinically by the main surgeon based on his experience and judgment, needle passage ease (VAS) – 0 to 3. Zero meaning "not at all" difficult and three meaning "greatly/very" difficult was estimated by the main surgeon based on experience of how much force needed to be applied in order to pass a needle through the tissue.

Estimation of pain level at: intercourse, vaginal examination, and of constant pelvic, thigh and groin pain follow up 1 month, 3 months and 12 months after the surgery (VAS).

Estimation of tape palpability: 1 month and 12 months using (VAS).

Estimation of cure rate: cure-no leakage at all, failure-inadequate improvement, leakage remained one year after the surgery. Recurrence; completely dry, based on questionnaires; physical exams.

Ethical Aspects

Following the protocol for performing clinical human research, this MD Thesis was approved by board of Helsinki on 03.02.2016 and extended on 23.07.2017, 0141-15-NHR. NIH registration code: NCT02867748.

RESULTS

A total of 99 women were recruited to the study. Forty-eight women were lost during the 12 months follow up due to personal issues such as new personal or family member's health problems, changing home location and not being able to make to the doctor's office, lack of commitment to the study. Eight out of 51 women left were interviewed by phone only at 12 months follow up and did not visit at doctor's office. Forty-three women completed 12 months follow up including visits at physician's office.

Ninety-nine women were randomly assigned into two groups. Fifty-two women in TVT-Abbrevo group and Forty-seven in Serasis group. Data based on demographic information showed no significant difference between the two groups ($p>0.05$) (Table 1).

Table 1. Preoperative information

Demographic data		TVT-ABB (n=52)	Serasis (n=47)	*p*-value (2-sided)
Age	Mean (SD)	54.8 (13.7)	51.7 (10.1)	0.178*
BMI	Mean (SD)	27.7 (3.07)	26.8 (2.8)	0.106*
Duration of urinary incontinence	Median (range)	2 (0.16–30)	2 (0.16–15)	0.979**
Parity	median (range)	3 (1–6)	3 (0–6)	0.901**

*Independent Sample T-test; **Mann–Whitney U test; TVT: tension free vaginal tape; ABB: Abbrevo; BMI: Body Mass Index; SD: standard deviation; n: number

Data collected for blood loss during surgery, difficulty passing a needle during surgical procedures, and additional necessary procedures such as anterior and posterior colporraphy showed no difference between the two groups ($p>0.05$) (Table 2). Blood loss category during surgery showed significant difference between the groups for 1 tailed *p*-value calculation ($p=0.042$) but not for 2-tailed.

Based on a raw data we noticed that passing a needle in the Serasis group appeared to be more difficult than in TVT-Abbrevo group. It got "2"-moderate as opposed to "0"-not difficult at all as defined in methods section.

On a visit to physician's office before the surgery, physical examination was performed to estimate the degree of incontinence, posterior, anterior and uterine prolapses (meaning the degree of uterine complete/incomplete descend into the vaginal cavity). Patients were followed for one year after the surgery and physical examination was performed and recorded using VAS grading system at 1st, 3rd and 12th months as mentioned before. Percentage of improved cases was calculated and compared between TVT-Abbrevo and Serasis groups. Improvement is considered a reduction by one in the grading system (Table 3). Friedman test was used to show significant statistical improvement (*p*-value <0.001) over time for each group with an exception of few cases. Urinary stress incontinence category score was" 2"– moderate on a grading scale 12 months after the surgery for few patients in both groups. Finally, Fisher's exact test and Pearson chi square test were used to calculate p-value which showed no significant difference between the two groups.

Pain questionnaire was administered before and after discharge from the hospital, 1, 3 and 12 months after the surgery (Tables 4a-g). The following data shows total number of patients and their pain scale choices based on VAS grading system. There was no significant difference in pain levels between the two groups based on calculated Pearson chi-square, Mann-Whitney U test and Fisher's exact test (*p*-value> 0.05). Friedman test was calculated for each group and showed significant statistical improvement overtime in pain scale (*p*-value<0.05).

Palpation of TVT-Abbrevo and Serasis tapes on physical exam were performed at doctor's office at the discharge from the hospital, and then during follow up visits at 1 month and 12 months. Improvement in palpation showed reduction by one in the grading system (VAS). Friedman test was used to show significant

Table 2. Surgery characteristics

Variables		TVT-ABB (n=52)	Serasis (n=47)	*p*-value
Blood loss (cc)	Median (range)	47.5 (10–180)	40 (10–160)	0.092 (2-sided)** 0.046 (1-sided)**
Difficulty passing a needle (VAS system)	0	10 (19.2%)	13 (27.7%)	0.29**
	1	42 (80.8%)	23 (48.9%)	
	2	0 (0.0%)	11 (23.4%)	
Additional procedures				1.00***
	Without additional	22 (42.3%)	20 (42.6%)	
	Procedures	-	-	
	Posterior colporrhaphy	1 (1.9%)	0 (0.0%)	
	Anterior and posterior	29 (55.8%)	27 (57.4%)	
	colporrhaphy	-	-	

**Mann–Whitney U test; ***Fisher's exact test; TVT: tension free vaginal tape; ABB: abbrevo; VAS: Visual Analogue Scale; n: number

improvement in palpation for each group over the year (*p*-value <0.001). Based on Mann–Whitney U test (*p*-value >0.05) there was no significant difference between the two groups. In TVT-Abbrevo group at 12 months physical exam two patients received higher palpation scores as opposed to Serasis group (Table 5).

In order to estimate the degree of improvement of USI and quality of life as defined in the methods section for each group, the mean was calculated for each questionnaire, UDI-6 and IIQ-7. A decrease in mean (answers for each question in the questionnaire summed and mean calculated), at one and three months is shown in (Table 6) indicating improvement. A slight increase in mean is seen at 12 months, which was due to the fact that few patients suffered from urinary urgency at the time of filling out UDI-6 and IIQ-7 standardized questionnaires. Patients presenting with urinary urgency were further evaluated before choosing a proper treatment. Based on patient's condition treatment consisted either of antibiotic drugs for UTI, anticholinergic drugs for overactive bladder, or other behavioral strategies until resolution of urinary incontinence symptoms. *P*-value is showed in (Table 7).

Questionnaires comparison by timeline for TVT-Abbrevo and Serasis groups showed that there was a significant improvement in USI cure rate and overall quality of life 12 months after the surgery for each group. Answers for each question in the questionnaires UDI-6, IIQ-7 were summed, results summarized, and *p*-value was calculated.

Table 3. Physical examination timeline

		Timeline							
		0		1		3		12	
Variable	Score	TVT-ABB	Serasis	TVT-ABB	Serasis	TVT-ABB	Serasis	TVT-ABB	Serasis
Urinary stress incontinence	0	0 (0.0%)	0 (0.0%)	52 (100%)	46 (97.9%)	52 (100%)	47 (100%)	16 (88.9%)	24 (96.0%)
	1	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)	1 (5.6%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.6%)	1 (4.0%)
	3	52 (100%)	47 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Anterior prolapse	0	20 (38.5%)	13 (27.7%)	51 (98.1%)	44 (93.6%)	51 (98.1%)	47 (100%)	17 (94.4%)	25 (100%)
	1	3 (5.8%)	7 (14.9%)	1 (1.9%)	3 (6.4%)	1 (1.9%)	0 (0.0%)	1 (5.6%)	0 (0.0%)
	2	24 (46.2%)	24 (51.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	3	5 (9.6%)	3 (6.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Posterior prolapse	0	19 (36.5%)	14 (29.8%)	51 (98.1%)	44 (93.6%)	51 (98.1%)	47 (100%)	18 (100%)	25 (100%)
	1	3 (5.8%)	9 (19.1%)	1 (1.9%)	3 (6.4%)	1 (1.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	2	26 (50.0%)	21 (44.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	3	4 (7.7%)	3 (6.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Uterine prolapse	0	37 (71.2%)	30 (63.8%)	49 (94.2%)	40 (85.1%)	52(100%)	47 (100%)	18(100%)	25 (100%)
	1	14 (26.9%)	17 (36.2%)	3 (5.8%)	7 (14.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	3	1 (1.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

TVT: tension free vaginal tape; ABB: abbrevo

Table 4a. Groin pain

Pain scale	TVT-ABB				Serasis			
	0	1	2	3	0	1	2	3
Before release from the hospital	39 (75.0%)	10 (19.2%)	3 (5.8%)	0 (0.0%)	39 (83.0%)	7 (14.9%)	1 (2.1%)	0 (0.0%)
After release from the hospital	47 (90.4%)	5 (9.6%)	0 (0.0%)	0 (0.0%)	45 (95.7%)	2 (4.3%)	0 (0.0%)	0 (0.0%)
1 month follow-up	52 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	47 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
3 months follow-up	52 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	47 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
12 months follow-up	22 (95.7%)	1 (4.3%)	0 (0.0%)	0 (0.0%)	27 (96.4%)	0 (0.0%)	0 (0.0%)	1 (3.6%)

TVT: tension free vaginal tape; ABB: abbrevo

Table 4b. Vaginal pain at intercourse

Pain scale	TVT-ABB				Serasis			
	0	1	2	3	0	1	2	3
Before release from the hospital	-	-	-	-	-	-	-	-
After release from the hospital	-	-	-	-	-	-	-	-
1 month follow-up	50 (98.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	44 (95.7%)	2 (4.3%)	0 (0.0%)	0 (0.0%)
3 months follow-up	51 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	47 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
12 months follow-up	22 (95.7%)	0 (0.0%)	1 (4.3%)	0 (0.0%)	27 (96.4%)	0 (0.0%)	0 (0.0%)	1 (3.6%)

TVT: tension free vaginal tape; ABB: abbrevo

Table 4c. Vaginal pain

Pain scale	TVT- ABB				Serasis			
	0	1	2	3	0	1	2	3
Before release from the hospital	8 (15.4%)	31 (59.6%)	13 (25.0%)	0 (0.0%)	7 (14.9%)	32 (68.1%)	8 (17.0%)	0 (0.0%)
After release from the hospital	20 (38.5%)	27 (51.9%)	5 (9.6%)	0 (0.0%)	26 (55.3%)	19 (40.4%)	2 (4.3%)	0 (0.0%)
1 month follow-up	51 (98.1%)	1 (1.9%)	0 (0.0%)	0 (0.0%)	47 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
3 months follow-up	52 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	47 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
12 months follow-up	23 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	27 (96.4%)	0 (0.0%)	0 (0.0%)	1 (3.6%)

TVT: tension free vaginal tape; ABB: abbrevo

Table 4d. Pelvis pain

Pain scale	TVT-ABB				Serasis			
	0	1	2	3	0	1	2	3
Before release from the hospital	24 (46.2%)	20 (38.5%)	8 (15.4%)	0 (0.0%)	21 (44.7%)	22 (46.8%)	4 (8.5%)	0 (0.0%)
After release from the hospital	36 (69.2%)	13 (25.0%)	3 (5.8%)	0 (0.0%)	36 (76.6%)	9 (19.1%)	0 (0.0%)	0 (0.0%)
1 month follow-up	52 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	46 (97.9%)	0 (0.0%)	1 (2.1%)	0 (0.0%)
3 months follow-up	52 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	45 (95.7%)	1 (2.1%)	1 (2.1%)	0 (0.0%)
12 months follow-up	23 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	28 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

TVT: tension free vaginal tape; ABB: abbrevo

Table 4e. Thigh pain

Pain scale	TVT- ABB				Serasis			
	0	1	2	3	0	1	2	3
Before release from the hospital	37 (71.2%)	9 (17.3%)	6 (11.5%)	0 (0.0%)	34 (72.3%)	12 (25.5%)	1 (2.1%)	0 (0.0%)
After release from the hospital	40 (76.9%)	12 (23.1%)	0 (0.0%)	0 (0.0%)	41 (87.2%)	6 (12.8%)	0 (0.0%)	0 (0.0%)
1 month follow up	52 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	46 (97.9%)	1 (2.1%)	0 (0.0%)	0 (0.0%)
3 months follow up	52 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	46 (97.9%)	1 (2.1%)	0 (0.0%)	0 (0.0%)
12 months follow up	23 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	27 (96.4%)	1 (2.1%)	0 (0.0%)	0 (0.0%)

TVT: tension free vaginal tape; ABB: abbrevo

Table 4f. Radiating pain

Pain scale	TVT-ABB				Serasis			
	0	1	2	3	0	1	2	3
Before release from the hospital	40 (76.9%)	9 (17.3%)	3 (5.8%)	0 (0.0%)	43 (91.5%)	4 (8.5%)	0 (0.0%)	0 (0.0%)
After release from the hospital	47 (90.4%)	5 (9.6%)	0 (0.0%)	0 (0.0%)	44 (93.6%)	3 (6.4%)	0 (0.0%)	0 (0.0%)
1 month follow-up	51 (98.1%)	0 (0.0%)	1 (1.9%)	0 (0.0%)	47 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
3 months follow-up	52 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	46 (97.9%)	0 (0.0%)	1 (2.1%)	0 (0.0%)
12 months follow-up	23 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	28 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

TVT: tension free vaginal tape; ABB: abbrevo

Table 4g. Coital pain (partner)

Pain scale	TVT-ABB				Serasis			
	0	1	2	3	0	1	2	3
Before release from the hospital	-	-	-	-	-	-	-	-
After release from the hospital	-	-	-	-	-	-	-	-
1 month follow-up	51 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	47 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
3 months follow-up	51 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	47 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
12 months follow-up	23 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	28 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

TVT: tension free vaginal tape; ABB: abbrevo

Table 5. Palpation of a tape on physical exam

Palpation score								
Timeline	TVT-ABB				Serasis			
	0	1	2	3	0	1	2	3
Before release from the hospital	0 (0.0%)	0 (0.0%)	0 (0.0%)	52 (100%)	0 (0.0%)	0 (0.0%)	1 (2.1%)	46 (97.9%)
1 months follow-up	16 (30.8%)	33 (63.5%)	3 (5.8%)	0 (0.0%)	36 (76.6%)	11 (23.4%)	0 (0.0%)	0 (0.0%)
12 months follow-up	11 (61.1%)	5 (27.8%)	1 (5.6%)	1 (5.6%)	23 (92.0%)	2 (8.0%)	0 (0.0%)	0 (0.0%)

TVT: tension free vaginal tape; ABB: abbrevo

Table 6. Improvement analysis for each group based on UDI-6 and IIQ-7 questionnaires

	TVT-ABB					Serasis				
Questionnaire	n	Mean	SD	Median	Min-max	n	Mean	SD	Median	Min-max
UDI-6 before surgery	52	0.98	0.4	1	0.5–2.0	47	0.84	0.31	0.83	0.5–1.67
UDI-6 1 month follow-up	52	0.18	0.2	0	0–0.67	47	0.09	0.18	0	0–0.67
UDI-6 3 months follow-up	52	0.18	0.2	0	0–0.67	47	0.14	0.24	0	0–0.67
UDI-6 12 months follow-up	23	0.63	0.6	0.5	0–2.50	28	0.39	0.47	0.25	0–1.5
IIQ-7 before surgery	52	2.12	0.6	2.1	0.86–3.00	47	1.99	0.59	2.15	0.43–3.0
IIQ-7 1 month follow-up	52	0.17	0.4	0	0–1.71	47	0.03	0.13	0	0–0.86
IIQ-7 3 months follow-up	52	0.11	0.3	0	0–1.00	47	0.05	0.15	0	0–0.86
IIQ-7 12 months follow-up	23	0.37	0.6	0.1	0–2.43	28	0.19	0.31	0	0–1.0

UDI-6: Urinary Distress Inventory - Short Form; IIQ-7: Incontinence Impact Questionnaire - Short Form; TVT: tension free vaginal tape; ABB: abbrevo; SD: standard deviation; min: minimum; max: maximum; n: number

We calculated *p*-value for UDI-6, IIQ-7 questionnaires before the surgery and 12 months after the surgery for both groups in order to assess the improvement of USI over time for both groups. Both groups showed neither significant difference before the surgery, nor 12 months post -surgery meaning that the improvement of USI was equal for both groups, *p*-value (2-sided=NS) (Table 8).

Additional information (Table 9) - one erosion and one failure in TVT-Abbrevo group and one failure in Serasis group overall. Erosion means that the tape extruded into the vaginal cavity or other adjacent tissue/organ and was palpable on the physical exam 12 months after the surgery. Cure rate evaluated based on the questionnaires and physical exam 12 months after the surgery. Only 43 women were physically examined at 12 months after the surgery. The rest answered questionnaires.

Table 7. Statistical difference between the questionnaires at different timeline points in each group

Questionnaire comparison by timeline	TVT-ABB &*p*-value	Serasis &*p*-value
UDI-6 before surgery vs.1 month	<0.001	<0.001
UDI-6 1month vs. 3 months	1	0.245
UDI-6 3 months vs. 12 months	0.001	0.007
UDI-6 before surgery vs. 12 months	0.039	0.004
IIQ-7 before surgery vs. 1 month	<0.001	<0.001
IIQ-7 1 month vs. 3 months	0.561	0.266
IIQ-7 3 months vs. 12 months	0.027	0.058 (2-sided)
		0.029 (1-sided)
IIQ-7 before surgery vs. 12 months	<0.001	<0.001

&Wilcoxon signed ranked test; UDI-6: Urinary Distress Inventory - Short Form; IIQ-7: Incontinence Impact Questionnaire - Short Form; TVT: tension free vaginal tape; ABB: abbrevo; SD: standard deviation; min: minimum; max: maximum; n: number

DISCUSSION

It has already been discussed that TVT-Abbrevo was developed to reduce post-operative thigh and groin pain and has the same efficacy as TVT-Obturator tape in treatment of USI.[15,16] Based on recent randomized trial conducted by Zullo et al.[16] efficacy, safety and complications were analyzed prospectively for 3 years and showed 87% percent cure rate in TVT-Abbrevo as in TVT-Obturator group. Significant difference was noted between the groups in postoperative pain. In TVT-Abbrevo group only one patient reported postoperative groin pain vs. nine patients in TVT-Obturator group.[16]

In our prospective randomized study, we followed patients for one year and evaluated the cure rate and pain side effects by comparing between two groups: one using TVT-Abbrevo and the other- Serasis tapes for treatment of USI. The cure rate after one year was 96% in Serasis group vs. 88.9% in TVT-Abbrevo group. There was no significant difference in postoperative pain between the two groups. Vaginal pain at intercourse, vaginal and groin pain was given a higher score in 3.6% of patients in Serasis group one-year post surgery. Palpability score of the tape at 12 months follow up was high in TVT-Abbrevo group for (5.6%) of patients including one complication-erosion into the vaginal cavity.

Pre-operative information such as age, BMI, duration of urinary incontinence and parity showed no significant difference between TVT-Abbrevo and Serasis groups, *p*-value >0.05. Background illnesses were not presented in the results chapter, however, there was no significant difference between the two groups as well. Conditions such as hypertension, diabetes mellitus, hypothyroidism and asthma were the common ones among our patients.

Blood loss in TVT-Abbrevo and Serasis showed no significant difference based on 2-sided *p*-value=0.092, however, 1-sided

Table 8. Statistical comparison between questionnaires for TVT-Abbrevo and Serasis groups before the surgery and 12 months after the surgery

		n	Mean	SD	*p-value (2-sided)	*p-value (1-sided)
UDI-6 before surgery	ABB-TVT	52	0.96	0.40	0.098	0.049
	Serasis	47	0.84	0.31		
IIQ-7 before surgery	ABB-TVT	52	2.12	0.59	0.301	
	Serasis	47	1.99	0.59		
UDI-6 12 months after the surgery	ABB-TVT	23	0.63	0.61	0.106	0.053
	Serasis	28	0.39	0.47		
IIQ-7 12 months after the surgery	ABB-TVT	23	0.38	0.62	0.205	
	Serasis	28	0.19	0.31		

*Independent sample t-test; UDI-6: Urinary Distress Inventory - Short Form; IIQ-7: Incontinence Impact Questionnaire - Short Form; TVT: tension free vaginal tape; ABB: abbrevo; SD: standard deviation; n: number

Table 9. Additional information		
Variables	**TVT-ABB (n=52)**	**Serasis (n=47)**
Erosion	1 (1.9%)	0 (0.0%)
Failure	1 (1.9%)	1 (2.1%)
	TVT-ABB (n=18)	**Serasis (n=25)**
Completely dry	16 (88.9%)	24 (96.0%)
TVT: tension free vaginal tape; ABB: abbrevo; n: number		

p-value=0.046 showed significant difference between the two groups. In TVT-Abbrevo median blood loss was 47.5 vs. 40 in Serasis group. Difficulty passing a needle showed no significant difference between the two groups *p*-value >0.05, however, in Serasis group we see higher difficulty score in (23.4%) of patients vs. (0.0%) in TVT-Abbrevo group. This difference could be attributed to the technique used while passing Serasis tape through the tissue and its attachment. In addition, anterior and posterior colporrhaphy was performed in both groups during the surgery for USI and there was no significant difference between the two groups, *p*-value >0.05.

On physical examination before the surgery, 1,3 and 12 months later we objectively evaluated USI improvement/cure, posterior, anterior prolapse and uterine prolapse using our grading system. Each group showed significant statistical improvement over the year on physical examination, *p*-value <0.001. USI evaluation was performed by supine cough stress test and results showed 96.0% cure rate in Serasis group vs. 88.9% in TVT-Abbrevo group 12 months after the surgery. One and three months after the surgery results showed 97% cure rate of USI or higher for both groups. Higher cure rate (96%) in Serasis group could be explained by the fact that the sample size after 12 months was significantly smaller than that of the previous months since half of the patients were lost to follow one year after the surgery. Therefore, a larger sample of patients is still needed in order decide whether there is a significant difference in cure rate between the TVT-Abbrevo and Serasis groups.

The rest of the categories showed equal results for both groups. No anterior, posterior or uterine prolapses were identified in both groups 12 months after the surgery.

Post-operating immediate and long-term pain was evaluated based on pain questionnaire and both groups did not show any significant difference in pain levels immediately after the surgery or 12 months after the surgery, *p*-value >0.05. There was a significant improvement in pain overtime for each group *p*-value <0.05. However, few patients (3.6%) in Serasis group reported significant vaginal, vaginal pain at intercourse and groin pain at one year follow up vs TVT-Abbrevo group. This slight difference could as well be attributed to a small sample of patients at 12th months follow up, other anatomical, physiological or psychological factors.

We evaluated the ability to palpate the Serasis and TVT-Abbrevo tapes one-year post-surgery. In TVT-Abbrevo as in Serasis group high palpation score was given right after the surgery and before release from the hospital with no significant difference between the two groups as expected. We showed an improvement in palpation score one-year post-surgery for each group, *p*-value <0.001. At 12th months follow up, in TVT-Abbrevo group (5.6%) of patients were given high palpation scores and included one erosion of the polypropylene tape into the vaginal cavity. Palpation scores were low in Serasis group 12 months post-surgery.

These results made us believe that Serasis, a soft knitted and less rigid tape, might result in more favorable outcomes in a long term, less dyspareunia or erosions. Further research is needed to evaluate the ability to palpate, produce local pain with the Serasis tape on a larger sample of patients.

Improvement/cure of USI was evaluated objectively as mentioned before and subjectively based on UDI-6 and IIQ-7 questionnaires before the surgery 1, 3 and 12 months after the surgery. Mean was calculated for each questionnaire and analyzed. A decrease in mean was noted at 1st and 3rd months after the surgery as we expected meaning that there was a significant improvement of USI in both TVT-Abbrevo and Serasis groups (p<0.05). Slight increase in mean was noted 12 months after the surgery and was attributed to urinary urgency that was reported by several patients. Those patients were treated for urinary urgency and the problem resolved. They did not repeat the questionnaires since then.

Overall, two procedures failed in TVT-Abbrevo group and one in Serasis group. Erosion of a tape in TVT-Abbrevo group into the vaginal cavity is a serious complication that we attribute to the stiffness of the tape.

CONCLUSION

This study shows that Serasis tape is as effective as TVT-Abbrevo tape for treatment USI. The soft nature of Serasis tape, however, did not alleviate completely postoperative pain such as vaginal or groin pain 12 months after the surgery in few patients, and needs a further research on a larger sample of patients. Cure rate based on physical exam and questionnaires was the same in both groups. Palpation scores were higher in TVT-Abbrevo group one-year post surgery as we expected. We attribute it to the stiffness of the tape that might have also led to the erosion of the TVT-Abbrevo tape into the vaginal cavity in one patient. Stiffness

could be one of the causes in addition to the age of a patient, background illnesses, BMI, etc. This needs further investigation in order to make correct selection of patients and to choose the best tape to use in order to reduce post-operative complications and increase effectiveness in a long term. Erosion complication was not observed in Serasis group one year after the surgery. Further research is needed on a larger sample of patients in order to conclude that Serasis has low rate of serious complications such as erosion/exposure of the tape into the vaginal cavity. Overall satisfaction of quality of life one year after the surgery was equal for both groups based on statistical analysis of questionnaires.

ETHICS

Ethics Committee Approval: This Medical degree thesis was approved by board of Helsinki on 03.02.2016 and extended on 23.07.2017, 0141-15-NHR. NIH registration code NCT02867748.

Informed Consent: Informed consents were obtained from the patients.

Peer-review: Externally peer-reviewed.

Contributions

Concept: Y.T.H., M.N., J.B.; Design: Y.T.H., M.N., J.B.; Data Collection or Processing: Y.T.H., M.N., J.B.; Analysis or Interpretation: Y.T.H., M.N., J.B.; Literature Search: Y.T.H., M.N., J.B.; Writing: Y.T.H., M.N., J.B.

DISCLOSURES

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The effect of surgical plication of uterosacral ligament to rectovaginal fascia on lower urinary tract symptoms in patients with posteroapical compartment defect

İsmail GÖKBEL[1], Deniz AKIN GÖKBEL[2], Mehmet Ferdi KINCI[2], Burak SEZGİN[2], Ahmet Akın SİVASLIOĞLU[2]

[1]Department of Obstetrics and Gynecology, Menteşe State Hospital, Muğla, Turkey
[2]Department of Obstetrics and Gynecology, Muğla Sıtkı Koçman University Training and Research Hospital, Muğla, Turkey

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ABSTRACT

Objectives: A competent rectovaginal fascia (RVF) and uterosacral ligaments (USL) are required to provide active and passive structural support to rectum and vagina. We aimed to reveal the effect of the anatomical improvement provided by plication surgery of RVF to USLs on the lower urinary tract symptoms (LUTS) in the posteroapical compartment defect.

Materials and Methods: This prospective study was carried out with patients who applied to the Urogynecology Polyclinic of Muğla Sıtkı Koçman University, Department of Obstetrics and Gynecology between August 2018 and March 2020. Patients with POP stage >1 and posteroapical compartment defects were included in the study. In the preoperative and postoperative periods (3rd, 6th, and 12th months), the lower urinary system symptoms of the patients were questioned and the Pelvic Organ Prolapse Quantification (POP-Q) scoring system was evaluated and were compared.

Results: Of the patients included in the study, 42 (82.35%) were multiparous, 7 (13.72%) were primiparous, and 2 (3.92%) were nulliparous. Statistically significant improvements were observed in lower urinary symptoms in the postoperative 3rd, 6th, and 12th month controls ($p<0.05$), while there were significant improvements in Aa, Ba, C, D, Ap, Bp, Pb, and TVL scores in the postoperative period ($p<0.05$).

Conclusion: Based on the results of this native tissue surgery; the suturing of RVF to USLs for posteroapical compartment defect seems an effective surgical intervention with satisfactory anatomical and symptomatic outcomes.

Keywords: Native tissue repair; posteroapical prolapse; rectovaginal fascia; uterosacral ligament; vaginal surgery

Address for Correspondence: İsmail Gökbel, Department of Obstetrics and Gynecology, Menteşe State Hospital, Muğla, Turkey
E-mail: drismailgokbel48@gmail.com **ORCID ID:** orcid.org/0000-0002-6034-8987
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INTRODUCTION

The etiology of pelvic organ prolapsus (POP) is multifactorial. Known risk factors for the disease include pregnancy, childbirth, congenital or acquired connective tissue abnormalities, pelvic floor denervation or weakness, aging, hysterectomy, menopause, and factors associated with chronically increased intra-abdominal pressure.[1-4]

Women with prolapsus often have a variety of pelvic floor symptoms, and only some of these symptoms are directly related to the prolapsus. Generalized prolapse symptoms include a feeling of drooping from the vagina, a lump or protrusion and a dragging discomfort or pain inside the vagina. Symptoms of bladder, bowel or sexual dysfunction are often present. Women may need to use their fingers to assist defecation or micturition.[5]

Treatment of women with pelvic organ prolapse directly depends on the severity of the symptoms, the woman's general health, and the surgeon's preferences and technical capacity. Available options for treatment include conservative, mechanical and surgical interventions.

A competent perineal body and uterosacral ligaments (USLs) are required to provide active and passive anatomical support to rectum and vagina.[6] The rectovaginal fascia (RVF) attaches to the USLs and cervical ring above, to the Arcus Tendineus Fascia Pelvis below, and the perineal body most distally, ensuring the anatomical integrity of the posterior compartment. Traditionally, it has been believed that posterior vaginal compartment prolapsus was largely due to defects in the RVF.[7] However, this condition, which can also be defined as an isolated rectocele, is very rare. In the vast majority of cases, herniation of both the rectum and the small intestine from the apex of the vagina to the vagina is seen as a result of the detachment of the RVF from the USL/cervical ring (rectoenterocele).[8] Rarely, the RVF breaks off from the perineal body, in which case the RVF must be surgically reattached to the perineal body.[9]

The intensity of symptoms caused by this anatomical physiopathology, which is also defined as a posteroapical compartment defect, is the tip of the iceberg. The current study aims to reveal the effect of anatomical improvement on the lower urinary tract symptoms (LUTS) provided by plication surgery of RVF to USL in posteroapical compartment defect.

MATERIALS AND METHODS

This prospective case-control study was approved by the local ethics committee for clinical research of Muğla Sıtkı Koçman University, Faculty of Medicine, Muğla, Turkey (approval no and date: 13/VII, August 8, 2018). Between August 2018 and March 2020, data from patients who underwent surgical plication of USL to RVF for posteroapical pelvic organ prolapsus (POP-Q stage >1) in our urogynecology clinic were analyzed. The necessary information was obtained from the hospital database and patient files.

The inclusion criteria are as follows: negative stress test and isolated posteroapical compartment defect. The exclusion criteria are as follows: positive stress test, presence of anterior compartment defect, history of previous pelvic floor surgery and pregnancy.

During this period, we performed 51 surgical plications of USL to RVF operation for posteroapical prolapsus by one surgeon with advanced urogynecology experience (AAS). The records of the preoperative and 3rd, 6th, and 12th month postoperative POP-Q stages were also recorded from patient files. The preoperative and 6th, and 12th month postoperative POP-Q stages were compared and analyzed.

Urogynecological patient evaluation forms were used in the diagnosis, treatment, and follow-up processes of the patients. In the anamnesis, the LUTS of the patients before and after surgery were questioned. Pre- and post-surgical LUTS were evaluated for recovery, the persistence of complaints, and de-novo occurrence. All patients had urogynecologic examination and POP-Q scoring. The follow-ups of the patients were carried out by the same physicians. The LUTS which were questioned are as follows: vaginal winding, urgency, frequency, abnormal emptying, nocturia, pelvic pain, fecal incontinence.

Description of the RVF-USL plication technique

The patients were prepared for the operation in the lithotomy position under sterile conditions under general or spinal anesthesia. In cases with a posteroapical compartment defect, the decision about where to make the incision was made according to one of the following:

In cases with posteroapical compartment defects, the index and middle fingers in sterile gloves were advanced from the posterior fornix to the distal vagina. The line where the vaginal rugae started was determined, and the vaginal mucosa was cut superficially with a scalpel no. 11, approximately 3 cm in the transverse plane.

In the patient with a posteroapical compartment defect, the index and middle fingers in sterile gloves were advanced from the posterior fornix to the distal vagina. In cases, whose vaginal rugae were lost, the posterior wall of the vagina was compressed between the index and thumb and palpated while the fingers were advanced. The tissue condensation line in the vaginal mucosa, formed by the shrinkage of the RVF detached from the

USL, was cut superficially with the scalpel no: 11 approximately 3 cm in the transverse plane.

The porous tissue under the part of the incision line facing the apex of the vagina was dissected with Metzenbaum scissors from the mucosa of the posterior wall of the vagina, and the extraperitoneal parts where the right and left USLs meet with the cervix were reached. The vaginal mucosa on the side of the incision line facing the vaginal entrance was resected by sharp dissection from the RVF. The approximately 0.5 cm wide RVF was exposed along the incision line. Using a non-absorbable polyester (Ethibond®) 2/0 suture, the suture needle was first inserted into the right USL and then exited from the ipsilateral part of the RVF. The same process was repeated on the left side. The sutures were tied and the RVF was suspended to the right and left USL. Bleeding was controlled. Then, the vaginal mucosa was closed by continuous suturing with synthetic absorbable polyglactin 910 (Vicryl rapid®) suture 2/0 on the repaired RVF. One roll of tampon was placed in the vagina. The cases were mobilized at the 8th postoperative hour. On the first postoperative day, the bladder catheter and the rolled tampon placed in the vagina were removed.

Postoperative patient follow-up

In the first postoperative week, the patients were evaluated in terms of general health status, wound healing, and possible early surgical complications. In the postoperative 3rd, 6th, and 12th month controls of the patients, both lower urinary tract symptoms (constipation, vaginal winding, urgency, frequency, abnormal urination, dysuria, pelvic pain, fecal incontinence, and defecation difficulty) were observed and the POP-Q scoring was also done. The symptoms and POP-Q scores of the patients were noted.

Statistical analysis

Statistical analyses were performed using the Statistical Package for the Social Sciences software Version 25 (SPSS, Inc., Chicago, IL). The data were expressed as the mean ± standart deviation. Changes in preoperative and postoperative LUTS and POP-Q scores were made using the dependent variable analysis method and the Wilcoxon Signed-Rank test. A statistically significant P value was set at ≤ 0.05.

RESULTS

The demographic characteristics of the patients included in the study are summarized in Table 1. Of the patients, 42 (82.35%) were multiparous, 7 (13.72%) were primiparous, and 2 (3.92%) were nulliparous. All of the patients who gave birth had a history of normal delivery, while 21 (41.18%) had a history of difficult delivery. The mean age of the patients was 51.86±13.69 years. The number of smokers was 14 (27.45%). The mean body mass index of the patients was 26.4±2.7 kg/m² and 28 (54.9%) cases were in the postmenopausal period.

The evaluation of the preoperative and postoperative POP-Q measurements of the patients is summarized in Table 2. According to these data, the postoperative recovery rate in Aa, Ba, C, D, Ap, Bp, Pb values in the postoperative controls of the patients was statistically significant ($p<0.05$). In addition, there was no statistically significant difference in genital hiatus (GH) and total vaginal length (TVL) compared to preoperative measurements.

The comparison of the preoperative and postoperative LUTS of the patients is given in Table 3. According to these data, the postoperative recovery rate was statistically significant in the patients' complaints of vaginal winding, urgency, frequency, abnormal emptying, nocturia, pelvic pain, and fecal incontinence in postoperative symptom inquiries ($p<0.05$). It was determined that these symptoms of the patients, which were detected in the preoperative period, were significantly regressed in the postoperative 12th month follow ups (Figure 1). Indeed, in the 3rd month follow up of the patients, significant improvements in LUTS are remarkable. The highest level of improvement in vaginal winding, urgency, frequency and nocturia complaints was detected at the sixth month controls of the patients. However, the highest level of improvement in fecal incontinence, abnormal emptying and pelvic pain complaints was detected at the third month review of the patients. After remarkable improvement

Table 1. Demographic and clinic characteristics of the patients

Characteristics	Total patients (n=51)
Age (years)	51.86±13.69
BMI (kg/m²)	26.4±2.7
Gravity	
Multiparous	42 (82.35%)
Primiparous	7 (13.72%)
Nulliparous	2 (3.92%)
Menopausal status	
Postmenopausal	28 (54.9%)
Premenopausal	23 (55.1%)
History of vaginal delivery	51 (100%)
Traumatic vaginal delivery	21 (41.18%)
Smoking	
Yes	14 (27.45%)
No	37 (72.55%)

BMI: Body Mass Index; n: number

Table 2. Preoperative and postoperative POP-Q measurements in RVF-USL patients (n=51)

		Aa	Ba	C	D	Ap	Bp	Gh	Pb	TVL
Pre	Mean (SD)	-0.93 (1.36)	-1.10 (1.75)	-4.17 (2.07)	-6.03 (2.38)	1.10 (0.88)	1.47 (1.01)	4.60 (1.19)	2.43 (0.86)	9.03 (1.22)
	Median	-0.50	-1.00	-5.00	-7.00	1.00	1.00	4.50	2.00	9.00
	Range	5	8	9	9	4	5	4	4	6
	Mean rank	3.17	3.05	2.88	2.82	3.93	3.95	2.32	2.92	2.55
Postop 3	Mean (SD)	-2.00 (1.53)	-2.03 (1.69)	-4.90 (1.69)	-6.70 (1.98)	-2.47 (1.04)	-2.47 (1.04)	4.87 (0.86)	2.13 (0.68)	9.13 (1.19)
	Median	-2.50	-3.00	-5.00	-7.00	-3.00	-3.00	5.00	2.00	9.00
	Range	7	8	10	9	4	4	4	4	7
	Mean rank	2.35	2.38	2.17	2.13	1.97	1.95	2.58	2.38	2.75
Postop 6	Mean (SD)	-2.27 (1.70)	-2.30 (1.70)	-4.63 (1.75)	-6.43 (2.01)	-2.63 (0.96)	-2.60 (1.04)	4.83 (0.91)	2.07 (0.52)	8.93 (1.11)
	Median	-3.00	-3.00	-5.00	-7.00	-3.00	-3.00	5.00	2.00	9.00
	Range	8	8	9	9	4	4	4	2	6
	Mean rank	1.95	1.98	2.48	2.60	1.73	1.77	2.52	2.38	2.35
Postop 12	Mean (SD)	-1.47 (1.96)	-1.50 (1.98)	-4.67 (1.89)	-6.43 (2.21)	-1.80 (1.58)	-1.90 (1.54)	4.87 (0.89)	2.03 (0.49)	8.93 (1.20)
	Median	-2.00	-2.00	-5.00	-7.00	-2.50	-3.00	5.00	2.00	9.00
	Range	8	8	10	10	5	5	4	2	6
	Mean rank	2.53	2.58	2.47	2.45	2.37	2.33	2.58	2.32	2.35
Pre - Postop 3 - Postop 6 - Postop 12	Chi-square	20.39	17.7	16.68	16.48	70.98	73.25	4.16	18.09	5.82
	p-value	<0.001	0.001	0.001	0.001	<0.001	<0.001	0.245	<0.001	0.121

*Statistically significant difference. Friedman's test ($\chi 2=17.43$; $p<0.05$); ¥value that makes a difference between Pre, POP-Q3, POP-Q6 and POP-Q12 values.
POP-Q: Pelvic Organ Prolapse Quantification, SD: standard deviation, TVL: total vaginal length, Gh: genital hiatus, Pb: perineal body, Postop: postoperative (month); Pre: preoperative (month); RVF: rectovaginal fascia; USL: uterosacral ligaments; n: number

in all symptoms, a non-statistical increase in the symptoms of frequency, abnormal emptying, nocturia and pelvic pain was observed at the patients' 12th month follow-up. However, the improvements in the symptoms of vaginal winding, urgency and fecal incontinence were stable at 12th month follow-up.

DISCUSSION

RVF was first described in 1969.[10] Richardson drew attention to the importance of this structure, which was not considered in surgical treatment for many years, in 1993.[11] Subsequent studies focused on repairing only the defected area of this fascia and on transverse repair.[12]

Colporraphy posterior (CP) is the most commonly used surgical method in the posterior compartment defects. In the study by Karram and Maher[13], the anatomic success rate was 83% and the dyspareunia rate was 18% after the CP operation. As a result of Abendstein et al.'s[6] study, it was concluded that vaginal mucosal repair did not contribute to the support mechanism of PB and USL. For levatorplasty, which is a method frequently added to this operation, the anatomical success was 76%–96%, while dyspareunia was found up to 50% according to the results of various studies.[13,14]

In the current study, the native tissue of women has been used for the surgical treatment of the posteroapical compartment defect. Patients with posteroapical compartment defects have several symptoms that affect their quality of life, especially the urgency and nocturia. These symptoms are the main reasons why these patients apply to the hospital. Therefore, it is very important to recover these symptoms, as well as anatomical improvement after surgery. In the study by Kilic et al.[15], it was stated that women with posterior POP should be carefully examined not only for anorectal or bulging symptoms but also for LUTS.

LUTS assessment was also performed for patients in the current study, as recommended in the relevant study. In this study, besides the anatomical improvement, symptomatological improvement was also obtained with the surgery applied to the patients. It was seen that these symptoms, which were detected in the preoperative period of the patients, were significantly regressed in the postoperative 12th month controls. Moreover, the abrupt onset of the cessation of the LUTS is noteworthy. This is compatible with the idea mentioning that the repair of distorted pelvic anatomy would lead to a symptom free state.

According to the Integral Theory; LUTS such as urgency, nocturia, abnormal emptying, frequency, low abdominal pain and deep dyspareunia arise due to laxity in the USL and clinically this symptom complex has been defined as Posterior Fornix syndrome by Petros and Ulmsten[16].

It should also be mentioned that the patterns of graphics show that none of the symptoms would be worsened in the longer term.

This study shows that the native tissue surgery performed in the posteroapical compartment has very good results regarding anatomical healing as well as LUTS.

A limitation of this study is the number of patients. There are very few studies on this subject in the literature. In order to generalize the data of this study, there is a need for large-scale studies with a larger number of patients in different centers and by different surgeons.

Figure 1. Bayesian Network output nodes (top row) predicting the likelihood of defects in the anterior (a), middle (m), or posterior (p) zones, or a diagnosis of tethered vagina syndrome (t). Intermediate diagnosis and test, and patient questions and clinical test nodes are as shown.

Table 3. Preoperative and postoperative lower urinary tract symptoms in RVF-USL patients (n=51)

		Constipation	Vaginal winding	Urgency	Frequency	Abnormal emptying	Nocturia	Dysuria	Pelvic pain	Fecal incontinence	Difficult defecation
Preoperative	Mean (SD)	1.93 (0.25)	1.80 (0.41)	1.60 (0.49)	1.23 (0.43)	1.73 (0.45)	1.37 (0.49)	1.83 (0.38)	1.83 (0.38)	1.90 (0.31)	1.93 (0.25)
	Median	2.00	2.00	2.00	1.00	2.00	1.00	2.00	2.00	2.00	2.00
	Range	1	1	1	1	1	1	1	1	1	1
	Mean rank	2.42	2.22	1.98	1.47	2.12	1.70	2.32	2.32	2.35	2.40
Postoperative 3rd month	Mean (SD)	1.97 (0.18)	1.97 (0.18)	1.90 (0.31)	1.87 (0.35)	2.00 (0.0)	1.90 (0.31)	1.97 (0.18)	1.97 (0.18)	2.00 (0.0)	2.00 (0.0)
	Median	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00
	Range	1	1	1	1	0	1	1	1	0	0
	Mean rank	2.42	2.55	2.58	2.73	2.65	2.77	2.58	2.58	2.55	2.53
Postoperative 6th month	Mean (SD)	2.00 (0.0)	2.00 (0.0)	1.97 (0.18)	2.00 (0.0)	2.00 (0.0)	1.97 (0.18)	1.97 (0.18)	1.97 (0.18)	2.00 (0.0)	2.00 (0.0)
	Median	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00
	Range	0	0	1	0	0	1	1	1	0	0
	Mean rank	2.55	2.62	2.72	3.00	2.65	2.90	2.58	2.58	2.55	2.53
Postoperative 12th month	Mean (SD)	2.00 (0.0)	2.00 (0.0)	1.97 (0.18)	1.90 (0.31)	1.97 (0.18)	1.83 (0.38)	1.93 (0.25)	1.93 (0.25)	2.00 (0.0)	2.00 (0.0)
	Median	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00
	Range	0	0	1	1	1	1	1	1	0	0
	Mean rank	2.55	2.62	2.72	2.80	2.58	2.63	2.52	2.52	2.55	2.53
Preoperative - Postoperative 3rd month - Postoperative 6th month - Postoperative 12th month	Chi-square	4.71	15.63	23.09	50.62	21.48	36.36	9.92	9.92	9.00	16.68
	p-value	0.194	**0.001**	**<0.001**	**<0.001**	**<0.001**	**<0.001**	**0.019**	**0.019**	**0.029**	0.112

Significant *p*-values are shown in bold.
*Statistically significant difference. Friedman's test (χ^2=17.43; p<0.05).
POP-Q: Pelvic Organ Prolapse Quantification, SD: standard deviation, RVF: rectovaginal fascia; USL: uterosacral ligaments; n: number

CONCLUSION

Based on the results of this native tissue surgery; the suturing of RVF to USLs for posteroapical compartment defect seems an effective surgical intervention with satisfactory anatomical and symptomatic outcomes.

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This study was originally conducted as a graduation thesis in obstetrics and gynecology.

ETHICS

Ethics Committee Approval: This prospective case-control study was approved by the local ethics committee for clinical research of Muğla Sıtkı Koçman University, Faculty of Medicine, Muğla, Turkey (approval no and date:13/VII, August 8, 2018).

Informed Consent: It was obtained.

Peer-review: Internally peer-reviewed.

Contributions

Concept: İ.G., D.A.G., B.S., A.A.S.; Design: İ.G., D.A.G., B.S., A.A.S.; Data Collection and/or Processing: İ.G., D.A.G., M.F.K; Analysis and/or Interpretation: İ.G., D.A.G., B.S., A.A.S.; Writing: İ.G., D.A.G., M.F.K., B.S., A.A.S.

DISCLOSURES

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Use of colpocleisis associated to rectopexy as an approach to concomitant apical prolapse and external rectal prolapse

Ana LEWIN[1], Ileana SÄNGER[1], Fabio LEIRO[2], Romina BIANCHI[3], Martina SANTILLAN ITURRES[4]

[1]Department of Female Pelvic Medicine and Reconstructive Surgery, Hospital General de Agudos J.M. Penna, Buenos Aires, Argentina
[2]Departament of Surgery, Hospital General de Agudos J. M. Penna, Buenos Aires, Argentina
[3]Section of Coloproctology, Hospital General de Agudos J.M. Penna, Buenos Aires, Argentina
[4]Faculty of Medicine, Buenos Aires University, Buenos Aires, Argentina

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ABSTRACT

Objectives: The primary objective is to describe the long-term anatomic and subjective outcomes in women undergoing obliterative surgery for the management of pelvic organ prolapse with rectopexy. The secondary objective is to describe the adverse perioperative events.

Methods: This is a retrospective cohort of women who underwent Le Fort colpocleisis with laparoscopic Protack rectopexy at a tertiary care center between 2013 and 2021. A composite outcome for recurrent pelvic organ prolapse and rectal prolapse was defined as subjective failure (vaginal or rectal prolapse symptoms), objective failure (prolapse to or beyond the hymen or full thickness rectal prolapse), or any retreatment for prolapse. Patient's subjective outcomes was recorded at baseline and in the last follow-up visit. Adverse perioperative events were defined a priori and collected up to 6 weeks after surgery.

Results: None of the patients presented recurrence of pelvic organ prolapse and only one presented a symptomatic recurrence of rectal prolapse, not externalized over the anal margin therefore did not require surgical treatment. All the patients improved their scores in the Pelvic Floor Impact Questionnaire – Short Form 20 (PFIQ-20) survey, finding occasional worsening of the symptoms associated with urinary incontinence and voiding urgency. Only one patient presented a minor postoperative complication, which did not require hospital admission.

Conclusion: Although good results were achieved with a low rate of recurrence, additional studies with larger number of patients are needed to confirm this findings.

Keywords: Apical prolapse; colpocleisis; pelvic organ prolapse; protack rectopexy; rectal prolapse

Address for Correspondence: Ana Lewin, Department of Female Pelvic Medicine and Reconstructive Surgery, Hospital General de Agudos J.M. Penna, Buenos Aires, Argentina
E-mail: dra.analewin@gmail.com **ORCID ID:** orcid.org/0000-0003-4432-4608
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INTRODUCTION

The simultaneous appearance of advanced prolapse of pelvic organs and rectal prolapse (RP), is observed in patients with severe damage of the pelvic floor. Even though they share the same pathophysiology, traditionally they have been treated as separate entities as they belong to different specialties. Their prevalence together is uncertain in the literature. It has been reported that 2% of women can present pelvic organ prolapse (POP) in stages III OR IV,[1] is less common the occurrence of rectal prolapse, estimated as 2.5 out of 100,000 people.[2]

Lately, pelvic floor specialists have opted for a multidisciplinary approach centered around the patient, establishing diverse strategies for the joint treatment of POP and RP, obtaining better surgical results and postoperative symptoms, referred to in the follow up consultations.

When choosing a synchronic treatment to treat POP and RP, the bibliography proposes correcting both defects through a single approach, abdominal or transperineal. There are many works that study the colposacropexy or the abdominal hysterosacrocolpopexy, which are considered the gold standard treatment for apical prolapse associated with rectopexy. The advantage of utilizing the same incision to perform both procedures with good postoperative results have been described when employing this method. Their joint use increases the risk of specific complications of the use of mesh, sacroiliitis, duration of the surgery and exposition to anaesthetic drugs. This may represent a problem to consider in patients with a frail state of health.

In elderly patients with comorbidities, the preference is for vaginal approach to correct apical defects, since the correction of prolapse through an abdominal route has three times higher risk than the vaginal route of producing venous thromboembolism.[3] When utilizing the vaginal route for correction in patients older than 80 years, the reconstructive surgery presents a higher risk of complications than the obliterative approach (24.7% vs. 17%).[4]

Ventral rectopexy is an abdominal technique that uses mesh for the treatment of RP. In the last few years, it has gained popularity since it avoids de novo incomplete bowel emptying and the surgical risk associated with complications of the anastomosis after colon resection.[5] Currently, a fixation technique to the sacral promontory has been developed through the use of a stapler with titanium helical fasteners, thus being able to complete the suspension avoiding the use of meshes.

Taking into account these considerations and evaluating the particular characteristics of the patients included in this study, we have come to the agreement jointly with the coloproctology service to perform in a single surgical act the protack abdominal rectopexy through a laparoscopy and a LeFort colpocleisis for the resolution of the concomitant presence of RP and POP. The primary objective of this study is to observe the long-term anatomic and subjective results and the secondary objective being to describe the adverse postoperative effects.

This is a retrospective observational study of cases report. For the recollection of them we have used the Hospital General de Agudos J. M. Penna Urogynecology service with the search criteria of the key words “obliterative surgery”, “colpocleisis”, “LeFort surgery” and selecting those results which also included the term “rectopexy”. This way, clinical histories of six patients who were operated in our institution between 2013 and 2021 were selected, in which the Urogynecology and Coloproctology were involved in the procedures.

In order to perform laparoscopic rectopexy, the patients were placed in Loyd Davies position and after pneumoperitoneum was done and trocars were placed, we proceeded to the desperitonization of mesosigma and opening of the peritoneal fold, liberating the superior rectum in all of its circumference. After this, both lateral sides of the rectosigmoid were fixed to the sacral promontory through the use of a stapler with titanium helical fasteners (ProTack™, Medtronic) using two tackers on each side. When a satisfactory hemostasis confirmed and with the reduction of the rectal prolapse, we continued with the vaginal approach, for which the patient was repositioned to a lithotomy with their extremities lower than 90º. When performing the LeFort colpocleisis two rectangular strips of vaginal mucosa were spun off, one anterior and one posterior and two lateral tunnels which allow the drainage of uterine or cervical secretions were created. The vaginal closing was done through the union of the vesicovaginal with the rectovaginal fascia with the rectovaginal and through suturing in various planes, concluding with a perineoplasty and high vulvar cleisis as reinforcement.

Adverse effects related to the surgery are defined as the ones which occurred during the surgery itself or within the first 30 postoperative days. According to the bibliography, the adverse effects include, damage of the neighboring organs (bladder, urethra, intestines), vascular lesion, hemorrhage greater than 500 cc, the need of transfusions, the need of conversion to a laparotomy, ileus, intestinal obstruction, pelvic abscess, surgical wound infection, sepsis, cardiorespiratory complications, deep vein thrombosis, pulmonary embolism, hospital readmission and surgical reintervention.

Recurrence of prolapse was defined according to anatomical and subjective criteria. When an apical descent that is over the

hymeneal line or an exteriorization of the rectal prolapse outside of the anal margin is produced, or in the face of the need of performing a new surgery for the correction of the prolapse or at the appareance of subjective discomforts due to the sensation of a foreign body in the vagina or rectum recurrence was diagnosed.

Before surgery, every patient completed the standardized Pelvic Floor Impact Questionnaire – Short Form 20 (PFIQ-20) survey to evaluate the presence of symptoms related to urinary and colorectal prolapse and their effect on the quality of life. All of them agreed to the publication of these case reports and signed an informed consent form.

We contacted five of these patients, since one passed away a few years before, and we supplied them with the same survey in order to evaluate their postoperative results.

CASE REPORT

Case 1: Eighty-five year-old patient, G5P4Ab1, with a history of arterial hypertension, left bundle branch blockage, frequent ventricular extrasystoles, mild chronic obstructive pulmonary desease and anal incontinence, with no desire to maintain coital function. The physical exam showed stage III pelvic organ prolapse (POP) (C+3), atonic anal sphincter and rectal prolapse 4 cm outside of the anal margin. It was decided to proceed with laparoscopic rectopexy and LeFort colpocleisis, each procedure lasting 100 and 40 minutes respectively. No intra or extra operative complications were registered. A follow up was done a year later and there were no signs of recurrence until the patient's death.

Case 2: Seventy year-old patient, G2P2, with a history of arterial hypertension, hypertensive stroke and anal incontinence, with no desire to maintain coital function. The physical exam showed stage IV POP (C+6) and rectal prolapse 6 cm outside of the anal margin. It was decided to proceed with laparoscopic rectopexy and LeFort colpocleisis, each procedure lasting 90 and 40 minutes respectively. No intra or extra operative complications were registered. After an eight-year follow up, no recurrence was evidenced.

Case 3: Eighty-two year-old patient, G3P3, with a history of ventricular arrhythmia, arterial hypertension, type II diabetes, anal incontinence and mixed urine incontinence, with no desire of maintaining coital function. The physical exam showed stage IV POP (C+7) and rectal prolapse 5 cm outside of the anal margin (Figure 1). It was decided to proceed with laparoscopic rectopexy and LeFort colpocleisis associated with the placement of a transobturator sling. Each procedure lasted 100 and 45 minutes respectively. No intra or extra operative complications were registered. After a six-year follow up, no recurrence was evidenced.

Case 4: Seventy year-old patient, G5P3C1Ab1, hypertensive, with a history of obstructive defecatory symptoms for which rehabilitation of the pelvic floor muscles has been indicated, a surgical history of a colpoperineoplasty done 28 years ago and a LeFort colpocleisis done three years ago, complicated by development of a perirectal abscess and perineal dehiscence. The patient was seen for vaginal prolapse, which extends to the hymeneal line, contained by fibrous bridge in the middle third portion, associated with rectal prolapse which protrudes 5 cm outside the anal margin. It was decided to proceed with laparoscopic rectopexy and LeFort colpocleisis, each procedure lasting 110 and 45 minutes respectively. No intra or extra operative complications were registered. After five-year follow up, chronic constipation, persistent atony of the external anal sphincter, intermittent appearance of rectal prolapse of 1 cm, not associated with others defecatory disorders, were evidenced. The coloproctology service indicated the continuation of rehabilitation of the pelvic floor musculature, which is still ongoing with symptomatic improvement.

Case 5: Seventy-two year-old patient, G6P5Ab1, with a history of chronic constipation, type II diabetes, COPD, smoker, with no desire of maintaining coital function, physical exam presents stage IV POP (C+5), a hypotonic anal sphincter and rectal prolapse of 9 cm outside the anal margin (Figure 2). It was decided to proceed with laparoscopic rectopexy and LeFort colpocleisis, each procedure lasting 80 and 45 minutes respectively. During the postoperative period, a skin infection above the abdominal incision was developed, which responded favorably to antibiotic treatment. After a four- year follow up, no recurrence was evidenced.

Figure 1. Genital prolapse stage IV C+7 and 5 cm rectal prolapse

Case 6: Seventy-three year-old patient, G4P4, with a history of Chagas disease, hidden urinary incontinence and anal incontinence, with no desire of maintaining coital function. Physical exam shows POP stage IV (C+5) and complete rectal prolapse with more than 15 cm of rectum exteriorization, which cannot be reduced in the office (Figure 3). Laparoscopic rectopexy and LeFort colpocleisis was done, completing each procedure in 60 minutes. No intra or extra operative complications were evidenced. It was decided to reevaluate urinary incontinence during post operation with an eventual placing of a trans-obturator vaginal tape (TOT) sling.

Results

Between 2013 and 2021, six rectopexies associated with obliterative surgery were done in our institution. All of the patients were symptomatic and presented stage II POP or higher, and with RP with 4 to 15 cm outside of the anal margin. One of these patients had been previously operated for POP on two separate occasions.

The average age of the patients was 75.5 years (70–85 years), all being multiparous and having 3 children (3–5 children) born on average, mostly through vaginal delivery. All patients had comorbidities, cardiovascular ones being the most common.

The average surgical time of the laparoscopic rectopexy was 90 minutes (60–110 minutes), 45 minutes (40–60 minutes) being employed for the obliterative surgery. Therefore, the average of the total surgical time when taking into account both procedures resulted in 135 minutes (120–155 minutes). One patient also received treatment for urinary incontinence with the tot sling procedure.

The average hospital stay was 2 days (1–3 days). As for the intra or postoperative complications, one case of skin infection on the access point of an abdominal trocar was encountered, with a positive response to antibiotic treatment. The hematic loss was low in all the cases, being lower than 100 cc, and no thromboembolic events were registered. No patient required rehospitalization due to postoperative complications.

The mean time of the follow up was 49 months (6–87 months). None of the patients presented recurrence of POP and only one of them presented symptomatic recurrence of rectal prolapse, not exteriorized outside of the anal margin and thus received rehabilitation with a positive response without requiring surgical treatment.

The PFIQ-20 survey results (Table 1), show the improvement in patients scores. In some patients, the worsening of symptoms associated with urinary incontinence and urinary urgency were registered, while the rest of the evaluated parameters show an improvement in all cases.

DISCUSSION

RP and POP share a common pathophysiology: advanced age, obesity, the chronic increase of abdominal pressure, constipation and a background of obstetric trauma and consequently a weakening of the pelvic floor and damage of the pudendal nerve, generating laxity on the structural support of the pelvic organs and debilitating the anal sphincter, predisposing the appearance of rectal prolapse.

Rectal prolapse is an infrequent condition which develops primarily in women, with rates of 6:1 in respect to men.[1] Rectal prolapse is classified as internal when intussusception of the descending colon or sigmoid within the inferior colonic segment and external when the rectum protrudes through the anus. This can be associated with symptoms such as the sensation of a foreign body in the rectum, difficulty during defecation, sensation of incomplete rectal evacuation and mucous secretion.

It has been reported that 9% to 27% of the patients with RP have concomitant appearance of POP. It is estimated that patients operated for RP have a relative risk of requiring surgery due to

Figure 2. Genital prolapse stage IV C+5 and 9 cm rectal prolapse

Table 1. Score of PFIQ-20 before and after the procedure		
	Basal PFIQ-20	**PFIQ-20 of last control**
Case 1	47	-
Case 2	39	10
Case 3	58	4
Case 4	24	4
Case 5	47	12
Case 6	52	12
PFIQ-20: Pelvic Floor Impact Questionnaire – Short Form 20		

uterine prolapse or of the vaginal walls, 3.1 and 3.2 respectively. Patients with RP are described to have a higher prevalence of urinary incontinence resulting in more severe symptoms than the general population. Only 45% of the patients mention this symptom to the colorectal surgeons during the RP evaluation.[7]

When treating patients with pelvic floor dysfunctions, it is important to carry out an integral and comprehensive approach, being those who present RP examined not only by colorectal surgeons but also by urologists or gynecologists specialized in pelvic floor dysfunctions. Kapoor et al.[8] found that the multidisciplinary approach associated with cost savings, improve postoperative recovery and increased patient satisfaction.

There are only a few studies that focus on the concomitant approach to genital prolapse of pelvic organs and rectal prolapse. In the available bibliography it is proposed the possibility of solving both by surgery through an abdominal approach (laparotomic or minimally invasive) or perform a transperineal approach for both pathologies, solving the rectal prolapse via Delorme or Altemeier techniques, and the vaginal via a reconstructive or obliterative surgery.

The decision on the approach will depend on the patient's comorbidities, surgical history, the patient's preference and negative to the employment of abdominal meshes, even though the choice is often influenced by the surgeon's experience without it being a truly correct criteria of selection.

Different studies address the results of associating surgical techniques such as rectopexy and colpopexy or hysterosacropexy, with the rate of complications being 25% in some of them.[5] Unger et al.[9] analyzed retrospectively 36 cases of women who had been concomitantly intervened by a sacrocolpopexy and a minimally invasive abdominal rectopexy, and found that the combination of both techniques increases the risk of requiring a transfusion (2.8%), development of abdomino-pelvic abscesses (11.1%) and osteomyelitis (5.6%). Weinberg et al.[10] considered that combining these procedures predisposes the body to a higher risk of superficial infection of the surgical site, organ or space infections, reopening of the wound and to urinary infections. Even though several of these studies consider that these adverse effects primarily occur at the expense of rectopexy, a large multicenter study which evaluated the results of laparoscopic rectopexy, determined that it is a safe technique. In the same study, the mortality rate of this surgery was 0.1%, the rate of complications unrelated to meshes was 11% and the rate of complications due to meshes was 2%, this last one being comparable to the rate in colposacropexies that utilize meshes.[11] In our study, the rate of complications was low and with a low impact on patients quality of life, without increasing morbimortality in any case.

Figure 3. A) Genital prolapse stage IV C and 15 cm rectal prolapse irreducible. **B)** Same patient six months after the operation

In elderly patients with comorbidities a transperineal approach is preferred for the treatment of RP and, in cases of minor prolapses than those described in our series of cases, anal encirclement is considered to be a technique with good long-term results.[12] Even laparoscopic approach is considered the gold standard,[13] while ventral rectopexy with mesh and rectopexy with sutures are the classic techniques. Patients with RP who present symptoms before surgery, anal incontinence and constipation, reach a higher grade of improvement after the ventral rectopexy,[14] a technique that gain popularity for avoiding *de novo* constipation generated by the extensive dissections and the lateral rectal stalk division.[5]

When conducting a systematic revision where both laparoscopic procedures are compared, Lobb et al.[14] found that the recurrence of RP is higher after a rectopexy with sutures, but this finding was not confirmed in the meta-analysis. Therefore, the rectopexy with sutures represents an alternative in which complications of mesh use are avoided, although it is postulated that it might not generate enough adherence to prevent recurrence and may cut the fixed tissue. Inspired by this technique, Karim et al.[15] were the first to describe a procedure free of mesh and sutures, that utilizes ProTackTM in order to execute the sacrum fixation.

Rectopexy with ProTackTM presents a high success rate. Karim et al.[15] in their series of 16 patients report a prolapse of the rectal mucosal and a total rectal prolapse 3 years after the procedure. Rectopexy with ProTackTM then results fast, safe, effective and possesses a low rate of recurrences, offering good functional results to patients usually treated through a transperineal approach.

Obliterative surgery for the treatment of POP is considered a minimally invasive technique and it represents an option of treatment for elderly patients, with comorbidities, a history of multiple abdominal interventions, with no desire of maintaining active vaginal coital function and for those who reject the use of mesh. This surgery possesses the advantage of being a fast technique with a low rate of complications, limited intraoperative blood loss, easy recovery, it also does not significantly alter body image, with a success rate higher than 90%.[4,16-18] The factors that determine the success of the surgery are, a postoperative anatomical change which determines a narrow genital hiatus of approximately 2.8 cm and total vaginal longitude of 4.5 cm or shorter.[19] Obliterative surgery provides improvement in the patients quality of life comparable to the improvements supplied by the vaginal reconstructive surgery.[18] In studies conducted by Barber et al.[20,21] the improvement of intestinal symptoms resulted similar to the improvements reported after prolapse reconstructive surgeries via abdominal and vaginal approach. In a study conducted by Gutman et al.[22] where intestinal symptoms, previous to the colpocleisis and a year after the procedure are compared, an improvement was found of all preexisting obstructive symptoms of colorrectal and anal discomfort, as well as in the majority of the symptoms of anal incontinence, with the exception of the incontinence of solid feces. Furthermore, in this study the development of symptoms of de novo intestinal discomfort was infrequent.[22] These findings coincide with the results obtained when comparing the items of quality of life of the PSIQ-20 survey before and after the combined surgical procedure. Although cases of *de novo* rectal prolapse appearance after performing a colpocleisis have been reported,[17,23-25] this fact might be associated with the severity of the initial pelvic floor damage in patients who received obliterative surgery, the simultaneous performance of the levator ani plication or some level of RP previous to the procedure that was not detected in the initial evaluation. Even then, its incidence is low and this phenomenon has not been studied in relation to the joint repair of RP and POP. In our series of cases only one event of rectal prolapse recurrence was found by associating LeFort colpocleisis and laparoscopic rectopexy. In this case, recurrence was intermittent and up to 1 cm, therefore it was decided to manage it through conservative treatment with pelvic floor rehabilitation and since it was not associated with any other colorectal symptoms, it has not required a surgical approach.

In regards to surgical times, as it has been shown in cases of patients with comorbidities and a high-risk clinical state, procedures will try to be time limited in order to reduce the risk. It is important to highlight that a sacrocolpopexy might take as much as twice the time that is required to complete a colpocleisis, more so if a laparoscopic approach is utilized (167 minutes vs. 60 minutes vs. 192 minutes, respectively).[26,27]

Laparoscopic rectopexy may require up to 171 minutes to complete and the association of techniques for the joint treatment of POP and RP may require approximately 240 minutes to complete both procedures via laparoscopy.[10]

In these cases, the resolution through combined laparoscopy for RP and an obliterative vaginal surgery for the treatment of POP was able to be done in 140 minutes (120–155 minutes), well below the usual required time in studies evaluating other approaches.

It can be concluded that the option of combining obliterative surgery with laparoscopic rectopexy complies with the desired criteria for the treatment of elderly patients and those with comorbidities since it presents a high rate in symptomatic improvement, with a low rate of recurrence which is maintained

long-term with a prolonged follow up period and through which it is possible to decrease surgical time and intra and postoperative complications.

The strengths of this study are the extensive follow-ups on and high rate of recruitment of operated patients. The limitations consist of the low number of cases and its design limitations.

As far as it is known this is the first study to evaluate the combination of an obliterative technique with a laparoscopic rectopexy for the concomitant approach of POP and RP. Even though good results have been achieved with a low rate of recurrence, more studies with a higher number of patients and randomization need to be done in order to confirm the findings of this work.

ETHICS

Informed Consent: Obtained.

Peer-review: Externally peer-reviewed.

Contributions

Concept: A.L., I.S., F.L., R.B., M.S.I.; Design: A.L., I.S., F.L., R.B., M.S.I.; Data Collection: A.L., I.S., F.L., R.B., M.S.I.; Analysis: A.L., I.S., F.L., R.B., M.S.I.; Literature Search: A.L., I.S., F.L., R.B., M.S.I.; Writing: A.L., I.S., F.L., R.B., M.S.I.

DISCLOSURES

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Post-prostatectomy incontinence in patients with adjuvant radiotherapy: is there a therapeutic space for transobturator sling?

Salvatore SIRACUSANO[1], Carolina D'ELIA[2], Federico ROMANTINI[1], Daniela FASANELLA[1]

[1]Department of Urology of Teramo, University of L'Aquila, Teramo, Italy
[2]Department of Urology of Bolzano, General Hospital, Bolzano, Italy

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ABSTRACT

Objectives: Stress urinary incontinence (SUI) is a common sequela in patients undergoing surgery for prostate cancer, ranging from 4% to 31% in patients treated with robot assisted radical prostatectomy (RARP), and from 7% to 40% in patients undergoing radical retropubic prostatectomy (RP).

At this moment, only poor-quality studies evaluated the surgical techniques proposed for these patients; moreover, a limited number of studies evaluated both adjustable and non-adjustable slings, but no randomized trials are available. Nevertheless, it's important to highlight, that patients at high risk of local recurrence after RP will undergo adjuvant radiotherapy (RT), increasing the risk of postoperative complications and failure, if surgically treated for SUI. In this context few studies analyzed the outcome of post-prostatectomy sling positioning in patients treated with radiotherapy.

The aim of this narrative review is to summarize current data regarding outcomes after sling placement in patients with history of radiotherapy.

Materials and Methods: Outcome definition and measures, design of the studies, follow-up, numerosity and the type of sling used (Argus, AdVance/XP, Invance) are still heterogeneous.

Due to different follow-up and the low number of patients it is difficult to compare data.

Results: The larger study was a prospective multicenter paper, evaluating the outcomes of the Argus-T Sling, and documenting a 61.2% success rate in patients undergoing radiotherapy, with a higher risk of sling removal and urethral erosion.

Conclusion: At present, due to the lack of large prospective studies it is impossible to draw definite conclusions.

Keywords: Radical prostatectomy; incontinence; sling; radiotherapy

Address for Correspondence: Salvatore Siracusano, Department of Urology of Teramo, University of L'Aquila, Teramo, Italy
E-mail: salvatore.siracusano@univaq.it **ORCID ID:** orcid.org/0000-0002-1709-9823
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INTRODUCTION

Stress urinary incontinence (SUI) is a common sequela in patients undergoing surgery for prostate cancer.

A systematic review focused on continence recovery after radical retropubic prostatectomy (RP) documented that incontinence rates at 12 months vary from 4% to 31% in patients treated with robot assisted radical prostatectomy (RARP),[1] and from 7% to 40% in patients who underwent RP.[2]

Unfortunately, incontinence represents an important burden for this kind of patients, with a significative influence on their quality of life.[3]

At this moment, there are no randomized trials comparing non-invasive and surgical therapies in male patients affected by SUI, and only poor-quality studies evaluated the several surgical techniques proposed for these patients.

A limited number of studies evaluated both adjustable and non-adjustable slings, but no randomized trials are available.

Argus adjustable system is a silicone device that makes it possible to regulate the tension of the bulbar sling, simply by tightening or releasing two silicone rings, with good results in terms of post operative continence, ranging from 92% to 100% in patients with mild incontinence.[4-6]

Nevertheless, it is important to highlight, that patients at high risk of local recurrence after RP will undergo adjuvant radiotherapy, increasing the risk of post operative complications and failure, if surgically treated with artificial urinary sphincter (AUS) for SUI.[7]

At present, only a few studies have evaluated the outcome of post-prostatectomy sling positioning in patients treated with radiotherapy.

The aim of our study was to evaluate the results of transobturator sling treatment in patients undergoing radical prostatectomy with adjuvant radiotherapy.

MATERIALS AND METHODS

On January 2021 the PubMed database was searched using a combination of the following key words: ("radiotherapy") AND ("male sling" OR "male slings") AND ("urinary incontinence" OR "enuresis") AND ("urinary sling" OR "urinary slings" OR "urethral sling" OR "urethral slings" OR "midurethral sling" OR "midurethral slings" OR "suburethral sling" OR "suburethral slings" OR "transobturator sling" OR "transobturator slings").

We included all human research articles published in the last 15 years; case reports, reviews, editorial comments or letters to the editor were not included in our narrative review.

We sought also references arising from review articles.

The first search retrieved 85 articles.

The two authors reviewed the records separately and disagreements were resolved by consensus by both authors.

Advance™ and AvanceXP™ and radiotherapy

Several studies with various designs evaluated the outcome of Advance or Advance XP positioning in patients undergoing radiotherapy (Table 1).

The AdVance sling (Boston Scientific, formerly AMS, Marlborough, MA, USA) was introduced in 2006 by Rehder and Gozzi[8] and is a retro-urethral tape positioned with a transobturator approach.

The rationale of this technique consists in a relocation of the proximal urethra in the pelvic floor, but without compression.

The AdvanceXP™ is an updated version of the AdVance, with increased sling arm length and an updated helical tunnelling needle shape.[9]

Thirteen studies evaluated the outcome of AdVance/AdVance in radiotherapy patients treated for post prostatectomy incontinence.

The majority of studies presented a prospective design,[10-16] and only one was a randomized study.[15]

All seven papers followed the patients for at least 13 months (range: 13–52 months) and the number of radiotreated patient included ranges from 3[14] to 24[12].

Only two studies evaluated a cohort composed only by irradiated patients[12,17] and reported conflicting results.

The first prospective study was conducted in 2009 by Cornu et al.[10] on 17 irradiated patients, hypothesing an association between radiation and failure of the procedure (p=0.039) and with 59% of cured/improved patients; these results were confirmed after one year, with a longer follow up, on 23 patients with a history of radiotherapy.[11]

Moreover, in a prospective study conducted on 24 (100%) irradiated patients, Bauer et al.[12] showed discrete outcomes with a 50% success rate and a cure rate of 25% obtained after 3 months; these outcomes were confirmed also at the maximum follow-up, in contrast with the data of a smaller series studied by the same author.[13]

Quality of life (QoL) and patient satisfaction were also improved by the procedure: the Urinary Incontinence Short Form (ICIQ-UI-SF) score was significatively decreased (p=0.008), whereas the Incontinence Quality of Life Questionnaire (I-QoI) score increased (p=0.009).[12]

Table 1. AdVance/Advance XP studies

Author	Year	Journal	Design	Patients	Irradiated	Follow-up	Outcome	Miscellanea
Cornu JN.	2009	Eur Urol	Prospective	102	17 (16.7%)	13	59% cured or improved vs. 85% in non-irradiated group	Radiation associated with failure (p=0.039)
Cornu JN.	2011	BJUI	Prospective	136	23 (17%)	21 (mean)	Failure trend associated with radiotherapy (p=0.0053)	No sling infection, erosion or explantation
Bauer RM.	2011	Urology	Prospective	24	24 (100%)	18	Success rate 50% (25% improved, 25% cured). 1-hour pad weight decreased significantly to 40 g (p=0.001) and PPD used to 2 (p=0.001). Median ICIQ-UI SF score decreased to 11.5 (p=0.009) and I-QOL score increased to 72 (p=0.008).	11 points satisfied
Bauer RM.	2011	BJUI	Prospective	137	17 (13.5%)	27	6/17 (35%) dry, 4/17 (23%) improved	Better outcomes for non-irradiated patients
Berger AP.	2011	Int Braz J Urol	Retrospective	26	5 (19%)	22	60% cured or improved; mean PPD decreased from 8.6 to 4.0. Cured: 1/5; improvement 2/5.	Radiotherapy associated with worse outcome (p=0.04)
Zuckerman JM.	2011	Can J Urol	Retrospective	27	27 (100%)	15.8 (mean)	70% benefit; PPD reduced from 4.2 to 1.1; 38% decreased efficacy	No erosions or infection; 2 intraoperative complications
Rehder P.	2012	Eur Urol	Prospective	156	11 (14.1%)	39	Cured or improved 54.6% vs. 65.6% in non-irradiated (p=0.0723)	One sling explantation
Collado Serra A.	2013	Urology	Prospective	61	3 (5%)	26	2/3 failure	No erosions
Torrey R.	2013	Urology	Retrospective	37	7 (19%)	17.3	No pad free vs. 63% in non-irradiated group; 2 (28.6%) were improved vs. 90.0% without prior RT; 71.4% no change or worse outcome vs. 10% without prior RT.	No RT: 22.5 OR in predicting the event of no pads or reduced pads postsurgery. QoL 1 (improved) 28.6% in RT group vs. 86.2% in no RT group (p=006).

Table 1. Continued

Author	Year	Journal	Design	Patients	Irradiated	Follow-up	Outcome	Miscellanea
Habashy D.	2017	Neurourol Urodyn	Retrospective	80	12 (15%)	36	RT group: using an additional 1.03±0.42 (p=0.019) PPD. PGI score was 3.7±0.70 (p=0.002) --> no difference	Mid-term outcomes: return to baseline.
Wright HC.	2017	Can J Urol	Retrospective	52	18 (34.6%)	61.5 (only 16 men)	Greater improvement in EPIC scores and PPD use was seen in non-irradiated men	RT: less satisfied at both short and long term follow up. Diminished efficacy at extended follow up, more pronounced in RT.
Papachristos A.	2018	ANZ J Surg	Prospective	72	18 (21%)	52	69% improved vs. 84% in non-irradiated group	Irradiation: worse continence outcomes (p=0.02)

RT: radiotheraphy; ICIQ-UI SF: The International Consultation of Incontinence Questionnaire – Short Form; QoL: Quality of Life; I-QOL: The incontinence quality of life questionnaire; OR: Odds ratio; EPIC: The Expanded Prostate Cancer Index Composite

Furthermore, in another prospective study conducted on 156 patients treated with AdVance (22 with history of pelvic irradiation), the multivariate analysis conducted by Rehder et al.[16] showed that irradiation is not a predictor of the outcome (p=0.0723).

The second study, conducted only on irradiated patients (n=27), the largest series, with a retrospective design, showed a 70% success rate in the mid-term follow up of 15.8 months; unfortunately, about 40% of the patients showed a decrease in efficacy with time and four patients needed a new incontinence procedure.[17]

The conflicting outcomes due to radiation were confirmed also by the prospective studies of Collado et al.[14] (2/3 irradiate patients unsuccessful) and Papachristos (worse continence outcomes in irradiated patients; p=0.02).[15]

Only a single randomized study was available in literature, comparing the outcome of the Advance and Argus slings in a series of 22 patients, with 3/11 irradiated patients in the AdVance group; unfortunately, no information was provided with regard to the outcome of the irradiated patients.[18]

The retrospective studies showed conflicting results. These studies however included a small number of irradiated patients (range: 5–27). The first retrospective single center analysis, conducted in 2011 by Berger et al.[19] on 5/26 irradiated patients, demonstrated an unsatisfactory outcome (20% cure rate and 60% improving; p=0.004) in the irradiated subgroup of patients in comparison with the non-irradiated one; these results were confirmed in 2013 by Torrey et al.[20], with no "pad free" patients after radiotherapy.

On the other hand, in 2011 Zuckerman et al.[17] reported a 70% benefit in a cohort of 27 irradiated patients, but with a decreasing efficacy in 38% of cases.

In 2014 Hoy and Rourke[21] conducted a retrospective analysis, comparing patients undergoing artificial urinary sphincter or advance placement, including also irradiated patients (3/76 in the sling group); unfortunately, no information about the outcome of these subgroups of patients was provided.

A recent retrospective study by Habashy et al.[22] on 12 irradiated patients confirmed the disappointing results of the previous series; at mid-term follow up, the patients treated with radiotherapy used on average the same number of pads per day as before the treatment, as confirmed by the PGI score.

The authors considered the radiotherapy independently predictive of a worse mid-term outcome.[22] On the other hand, Wright et al.[23] retrospectively analyzed a cohort of 18 patients receiving pelvic irradiation and documented a good overall satisfaction at short- and long-term follow up, although smaller with regard to the non-irradiated patients.

InVance and Radiotherapy

The InVance suburethral sling (American medical system) is a non-adjustable rectangular polyester sling positioned under the bulbar urethra via a perineal incision, with the aim to obtain a bulbourethral compression (Table 2).

Table 2. InVance studies

Author	Year	Journal	Design	Patients	Irradiated	Follow-up (months; median)	Outcome	Miscellanea
Fassi-Fehri H.	2007	Eur Urol	Prospective	50	8 (16%)	6	75% incontinent vs. 16%	Radiotherapy is considered a bad prognosis criterion
Collado A.	2009	Arch Esp Urol	Prospective	27	3 (11%)	18	61% cure rate in the bad prognosis group (radiotherapy, 3 pads/day, bladder neck incision, urodynamic anomalies) vs. 100% in the good prognosis group	No erosion or explantation
Lanoe M.	2009	Prog Urol	Retrospective	84	12 (14.3%)	20 (mean)		Univariate analysis: incontinence due to a bitherapy including external radiotherapy is associated with treatment failure (p=0.031). Multivariate analysis: bitherapy including radiotherapy is the so independent treatment failure risk factor (p=0.017).
Carmel M.	2010	BJU Int	Prospective	45	12 (26.6%)	36		Success rate unaffected by radiotherapy (p=0.448)
Spie R.	2011	Prog Urol		106	24 (22.6%)	12.8	Continence: 52.6% vs. 63.2% (p=NS)	8.3% explantation vs. 4.8%; 45.8% vs. 25.6% transient perineal pain; no impact of previous radiotherapy on urodynamic parameters and continence

NS: not specified

Five studies evaluated the results of the InVance placement in irradiated patients.

Fassi-Fehri et al.[24] prospectively assessed the short-term results (median follow up: 6 months) in 8/50 patients with history of radiotherapy who had undergone InVance positioning after prostatic surgery or pelvic trauma. The incontinence rate was 75% vs. 16.3% in the irradiated and non-irradiated group of patients, respectively, defining the radiotherapy as a "bad prognostic criterion".[24] The data of Fassi-Fehri were confirmed by the small series of Collado et al.[25]

At a mid-term follow up of 18 months, the three irradiated patients, included in the "bad prognosis group" (history of irradiation or bladder neck incision, 3 pads/day, urodynamic abnormalities), showed a lower cure rate in comparison with the patients included in the "good prognosis" group (61% cure rate in bad prognosis group vs. 100% in good prognosis group, p=0.03).[25]

The author concluded that InVance positioning is an adequate procedure for patients with mild-moderate incontinence, without urodynamic abnormalities and who have not undergone radiotherapy.[25]

Even in 2009, Lanoe et al.[26] highlighted as history of radiotherapy could be the sole independent treatment failure risk factor (p=0.017).

On the other hand, Carmel et al.[27] and Spie et al.[28] showed promising results at mid- and long-term follow-up.

A history of radiotherapy did not adversely influence the cure rate of 12/45 patients prospectively evaluated by Carmel et al.[27] (p=0.448), and the data regarding a larger series of Spie et al.[28] (n=24 irradiated patients compared with 82 non irradiated ones) are supporting these evidences.

Argus and Radiotherapy

The Argus-T is a re-adjustable radio-opaque cushioned system with silicone foam suburethral sling device, which make it possible to adjust the sling tension effectively not only during surgery but also in the first few days after surgery.[4]

Only three studies evaluated the success rate of patients undergoing Argus or Argus T implantation after radiotherapy (Table 3).

The retrospective series by Hübner et al.[29] showed good results in irradiated patients, with 20/22 dry patients at mid-follow up (18 months) and only two explantations of the sling.

With regard to the prospective studies, the data of the 2-center evaluation by Bauer et al.[30] on 13 irradiated patients confirmed the results of Hübner et al.'s[29]; at a long-term follow up of 28.8 months, the risk analysis did not show differences in patients that received radiotherapy (p=0.581), with regard to the number of pads used and I-QoL and ICIQ-SF scores.

In contrast, Siracusano et al.[4] conducted the largest prospective study on the Argus-T device in irradiated patients. Forty-nine patients with a history of radiotherapy for prostate cancer were treated with the Argus sling and followed for a median follow up of 22 months and evaluated with the Visual Analogue Scale (VAS) score for continence and a QoL score.

The overall success rate was 86.2%, but only 61.2% of irradiated patients showed successful results.

Moreover, the irradiated patients were more likely to undergo sling adjustment or sling removal and postoperative complications (p=0.04, p=0.002, p=0.01). Nevertheless, the irradiated patients, too, showed a significant overall reduction of daily pad number and an improvement of their QoL (p<0.0001).[4]

Table 3. Argus studies

Author	Year	Journal	Design	Patients	Irradiated	Follow-up (months; median)	Outcome	Miscellanea
Hübner WA.	2011	BJU Int	Retrospective	101	22 (21.8%)	18	20/22 dry	Two erosions and one infection; two explantations of the sling
Bauer RM.	2015	Urology	Prospective	42	13 (30.9%)	28.8	PPD use: 6.3 to 2.7; 24 h pad weight: 315 g to 130 gr; IQOL score: 6.9 to 90.8 ICIQ-UI SF score: 15.9 to 3.9 risk analysis: no difference with and without radiotherapy ($p=0.581$)	Two explantations
Siracusano S.	2017	Urology	Prospective	182	49 (26.9%)	22	Success rate 61.2%; significant overall reduction of daily pad number and an improvement on their QoL (p<0.0001)	Irradiated patients: high percentage of sling adjustment or sling removal and post-operative complications (p=0.04, p=0.002, p=0.01)

I-QOL: The incontinence quality of life questionnaire; ICIQ-UI SF: The International Consultation of Incontinence Questionnaire – Short Form, QoL: Quality of Life

DISCUSSION

The surgical treatment of male urinary incontinence after radical prostatectomy is still a complex issue today, although guidelines in this regard have existed for several years. In the context of stress urinary incontinence stabilized one year after radical prostatectomy of stress incontinence is now feasible. In this way patients with milder degrees of incontinence and without bladder dysfunction are usually candidates for artificial urinary sphincter placement or sling surgery with overlap success rates [European Association of Urology (EAU) guidelines]. In particular, using the sling would result in a lower risk of surgical complications[3] while in case of severe incontinence the AUS shows a more predictable success profile with respect to using the sling.

In this context minimally invasive approaches, such as robotic surgery, urinary incontinence represents up today an important post-operative complication, causing a devastating reduction in the quality of life that is added to the sequelae caused by radiotherapy.

In these patients, the resolution of incontinence is still problematic, because there are still no satisfactory degrees of recommendation for surgery.

In particular, the artificial urinary sphincter is more widely used, but radiation may be a risk factor for an increase in complications[7], and on the other hand, the slings generally have a lower success rate, if compared with patient with no history of radiotherapy. In this regard, the review of literature that we carried out shows that the transobturator sling is still considered as being little effective, therefore, to facilitate our analysis, we discussed the "suspensive sling" which refers to the AdVance system and the "compressive sling", which refers to the InVance and Argus-T devices, separately, since the above reported devices are the most used for the transobturator approach in patients suffering from UI after adjuvant RT.

The rationale of the AdVance sling is the relocation of the sphincteric unit in the pelvic floor, which means a suspension of the bulbar urethra. This relocation would allow a resumption of sphincter activity when the sphincter is intact and the suspension of the bulbar urethra is possible. The satisfaction of these two conditions is essential to restore continence.

In the majority of cases, the authors reported a limited success compared to patients without adjuvant radiotherapy[14,15,17,19,20,22] and, at same time, the number of radiotreated patients who underwent the placement of the AdVance device is too small to suggest a possible cause of failure.[10-23]

In this way, we believe that sphincteric unit and bulbous urethra fibrosis could contribute to limit the success of this device, because the pelvic floor is fixed and not susceptible of suspension.

Nevertheless, to date the only negative prognostic factor in patients undergoing this implant is related to the presence of a preoperative detrusor overactivity.[22]

In this regard, the experience with InVance is very limited and the only currently available device within the compression system is offered by the Argus-T sling, with results in the mid/short-term. This latter device is not very effective in patients who are radiotreated compared to non-radiotreated patients and in the largest series[4] the number of readjustments was higher than those performed for non-radiotreated patients, with a consequent disadvantage in terms of costs/benefits.

In literature, nowadays none of the transobturator devices is effective in treating urinary incontinence in a post-radical prostatectomy patients undergoing adjuvant radiotherapy. In this context, we currently only have empirical solutions aimed at treating patients who did not have any benefit from the use of the transobturator sling. Usually, the use of bulking agents as well as the use of a transcorporeal artificial sphincter could represent the only two possible surgical solutions. In particular, with regard to bulking agents, we do not have reliable data in the literature, while for the use of transcorporeal AUS, the results to date are contradictory as the studies are exclusively of a retrospective type, the population that underwent this type of surgery is extremely small and data on radiation field exposure are not available.[31] In conclusion, suspensive and compressive devices do not seem to offer satisfactory outcomes in this group of patients, since the possibility of continence recovery is in any case low.

CONCLUSION

Only long-term randomized longitudinal studies will allow us to understand if a sling can be a valid alternative to the artificial sphincter that at present represents the only reliable possibility for these patients.

At the moment, due to the lack of large prospective studies, it is impossible to draw definite conclusions.

ETHICS

Peer-review: Externally peer-reviewed.

Contributions

Concept: S.S.; Design: D.F.; Data Collection: D.F.; Analysis and Interpretation: C.D.; Literature Search: F.R.; Writing: S.S.

DISCLOSURES

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The *Damnatio Memoriae* of J. Marion Sims

L. Lewis WALL

Selina Okin Kim Conner Professor Emeritus in Arts and Sciences, Emeritus Professor of Anthropology, Emeritus Professor of Obstetrics & Gynecology, Washington University in St. Louis, MO, USA

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ABSTRACT

J. Marion Sims (1813–1883) was one of the most prominent surgeons of the 19th Century, often referred to as the "Father of Gynecology" for his many contributions to the diagnosis and treatment of female pelvic floor disorders. His most notable contribution was the first reliably successful operation for the treatment of obstetric vesico-vaginal fistula. After Sims's death, the medical profession raised funds to erect a monument to his memory in New York City. Sims developed his surgical approach to fistula closure while operating on a series of young, enslaved African-American women in Alabama. Modern writers have condemned Sims for providing innovative surgical treatment to women with a heretofore devastating and incurable condition. For several years these critics have been systematically seeking to eliminate Sims's memory from the places where he had been honored. Because vesico-vaginal fistulas from obstructed labor are now almost unknown in countries with effective systems of maternal health-care, present-day critics fail to understand the immense suffering caused by these injuries. The argument is made here that a vesico-vaginal fistula was such an overwhelming injury that it dominated all aspects of the day-to-day lives of women with this condition. Rather than being unwilling participants in Sims's surgical endeavors, it is far more likely that these women—even though they were enslaved—were active partners with Sims in their joint search for a cure. The extensive experience of modern surgeons working with poor women suffering from vesico-vaginal fistulas in Africa and Asia supports this perspective.

Keywords: J. Marion Sims; vesico-vaginal fistula; obstructed labor; history of gynecology

INTRODUCTION

J. Marion Sims (1813–1883) was one of the most influential figures in 19th century surgery (Figure 1). He is often referred to as the "Father of Gynecology" for his many contributions to the surgical treatment of disorders of the female pelvic organs.[1,2] Among his many medical contributions are the Sims vaginal speculum (still one of the most useful gynecological instruments ever created),[3] the use of the left lateral decubitus ("Sims") position for pelvic examination,[3] the description of provoked vulvar vestibulitis ("vaginismus") and its treatment by hymenal excision in selected cases,[4] the development of the post-coital test as part of the evaluation of infertility,[5] techniques that made intra-peritoneal surgical operations far safer than they had been before,[6] and the creation of the world's first specialist institution for the treatment of childbirth injuries and other gynecological disorders: the New York Woman's Hospital.[1,7]

Address for Correspondence: L. Lewis Wall, Selina Okin Kim Conner Professor Emeritus in Arts and Sciences, Emeritus Professor of Anthropology, Emeritus Professor of Obstetrics & Gynecology, Washington University in St. Louis, 1036 Dautel Ln, St. Louis, MO, 63146 USA
E-mail: WALLL@wustl.edu **ORCID ID:** orcid.org/0000-0003-2133-7051
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The Obstetric Vesico-Vaginal Fistula in the 19th Century

Above all, Sims is best-known for developing the first consistently (but not universally) successful operation for the closure of vesico-vaginal fistulas. These injuries were frequent complications of prolonged obstructed labor in the 19th century, when skilled obstetric care was rarely available.[8] Although vesico-vaginal fistulas from obstructed labor have been eliminated from the obstetrical experience of wealthy industrialized nations,[9] they still occur with disturbing frequency among poor women in poor countries. Obstetric fistulas are an affliction of "the bottom billion" of the world's population.[10,11]

Many surgeons had tried to repair vesico-vaginal fistulas before Sims developed his protocol for the successful treatment of this condition. These prior efforts were almost always unsuccessful.[8] Occasionally a serendipitous surgical operation produced a cure, but the reasons it succeeded were elusive and unclear.[12] So, depressing in general were the results of these operations that surgeons referred to vesico-vaginal fistula as "the opprobrium of surgery." Surgeons were ashamed that they could not do better; but in spite of the overall dismal results of attempts at fistula closure, the lives of women suffering from this malady were so overwhelmingly wretched that they returned time and again for additional treatment, pleading with their surgeons to "try just one more time" in the hope that the *next* operation would successfully mend their injuries and restore them to normal living.

Figure 1. J. Marion Sims (1813–1883). From J. Marion Sims, The Story of My Life; New York: Appleton, 1884 (public domain)

In 1829, London surgeon Henry Earle referred to "the present miserable condition" of the fistula patient, "in which she must feel her life a loathsome burthen to herself and others".[13] Earle confessed, with great sadness, "…that, in the majority of cases, little can be done to obtain a cure…".[13] He declared "that under the most favourable circumstances, these cases present the greatest obstacles, and are certainly the most difficult that occur in surgery. I do not mention this to discourage you from making attempts to relieve patients suffering under this great calamity," he admonished, "on the contrary, I would strongly urge you not to abandon them, and not to be deterred by many failures".[13] He concluded, hopefully, saying "I have succeeded in perfectly restoring three such cases," but cautioned that "… I performed upwards of thirty operations before success crowned my efforts".[13] Fistula surgery was not for the faint of heart.

The transformation of vesico-vaginal fistula repair from a desperate surgical gamble into an operation with a substantial probability of success began with J. Marion Sims. His operation—which involved placing the patient in a knee-chest or hands-and-knees position during surgery, paring the fistula edges with a sharp knife, closing the defect with fine silver-wire sutures, draining the bladder with an indwelling S-shaped metal catheter, and adhering to a meticulous regimen of post-operative care—was described in an 1852 paper published in the *American Journal of the Medical Sciences*.[14] The surgeon and medical historian Ira Rutkow has placed Sims's fistula paper "among the most influential ever written by an American surgeon".[15]

Although the various individual components of Sims's operation had been described previously,[16] Sims's program for surgical repair—described in his clear writing style and accompanied by numerous line drawings that took fellow surgeons through his operation step-by-step—revolutionized the treatment of vesico-vaginal fistula. The development of this successful operation for vesico-vaginal fistula in turn jump-started progress in the surgical treatment of many other gynecological disorders, which had been largely ignored by the medical profession. It was upon the foundations laid in discovering how to treat vesico-vaginal fistulas successfully that modern gynecological surgery—and particularly modern vaginal surgery—developed.[17-19]

The Sims Statue in New York City

These were the reasons that members of the medical profession raised funds to erect a statue in Sims's honor after his death in 1883.[20] They regarded Sims as having opened the way for

the successful surgical treatment of conditions that previously had been regarded as hopeless. At the time of his death Sims was advocating for the creation of a specialist women's cancer hospital in New York City, a vision that later reached fruition in the form of the Memorial Sloan-Kettering Cancer Center, an outgrowth of the New York Woman's Hospital.[21]

To his medical contemporaries, Sims was a path-breaking innovator whose many contributions spurred the transformation of gynecology from a medical backwater into the vanguard of 19th century clinical practice. Sims was lionized by practitioners and patients throughout the United States and Europe, and by the end of his life he was dividing his time equally between both sides of the Atlantic. As surgeon James Wyeth wrote after Sims's death, "In New York, London, Paris, Brussels, Berlin, Vienna, Rome, Madrid, Lisbon, and St. Petersburg he found himself everywhere sought after, not only by the patients he could benefit, but by the leading members of his own profession, who were anxious to pay tribute to his wonderful genius".[22]

The Sims memorial statue was originally erected in New York City's Bryant Park,[23] but was later moved to a location in Central Park across from the New York Academy of Medicine[24] (Figure 2).

The inscription on the statue's original pedestal in Bryant Park read "J. Marion Sims, MD, LLD. Born in South Carolina, 1813, died in New York city in 1883. Surgeon and Philanthropist. Founder of the Woman's Hospital of the State of New York. His brilliant achievements carried the fame of American Surgery throughout the civilized world, in recognition of his services in the cause of science and mankind he received the highest honors in the gift of his countrymen and decorations from the governments of France, Portugal, Spain, Belgium, and Italy".[24]

On the occasion of the dedication of the Sims statue in Bryant Park in 1894, Dr. George F. Shrady, editor of the *New York Medical Record*, confidently editorialized about Sims's legacy, declaring "Time has now so softened the asperities of criticism and calm judgment has so cooled the temper of envy that no one will now question his genius or doubt his talents".[25] Shrady turned out to be quite wrong. The prevailing view of Sims among the general public today is quite negative—and unjustly so.

What is contentious about Sims is the fact that his first operations to cure vesico-vaginal fistula were performed on young, enslaved African-American women in Alabama who had developed their injuries from prolonged obstructed labor. Sims gathered a group

Figure 2. The Statue of J. Marions Sims as it stood in New York City's Central Park, prior to its removal.

of these women together on his property in Montgomery, where he maintained a small hospital for the treatment of enslaved patients. There, with this handful of fistula patients, Sims labored diligently for nearly three and a half years—from January, 1846, to June, 1849—trying to repair their injuries.[14,25-27]

A wave of political "wokeness" has surged across the United States as public awareness has grown regarding the country's pervasive and persistent racial and social injustices. There have been multiple protests over monuments and statues that had been erected in honor of past historical figures whose beliefs are now at odds with the current zeitgeist. Such protests are grounded in modern ideology and are often raised more for reasons of current political expediency than they are rooted in solid historical research and a deep understanding of the past. As the prescient British historian Herbert Butterfield wrote, "Real historical understanding is not achieved by the subordination of the past to the present, but rather by our making the past our present and attempting to see life with the eyes of another century than our own".[28]

Ethnocentrism and Presentism

"Ethnocentrism" is the cardinal sin in social anthropology, defined by William Graham Sumner as the view "in which one's own group is the center of everything, and all others are scaled and rated with reference to it".[29] In ethnocentrism, Sumner wrote, "Each group nourishes its own pride and vanity, boasts itself as superior, exalts its own divinities, and looks with contempt on outsiders. Each group thinks its own folkways the only right ones, and if it observes that other groups have different folkways, these excite its scorn".[29] The ethnographer who seeks to understand another society must constantly be on guard against ethnocentrism—the hidden values and inherent biases that he or she brings to the field that can warp their interpretation of another social world.

In like fashion, "presentisim" is the cardinal sin of historical writing. Presentism is the view that one's own time (and culture) is the center of everything, and that all other historical time periods should be evaluated with reference to the present. Presentism sees today as the culmination of history, and looks down contemptuously on other times and places. If current assumptions are carried over uncritically into the evaluation of the past, the writing of history becomes nothing more than the projection of present grievances onto past actors. And if we start our investigation of the past with a sense of indignation or even outrage, that is all that we will see. Presentist historians—of which there are many—take special delight in pronouncing judgment upon previous eras rather than attempting to understand them as they were.

Mitch Daniels has wisely suggested that we spend "more time … trying to understand and empathize with those who struggled with harder problems than ours" and that if we did so this "might enable us to learn from their accomplishments as well as their mistakes, and look a little less absurd to our successors when their 'present' comes".[30]

We are living through an epidemic of presentism, and J. Marion Sims is one of its victims. It was Sims's great misfortune to have been born into, to have been socialized by, and to have learned the practice of medicine in a slave-holding society. Slaves and slavery were inescapable parts of the world in which he lived, and Sims accepted them without much questioning. Neither Sims nor his patients got to choose the times in which they lived, but his modern critics have been unable to forgive Sims for having been born in such circumstances, nor can they forgive him for having operated on enslaved patients who were victims of horrific childbirth injuries.[31-36] The fact that Sims's life circumstances associated him with slavery is unforgiveable in the eyes of his modern, presentist critics. For them, Sims must therefore be eradicated from the historical record in punishment for his alleged misdeeds.

The *Damnatio Memoriae* of J. Marion Sims

Damnatio memoriae, or, "the condemnation of memory," is a Latin phrase used to describe the erasure from history of persons who have fallen out of favor. The phrase perfectly encapsulates the perspective of modern writers who view with contempt past figures whose opinions differ from their own. The term *damnatio memoriae* originates in the ancient Roman practice of attempting to erase the memory of enemies of the state after they had died and to penalize anyone who persisted in remembering those who had been thus exorcised. According to the *Oxford Classical Dictionary*, there was no "set package" of procedures utilized to erase the memories of those condemned; rather, a variety of punishments was inflicted upon the memory of the dead, including destruction or removal of their images, prohibition of the display of their images, erasure of their names from inscriptions, forbidding the perpetuation of their personal names within the family, and so on.[37] In modern times, these techniques have been amplified and perfected by Stalinist historians of Russia and like-minded academics who have succeeded in eliminating disfavored political figures from the contemporary historical record.[38]

In similar manner, J. Marion Sims is becoming the medical equivalent of J.K. Rowling's fictional Lord Voldemort: "He-who-must-not-be-named." Sims's name and images have been under assault for several years. His statue in Central Park was taken down from its pedestal and moved to storage at Green Wood

cemetery where he is buried.[39] Lectures given in Sims's honor have been eliminated by the American Urogynecology Society. The J. Marion Sims Foundation in his home town of Lancaster, SC, has been renamed the "Arras" foundation and his name has been stricken from the hospital there, to become the unwieldy "Medical University of South Carolina Health Lancaster Medical Center." The Sims women's dormitory at the University of South Carolina (formerly Columbia College, Sims's own alma mater) has had his name removed from the building, to become now only the "S" wing of a larger residence hall. Professorships in gynecology at the University of South Carolina and the University of Alabama-Birmingham that formerly bore Sims's name no longer do so. There are even efforts to get instrument manufacturers to rename the Sims vaginal speculum so that "Sims" is no longer uttered in clinical settings where such instruments are used!

Mitch Daniels noted that "Presentism's principal tributaries are a lack of knowledge and a deficient capacity for empathy"[30] – characteristics on full display among Sims's modern critics.[31-36] How might the story of J. Marion Sims's first fistula patients look, if rather than simply condemning Sims because these injured women were enslaved, we looked empathetically at their medical condition, understood how severely affected they were by it, and considered Sims in his role as a clinician who was trying to solve a complex problem for the benefit of his patients without any firm precedent to guide him in an era in which surgical technology was still quite primitive?

J. Marion Sims and the Vesico-Vaginal Fistula

Sims was born in South Carolina in 1813, attended Columbia College (now the University of South Carolina), and studied at the Charleston Medical College before transferring his studies (as was common practice in early 19th century medical education) to the Jefferson Medical College in Philadelphia, where he graduated in 1835.[1,2] His initial attempt to set up practice in his home town of Lancaster, SC, was a dismal failure: his first two patients—both sickly infants with diarrhea—died. Distraught, discouraged and depressed, Sims struck out for Alabama to make a new start on the western frontier. He soon discovered that he had a knack for surgery and a bedside manner that patients found attractive. Within a few years he was the most successful surgeon in Montgomery, Alabama. As he later wrote, "I was the first man at the South that had ever successfully treated club-foot. I was also the first man that had ever performed an operation for strabismus, or cross-eyes. At the end of five years, I had established a reputation as a judicious practitioner and as a skillful surgeon, and was getting as much as I could do".[27]

In the summer of 1845, quite by chance, Sims encountered three young enslaved women—named Betsey, Lucy, and Anarcha—all of whom had recently delivered following prolonged obstructed labors and all of whom had developed a vesico-vaginal fistula.[26,27] Vesico-vaginal fistula was not a condition that Sims had ever seen before. He examined each woman, read what he could find on the subject of fistulas—including the treatise by Henry Earle—and sorrowfully told each one of these patients that nothing could be done. They were incurable. They would each have to return home and manage their lives as best they could.

After a chance emergency in which Sims performed a pelvic examination on a woman positioned on her hands and knees, he suddenly realized that if he were to perform a similar exam on a fistula patient with a speculum in place to elevate the perineum away from the vaginal canal, the air would rush in, distending the vagina and making the fistula fully visible to the examiner. Because lack of adequate exposure of the operative field was one of the huge obstacles to closing a fistula successfully, Sims realized that fistula closure—which he had heretofore regarded as impossible—might be achievable after all.

Fresh with this insight, Sims rushed back to his hospital where the last of the three fistula patients—a young woman named Lucy—was preparing to return home. Sims asked to examine her again and, with the aid of two medical students who were "reading" medicine with him in his office, he put Lucy in a hands-and-knees position, bent a pewter spoon into a crude right-angled speculum, lifted her perineum upwards to open the vaginal fourchette, and looked inside. Lucy's vagina distended as he had hoped, and Sims was able to see the vaginal canal and the entire fistula "as accurately as if it had been cut out of a piece of plain paper".[27] Prior to this serendipitous insight, Sims had believed—as did almost all the clinicians of his day—that large fistulas in which sloughing of the surrounding tissues had occurred—such as Lucy's fistula--were incurable. Sims had been unwilling to subject the enslaved women to futile surgery when he believed they were incurable. But now, Sims concluded that such injuries might be reparable after all. "I said at once," he recalled, "Why cannot these things be cured? It seems to me that there is nothing to do but pare the edges of the fistula and bring it together nicely, introduce a catheter in the neck of the bladder and drain the urine off continually, and the case will be cured".[27]

Sims decided to try to help these women. He kept Lucy in Montgomery. He wrote to the slave-owners who held Betsey and Anarcha, saying that he had changed his mind. Full of hope and enthusiasm, he was now willing to undertake their care. As he later wrote in the *New York Medical Gazette*, "…I was fortunate

in having three young healthy colored girls given to me by their owners in Alabama, I agreeing to perform no operation without the full consent of the patients, and never to perform any that would, in my judgment, jeopard life, or produce greater mischief on the injured organs—the owners agreeing to let me keep them (at my own expense) till I was thoroughly convinced whether the affection could be cured or not".[40]

Sims was overly sanguine about his prospects for success. He initially thought he would cure them all in a matter of six months.[27] As it turned out, it took him three and a half years. He operated on Lucy, Betsey, and Anarcha upwards of 40 times before he closed their fistulas;[14,40] but he always acknowledged his debt to "the heroic fortitude of my patients … for an operation by which nine tenths of all cases of this hitherto intractable affection may now with certainty be cured".[40]

How should these historic events be understood?

Unjustified Presentist Assumptions about Vesico-Vaginal Fistula

The attacks on Sims by presentist writers for not having practiced medicine according to their own personal 21st century values, are based upon a series of unquestioned assumptions. Because they have no experience with the kind of destruction that may be produced by obstructed labor, these writers all assume that a vesico-vaginal fistula is a kind of "tear" and that a fistula must therefore be similar to the sorts of simple perineal lacerations that often occur with vaginal delivery. These writers thus begin their criticisms of Sims by trivializing the injuries his patients experienced.

Having trivialized the injury, they then minimize its consequences. These writers assume that the incontinence associated with a fistula is the same as the relatively common, mild stress incontinence that may develop during pregnancy or after childbirth in which a few drops of urine are lost with vigorous coughing, sneezing, or other kinds of straining. These writers assume that a fistula is a trival complaint, unworthy of surgical attention.

Sims's presentist critics then assume that because these women were enslaved, they were unwilling participants in Sims's attempts to repair their fistulas. They further assume that because Sims's patients were enslaved, these women exercised no agency of any kind in their interactions with him. They are portrayed as entrapped, brutalized "laboratory rats" on whom Sims experimented for his own purposes.

None of these assumptions is correct.

Obstetric vesicovaginal fistulas are not "tears;" they are the result of crush injuries to the soft tissues separating the bladder from the vagina. The crush injury occurs over a prolonged period of time when the fetal head is trapped in the birth canal during obstructed labor (Figure 3). Here the trapped fetal skull is pressed relentlessly against the laboring woman's pelvic bones by the uninterrupted contractions of her laboring uterus. Eventually this pressure shuts off the blood supply to the soft tissues trapped between the two boney plates, leading to necrosis, sloughing, and the creation of gaping tissue-defects between the bladder and the vagina, and to continuous, uncontrollable loss of urine around the clock (Figure 4). For the women victimized by this injury, the consequences were horrific.

The Plight of the Fistula Sufferer, Then and Now

The 19th century German surgeon Johannes Dieffenbach was one of the most empathetic observers of the plight of the woman with a vesico-vaginal fistula. In a memorable and often-quoted passage, he wrote: "The inconveniences resulting from vesico-vaginal fistulae are of the most deplorable kind. Those connected with the married state do not require explanation. The constant

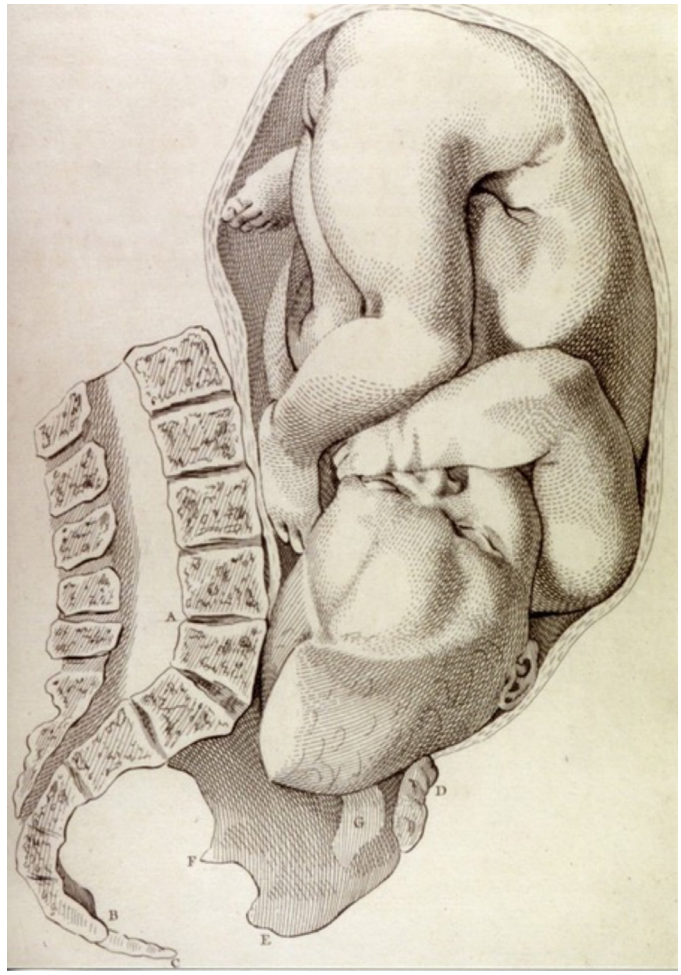

Figure 3. Obstructed labor from absolute cephalo-pelvic disproportion. From William Smellie, A Sett of Anatomical Tables, London: 1752 (public domain)

passage of the urine into the vagina must necessarily produce considerable irritation, and even inflammation; the external genital organs, the perineum, insides of the thighs, and legs, are exposed to the same injurious actions; the skin assumes a bright-red colour, and is partially covered with a furuncular eruption. The patients complain of a most disagreeable burning and itching sensation, which often compels them to scratch themselves until the blood comes forth, and thus aggravate their sufferings. Others are obliged to shave off the hair from the external organs, which are sometimes covered with a calcareous deposit from the urine. Frequent washing with cold water is of little avail, since the linen is quickly saturated with the fluid which escapes. Position avails little, and the bed, even when consisting of a hair-mattress, is quickly soaked through, and emits a most disagreeable odour; the wretched patients themselves are compelled to pass their lives on a straw-bed, the materials of which are changed every day. The air in the chambers of such patients acts injuriously on their lungs, and wherever they go they taint the atmosphere. Washing and inunction are attended with no advantage. Perfumes only increase the disgusting effect of the smell. This unhappy accident breaks through all family ties; the most tender-hearted mother is driven from the society of such an afflicted child; she is confined to a solitary chamber, or sits on a perforated stool of naked wood, or a plank, with an open window to the apartment, unable to cover the seat with any cloth. Some of these unhappy patients fall into a state of indolence; others present a stupid resignation; while others would willingly resign their lives to get rid of the misery which surrounds them".[41]

This was the situation in which Sims's patients found themselves in 1845, and this is how they would have lived for the rest of their lives unless someone repaired their injuries.

Figure 4. A vesico-vaginal fistula from obstructed labor

Photo by the author, with permission

In addition to Betsey, Lucy, and Anarcha, Sims found several other enslaved women with fistulas who "had been hidden away for years in the country because they had been pronounced incurable".[27] These women were all utterly alone and miserable, having been abandoned to live out the rest of their days marinating in their own excrement, without hope of relief. Almost anything would have been better than this. Modern writers from comfortable middle-class backgrounds who have had the advantages of giving birth with the assistance of trained attendants and effective interventions in those cases in which deliveries go awry, do not understand how the constant, unremitting urinary leakage dominates every waking moment in the life of a woman who has a vesico-vaginal fistula. It is an unrelenting "water torture" that gradually drives the fistula victim to despair, sometimes even to suicide. A vesico-vaginal fistula would have dominated the life of an enslaved woman even more than her condition of servitude. Every other consideration in life is pushed to one side for the woman who has a vesico-vaginal fistula.

Dr. George Hayward, the famous Boston surgeon who was the first to report the successful closure of a vesico-vaginal fistula in North America, knew well the suffering of the fistula patient. One of his early fistula cases was a woman of about 30 years of age, the mother of several children, whose last pregnancy had ended with prolonged labor and a vesico-vaginal fistula. She was so desperate for cure that she travelled over 1,000 miles to see Hayward—no small feat in 1840.[42]

Hayward reported that "No means that had been adopted, had had the slightest effect in controlling the continual flow of water, and the consequence was that her limbs, from the upper part of the thighs to the knees, were inflamed, excoriated, and extremely sensitive. Under these circumstances, she made the journey with the greatest difficulty, but so loathsome was her condition, that she was ready to make any sacrifice, if by so doing she had the least chance of relief".[42]

Upon examining her, Hayward found that "a large portion of the bladder had sloughed off, so that in fact there was no receptacle for the urine".[42] This was a terrible case. "I told her," recounted Hayward, "that I considered the case very unfavorable for any operation, and that the prospect of benefiting her was almost hopeless".[42]

Undeterred, this suffering woman looked Hayward squarely in the eye, and responded without hesitation. "She replied," Hayward recalled, "that her life was a burden to her as it was; that she would take any chance, however small, and incur the greatest risk rather than remain in her present condition".[42]

Hayward, like Sims in his own later cases, resolved to try to cure this patient. Hayward operated on her six times, each time reducing the size of the defect in her bladder, until finally only a tiny opening remained. She was not "cured"—for she still had a fistula—but the leakage diminished greatly. The excoriation on her skin went away, her health improved, she could walk again—and she even began to ride horseback. She also subsequently became pregnant and gave birth again (without further obstetrical disaster). "Her condition was entirely changed," Hayward reported; "life was no longer burdensome, and she was rendered by these operations a happy and useful member of society".[42] In the 1840s, this was a surgical triumph, even though technically the fistula was not completely repaired.

Hayward's case was not unique then; nor is it unique now. There are millions of women—poor women of color in impoverished countries—who suffer with fistulas today.[7,9,10,43] These women understand the reality of living with a fistula, even if middle-class academic critics in wealthy countries do not. As Drs. Reginald and Catherine Hamlin—who together founded the Addis Ababa Fistula Hospital for Poor Women with Childbirth Injuries and who had more combined experience with fistula patients than any two surgeons in history—wrote, the fistula sufferer is reduced "to the ultimate state of human wretchedness." They said, "Constantly in pain, incontinent of urine or faeces, bearing a heavy burden of sadness in discovering their child stillborn, ashamed of a rank personal offensiveness, abandoned therefore by their husbands, outcasts of society, unemployable except in the fields, they live, they exist, without friends and without hope".[44] Reginald Hamlin called these determined and hopeful women "fistula pilgrims".[45] He marveled at the lengths to which they went to make their way to Addis Ababa, journeying hundreds of miles over weeks or months—sometimes even years—in search of a cure for their loathsome condition. They would let nothing stand in their way. Other authors have reported the same thing many times over.[46-54] Sims's patients were no different.

Inadvertently Creating A "Sisterhood of Suffering"

In bringing these enslaved patients together as a group in his hospital, Sims inadvertently created a powerful "sisterhood of suffering." It is doubtful that he could have foreseen the remarkable social changes that took place among these women as the result of his bringing them together in this way. Rather than being alone and isolated out in the countryside where they knew no one with a similar malady, these women were unexpectedly brought together into community in Montgomery. Probably for the first time in their lives, they found fellow-sufferers who understood exactly what they were going through, who sympathized with and supported them, who would not turn away in disgust because of their condition, who would care for one another with empathy and compassion. This was psychologically transformative. This phenomenon is seen repeatedly today in African fistula centers where such women are brought into community with one another.[8,45,48]

During his initial attempts at fistula repair, Sims had the assistance of many physicians from the surrounding community. Although he was able to dramatically reduce the size of the fistulas, he did not manage to close them completely, though he made many attempts using different techniques. Sims's later operations were small affairs—he was attempting to close tiny, refractory holes, not operating on the large, dramatic defects that had originally excited the attention of his medical colleagues.[14] The other doctors could not be bothered to take time from their busy practices for such minor procedures, so Sims enlisted the help of the patients themselves, training them to serve as surgical assistants as he operated on each one of them in turn.[26,27]

No one had more invested in Sims's success than did his patients. Everything that made life worth living was on the line for them. They were fully aware of the ghastly nature of their injuries. They understood what Sims was trying to do and what it would mean if he succeeded. They had seen large defects in the vesico-vaginal septum reduced to tiny openings, and they knew how near he had inched towards ultimate success. It is no surprise that when Sims became depressed at his persistent failures and stopped operating as he tried to figure out what to do, that his patients begged him to continue. He recalled that they were "clamorous" in their demands that he persevere, begging him to 'try only one more time" to repair their injuries.[26,27] For anyone who has extensive experience with modern fistula patients, these statements ring true.

Margaret Murphy, one of the first social scientists to investigate the lives of African fistula patients in the 20th century, wrote about her experiences with these women at the fistula center on the grounds of the Ahmadu Bello University Teaching Hospital in Zaria, Nigeria, saying: "Many practical difficulties in gaining treatment are experienced by these patients. Their low socioeconomic status and the long distances to be travelled for treatment impose hardships even in reaching the hospital. Their offensiveness to others makes travel on public transport difficult, and they are seldom accompanied and protected by their husbands, unlike other patient groups. Their only chance of again leading a normal life is by surgical repair, and once they know this, they are strongly motivated towards seeking treatment; they overcome incredible obstacles to obtain it. Once they reach hospital there are further problems. Hospital officials and the general public may grumble about the tenacity

with which such patients wait around the hospital for treatment, forced to beg for food, unacceptable in their own communities. Their reluctance to leave, until they are cured, the one place that offers them hope for the future is understandable".[53]

In this, Sims's first patients were no different than their modern African sisters.[8,44-54]

The terrible legacy of slavery still haunts America in the 21st century, but attacking J. Marion Sims for having operated on enslaved women with fistulas does not right perceived past wrongs. It only ignores the epidemic of vesico-vaginal fistulas in poor countries today.[8,10,11,43,45,46,48-50] Within the context of their time and the structure of their society, J. Marion Sims and his enslaved patients together solved one of the great challenges of 19th century surgery. How that was done then does not meet our ethical standards today, but Sims should be judged by standards that he knew and to which others expected him to adhere in his own time, not by our conceptions nearly 200 years later. Indeed, much of what we do now will likely not pass muster in light of the ethical standards 200 years in the future. We must do the best we can with the understanding and expectations at our disposal.

Sims's fistula operations were lawful according to the legal system of his day; were done for the direct therapeutic benefit of his patients; were carried out with his patients' knowledge, cooperation, and assent; and met the ethical expectations of the medical community in which he practiced.[55] Sims himself always recognized the contributions that his enslaved collaborators had made towards their conjoint surgical success. At the end of his 1857 lecture on "Silver Sutures in Surgery," Sims hailed "the indomitable courage of these long-suffering women," and said that it was their "persevering efforts" "more than… any…other single circumstance," that had led to the success of his surgical regimen.[26]

Millions of oppressed women in poor countries are still victims of untreated obstructed labor today, but Sims's modern critics are deafeningly silent about this epidemic of preventable obstetric suffering and the hideous childbirth injuries it produces. By comparison, Sims knew firsthand what such injuries meant for the women of his times, and he worked to alleviate their suffering. Rather than condemn Sims for not holding modern progressive values, we would do better to use the present-day experiences of obstructed labor among poor women in poor countries to understand what life was really like in Alabama 175 years ago. Through the modern-day suffering of fistula victims in Africa and Asia, we have the tools (to paraphrase Herbert Butterfield), to make the past our present and to see life with the eyes of another century than our own. In this way lies true understanding, enhanced empathy, and the possibility that we can change things for the better.

ETHICS

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