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PELVIPERINEOLOGY

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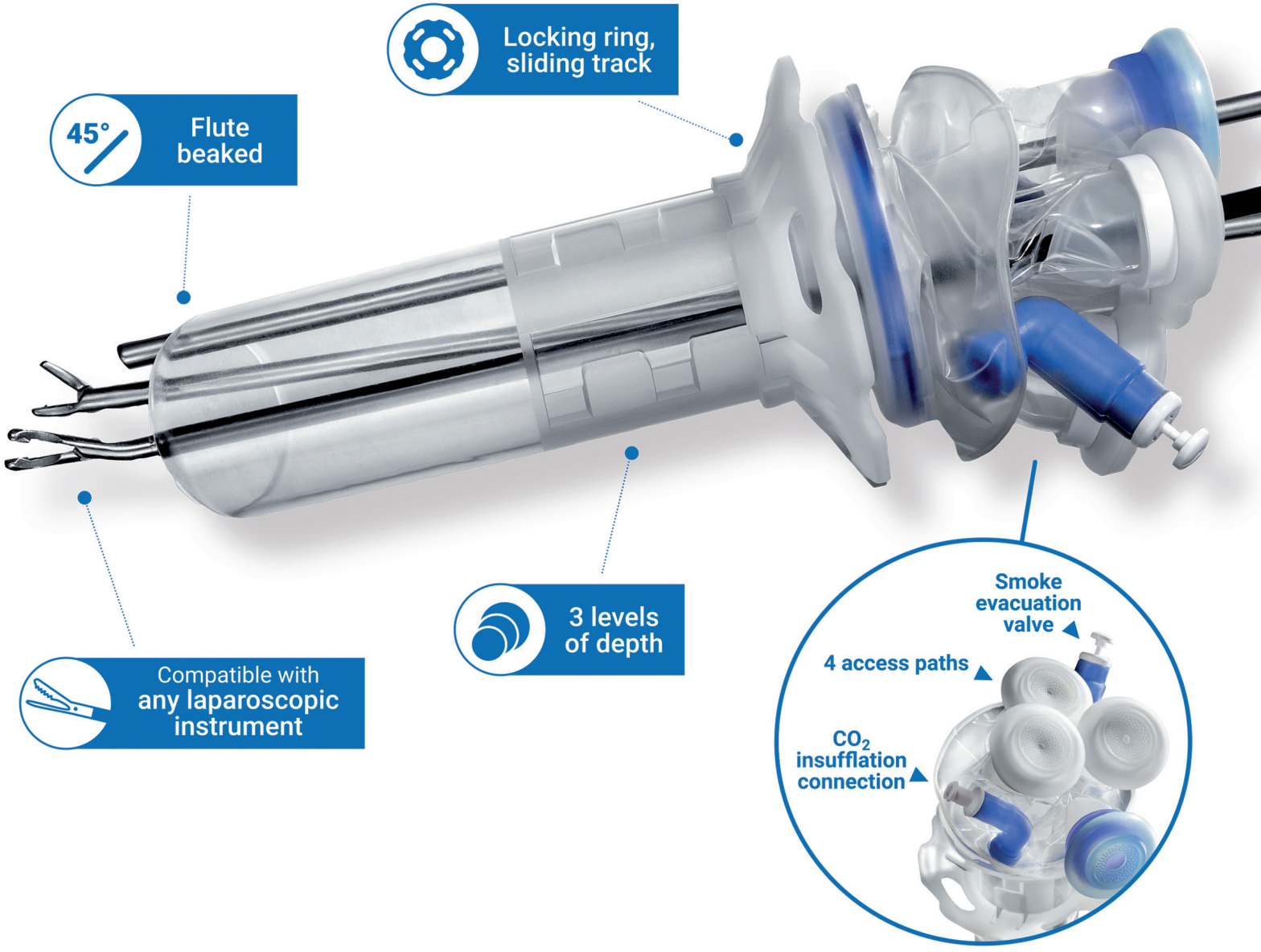

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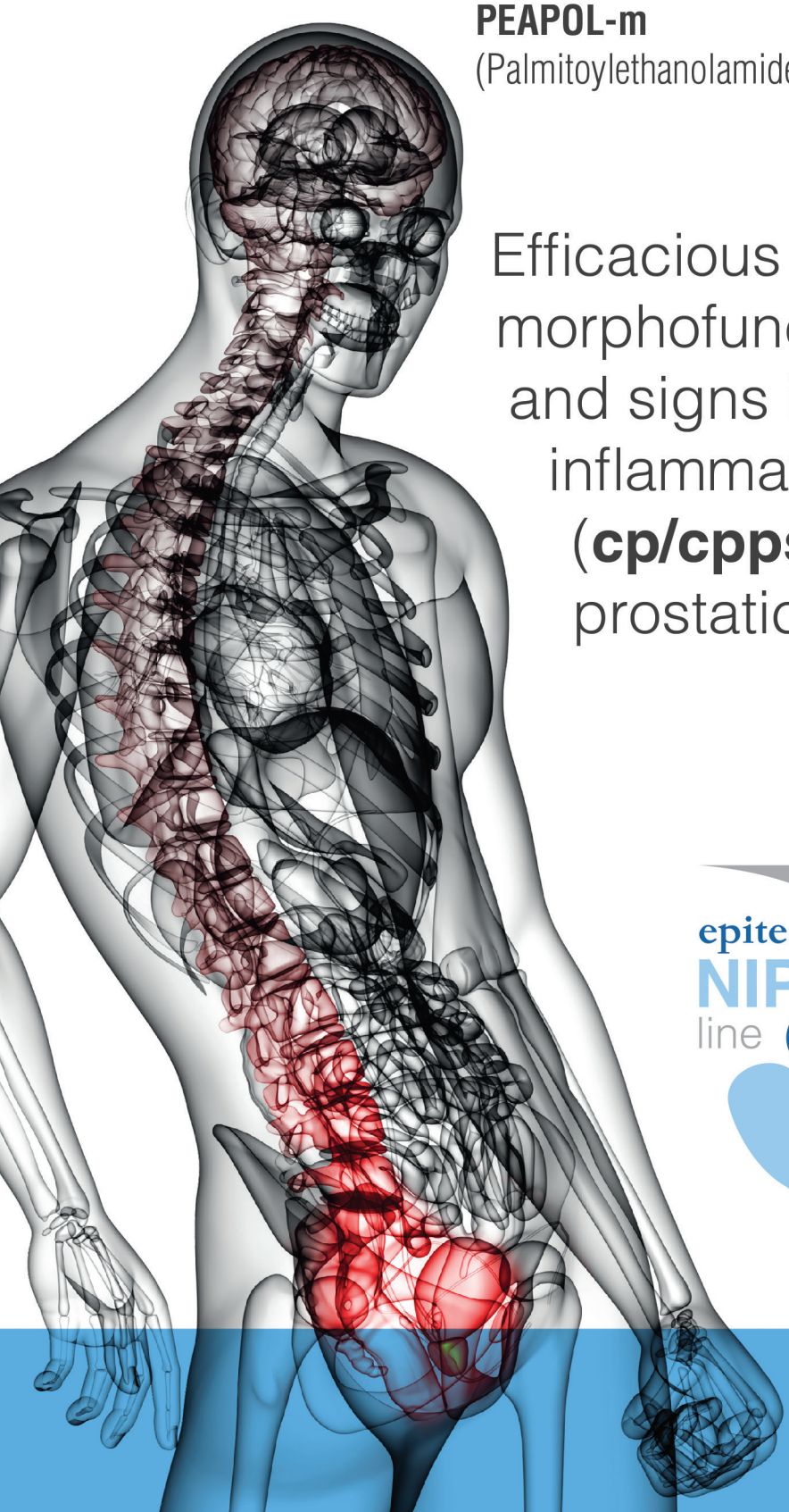

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Pelviperineology 2021;40(1):1-2

Dear colleagues,

It is my pleasure and honor to address you as the new editor in chief of *Pelviperineology*. I am particularly delighted to write my inaugural editorial in this issue, which is the first issue of the 40th year of publication of the journal.

I start this editorial by expressing my sincere appreciation to the Executive Committee of the International Society for Pelviperineology (ISPP) for trusting me with the prestigious position of editor in chief.

Jacob Bornstein
Editor in Chief, Pelviperineology

Let me begin by introducing myself. I am a Professor and the Chairman of the Department of Obstetrics & Gynecology, Galilee Medical Center, Bar-Ilan University, Azrieli Faculty of Medicine, Israel. I first became interested in urogynecology and pelvic floor disorders in 2003, while spending my sabbatical in Australia, with Professor Peter Petros. In Australia, based on Peter's integral theory and my experience with lower genital pain treatment, we developed a theory on the pathogenesis of pain associated with the laxity of uterosacral ligaments.

Subsequently, I became the President of the International Society of Vulvovaginal Disease and chaired several international terminology committees on genital tract diseases. I authored about 200 papers in peer-reviewed journals, two books, and several chapters. Further, I served on the editorial boards of several journals, including *The American Journal of Obstetrics and Gynecology, The Journal of Lower Genital Tract Disease,* and *Gynecologic and Obstetrics Investigation.*

My vision is to elevate the journal's standing to a top-level, modern publication with global readership, a leader in the development, evaluation, and promotion of the science of our specialty and introduce it to major medical database search engines. The journal has just been successfully indexed in Scopus, and we expect it to be indexed in PubMed soon.

Now, I turn to you, dear readers of the journal: This year is critical to the success of the indexing process. During this year, we will be evaluated by major search databases for the variety and scientific level of our publications. Without the involvement of readers, who are experts in the field and supporters of the journal, the journal will find it impossible to achieve its goal of becoming indexed in global databases. I look forward to receiving your valuable contributions in the coming issue.

This journal has traditionally promoted the study of the integral theory, which will continue to be the essence of its publications. Nevertheless, I wish to broaden the perspectives of the journal, while maintaining its excellence, by including research on pelvic and lower genital tract pain. Quite a few articles on this subject have already been published in *Pelviperineology* and, now, we announce pain as a major area of the journal's research interest.

From this issue onward, we will be publishing a special section titled "In the path of giants". In each future issue, we will be interviewing one of the pioneers in the pelviperineology specialty. We start with Professor Peter Petros from Australia. Peter, whose classic publications have permanently changed our understanding of the pelvic floor and ongoing scientific contributions are particularly noteworthy, is a good friend of the journal and supports it in every way he can.

In addition, we plan to introduce some other initiatives in the upcoming issues: debates on controversial issues, videos of interesting conditions and procedures, and transcripts of webinars initiated by the journal. In addition, we intend to maintain an open-minded attitude toward your ideas and comments.

Address for Correspondence: Jacob Bornstein MD, MPA,
Department of Obstetrics and Gynaecology, Galilee Medical Center, Nahariya & Azrieli Faculty of Medicine, Bar Ilan University, Safed, Israel
E-mail: Editor-in-chief@Pelviperineology.org **ORCID ID:** orcid.org/0000-0003-1932-5270

This journal has been led by Professor Giuseppe Dodi for many years. Professor Giuseppe Dodi significantly advanced the journal's scope and academic reputation. This is the appropriate time to thank him for the elegant manner in which he passed the chief editor's role to me and for his continuing support. My goal is to uphold his legacy, as well as adding my own designs.

Further, I take this opportunity to acknowledge the support rendered by the journal's publisher, "Galenos", particularly Ms. Duygu Yıldırım and, until recently, Ms. Özlem Akgüney Küççük.

We will continue cooperating with the ISPP under the leadership of Professor Menahem Neuman, as well as with our affiliated national societies, such as the Associaciòn LatinoAmericana de Piso Pelvico, Israeli Society for Urogynecology and Pelvic Floor Medicine, Pelvic Reconstructive Surgery and Incontinence Association (Turkey), Perhimpunan Disfungsi Dasar Panggul Wanita Indonesia, and Romanian Uro-Gyn Society.

I further use this opportunity to thank the journal's reviewers and editorial board members. These people form the backbone of any peer-reviewed journal. The comprehensive and considerate analyses sent to us by referees are essential to maintaining the journal's reliability. Further, we are working constantly to minimize the time gap between manuscript submission and the editor's decision.

Just as I assumed my new role as the journal's editor in chief, we experienced the tragic loss of Dr. Maurizio Spella. Dr. Spella was a senior editor of the journal, and I reiterate that he will be missed by all. Professor Giuseppe Dodi wrote an essay in his remembrance. On behalf of all at the journal, we send our condolences to his family.

I conclude this inaugural editorial by promising that I will spare no effort to lead the journal to achieve all its objectives. It will be possible only with your help and active participation.

Wishing you a safe and healthy 2021.

Best regards,

Professor Jacob Bornstein MD, MPA

Editor in Chief, Pelviperineology

Pelviperineology 2021;40(1):3-5

This section in Pelviperineology Journal, aims to interview the outstanding clinicians and scientists that had a special impact on the profession of pelviperineology over the years.

This photo of Professor Peter Petros was taken at a scientific meeting of ISPP in Bucharest Romania, where he demonstrated the TFS tensioned minisling for cure of prolapse, chronic pelvic pain, bladder and bowel dysfunctions

Professor Peter Petros

Interviewers: Jacob Bornstein, Darren M. Gold, Pelviperineology

Professor Peter Petros is well known to the readers of Pelviperineology. He is the "father" of the "Integral theory", the midurethral sling, and author of the book "The Female Pelvic Floor - Function, Dysfunction and Management According to the Integral Theory". He is the author of more than 260 peer-reviewed articles. He is PhD, DS (Doctor of Surgery), MD (Doctor of Medicine), DSc (Doctor of Science). We interviewed him for this section.

The photo with Dr Sidi Muctar, German Urologist, was during their joint development of the first ever minisling operation for cure of post-prostatectomy urinary incontinence

• What, would you say, is your main achievement in the field of pelviperineology?

Undoubtedly it was my first publication, “The Integral Theory of Female Urinary Incontinence”, in Acta Obstetricia et Gynecologica Scandinavica 1990, 79 pages. It is the “mother” of virtually every new direction in pelvic floor science since 1990. On rereading it recently, I was amazed at the depth, breadth and accuracy of the original concepts and predictions, written hardly 4 years after I had commenced my research: the key role of ligaments in stress and urge incontinence; prediction of bladder stretch receptors, not discovered until 20 years later; the reflex role of the pelvic floor muscles in opening and closure of the urethra and how they stretch the vagina to control urge incontinence, nocturia and chronic pelvic pain; in 2012, these concepts led to a method for cure of the 50% of women who continue to leak horribly after successful closure of obstetric fistula; in 2020, to an 86% cure of day/night enuresis in young children. The animal experiments in 1990 led to the midurethral sling, now the gold standard with 10,000,000 operations to date, posterior slings for cure of chronic pelvic pain, urge incontinence and nocturia, obstructed micturition and defecation and the first “mini sling” in 2004. When all the derivatives from the 1990 publication are taken into account, the number of citations number into many thousands.

Professor Peter Petros teaching in China Jiao Tong University Shanghai

• What in your youth and in early and late training years, prepared you to become top-notched in your field?

My mother told me that as a child I was always inquisitive. I grew up in north Queensland on a cane farm and initially went to a "bush school", with three classes taught by one teacher. When I was 13, we moved to Sydney, where I attended Sydney Boy's High, a selective academic high school. As well as science and maths I studied classics, including the ancient Greek language. That was the most profound intellectual influence for my research work, in particular, Plato's dialogues, which apply the Socratic method to examine all possible explanations (hypotheses) and by logical deduction, arrive at a true answer by eliminating logically inconsistent alternatives. A later influence, was my Obstetrics and Gynaecology training at the Royal Hospital for Women in Sydney, a punishing 1:2 rosters, another training in fundamentals: Bruce Dawson, superb anatomist, David Howell, whose intuitive handling of connective tissue was inspirational in developing my day care surgical methods and then there was Bill Garrett, D Phil. Oxon and prime inquisitor. Not surprisingly, I later learned he was also a classics scholar.

• You have changed the understanding that was common in the past. What did you first notice that alerted you to the fact that our current understanding of the subject was incorrect?

So much. Virtually everything being taught at the time made no sense to me. In 1986, everyone accepted that urethral closure was by intrabdominal pressure compressing five layers of urethral wall tissue to close it. Yet it is common knowledge that straining on micturition accelerates urine flow. Then there was "detrusor instability", where an arbitrary 15 cm pressure rise on urodynamics was elevated by an "expert committee" not as a diagnostic aid like X-ray, but as an actual clinical condition. Something without precedent in medicine! Many patients I saw who wet several times per day and did not show "detrusor instability" on urodynamics, were told the cause of the urge incontinence was all in their head and were sent off to psychiatrists.

• How did you proceed to determine what was the scientific truth?

By deduction, testing all the hypotheses, including my own, for truth or falsity. My own "Eureka moment", stopping urine loss with coughing by one-sided mechanical support of the pubourethral ligament invalidated the "pressure equalization" theory. Instant relief of urgency by tensioning the vagina suggested that a lax vagina was the cause of the urge symptom, not some pressure recording from urodynamic testing.

• How did you know you were right with your new approach?

I have always believed that Nature is perfect, that every anatomical structure has a purpose and that the pelvic floor worked holistically. So, the starting point for surgery was to mimic

nature. For pathogenesis, everything is subject to anatomy and basic physiology. A striated muscle contracts efficiently only over a short distance. The original X-ray and ultrasound studies from the 1990 theory indicated that the three directional muscles contracted against ligaments. I developed a series of "simulated operations", applying mechanical support and observing what happened. For example, inserting a speculum to support the apex of the vagina (uterosacral ligaments) relieved both urgency and pain; a large tampon placed in the apex at night helped reduce nocturia and improved bladder emptying. It was not a big step to repair these ligaments using tapes to create new collagen. Evolved from all this were two core tenets of the Integral Theory paradigm for surgery: Structure (prolapse) and function (symptoms) are related. "Repair the structure and you will improve the function." Next came the diagnostic algorithm, which uses symptoms to identify which ligaments needed repair. And later, "It is helpful for the modern pelvic floor surgeon to think firstly as an architect, secondly as an engineer: as an architect, to design the form of the reconstruction; as an engineer, so the construction can withstand the pelvic forces imposed upon it."

• Looking backwards, would you have done anything differently? If yes, what, and how?

I was and remain, naïve. I still believe that our prime purpose as a doctor is to help patients, seek scientific truth, share knowledge, follow the Hippocratic tradition of teaching fellow doctors free of charge. What I found was very different, opposition by vested interests, often vicious and personally targeted. It was difficult to publish anything different from "received wisdom". Statistically validated data was ignored. How could I do anything different? Without truth, there is no science. "Teaching" was most satisfying, for never did I even once "teach" without learning something substantial in return.

• Any advice for a new physician that looks up to you and wishes to make a difference?

Never ignore anomalies found in your scientific experiments. There is always a reason. Look for it. Many discoveries come from pursuing anomalies. Learn to be self-critical. If you form a hypothesis, be the first to challenge it. That is the best way to prove it. Respect our Hippocratic traditions, our craft, our colleagues. Be sincere. Be honest. Do the right thing for the right reason.

In memoriam: Maurizio Spella, M.D.

Giuseppe Dodi

Editor Emeritus of Pelviperineology

giuseppe.dodi@unipd.it

Maurizio Spella, M.D. (1962–2021)

Maurizio Spella had an important role in the journal "*Pelviperineology*". My relationship with him began about thirty years ago when he enthusiastically accepted to collaborate on an initiative that I had called Pelvic Floor Digest. In the 90s I realized that the multidisciplinary view of the pelvic floor needed cultural support and that it was necessary to exchange information between specialists in the fields of urology, gynaecology and coloproctology through a well-coordinated selection of articles from the main journals of the three specialties. Maurizio helped me to organize this collection online. Those years saw the beginning of the great diffusion of internet, and when systematic searches on the web were simplified, obtaining the same results automatically, Maurizio collaborated to transform the old coloproctology journal into "Pelviperineologia", trying to achieve a similar result in another way. The management of the journal, with the digest as a section, was very gradual and simple, based above all on passion, scientific and clinical curiosity.

Only after Bruce Farnsworth proposed the English version and therefore the internationalization of the journal, Maurizio began to take on the task of creating the system for receiving articles in an innovative way. The creation of iSubmit was due to him, to his creativity and experience in information technology. His idea was to transform the system into a real publisher that from the manuscript and the collection of the articles, through the entire editorial process, only required the evaluations of the chief editor.

Unfortunately, his premature death did not allow him to see the complete realization of this ambitious project. Once completed, it would have been the synthesis of a single vision, managing to merge software, medical and editorial aspects: putting data security and software stability first, creating a system that was expandable without set limits, taking care of the user interface with maniacal precision. With regard to this last aspect, Maurizio was studying rather innovative systems - rarely seen in other software in this field - to compare the articles, make corrections, and overall facilitate the entire management of an article from writing to publication, allowing even small scientific organizations to publish a scientific journal in a cheap but professional way.

Maurizio was not only a doctor with a passion for computer science. He was a person of extraordinary humanity and a boundless medical culture. His mind was like an immense server in which with extreme ease and mnemonic capacity any notion, information and feeling was processed with exceptional speed, efficiency and generous availability, always offering brilliant solutions and proposing to his friends and collaborators the absolute novelties of his invention. Alongside this, his great modesty, even in the silent awareness of his abilities, meant that he was in no way interested in appearing, reasoning more and more with his heart than with material and economic interests.

His family events led him to leave the hospital where he could expect a brilliant career in general medicine. The incredible attention with which he followed some of his close relatives with highly disabling diseases, starting with his mother, had led him to transform his house into a real intensive care unit that, helped by Maria Teresa, his wife, a doctor as well, he managed with amazing competence. Their death had produced in him a sense of loneliness and defeat, unjustified in the opinion of those who knew and loved him, because this seemed to us a struggle against the events of nature, a struggle in which he acted with passion and dedication of a saint. The extraordinary thing is that shortly after the fatal CVA that hit him on Christmas Eve, the elderly father also passed away, as if he could not survive deprived of Maurizio's presence, attention and assiduous care, and the funeral ceremony was celebrated together for the father and the son, while Maurizio's organs were donated, with a gesture of great generosity, by his family.

Also, his spirit and his teachings will continue to live in all of us who have known him through his work and his ideas. There is also hope that his editorial vision, in the tumultuous progress of the web, can become a reality.

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Pelviperineology 2021;40(1):8-10

Slings operations work very differently from mesh sheet implantations and should not be banned

PETER PETROS

University of Western Australia, School of Mechanical and Mathematical Engineering

ABSTRACT

Baroness Cumberlage has overreacted banning midurethral slings along with mesh sheets placed behind the vagina.

We should all support the banning of mesh sheets. Midurethral and other slings work differently from mesh which does not correct the prolapse. Mesh sheets just block the prolapse from descending. In the process the vagina is fibrosed. This can trap nerves to cause pain, and interfere with the closure and opening mechanisms of the bladder to cause massive incontinence. These mechanisms rely on a vagina which has adequate elasticity.

The midurethral sling operation is the most validated operation in surgical history with more than 1,000 publications attesting to its safety and efficacy. It was tested with animals and seven prototype operations prior to release in 1996, 10 years after the animal experiments began.

Slings work differently. They have very little contact with the vagina and so don't fibrose it. Nerve trapping is rare. Banning slings leaves women with very few options.

Hopefully the authorities will re-examine mesh slings and restore them. Of significant help to this are 3-year data from sling operations using next generation tapes with no erosions at all in that 3 years.

Keywords: Midurethral slings; ban; mesh sheets

The persistent media campaign against mesh products in the United Kingdom (UK) successfully resulted in the banning earlier this year of all mesh slings and mesh kits by the UK government. Unlike the Food and Drug Administration (FDA) where suppliers of mesh kits were put on notice to provide the data to justify their continued sale, the UK government instituted the Cumberlage report,[1] and acted on its recommendations. As the co-inventor of the now discontinued midurethral sling (MUS), the subject of this editorial, I fully endorse the recommendations for thorough premarket testing on any implantable device, for that is exactly the course which the late Ulf Ulmsten and I followed with the MUS. I also endorse the ban against mesh sheets which did not follow the exhaustive testing of the MUS.

The Cumberlage report,[1] unfortunately, is not based or robust scientific data. It consisted of opinions mainly from non-experts, including a journalist. It does not take into consideration the vast 10-year clinical and scientific background of the MUS. Apparently not considered were well reasoned scientific opinions from expert committees from almost every learned body, which generally concluded that the benefits of slings far outweighed their complications and, even years ago, that mesh sheet surgery required more proof.

Address for Correspondence: Peter Petros, University of Western Australia, School of Mechanical and Mathematical Engineering
E-mail: pp@kvinno.com **ORCID ID:** orcid.org/0000-0002-9611-3258
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The Cumberlage report made no differentiation between mesh sheets and slings. Mesh sheets applied behind the vagina to block descent of organs is a very different methodology from slings.

Mesh sheets fibrose vagina, may trap nerves, leading to pain, may inhibit movements essential for bladder closure and evacuation.[2] Nor do mesh sheets actually cure the prolapse. Simple 2D ultrasound shows that the prolapse is still there behind the mesh. The mesh blocks it coming down. In contrast, slings, using narrow tapes less than 1 cm in width, attach organs directly to the skeleton and create new collagen to restore structure and function.[3] Because they have very little contact with the vagina, slings avoid trapping nerves and preserve vaginal elasticity needed for bladder function.[2] Complications typical of large mesh are rarely seen with MUS.

The Cumberlage report bundled MUS with mesh sheet surgery and banned both. It ignored that the MUS was the most validated operation in the history of surgery with a profound experimental and clinical base. In fact, the MUS was not released until 1996, 10 years after the first animal experiments started in 1986 at Royal Perth Hospital by the author,[3] ironically, to test the safety and efficacy of the tape![2]

The animal experiments[3] were critical to the underlying hypothesis, that the cause of stress urinary incontinence (SUI) was ultimately due to collagen defects in the pubourethral ligaments (PUL); a tape placed in the exact position of PUL would harness the wound reaction from the tissues to create a collagenous neoligament. This "neoligament" principle was later extended to cure weakened ligaments such as cardinal, uterosacral, arcus tendineus fascia pelvis (ATFP) which caused prolapse, consistent with the three-level support system proposed by DeLancey's anatomical studies.

The animal experiments were analysed by the author and Professor John Papadimitriou, who is an acknowledged world expert on macrophages and inflammation research. Included in the animal testing was clinical monitoring over 3 months, radioactive Gallium studies, X-ray studies, regular biochemical and hematology testing of the animals, anatomical studies, biomechanical testing of the neoligament for breaking strength, extensive histology and bacteriology.[3] The animal experiments proved that tape implantation was safe and would create a collagenous neoligament to reinforce weak ligaments.

The first prototype human operations underwent 5-year Royal Perth Hospital EC surveillance, between 1988 and 1993. Tapes were implanted in the position of the PUL. The prototype human studies were subjected to thorough clinical, bacteriological, radiological, hematological and biochemical observations. Meanwhile Ulmsten, Nilsson and others performed their own parallel studies in Scandinavia. By the time the MUS was released in 1996, the MUS had undergone 10 years study for safety and efficacy under Ethics Committee surveillance in several international locations. Since 1996, the MUS has been the subject of >1000 scientific papers, (including 17-year data), 10,000,000 MUS surgeries. It has been endorsed by almost every learned body. In contrast, mesh sheet surgery for prolapse has had very little premarket scientific testing.

The Cumberlage statement of inadequate premarket certainly applies to mesh sheets. It clearly cannot apply to slings, as implied in her statements banning them.[1]

The real reason for banning seemed to be anecdotal complications from many suffering women. This important issue was examined in detail in a previous International Urogynecology Journal (IUJ) editorial, *Should surgeons continue to implant mesh sheets behind the vagina?*[4] The editorial concluded that though mesh sheets worked well in many cases, reports of severe pain due to nerve entrapment and scar-induced disturbance of the control mechanisms of the bladder to cause massive urine loss "tethered vagina Syndrome," posed an important question: are severe disabling complications sufficient to prevent mesh sheets being done at all? Fortunately, it has been proven that mesh sheets are not necessary for repair of major prolapse. In a multicentre study of 616 women, Liedl et al.[5] demonstrated that tensioned mini slings applied to cardinal and uterosacral ligaments in women with mostly 3rd or 4th degree uterine/apical prolapse were sufficient to achieve a 90% anatomical cure at 12 months.[5] There was no vaginal excision. Dislocated or overstretched vagina was refashioned and re-attached.

The Cumberlage decision in the UK leaves women with poor outdated treatment options, "native tissue" vaginal repairs with up to 80% failure rates according to the prospect study or the Burch Colposuspension with all the complications which led to its demise a few short years after introduction of the MUS.

There are cogent scientific reasons why slings should not be discontinued. Ligaments are key elements in the three-level support system for organs. Collagen leaches out of the ligaments after the menopause to cause prolapse and incontinence.[2] A tape placed along ligaments as in the MUS is the only validated surgical method which can create new collagen to repair organ support.

And finally, technical advances. Ninety percent cure rates are being achieved for ISD (Intrinsic sphincter defects) and SUI using TFS mini slings, with zero erosions at 3 years.[6,7]

Ethics

Peer-review: Externally peer-reviewed.

DISCLOSURES

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Diabetes mellitus in pregnancy does not delay postpartum pelvic floor recovery

NETA BENSHALOM-TIROSH, MIRIAM ERENBERG, YAEL BAUMFELD, ZEHAVA YOHAY, HANNAH GLINTER, ELLA PARDO, DAN TIROSH, DAVID YOHAY, ADI Y. WEINTRAUB

Department of Obstetrics and Gynaecology, Soroka University Medical Center and Faculty of Health Sciences, Ben-Gurion University of the Negev, Beer-Sheva, Israel

ABSTRACT

Objective: Evaluate the impact of diabetes mellitus (DM) on postpartum pelvic floor dysfunction symptoms recovery.

Materials and Methods: A prospective cross-sectional study. Participants completed "Pelvic Floor Distress Inventory-20" questionnaires during third trimester, and three months postpartum. Statistical analysis was conducted to determine differences between questionnaire scores in both periods, comparing recovery among women with and without diabetes in pregnancy.

Results: A total of 192 participants were divided into diabetes (n=66) and control (n=126) groups. At three months postpartum, 114/192 (59.4%) women completed both questionnaires. There was a significant difference between the questionnaire summary score during pregnancy, and three months postpartum ($p<0.001$). No significant differences were noted in the extent of symptoms recovery between women with and without diabetes ($p=0.2$ for total score).

Conclusion: There is a clinically and statistically significant spontaneous recovery of pelvic floor dysfunction symptoms in the postpartum period. DM in pregnancy does not delay this postpartum recovery.

Keywords: Colorectal anal dysfunction; diabetes mellitus; pelvic floor dysfunction; PFDI-20; urinary incontinence

INTRODUCTION

Pelvic floor disorders (PFD) include pelvic organ prolapse (POP), colorectal and anal dysfunction (CRAD) and urinary distress (UD). PFD symptoms have a major effect on women's quality of life, with psychosocial effects including discomfort, anxiety, embarrassment, loss of self-esteem and frustration.[1] The treatment of PFD holds an overwhelming economic burden, and is a major public health concern.[2]

The reported prevalence of PFD during and after pregnancy varies.[3] Many risk factors are involved in pregnancy and postpartum PFD, with growing evidence for the important impact of the mode of delivery.[4] The effects of pregnancy, even without birth-related pelvic floor injury, have also been implicated as an independent risk factor for PFD.[5] Other pregnancy related risk factors investigated include parity, instrumental delivery, obstetrical trauma, episiotomy, length of the first and second stages of labor, use of epidural anesthesia and neonatal weight.[6]

Address for Correspondence: Neta Benshalom-Tirosh, Department of Obstetrics and Gynaecology, Soroka University Medical Center and Faculty of Health Sciences, Ben-Gurion University of the Negev, Beer-Sheva, Israel **E-mail:** netabt@gmail.com **ORCID ID:** orcid.org/0000-0003-1627-0200
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However, many aspects of the PFD pathophysiology associated with pregnancy, delivery and the puerperium remain unknown.

The prevalence of diabetes mellitus (DM) during pregnancy is about 7%, most cases being gestational DM.[7] Of note, there is a constant increase of the prevalence of DM due to the gradual increase in Body Mass Index and the epidemic of obesity during recent decades.[8] Diabetes in pregnancy, both gestational diabetes mellitus (GDM) and pregestational DM, is an independent risk factor for obstetrical complications affecting both the mother and the fetus, including gestational hypertension, a higher rate of cesarean deliveries, large for gestational age neonates, and shoulder dystocia.[9]

Diabetes and pre-diabetic conditions, such as insulin resistance and impaired fasting glucose, have been described as risk factors for PFD, especially for urinary incontinence.[10] However, there is scarce data regarding the relationship of DM during pregnancy to PFD symptoms.[11] This relationship might be of interest, since gestational DM and insulin resistance during pregnancy are often transient conditions, coming to resolution after the early postpartum period.

The Pelvic Floor Distress Inventory-20 (PFDI-20) questionnaire is a short version of the Pelvic Floor Distress Inventory (PFDI),[12] designed to assess the extent of PFD symptoms and their effect on the patient's quality of life.[13] This questionnaire has been validated for use in the Hebrew language as well as for the pregnant population.[14,15]

The aim of this study was to investigate the prevalence of PFD symptoms in Israeli women with and without DM in pregnancy. Furthermore, we intended to compare the postpartum recovery from PFD symptoms in these women and evaluate various obstetrical factors that may correlate with these changes.

MATERIALS AND METHODS

A prospective cross-sectional study was conducted between February 2017 to June 2017 in the Department of Obstetrics and Gynaecology at the Soroka University Medical Center (SUMC), Beer Sheva, Israel. SUMC is a tertiary center serving a population of more than a million, with approximately 17,000 deliveries annually. Approval of the Institutional Review Board was obtained; verbal informed consent was given prior to administrating the questionnaires.

PFDI-20 in the Hebrew language was distributed to all participants. The PFDI-20 consists of items that concern the three components of PFD:[16] 1) POP distress inventory (POPDI), 6 items; 2) colorectal and anal dysfunction (CRAD) inventory, 8 items; and 3) urinary distress inventory (UDI), 6 items. Participants are requested to answer either yes or no to the questionnaire items. "No" is given a value of "0" whereas the answer "yes" is followed by a scale of bother, ranking between 1 and 4 (1 = "not at all"; 2 = "somewhat"; 3 = "moderately"; and 4 = "quite a bit"). For each patient, there is an option to calculate a Scale Score and a Summary Score. The Scale Score is the mean value of all questions answered per scale multiplied by 25, so that each scale (POP, CRAD and UD), may receive a maximum score of 100. The Summary Score is the sum of all three Scale Scores (range: 0–300).

Inclusion criteria included age over 18 years, delivery at SUMC and adequate understanding of the Hebrew language. Inclusion criteria for the diabetes group included women with either a pregestational diagnosis of DM, or diagnosed with GDM during the index pregnancy, based on an oral glucose tolerance test, or fasting glucose indicating overt diabetes.[17] Exclusion criteria included multiple pregnancies.

Patients were recruited either during the third trimester of pregnancy at the outpatient clinic, or at labor and delivery or maternity ward within 24 hours of delivery. After giving an informed consent, women were asked to fill out the PFDI-20 questionnaire (reflecting symptoms in the third trimester), either by filling the questionnaire form or assisted by an interviewer. All women gave their consent for a follow-up questionnaire three months after delivery, to reflect the women's state during the postpartum period. The second questionnaire was sent via an electronic application, and women who did not respond electronically were contacted for a telephone interview.

Data regarding maternal baseline characteristics, including age, gravidity, parity as well as clinical information regarding the index delivery (e.g. mode of delivery, neonatal birth weight, perineal tears), were obtained from the hospital's computerized medical records.

Statistical analysis

Statistical analysis was performed using the SPSS software package, version 20 (SPSS Inc, Chicago, IL). Categorical variable data is presented using percentile and statistical significance was tested using the X^2 or Fisher's exact test, as appropriate. Numerical variable data is presented using median and interquartile range and statistical significance was analyzed using Mann-Whitney U test. Continuous variable data is presented using mean and standard deviation, Student t-test was used for statistical analysis, paired t-test was used when appropriate. P-value of 0.05 and under was considered statistically significant.

A post-hoc sample size calculation was performed using the data found in our study. Considering a ratio of 1:1 in the control versus the study group and a mean total score for the study

group of 70 with SD of 47 and for the control of 28 with SD of 37, the sample size calculated with a power of 80% and alpha of 0.05 was 20 in each group.

RESULTS

A total of 192 women were recruited during the study period, 66 women in the DM group and 126 in the control group. At three months postpartum, 114/192 (59.4%) women have completed the second questionnaire, and were included in the analysis comparing both periods. Of these, 45/66 (68.2%) women in the DM group and 69/126 (54.8%) in the control group. Baseline characteristics of both groups are presented in Table 1. Maternal age and maternal weight were significantly higher among the DM group. Perinatal and neonatal characteristics are presented in Table 1. Women with DM during pregnancy delivered earlier than the control group (38.5±1.3 weeks vs 39.2±2.2 weeks of gestation, respectively, p=0.02), and had a larger proportion of cesarean deliveries (30.8% vs 13.5%, p=0.01). No differences were noted between the groups regarding the mean birthweight, rates of epidural anesthesia, the duration of second stage of labor and perineal tears.

The decrease in self-reported PFD symptoms three months postpartum compared with during pregnancy was statistically significant in 12/20 PFDI items, in our study population (Table 2). The overall PFDI-20 score was significantly decreased (p<0.001), and this decrease was significant for all components of the PFDI-20: POP distress (p<0.001); colorectal and anal distress (p=0.01); and UD (p<0.001).

The differences in the mean PFDI-20 scores at third trimester versus three months postpartum (delta score change) among patients with and without diabetes are presented in Table 3 and Figure 1. No significant differences were noted in the extent of

Table 1. Demographic, perinatal and neonatal characteristics of the diabetes and the control groups

Variables		Diabetes (n=66)	No diabetes (n=126)	p-value
Maternal age, (year)		32.3±5.2	29.3±4.9	<0.001
Weight, (kg)		85.4±20	76.7±14.9	0.002
Height, (cm)		162.3±7.1	163.1±6.7	0.63
Gravidity		3.24±1.94	2.86±1.84	0.17
Parity		1.59±1.67	1.42±1.34	0.68
Previous vaginal deliveries		1.38±1.72	1.23±1.40	0.93
Previous cesarean sections		0.21±0.57	0.10±0.35	0.18
Past miscarriages		0.65±0.95	0.44±0.72	0.22
Delivery week, (weeks)		38.5±1.3	39.2±2.2	0.02
Birth weight, (grams)		3,221±471	3,233±553	0.89
Duration of 2nd stage, (minutes)		47.4±81.5	51.1±74.2	0.79
Duration of 3rd stage, (minutes)		12.8±8.4	12.5±5.3	0.82
Time from rupture of membranes to delivery, (minutes)		338±341	357±411	0.82
Mode of delivery	Vaginal	43 (66.2%)	101 (80.2%)	0.01
	Vacuum	2 (3.1%)	8 (6.3%)	
	CS	20 (30.8%)	17 (13.5%)	
Epidural anestesia		27 (41.5%)	42 (33.6%)	0.19
Episiotomy		1 (1.5%)	11 (8.7%)	0.06
3rd degree tear		0 (0%)	2 (1.6%)	NS
4th degree tear		1 (1.6%)	0 (0%)	NS

NS: Not significant; CS: Cesarean section; n: Number
Data is presented as Mean ±SD or Frequency (%) when appropriate

Table 2. Differences in PFDI-20 Scores during pregnancy and three months postpartum among the study participants

Variables	During pregnancy	Three months postpartum	p-value
PFDI-1	1.82±1.36	0.26±0.79	<0.001
PFDI-2	1.42±1.51	0.30±0.78	<0.001
PFDI-3	0.39±0.95	0.17±0.71	0.04
PFDI-4	0.38±1.02	0.31±0.96	0.71
PFDI-5	1.30±1.49	0.31±0.74	<0.001
PFDI-6	0.06±0.33	0.03±0.29	0.55
PFDI-7	0.82±1.32	0.46±1.28	0.14
PFDI-8	0.80±1.24	0.48±0.99	0.03
PFDI-9	0.11±0.57	0.08±0.46	0.71
PFDI-10	0.19±0.70	0.09±0.49	0.17
PFDI-11	0.74±1.24	0.66±1.25	0.81
PFDI-12	0.77±1.26	0.54±1.17	0.07
PFDI-13	1.06±1.50	0.68±1.17	0.01
PFDI-14	0.50±1.23	0.30±0.87	0.33
PFDI-15	2.32±1.42	0.65±1.12	<0.001
PFDI-16	1.02±1.47	0.40±0.94	<0.001
PFDI-17	1.39±1.55	0.75±1.29	<0.001
PFDI-18	1.13±1.47	0.52±1.11	<0.001
PFDI-19	0.56±1.13	0.11±0.50	<0.001
PFDI-20	1.32±1.49	0.30±0.85	<0.001
Scale Score POP	22.31±17.01	5.71±11.19	<0.001
Scale Score CRAD	15.54±16.31	10.31±15.46	0.01
Scale Score UDI	32.25±22.73	11.33±16.40	<0.001
Summary score	70.11±46.64	27.57±36.57	<0.001

PFDI: Pelvic Floor Disability Index; POP: Pelvic organ prolapse; CRAD: Colorectal-anal distress; UDI: Urinary distress Inventory; SD: Standard deviation
Data is presented as mean ± SD

Table 3. The Change in Pelvic Floor Dysfunction Score during pregnancy and three months postpartum

Variables	Diabetes (n=45)	No diabetes (n=69)	p-value
POP Score - during pregnancy	19.07±17.95	20.17±15.18	0.73
POP Score - 3 months postpartum	7.13±12.13	5.12±10.81	0.36
Delta POP	-13.70±17.92	-15.53±15.83	0.57
CRAD Score - during pregnancy	14.17±13.95	13.99±13.74	0.95
CRAD Score - 3 months postpartum	13.14±19.30	8.65±12.72	0.18
Delta CRAD	-1.34±15.03	-5.34±14.43	0.16
UDI Score - during pregnancy	31.85±23.82	28.68±23.15	0.48
UDI Score - 3 months postpartum	15.00±19.00	9.42±14.57	0.10
Delta UDI	-16.85±20.45	-19.26±19.43	0.53
Total score - during pregnancy	65.09±46.53	62.85±42.98	0.79
Total score - 3 months postpartum	34.98±42.83	23.65±32.20	0.13
Delta total score	-30.11±37.10	-39.38±37.10	0.20

POP: Pelvic organ prolapse; CRAD: Colorectal-anal distress; UDI: Urinary distress inventory; n: Number
Data is presented as mean ± SD

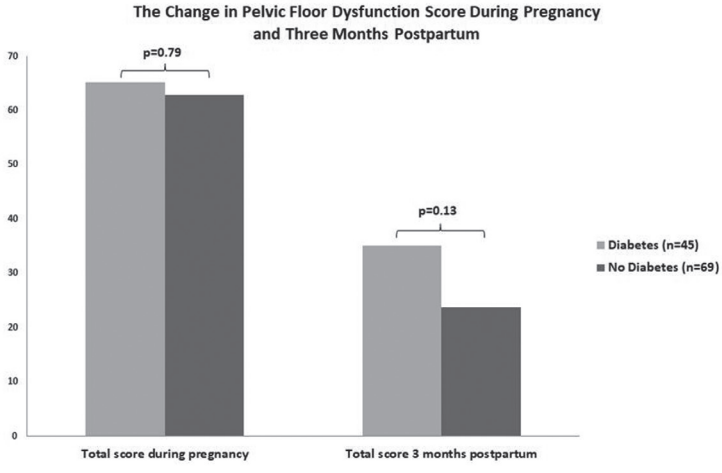

Figure 1. The change in Pelvic Floor Dysfunction Score during pregnancy and three months postpartum

recovery of the overall PFD symptoms between women with DM and the control group (p=0.2). This was also the case when stratifying these changes according to the three components of PFDI-20 [delta POP score (p=0.57), delta CRAD score (p=0.16) and delta UDI score (p=0.53)].

DISCUSSION

Pelvic floor symptoms are a common complaint during pregnancy, specifically during the third trimester and the immediate postpartum period. These symptoms can be reversed during the puerperium, although they have been reported to sustain as long as 6-12 months after delivery.[18] Parity and pregnancy outcomes, such as mode of delivery and labor dystocia as well as perineal tears,[6,15] have been recognized as risk factors for long term PFD. Women still experiencing PFD symptoms postpartum reported a negative effect on health-related quality of life measures.[19]

The effect of pregnancy on PFD symptoms is thought to result from the influence of the growing uterus and increased weight bearing of the pelvic floor muscles, as well as from hormonal changes.[20] During pregnancy, collagen rods begin to loosen in a response to secretion of placental hormones, specifically relaxin,[21] resulting in weakened ligaments. This process accelerates 24–48 hours before labor, allowing the ligaments to stretch against the fetus' head during delivery. These changes contribute to the prevalence of PFD during the second and third trimester.[21] However, the postpartum resolution of the mechanical and hormonal changes does not explain the persistence of symptoms over an extended period of time. A possible explanation is that PFD symptoms may develop postpartum in some patients, thus maintaining an overall similar prevalence of these complaints.[5,11] Additionally, since PFD symptoms have even been previously reported to be sustained as long as 6–12 months after delivery, it is possible that the three months follow up period undertaken in many studies may represent an uncomplete recovery.

Previous reports have established an association between DM and pelvic floor symptoms. The prevalence of urinary stress incontinence was found to be 33%–39% in women with impaired fasting glucose or diabetes, compared to 16%–26% in the control populations.[10,22] This may be partially related to the association between DM and obesity; although both have been shown to be independent risk factors for PFD.[23] Possible explanations for this association between urinary incontinence and other PFD symptoms to DM have been related to microvascular changes and peripheral neuropathy, in addition to polyuria symptoms associated with diabetes.[24] Additional factors impairing adequate tissue repair and wound healing may also play a role in the development of PFD in diabetic patients (for example POP).[25] There is also evidence that DM and insulin resistance alter the electromyographic activity of the pelvic floor muscles.[26]

In the current study, there was an overall improvement in PFD scores in both the DM and the control groups three months postpartum. In a previous study, comparing PFDI scores during the third trimester and three months postpartum in

our population, in almost half (9/20) of the PFDI items there was a significant change between the two study periods, with mixed trends of improvement or worsening.[15] In the current study, 12/20 items were significantly different between the two study periods, and all three components of the PFDI showed statistically significant improved scores.

A limited number of studies have specifically investigated the association between GDM and the postpartum recovery of pelvic floor symptoms. Chung et al.[11] evaluated in a large cohort of over 6,000 women the effect of GDM on urinary incontinence during pregnancy and a postpartum follow-up and found that GDM was an independent risk factor for urinary incontinence, and that women continued to exhibit urinary stress incontinence symptoms up to two years postpartum, although there was no reference to the effect of GDM on the recovery rate.[11] Of note, women in the GDM group had a higher rate of neonates with a birthweight ≥4000 gr (9% compared with 2.7% for non GDM), but also a higher rate of cesarean delivery (46.7% vs 32.2% in non GDM group), which in turn offers potential benefit in terms of pelvic floor injury.[11] Kim et al.[27] surveyed women up to 5 years from delivery and analyzed the frequency of urinary incontinence during and after a pregnancy with GDM. Around 50% of their population reported incontinence symptoms at least once a week during and after pregnancy. Surprisingly, the rate of women reporting symptoms of incontinence was significantly higher as the interval from delivery increased. This may be due to age, or to other variables affected by the latency period from delivery to survey.[27]

Our prospective analysis has shown no statistically significant difference in PFD symptoms between patients with and without DM in pregnancy. Moreover, no effect on the postpartum recovery of PFD symptoms as evident from the PFDI scores was noted between patients with or without DM in pregnancy. To the best of our knowledge this has not been directly assessed in previous studies. Our findings imply that the postpartum improvement in PFD symptoms is probably related to the resolution of the mechanical and hormonal changes affecting these symptoms during pregnancy, rather than diabetes associated changes. However, future studies should focus on the long-term effect of DM in pregnancy on PFD.

The strengths of this study are its prospective design as well as the use of validated questionnaires to assess pelvic floor symptoms. Our population is a heterogeneous population of diverse ethnicity and parity which increases the generalizability of these findings to the Israeli population as well as to other countries.

One of the major limitations of the study is the heterogeneity of the DM group which included both GDM (n=48, of which 28 did not require neither oral nor insulin treatment) and pre-gestational DM (n=9), as well as women with DM with unknown time of onset (n=9). This heterogeneity, as well as heterogeneity in recorded treatment for DM (oral hypoglycemic treatment in n=10, insulin treatment in n=20, the rest not recorded) has possibly impaired the ability to isolate the effect of diabetes during the gestational period on PFD symptoms. However, if pregestational diabetes, having a greater potential for long-term diabetic complications, has indeed affected the results, the fact that the postpartum PFDI scores for the diabetes group were still not significantly different from the non-diabetic controls, strengthens our argument that diabetes was not a significant factor in postpartum PFD symptoms recovery. Another consideration is that the population of the study was a relatively young population, with a mean maternal age of 32 in the diabetes group, and therefore the plausibility that these women who have pregestational diabetes suffer from advanced microvascular disease is small.

A second limitation is that the response rate for the second questionnaire was about 60%. It is noteworthy that this response rate was higher compared to previous studies in our population, especially in the DM group.[15] The higher response rate in the current study may be attributed to the fact that for the second questionnaire women were first approached electronically, and those who did not respond were contacted by a telephone interview.

Patients were recruited either during the third trimester of pregnancy at the outpatient clinic, at labor and delivery or the maternity ward within 24 hours of delivery. It is possible that the first 24 hours after delivery is not the optimal timing for recruitment, as some women were too weak or did not feel up to participating in the study after delivery.

Differences in mode of delivery may have also served as a limitation in the current study, as the vaginal delivery rate was higher among non-diabetic group, possibly leading to more extensive vaginal floor injury, or delayed recovery, minimizing potential differences between diabetic and non-diabetic groups.

Finally, there is a possible bias due to the difference between methods of answering both questionnaires (first; self-reported questionnaire or interview, second; electronic version or telephone interview). Women who first responded by self-reporting may feel reluctant to answer personal questions over the phone, thus “minimizing” the report of their discomfort.

CONCLUSION

Our study has demonstrated that there is a clinically and statistically significant spontaneous recovery from PFD

symptoms during the postpartum period. DM in pregnancy did not delay the postpartum pelvic floor recovery, suggesting that in young women the main effect is of pregnancy itself, and that the effect of DM on the pelvic floor seen in other studies may be related to a long-standing disease. Future studies should focus on evaluating PFD stratified by the different types of DM during pregnancy (gestational vs pregestational) and according to diabetic control status as well as evaluate the long-term effects of DM in pregnancy on PFD.

Contributions

Concept: N.B.T., M.E., D.Y., A.Y.W., Design: N.B.T., M.E., D.Y., A.Y.W., Data Collection or Processing: N.B.T., M.E., Z.Y., H.G., E.P., D.T., Analysis or Interpretation: N.B.T., Y.B., Z.Y., D.T., D.Y., A.Y.W., Literature Search: N.B.T., D.T., A.Y.W., Writing: N.B.T., Y.B., D.Y., A.Y.W.

Ethics

Ethics Committee Approval: Approval of the Institutional Review Board was obtained (Department of Obstetrics and Gynecology at the Soroka University Medical Center (SUMC), Beer Sheva, Israel) (IRB decision number: SOR-199-16, approval date: 07/07/2016).

Informed Consent: All women gave their consent for a follow-up questionnaire three months after delivery, to reflect the women's state during the postpartum period.

Peer-review: Externally peer-reviewed.

DISCLOSURES

Conflict of Interest: The authors declare that they have no conflict of interest.

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ORIGINAL ARTICLE

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Motivators of seeking pelvic floor physical therapy in ultra-orthodox Jewish women

LEA TENE[1,2], MENAHEM NEUMAN[1,3], LEONID KALICHMAN[2], JACOB BORNSTEIN[1,3]

[1]Department of Obstetrics and Gynaecology, Galilee Medical Center, Nahariya, Israel
[2]Department of Physical Therapy, Recanati School for Community Health Professions, Faculty of Health Sciences, Ben-Gurion University of the Negev, Beer-Sheva, Israel
[3]Department of Obstetrics and Gynaecology, Azrieli Faculty of Medicine, Bar Ilan University, Safed, Israel

ABSTRACT

Objective: Almost 50% of women with one or more children experience pelvic organ prolapse, and physical therapy for pelvic floor rehabilitation is one of the first-line treatments for women with pelvic organ prolapse seeking medical care. This study aimed to investigate whether ultra-orthodox women would proceed with pelvic floor rehabilitation taking into account Jewish religious laws—Halacha—or medical motivations.

Materials and Methods: Between January and May 2015, 65 ultra-orthodox women aged 20–65 undergoing pelvic floor rehabilitation completed a questionnaire regarding their pelvic floor function, religion, and treatment motivations.

Results: Most women considered both medical and Jewish religious law reasons for seeking treatment for pelvic organ prolapse (POP).

Sixty-five women completed the survey. More women sought treatment taking into consideration both medical and Jewish religious law reasons, as opposed to medical or Jewish religious law reasons alone. Upholding religious commandments was an important factor in seeking medical treatment.

The motivation to seek treatment for POP symptoms usually involves both medical and religious law reasons in ultra-orthodox Jewish women.

The study's strength is that it is novel in examining the religious motivations for seeking therapy for symptoms associated with POP. However, no control group was included in this study, which is a limitation.

Conclusion: The findings indicate that Jewish religious law motivations were an extremely important factor among ultra-orthodox women presenting for pelvic floor rehabilitation.

Keywords: Pelvic floor; pelvic floor rehabilitation; physical therapy; treatment; ultra-orthodox

INTRODUCTION

Pelvic floor medicine deals with the treatment of tissue, muscle, and ligament deficiencies in the pelvic floor. These deficiencies sometimes result in urinary and fecal incontinence, sexual dysfunction, organ prolapse, and organ dysfunction.[1] Each symptom deeply affects a woman's quality of life.[2] Religious,

Address for Correspondence: Jacob Bornstein, Department of Obstetrics and Gynaecology, Galilee Medical Center, Nahariya, Israel and Department of Obstetrics and Gynaecology, Azrieli Faculty of Medicine, Bar Ilan University, Safed, Israel
E-mail: mdjacob@gmail.com **ORCID ID:** orcid.org/0000-0003-1932-5270
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especially ultra-orthodox Jewish women suffer twofold: everyday functioning is impaired, and their ability to properly fulfil religious commandments is damaged. In the ultra-orthodox Jewish community, the Jewish religious law—*Halacha*—has a great influence on every aspect of life. Thus, a medical problem will be handled when it is medically disturbing and especially when the problem leads to a conflict with Jewish religious law and the ability to fulfil religious commandments.

Urinary incontinence can arise from physical effort,[3] leading to inability to restrain urine release, which impairs quality of life. Fecal incontinence is associated with impaired activity of the pelvic floor sphincters; however, its social consequences are far more extensive.[4,5] Between 9% and 39% of women aged over 60 report daily urinary leaks,[6] whereas the prevalence of fecal incontinence is between 2% and 6%.[7] It affects approximately 9% of women during the first 3 months postpartum.[4] Moreover, when lack of gas control is considered, the frequency is even higher. Pelvic organ prolapse (POP) is a condition in which one or more pelvic organs have descended. It can occur with each of the pelvic organs, in part of an organ, or in several organs together.[8] Prolapse occurs when the pelvic ligaments and muscles are damaged, weak, or under high or continuous pressure.[9] Almost 50% of women with one or more children experience prolapse, and among them, 10%–20% are symptomatic.[10]

In this study, we focused on pelvic floor rehabilitation with regard to three conditions: incontinence, POP, and pain during vaginal intercourse. The aim of this study was to examine whether Jewish religious law repercussions are an additional cause for ultra-orthodox women to seek pelvic floor rehabilitation treatment, beyond the general medical motivation common to all women. We hypothesized that ultra-orthodox women attribute great importance to the Jewish religious law implications of a medical issue and seek pelvic floor physical therapy based on medical reasons and their ability to fulfil religious commandments.

MATERIALS AND METHODS

This study was conducted among ultra-orthodox religious women from the ultra-orthodox cities of Bnei Brak and Elad. The inclusion criteria were women aged 20 to 65 years who presented for pelvic floor rehabilitation and who agreed to fill out the questionnaire.

Ethics: This study was performed in line with the principles of the Declaration of Helsinki. The IRB at Galilee Medical Center (Helsinki Committee) approved this study (approval number: 0058-20-NHR, given on July 21st, 2020). Participation in the study was voluntary. Patients who met the inclusion criteria received an explanation of the methods and procedures of the study, and if they were interested in participating, they signed an informed consent form. After signing the form, they filled out the questionnaire in a separate room next to the clinic. They were requested to complete the questionnaire anonymously after completing all treatment procedures, so that patient-therapist relationships to not affect their answers.

Tools: The questionnaire included 140 questions and was based on several Hebrew questionnaires as well as questions relevant to the topic of research. It was developed by the researchers and adapted to the unique topic of research and the target population. The questionnaire used a Likert scale where 1 expressed disagreement with the statement, opinion, or action, and 5 expressed strong agreement. For some of the questions, it was also possible to mark 6—irrelevant—because not all women experience the same symptoms.

After asking for the patients' demographic information, the questionnaire was divided into eight groups of statements according to subject. In each group, the means of the answers on a scale of 1 to 5 or 1 to 6 were calculated.

Procedure

The data were collected in pelvic floor rehabilitation clinics in Bnei Brak and Elad by a single researcher (L.T.). The study continued until the desired number of subjects was reached. Questionnaires were in Hebrew and were filled out anonymously.

Statistical analysis

All statistical computations were performed using SPSS 21.0 for Windows (SPSS, Chicago, IL, USA). Descriptive statistics were used to characterize the sample, and the data are presented as means with standard deviation (SD) or as proportions. To examine the significance of the statements, we used different analyses. We compared the differences between the two age groups (20–50 and 50+ years) using a chi-square test. To check the ranking of sections dealing with the same domain, we used ANOVA for repeated measures. This process upgraded the sections, from the highest-average to the lowest-average section.

RESULTS

A total of 65 women, who identified as ultra-orthodox, completed the survey, and their demographic characteristics are presented in Table 1. The average age of the participants was 37.5 years (SD=1.57), ranging between 21–63 years, and most (95.4%) were married. The majority of the participants (78.5%) were native Israelis; of the remaining participants, four were from Turkey, Yemen, and Morocco (6.2%), four from France and Belarus (6.2%), one from Argentina (1.5%), and five were from the United States

(7.7%). The majority (66.2%) of the participants had studied in a seminar, and 80% of the women declared that they were currently working. Only a few (6.2%) participants were pregnant at the time of the survey. Table 2 presents the three conditions of pelvic floor impairments that were studied. In the questionnaire, participants were asked to indicate the impairments from which they suffered and to answer the questions relevant to their condition. As shown in Figure 1, 100% of the women aged 50+ years reported urinary incontinence, compared to 67% of those aged between 20–50 years. This difference was statistically significant (p=0.02). In terms of prolapse, 38.5% of women aged 50+ years reported prolapse compared to 46.2% of women aged 20–50 years, which was not statistically significant. Women aged 20–50 years were significantly more likely to report sexual difficulties than those aged over 50 (36.5% vs 7.7%, respectively; p=0.04).

Figure 2 shows the mean period of time in years from symptom appearance to questionnaire completion. This period was the shortest for women with fecal incontinence (M=1.5 years, SD=1.00). The time period between symptom onset and questionnaire completion was longest among women with urinary incontinence. This finding may be related to the time taken for a patient to obtain a medical referral, which does not always coincide with the appearance of symptoms.

Table 1. Participants' demographic characteristics

Characteristic		N=65 (%)
Age	20-50	52 (80.0)
	50+	13 (20.0)
Religious status	Ultra-orthodox	65 (100)
	Nationalist-religious	0 (0)
	Traditional	0 (0)
	Unknown	0 (0)
Marital status	Divorced	2 (3.1)
	Widow	1 (1.51)
	Married	62 (95.4)
	Unmarried	0 (0)
Region of origin	Israel	51 (78.5)
	Asia and Africa	4 (6.2)
	Europe	4 (6.2)
	South America	1 (1.5)
	North America	5 (7.7)
Education	<12 years	0 (0)
	=12 years	10 (15.4)
	Seminar	43 (66.2)
	College/B.A. degree	11 (16.9)
	M.A. degree	1 (1.5)
Currently working	Yes	52 (80.0)
	No	13 (20.0)
Currently pregnant	Yes	4 (6.2)
	No	61 (93.8)
Number of children (mean ± standard deviation)	-	5.6 ± 3.6

Table 2. Presence of pelvic floor impairments*

Characteristics		N=65 (%)
Urinary or fecal incontinence	Yes	48 (73.8)
	No	17 (26.2)
Prolapse of one or more pelvic organs	Yes	29 (44.6)
	No	36 (55.4)
Difficulty or pain during intercourse	Yes	20 (30.8)
	No	45 (69.2)

*Women could suffer from more than one impairment

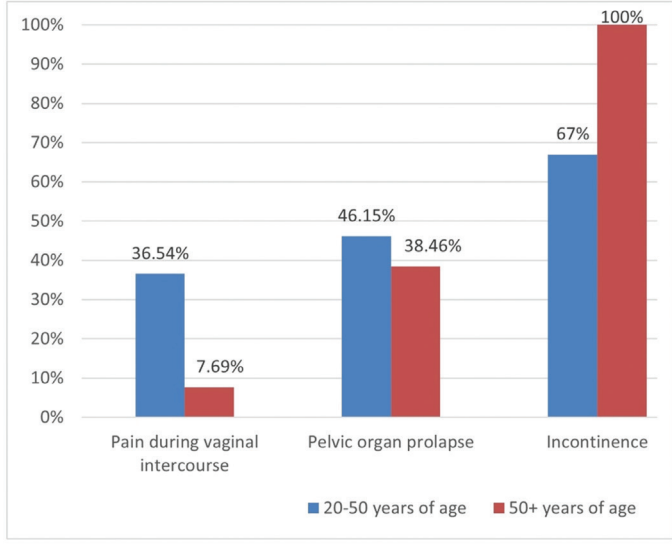

Figure 1. Pelvic floor dysfunction by age (N=65)

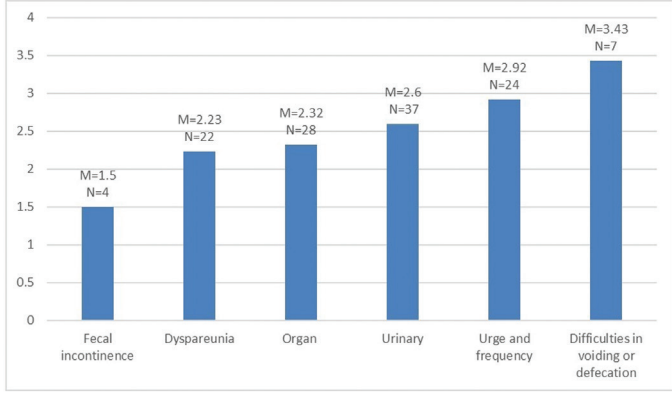

Figure 2. Average time between symptom onset and presentation for treatment

M: mean, N: Number

We then asked the following question with regard to each of the three main pelvic floor disorders: "In general, if you were asked to define the most crucial motivation when referring to physical therapy treatment, what is your answer?" Of the 42 women experiencing urinary incontinence, 50% reported both Halacha and medical motivations to seek treatment, whereas 45.2% reported solely medical motivation, and 4.8% reported solely Jewish religious law motivation (Figure 3). Of the 28 women experiencing POP, 42.9% reported combined motivations, 39.3% reported solely medical motivation, and 17.9% reported solely Jewish religious law motivation (Figure 4). Of the 19 women who reported pain during vaginal intercourse, 63.2% reported combined medical and Jewish religious law motivations, 21.1% reported solely medical motivation, and 15.8% reported solely Jewish religious law motivation (Figure 5).

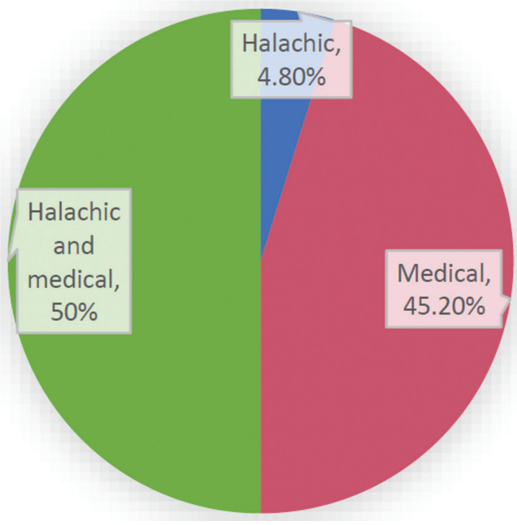

Figure 3. Motivation to pursue physical therapy (N=42)
Halachic: Related to Halacha, the Jewish religious law; N: Number

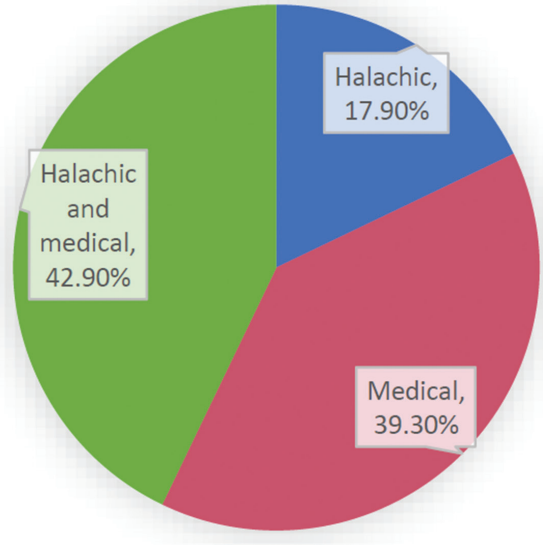

Figure 4. Most important motivation to seek treatment for pelvic organ prolapse (N=28)
Halachic: Related to Halacha, the Jewish religious law; N: Number

All women, regardless of their specific pelvic floor disorders, were asked about Jewish religious law or medical motivations for treatment (Figure 6). Of the 65 women who reported whether they had Jewish religious law or medical motivations to pursue treatment for each of their particular symptoms, only 3.1% reported only Jewish religious law motivations for all disorders. While 23.1% reported only medical motivations for all disorders, 73% reported combined medical and Jewish religious law motivations for seeking treatment.

The Jewish religious law was shown to be an extremely important aspect of life for ultra-orthodox women with their responses to statements such as "Religion plays a central part in my life" (mean=4.84, SD=0.35) and "I feel obligated to fulfil religious commandments" (mean=4.94, SD=2.42).

When asked which situations would cause them to seek treatment immediately, difficulty getting pregnant because of a

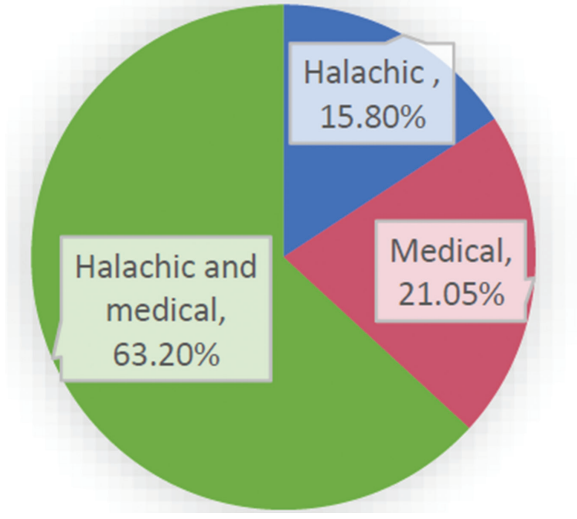

Figure 5. Most important motivation to seek treatment for pain during vaginal intercourse (N=19)
Halachic: related to Halacha, the Jewish religious law; N: Number

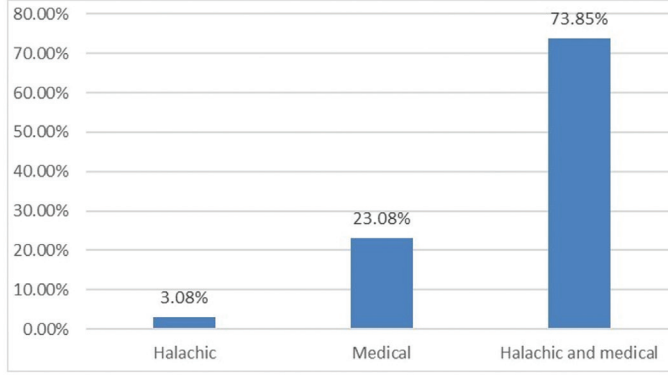

Figure 6. Main motivations for seeking physical therapy (N=65)
Halachic: related to Halacha, the Jewish religious law; N: Number

pelvic floor impairment was reported to be the most worrisome (mean=4.98, SD=0.14), followed by the feeling that their physical condition causes them to be ashamed in front of their husbands (mean=4.75, SD=0.74). The least worrisome situation was urinary incontinence (mean=4.00, SD=1.18), though it should be noted that the score, however, indicates a high degree of motivation to seek immediate treatment.

DISCUSSION

The most common motivations for women seeking treatment for pelvic floor disorders involved both medical and Jewish religious law motivations, which supports the research hypothesis. Of the 65 women who completed the questionnaires, only two indicated solely Jewish religious law motivations, whereas 15 noted solely medical motivations.

Between 7% and 37% of women in this study aged 20 to 39 years reported a certain level of incontinence, and nearly half of all women reported symptoms of POP. Many women are diagnosed by their gynaecologist as suffering from slight prolapse; however, it will not always be felt or accompanied by symptoms.[11] POP can cause symptoms such as loss of urine, difficulty in emptying the intestines, pain in the lower back or pelvis, pain or discomfort while having sexual intercourse, and decreasing self-image and quality of life.[10,12]

Ultra-orthodox women have an obligation to pray, which cannot be done if she is viewed as unclean.[13] Urinary or fecal incontinence will prevent a woman from praying, and bleeding due to POP prevents immersion in the ritual bath—the Mikveh.[14] In the worst-case scenario, if an ultra-orthodox woman prays while she is seen as unclean, her prayer would be considered an abomination as if she had not prayed at all.[15-17] For an ultra-orthodox woman, this seriously impairs a religious way of life.

Pelvic floor disorders are also unpleasant and awkward from a personal and conjugal perspective. While this is common to all women, there are additional Jewish religious law implications for ultra-orthodox women.[18] Pain or difficulty in sexual relations can occur as a result of over-contraction of the pelvic-floor sphincters or due do provoked vulvodynia—oversensitivity of the vestibule.[19] Additionally, it can arise among couples during sexual intercourse when the woman experiences different forms of pain in the pelvic area. The pain impairs daily functioning and prevents the possibility of sexual contact.[20] This situation causes many couples to avoid intercourse, and as a result, it prevents an essential part of Jewish religious marital life, as well as procreation.[21,22]

We discovered that among women experiencing urinary incontinence, the effect on their ability to fulfil religious commandments was significant and difficult. However, there was no significant difference in the proportion citing combined medical and Jewish religious law motivations for seeking treatment and those citing only Jewish religious law motivations. A higher proportion of women reported combined motivations for seeking treatment for prolapse; however, several women reported that they would immediately seek treatment if the prolapse led to difficulties or delays with immersion in the ritual bath. Among those who sought treatment due to difficulties during intercourse, combined Jewish religious law-medical motivations were the most common, and women indicated a strong correlation between the ability to fulfil commandments and bodily functioning. This symptom, in particular, influences both the woman's personal life and her relationship with her partner. Thus, when there is Jewish religious law difficulty in addition to a medical dysfunction, the consequences are more severe and affect quality of life, and it motivates religious women to actively seek out treatment.

Bilu and Witztum[23] suggest that the starting point in the dialogue of the healthcare provider with ultra-orthodox women must consider understanding that religion is what provides the main set of emotions through which their illness is experienced. On this basis, therapeutic approaches can be creatively integrated into spiritual–religious elements.[23]

The study is novel in examining the religious motivations behind seeking therapy for symptoms associated with POP. However, no control group was included in this study.

Multidisciplinary teams of medical professionals who treat women with pelvic floor disorders should be prepared to treat patients from diverse cultural/ethnic and religious backgrounds.[24]

CONCLUSIONS

Caregivers engaging in these sensitive and intimate issues should recognize not only the language and terminology unique to diverse populations but also the factors that motivate them to seek treatment for these issues. This study demonstrated that the importance of Jewish religious law in the eyes of ultra-orthodox women is integrated into their daily lives and shapes their care-seeking behavior.

Ethics

Ethics Committee Approval: This study was performed in line with the principles of the Declaration of Helsinki. The IRB at Galilee Medical Center (Helsinki Committee) approved this study (approval number: 0058-20-NHR, given on July 21st, 2020).

Informed Consent: Patients who met the inclusion criteria received an explanation of the methods and procedures of the

study, and if they were interested in participating, they signed an informed consent form.

Peer-review: Externally peer-reviewed.

DISCLOSURES

Conflict of Interest: The authors have no conflicts of interest.

Financial Disclosure: The authors declared that this study has received no financial support.

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Does acupuncture have any effect on obstructed defecation syndrome?

SHUQING DING[1], YIJIANG DING[2], LINGLING WANG[3], HUIFENG ZHOU[2], XUN JIN[3]

[1]Pelvic Floor Medicine Committee of World Federation of Chinese Medicine Societies, Nanjing, China
[2]National Center of Colorectal Diseases of Chinese Medicine, Affiliated Hospital of Nanjing University of Chinese Medicine, Nanjing, China
[3]Nanjing University of Chinese Medicine, Nanjing, China

ABSTRACT

Objective: Obstructed defecation syndrome (ODS) is a group of symptoms that are mainly caused by pelvic floor dysfunction concerning bowel symptoms. It is challenging in clinical practice. Acupuncture has advantages in the treatment of complex symptoms because of its multi-target and bi-directional regulation of the human body. Since, 2,500 years ago, acupuncture has been applied empirically to the treatment of constipation. Does acupuncture have any effect on ODS?

By showing the clinical thoughts, methods, and achievements of acupuncture series in ODS in recent ten years by the author's team, and two scientific papers published in English on acupuncture treatment of chronic intractable constipation and stress urinary incontinence, it is proved that the core scheme of acupuncture treatment of ODS is flexible.

In order to raise awareness of the therapeutic effect of acupuncture in ODS, it can be integrated into existing practice to get opportunities for multi-disciplinary cooperation and further research and development.

Materials and Methods: By summarizing the diagnosis and treatment of ODS, the first-line selection of pelvic floor rehabilitation and the minimally invasive sacral neuromodulation were reviewed, and it was pointed out that there was a gap between the high demand of patients and the expectation of cost-effectiveness. Then, on the basis of modern eastern and western medical achievements, the holistic concept was introduced into the treatment of pelvic floor dysfunction, and an acupuncture scheme suitable for ODS was proposed.

Results: Acupuncture is based on the idea of improving the patients' central nervous system, autonomic nervous system, and intestinal nervous system, and is effective in treating ODS. The acupoints were set in two groups when the patient in a supine position, which includes ST 25 (Tian Shu), SP 15 (Da Heng), SP 14 (Fu Jie), CV 6 (Qi Hai), CV 4 (Guan Yuan), ST 36 (Zu San Li), ST 37 (Shang Ju Xu); When a patient is in the prone position, it includes BL 20 (Pi Shu), BL 23 (Shen Shu), BL 25 (Da Chang Shu), BL 33 (Zhong Liso), BL 34 (Xia Liao), and GV 20 (Bai Hui). The key was the technique of deep needling of the ST 25 (Tian Shu) and deep needling of the BL 33 (Zhong Liso) & BL 34 (Xia Liao). It needs 2-15 Hz sparse-dense wave electrical stimulation, 30 minutes each time, a total of 20 times, which was a scheme that could achieve satisfactory short-term and long-term effects.

Conclusion: At present, clinical and basic experimental studies have proved that acupuncture plays a role in treating ODS in a multi-target way. This is a very promising research direction of pelvic floor integrated medicine.

In the future, further study on optimizing the protocol and meeting the patient's gap individually and cost-effectively.

Keywords: Acupuncture; obstructive defecation syndrome; pelvic floor symptoms; constipation; protocol; electronic stimulation; sacral nerve modulation; pelvic floor rehabilitation

Address for Correspondence: Shuqing Ding, Pelvic Floor Medicine Committee of World Federation of Chinese Medicine Societies, Nanjing, China
E-mail: njgczx@gmail.com **ORCID ID:** orcid.org/0000-0002-5875-8629
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INTRODUCTION

Obstructed defecation syndrome (ODS) is a type of constipation, which is a kind of pelvic floor dysfunction disease concerning bowel symptoms, characterized by fragmented stools, overstraining at defecation, sense of incomplete evacuation, tenesmus, urgency, pelvic heaviness, and self-digitation.[1]

A pelvic floor is a functional unit connecting the bladder, uterus, rectum, and other organs through muscles and ligaments, which is controlled by the same nervous system at different levels. The functions of any organs in the pelvic floor are balanced with each other, rather than existing alone. In addition to the above-mentioned defecation symptoms, patients may also have overlapping urination, pelvic floor relaxation, and sexual symptoms.

Patients usually cannot get satisfactory results from general lifestyle changes, fiber diet, exercise, and laxatives. Some patients may even become addicted to taking laxatives, suppository, or rectal irrigation. ODS greatly affects patients' quality of life, physically and mentally.

Western medicine doctors may recommend patients to physiotherapists for pelvic floor biofeedback therapy, which is the first choice recognized by gastroenterology,[2] and colorectal specialists.[3] However, patients often quit behavioural training from frustration and other reasons.

Some selected patients may benefit from sacral neuromodulation (SNM), a minimally invasive surgical technique, with a total success rate of 73%. It is promising but still not well accepted worldwide mainly due to the cost-effectiveness and complications from the device and operation itself.[4]

In 2008, the author published the preliminary research results of acupuncture treatment in ODS in China and conducted a series of studies later,[5-7] which showed that acupuncture in ODS had advantages combining with the above-mentioned methods.[8]

It is hoped that through further multidisciplinary cooperation and multi-centre research, acupuncture will be applied and popularized effectively in pelvic floor disorders.

Obstructed defecation syndrome (ODS)

Symptoms and pathophysiology

ODS is characterized by fragmented stools, overstraining at defecation, a sense of incomplete evacuation, tenesmus, urgency, pelvic heaviness, and self-digitation.[1]

ODS is frequently encountered in colorectal, gastroenterology, or gynaecology clinics. According to the Rome II Criteria of functional gastrointestinal disorders, the incidence of chronic functional constipation is 6.07% to 11.5%. In China's general population, the incidence is double in aged female patients. Among these, nearly 60% of patients with constipation suffer from ODS.[8]

Based on the pelvic floor integral theory of Petros and Ulmsten put forward for the first time in 1990, the pelvic floor is regarded as a functional unit connecting the bladder, uterus, rectum, and other organs through muscles and ligaments, which is controlled by the same nervous system at different levels. The functions of any organs in the pelvic floor are balanced with each other, rather than exist alone.[9] So in addition to the above-mentioned defecation symptoms, ODS patients may also have overlapping urination, pelvic floor organ prolapse, and sexual symptoms.

Other related pathophysiological factors also involved the pelvic floor dysfunction, including the muscle system (puborectalis muscle and/or the internal anal sphincter can't relax during defecation), peripheral nervous system (sacral parasympathetic nerve and/or pudendal nerve neuropathy),[10,11] central nervous system (Parkinson's disease),[12] and psychological or behavioural issues,[13] etc.

MATERIALS AND METHODS

Diagnosis and evaluation

ODS is a challenging disease. A well-trained multidisciplinary team is needed in the pelvic floor center for its comprehensive evaluation. The diagnosis of ODS is based on a careful collection of patients' clinical history. The severity of symptoms may be objectively evaluated using a validated score.[14] After testing, ODS is defined as three major subtypes of constipation, which are usually identified as normal colonic transit, slow transit, and functional defecation or not. Digital rectal examination is a useful bedside tool for evaluating functional defecation, which is used to identify dyssynergia and rectocele and is convenient to select patients for further confirmatory physiology testing,[15] including anorectal manometry, transanal or transperineal dynamic ultrasound,[16] magnetic resonance imaging defecography,[17] and psychological evaluation which may offer the morphological and functional abnormal evidence of the patients.[18]

Then ODS has subsets of dyssynergic defecation, pelvic floor relaxation, and mixed presentations. Dyssynergic defecation is most often associated with an inability to coordinate abdominal, rectoanal, and pelvic floor muscles during defecation. On rectal examination, the patient may have a high resting tone, and on bear down descent may be poor or paradoxical. Pelvic floor relaxation patients may have a normal or lower resting tone, and on bear down perineum descent great, may manifest

rectocele, intussusception even pelvic organ prolapse of rectum, intussusception, uterus or bladder. The difference in rectal sensation (hyper- or hypo-) and compliance (hyper- or hypo-) of patients also participate in the above-mentioned different subtypes, thus enriching the details of ODS.

Patients suffering from severe chronic defecation symptoms often represent an acquired behavioural disorder and may have potential psychological issues. In our 90 cases research on chronic functional constipation, 35 (38.9%) cases had the problem, of which 14 cases had mild to moderate depression while 21 cases had severe depression and anxiety; almost all the patients had sleeping issue. Additionally, patients complain of fatigue, weakness, some female patients may have menstruation shortage or weight loss due to endocrine or nutrition dysfunction.[8] Although not directly life-threatening, this psychosomatic disease adversely affects a patient's social and personal life as 4 "D", an abbreviation of discomfort, depression, dollar costs, and drug toxicity.

Pelvic floor rehabilitation

In view of the complexity of etiology, pathology, and overlapping symptoms, a multidisciplinary approach seems to be the key,[1] which requires a holistic method to fix the functional balance, namely pelvic floor rehabilitation.

Basically, the ODS patients cannot get satisfactory results from the management for constipation, such as changing lifestyle, fiber diet, exercise, laxatives, etc., And some patients may even take more laxatives, suppository, or rectal irrigation for temporary relief. It greatly affects patients' quality of life physically and mentally.

Being safe and non-invasive, pelvic floor biofeedback therapy has been considered as the first choice on ODS for rehabilitation in western medicine, recommended by international guidelines on gastroenterology,[2] and colorectal.[3] This kind of retraining from maladaptive behaviour can improve the defecation effort by learning, and help patients to cultivate a better understanding of pelvic floor muscle self-control and brain-gut reflex reconstruction.

A successful biofeedback therapy requires proper cognitive preparation, guidance, and instruction before using the instrument. The success of biofeedback depends on patient selection, a well-trained therapist, and treatment compliance. Biofeedback effectively relieves symptoms of defecatory disorders in 69% of affected adults.[19] Therefore, if patients have a mental disability or have severe anxiety and depression, they may have no ability or motivation to fulfil the repeated trial and error training, or if they cannot get the encouragement from a well-trained therapist, they may easily quit from the frustrated behavioural treatment.[20]

Sacral nerve modulation

If the patients are dissatisfied with non-surgical treatment, some selected patients may benefit from the sacral nerve modulation (SNM), it has shown great potential in treating pelvic floor dysfunction in recent decades.[21] This minimally invasive procedure includes two stages. Initially, an electrode is implanted into the posterior sacral foramen (mostly the right S3) to stimulate the sacral nerve roots; a temporary electrode lead is connected to a portable battery unit outside the body. After 2–3 weeks of testing, if symptoms are improved by more than 50%, the second stage operation is considered feasible and this is replaced by the implanted battery for permanent stimulation.

A systematic review,[21] assessed the therapeutic effects on chronic constipation. There are 13 studies using SNM in chronic constipation all over the world, and the success rate in the first stage is 42%–100%. then 87% of patients improved after the permanent implantation, and the average follow-up time was 28 months. Another systematic review showed that the total "success rate" of patients who received permanent implantation was 73%, and the removal rate of instruments was about 12%.[4] The balance of risk versus benefit must be fully understood by patients and clinicians, and realistic expectations set out before treatment.[4]

It is promising but still not well accepted worldwide mainly due to the cost-effectiveness and complications from the device and operation itself as well.

On the basis of ODS clinical research and management update, the multidisciplinary pelvic floor team of Nanjing University of Traditional Chinese Medicine and National Center of Integrated Colorectal Surgery started to carry out acupuncture research in the "*sacral nerve modulation era*" in 2005.

Most of the original works were published in Chinese. This is the first original paper on teamwork and achievement published in English since then. The authors will exhibit a set of acupuncture protocols based on clinical trials and research evidence or animal studies finding, combining with the authors' expertise to meet the gap of patients' needs cost-effectively.

Acupuncture for ODS

Acupuncture based on traditional Chinese medicine treats patients as a whole. The first record for constipation was from "Inner Canon of Yellow Emperor (Huangdi Neijing)" around 2,500 years ago. It has been empirically practiced in China for several millennia, and the technique treating constipation is now being

increasingly accepted by practitioners and patients worldwide, including the United States.[22,23]

Acupuncture has a bidirectional holistic and physiologic limit modulation effect in treatment. Bidirectional modulation, namely, an unbalanced (hyperactive or hypoactive) pathophysiological state can be normalized by acupuncture based on the patient physique individually, it is not a purely excitatory or suppression process. Holistic modulation means acupuncture has a multi-target and multi-system effect through meridians by adjusting Yang et al.[24] It is an option for complex pathological mechanism diseases like chronic constipation.

The goal of the acupuncture program is to regulate the whole pelvic floor muscle and nerve function from the philosophy of Chinese medicine and Western medicine.

RESULTS

Acupoints selection[25]

The nervous system is composed of the central nervous system (CNS), autonomic nervous system (ANS) (sympathetic nervous system, and parasympathetic nervous systems), and enteric nervous system (ENS). The selection of acupoints in the sacrum, lower abdomen, back, and the head is based on this design concept.

The first group set when the patient in a supine position, which includes ST 25 (Tian Shu), SP 15 (Da Heng), SP 14 (Fu Jie), CV 6 (Qi Hai), CV 4 (Guan Yuan), ST 36 (Zu San Li), ST 37 (Shang Ju Xu); The second group set when patient in the prone position, which includes BL 20 (Pi Shu), BL 23 (Shen Shu), BL 25 (Da Chang Shu), BL 33 (Zhong Liao), BL 34 (Xia Liao) and GV 20 (Bai Hui).

Figure 1 shows the appearance of acupoints and needles penetration.

The most important acupoints are ST 25 (Tian Shu), BL 33 (Zhong Liao) & BL 34 (Xia Liao), and GV 20 (Bai Hui) which respectively represent the regulation of ENS, ANS, and CNS.

Acupoint ST 25 deep needling technique[26]

Patients take the supine position, the acupoints ST 25 (Tian Shu) is located two inches (50 mm) away from the navel, use needles (size 75×0.30 mm) slowly penetrate 40–50 mm vertically in-depth, according to the thickness of the patient abdominal wall until the needle tip reaches the peritoneal layer.

During the process of needle insertion, the operator feels heavy, with a little resistance, just like the feeling of fish biting the hook, and then continues to deepen the needle. When there is a significant breakthrough under the needle tip, the patient may feel pulled and then stop inserting the needle.

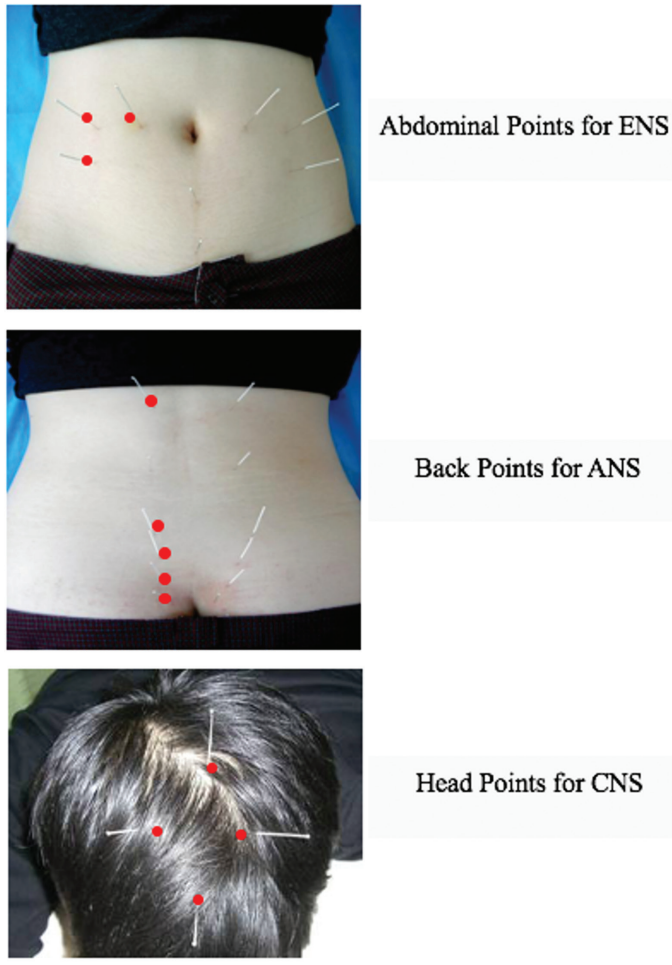

Figure 1. Appearance of needles in patients
ENS: Enteric nervous system, ANS: Autonomic nervous system, CNS: Central nervous system

Compared with the shallow needle (the needle tip only enters the fascia layer, but does not penetrate the peritoneum), the deep needle technique has a faster response.

Acupoints BL33& BL34 deep needling technique[27]

Patients take the prone position, the acupoints BL 34 (Xia Liao) and BL 33 (Zhong Liao) are located in the 4th and 3rd sacral foramen, use needles (size 75×0.30 mm/0.40 mm or 100×0.30 mm/0.40 mm) slowly penetrate 75–100 mm into the anterior sacral foramen at 90° and 70° angles respectively.

Figure 2 shows the needles position confirmed into the anterior sacral foramen in the 3D-computed tomography image, sagittal view).

When the needle is inserted deeply, the operator may feel slippery at first, and then a little sticky, but without resistance. At the same time, the patient may feel sore or a heavy feeling, radiating to the anus or perineum, or pelvis. There is no severe sharp pain. This technique is similar to implanting electrodes into the sacral foramen of the SNM procedure.

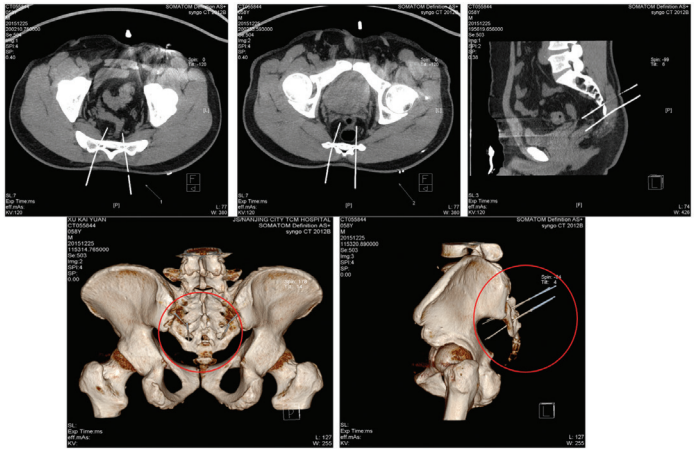

Figure 2. The needle position confirmed into the anterior sacral foramen in 3D-CT image, cross-section and sagittal view
CT: Computed tomography

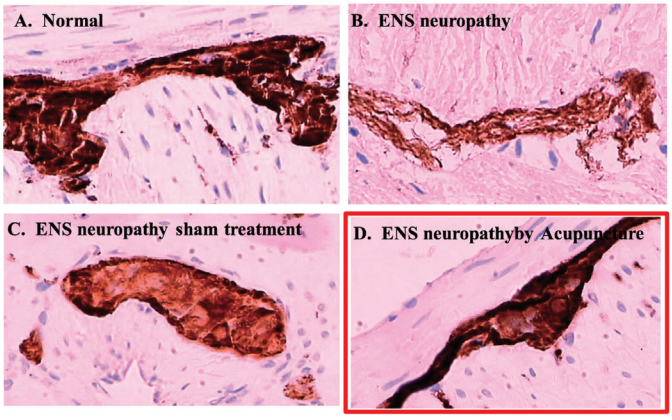

Figure 3. Protein gene product 9.5 (PGP9.5) positive expression in rat intestinal myenteric plexus (×400)
ENS: Enteric nervous system

Appropriate electronic stimulation parameter[28]

Electro-acupuncture is a method of regulating nerves or muscles function. That is to say, in terms of the functions of viscera, meridians, and qi, and blood in traditional Chinese medicine, the electro stimulator is connected to the needle handle of specific acupoints with a pair of positive and negative electrodes.

The electronic stimulator (Han's, LH 202 h, China) was connected on BL 33 (Zhong Liao) and BL 34 (Xia Liao) when in the prone position, while on ST 25 (Tian Shu) and SP 14 (Da Heng) when in the supine position for 30 minutes. By disperse-dense wave, 2/15 Hz, and suitable intensity based on patients' tolerance, preferably with the skin around the acupoints shivering mildly without pain.

Electrical stimulation parameters were set from a single-center randomized controlled clinical trial. Randomized controls at 2 Hz, 15 Hz, and 100 Hz were applied to patients with ODS to study their differences. The results showed that 15 Hz was the best for defecation, and 2 Hz and 15 Hz were better than 100 Hz for the stress and mental symptoms. And then a sparse-dense wave of 2/15 Hz was determined.[29] It is different from other research parameters of patients with stress urinary incontinence (continuous wave of 50 Hz and a current intensity of 1 to 5 mA).[30]

Course and follow-up

Routinely, the two sets of acupoints were used alternately, one set per day, with 20 sessions being a therapeutic course. Every session was for 30 minutes once daily. After a 4-week acupuncture session, it was found that dyssynergic defecation usually responded better than pelvic floor relaxation but if the treatment was prolonged to 8 weeks, the results reversed from this observation. So, some patients may need to prolong treatment courses if acupuncture responds slow.

Generally, the effects of acupuncture include the latent period, ascending period, peak period, and decline period. It may vary according to indications, stimulation parameters, and patient individuals. Some effects have a short latency and fast response, which is called rapid attack (neural reaction); On the contrary, it is called slow (e.g., humoral reaction).

Some patients may have resistance reaction, which means that there will be a good and rapid response during the acupuncture, and then there will be no result when given the same stimulus. If this is the case, it will be released after the end interval of 1 or 2 weeks, and it will be restored to its original effect or better.

Patients were given follow-up telephone calls at one and three months after the conclusion of treatment as scheduled by a research fellow. The follow-up data requested including Wexner Constipation Scoring System,[31] stool consistency, awareness to defecate, and PAC-QOL in the research.[32] Other overlapping symptom responses may require other questionnaires.

Follow-up time is important and prolongs the treatment session intervals after the regular sessions, since function after acupuncture may deteriorate with time. Prolonging the treatment interval, ceasing gradually, is a way to obtain a long-term efficacy. If symptoms return, acupuncture still works when re-applied.

Supporting evidence for acupuncture protocol in ODS

Clinical evidence: ST 25 and ST 36 and deep needling for severe constipation.[33]

The author made a comprehensive exposition of the core acupoints in the above-mentioned ODS treatment, with emphasis on the functions and deep needling techniques of acupoints ST 25 and ST 36. This important result has been confirmed by a

large paper entitled "Acupuncture Treatment of Chronic Severe Functional Constipation: Randomized Trial" published in the Western mainstream core journal "Annals of Internal Medicine" in the United States (US).

This multi-center trial had 1,075 participants from 13 hospitals, which showed that during the 8-week treatment period, electronic acupuncture can alleviate the symptoms of patients with chronic severe constipation and improve their quality of life; These effects persisted throughout the 12-week follow up.

Experimental evidence: ST 25 and ST 36 repair the ENS[34]

In the experimental scientific research, by comparing the expression of protein markers Protein Gene Product 9.5 (PGP 9.5) in normal group, Enteric nervous system (ENS) neuropathy group, ENS neuropathy sham treatment group, and ENS neuropathy acupuncture group, the author confirmed that acupoints ST 25 and ST 36 were beneficial to the recovery of intestinal function in ENS neuropathy model rats.[33]

The expression of PGP 9.5 was a characteristic marker for evaluating the function of intestinal ganglia. Figure 3 shows evidence of histopathological results.

Clinical evidence: sacral nerve modulation by acupuncture for pelvic floor dysfunction[30]

The author made a comprehensive exposition of the core acupoints in the above-mentioned ODS treatment, with emphasis on the functions and deep needling techniques of acupoints BL 33 & BL 34. This important result has been confirmed by a large paper entitled "Effect of Electroacupuncture on Urinary Leakage Among Women with Stress Urinary Incontinence a Randomized Clinical Trial" published in the Western mainstream core journal "*JAMA*" in the US.

This multi-center, randomized, participant blind, and sham electroacupuncture controlled clinical study was carried out in 12 hospitals in China, and 504 female patients with stress urinary incontinence were recruited. Participants in the electroacupuncture group received acupuncture at bilateral BL 33 (Zhong Liao) and BL 35 (Hui Yang) with 50 Hz continuous-wave stimulation for 30 minutes. During the 6-week of 18 sessions treatment period, electroacupuncture involving the lumbosacral region showed a greater reduction in leakage of urine than sham electroacupuncture. The effect lasted 24 weeks after treatment.

According to this study, the emphasis is placed on bilateral BL 33 and deep needling technique (needle diameter is 0.30×75 mm), which is almost the same technique used by the author in ODS treatment.

DISCUSSION

Potential pathophysiological mechanisms

Acupuncture treatment for ODS is explained by two theories, the traditional meridian theory, and the modern nerve-electrophysiology theory.

From the neuroanatomy point of view, human defecation function is dominated by the CNS, ANS, and ENS. ANS innervation comes from C6 to T2 and S2 to S4 segments of the spinal cord and controls gastrointestinal function. It has been suggested that acupuncture could influence the visceral sensory system by stimulating the somatic sensory system. A series of investigations undertaken on somatoautonomic reflexes have provided good evidence of the importance of cutaneous input in autonomic control of GI motility.[22] The ENS takes its input from the intestine's myenteric plexus and Cajal cells, while CNS from the brain-gut axis. Stimulation of the corresponding points on the head (GV20) and back (BL23, BL25, and BL33-34, from the 3rd to 4th sacral foramen respectively) and abdomen (ST25 SP14 SP15 CV4 and CV6) will modulate the intestinal function.

It has been proven that stimulation of the sacral nerve can promote colonic motility, and improve pelvic floor sensation.[4,21] These neurophysiological findings influenced our selection of acupoints for a clinical study.[35,36] In our 90 cases of research on chronic functional constipation, over 90% of patients have sleeping dysfunction. We found that the acupoint GV20 can improve insomnia quickly, and has an indirect effect on bowel movement.

CONCLUSION

Acupuncture treatment has no requirements for ODS candidates, and it will react quickly compared to the pelvic floor biofeedback therapy. This is a minimally invasive, cost-effective, and flexible method compared to the SNM implantation procedure. Acupuncture is a multi-target holistic therapy, but it still has limitations for pelvic floor dysfunction. For different subset individuals, it is necessary to optimize the treatment scheme or may integrate other modalities.

In addition, acupuncture is not only a physical stimulus to the human body but also a face-to-face communication process between doctors and patients in the daily treatment, which plays the role of psychological counselling. Besides, acupuncture itself can improve mental and sleeping disorders through neural regulation.

Acupuncture has important potential for treatment and to be integrated into Western Medicine. It is an evidence-

based contribution from the treatment of patients, and it is a combination of systematic "Tao" and individualized "technique".

Enthusiasm for research is growing, and the cooperation of multidisciplinary teams will speed up the process of integrating acupuncture into conventional western medicine in near future.

Contributions

Concept: S.D., Y.D., L.W., H.Z., X.J., Design: S.D., Y.D., L.W., Data Collection or Processing: S.D., H.Z., X.J., Analysis or Interpretation: S.D., L.W., Literature Search: S.D., X.J., Writing: S.D., L.W., H.Z.

Ethics

Ethics Committee Approval: Not necessary for it is included several researches published data.

Informed Consent: Not necessary for it is included several researches published data.

Peer-review: Externally peer-reviewed.

DISCLOSURES

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

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Effects of the apical suspension of the upper vagina by cervicosacropexy or vaginosacropexy on stress and mixed urinary incontinence

WOLFRAM JÄGER, ANDREAS BRAKAT, SEBASTIAN LUDWIG, PETER MALLMANN

Department of Obstetrics and Gynecology, Division of Urogynecology and Pelvic Reconstructive Surgery, University Hospital Cologne and Medical Faculty, Cologne, Germany

ABSTRACT

Objective: Cervicosacropexy (CESA) and vaginosacropexy (VASA) are standardized surgical procedures to elevate and tighten the apical end of the vagina. A combination of CESA or VASA, and a transobturator tape was reported to cure urgency urinary incontinence (UUI). However, the efficacy of CESA or VASA in curing stress urinary incontinence (SUI) has not been investigated.

Materials and Methods: Patients with SUI were asked to specify the situation when they urinated involuntarily. All of these patients were never operated on the genital tract before. In all the patients, the uterosacral ligaments were replaced by polyvinylidenefluoride tapes of identical length. The surgical outcomes in terms of vaginal anatomy and urinary incontinence were established several weeks after surgery. SUI was subdivided into SUI 1 (urinary loss while sneezing and coughing) and SUI 2 (urinary loss while performing other activities).

Results: In addition to the anatomical effect, the apical fixation of the upper vaginal wall by CESA and VASA led to continence in 57% of the patients. The continence (cure) rate was higher in patients with SUI 1 (73%) than that in patients with SUI 2 (51%). The cure rate decreased with increase in the age of the patient at surgery. Of the 161 patients, 144 (89.4%) patients with SUI 2 were clinically having UUI. CESA and VASA led to continence in 39.1% and 29.3% of these patients, respectively.

Conclusion: CESA and VASA can establish urinary continence in 29% to 48% of patients with stress and UUI. Continence rates decreased with patients' age.

Keywords: Cervicosacropexy; mixed urinary incontinence; stress urinary incontinence; urgency urinary incontinence; vaginosacropexy

INTRODUCTION

The Integral Theory by Petros and Ulmsten states that urinary continence in women is based on the integrity of the pubourethral ligaments (PULs) and the uterosacral ligaments (USLs).[1-4] This theory was supported when suburethral tapes to replace the PULs led to continence.[5] In stress urinary incontinence (SUI) the increased pressure during coughing or sneezing leads to a short opening of the urethrovesical junction (UVJ), leading to loss of urine. The tapes compress the UVJ when vertical pressure

Address for Correspondence: Sebastian Ludwig, Department of Obstetrics and Gynecology, Division of Urogynecology and Pelvic Reconstructive Surgery, University Hospital Cologne and Medical Faculty, Cologne, Germany
E-mail: sebastian.ludwig@uk-koeln.de **ORCID ID:** orcid.org/0000-0002-9170-9546
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is exerted on the bladder and the patient remains continent.[1,6] While the replacement of the PULs by tapes is an established treatment modality for SUI the role of the USLs for continence is not defined so far.

Descensus of the uterus and the vagina is often associated with urinary incontinence.[7,8] In these patients the USLs are stretched; however, it is not known if that is the cause or the effect of the descensus. The role of the USLs in urinary continence and incontinence has not been investigated in detail.[9] With increasing age, the major problem of urinary incontinence is the sudden urge to void along with nearly immediate loss of urine. Urgency urinary incontinence (UUI) was primarily considered as a neurological disorder, with effects on the detrusor muscle, and was treated accordingly.[10] It was observed that medical treatment could improve symptoms and reduce incontinence episodes. However, it did not lead to normal continence.[11-13]

Another prediction of the Integral Theory is the significance of the intact USLs. In the Petros's "bridge allegory," it was stated that both suspensions in the front and in the back must be intact to hold the road (vagina) in balance.[2,3,14] The USLs put tension on the upper vagina to stabilize the bladder resting on that part of the vagina. When that tension decreases, the pressure of the full bladder can stretch the vagina, especially in the upright body position.

Some women develop an instability of the UVJ with increasing age, which could lead to the sensation of "urgency" and urine loss.[15,16] This hypothesis was supported by the finding that the elevation of this part of the vagina during clinical vaginal examination leads to the disappearance of the feeling of "urgency" in respective patients.[1,2]

To elevate the upper part of the vagina, we developed a surgical procedure to restore the posterior suspension of the vagina, namely the USL.[17-20] Studies have reported that the length of the USL is approximately 8.5–9.3 cm.[21,22] Tapes were either sutured to the cervix through cervicosacropexy (CESA) or at the vaginal stump through vaginosacropexy (VASA) and tunneled along the uterosacral folds to the sacral bone where they were fixed.[18,23,24] In patients with stress and UUI (mixed UI) a CESA or VASA tape was placed together with a transobturator tape (TOT).[19] That resulted in continence in 75% of the patients.[25] It was hypothesized that this was due to the TOT effect on the stress factor and the CESA or VASA effect on the urgency factor.

In a randomized clinical trial (URGE 1), we evaluated the effectiveness of CESA or VASA in patients with UUI comparing the surgical approach with an established medical treatment.[25] Several of these patients with UUI were also suffering from MUI. During the study it was observed that CESA or VASA could lead to continence also in these patients with MUI.[25,26] That was interpreted as an effect of CESA or VASA on the suburethral hammock. During further treatment of patients with MUI the surgical procedures were separated. In the first step, the CESA or VASA structures were placed. If the patients were still incontinent a TOT was placed several weeks later.

In this study we identified the stress-related symptoms that could be cured through CESA and VASA. Our results offer novel insights into the treatment of urinary incontinence in women.

MATERIALS AND METHODS

The present study was conducted in 224 women with urinary incontinence who presented to the University Hospital of Cologne, Department of Obstetrics and Gynaecology, between January 2011 and December 2018. Only patients who never had undergone any surgery that could influence urinary incontinence were included in the study. Patients who had undergone colporrhaphy or a suburethral tape procedure were excluded from the study.

The diagnosis of urinary incontinence was established according to the recommendations of the International Continence Society by using established and validated urinary incontinence questionnaires.[19,20,27]

All the patients were additionally advised to perform a micturition protocol and maintain a specially designed bladder diary comprising questions on UUI symptoms for 12 days. Urodynamic measurements were performed only in the first year. However, treatment decisions were based on the clinical symptoms of the patients. A follow-up appointment was scheduled 2 weeks later for clinical examination, and an interview was conducted during this appointment.

The questions during the interviews comprised everyday situations to avoid misinterpretations or misunderstandings of the questionnaire. The following question was asked to differentiate patients with SUI and those with UUI:

"Do you lose urine when coughing or sneezing?"

When the answer to this question was affirmative, patients were categorized into SUI grade 1 (SUI 1). These patients were usually treated with a TOT. They were operated by CESA or VASA only when incontinence was associated with a descending uterus or vaginal stump.

To define UUI, the following question was asked to the patients:

"Imagine you are watching News on TV. Suddenly you feel the need to void urine. What do you do?"

The patients who gave the answer "When I get the feeling to void, I have to go immediately. Sometimes I reach the toilet in

time, sometimes I already lose urine on my way to the toilet." and those who reported immediate urine loss with the feeling of urgency were classified as having UUI.

All patients with SUI and UUI were further asked the following questions to specify when they lost urine:

1) when still sitting on the chair?

2) when getting up from the chair?

3) on the way to the toilet?

4) other occasions?

When the answers to one or more of these questions were affirmative, patients were categorized as SUI grade 2 (SUI 2).

Thus, patients were categorized as SUI 1 and SUI 2. When they also had UUI symptoms, they were categorized as mixed urinary incontinence grade 1 (MUI 1) or MUI grade 2 (MUI 2). The corresponding answers were recorded both in a documentation sheet and electronically. The interviews were conducted during the initial presentation at the clinic and at 1 and 4 weeks postoperatively and the responses were documented accordingly.

Surgical treatment consisted of the CESA and VASA procedures. The corpus uteri was removed in patients undergoing CESA, and the CESA-structure (Dynamesh CESA, FEG, Aachen, Germany) was sutured to the cervical stump. The lateral USL parts "arms" were pulled through the peritoneal tunnel of the USL and fixed in front of the first sacral bone (S1). The "arms" were 8.8 cm in length for all patients.[18]

A similar procedure was followed in patients undergoing VASA. In patients who had hysterectomy the structure (Dynamesh VASA, FEG, Aachen, Germany) was sutured to the vaginal stump, and the "arms" were longer (9.3 cm).[17] The CESA and VASA operations are being performed through laparoscopy since 2016.[25,26]

This study was approved by the Ethics Committee of the Medical Faculty of the University of Cologne, Germany (approval no: 20-1080).

Statistical analysis

The cure rate between groups was compared using a nonparametric test at a significance level of 5%. Between-group analysis for categorical variables was performed using the χ^2 or Fisher's exact tests. Pre- and post- scores were compared using the Wilcoxon test, and between-group comparisons of scores were performed using the Mann-Whitney U test. Binary logistic regression analyses were performed to study the influence of age on the treatment outcome. All analyses were performed using SPSS version 25 (SPSS, Chicago, Ill., USA) at a significance level of 5%.

RESULTS

The study was conducted in 234 patients fulfilling the study criteria. Follow-up data of 10 patients were not available; and thus, the final analysis was performed on a total of 224 patients. According to our classification, 63 patients exhibited SUI 1 and 161 patients exhibited SUI 2. Of the 244 patients, 183 patients also presented with clinical symptoms of UUI and were considered as MUI. They were categorized either as MUI 1 (n=39) or MUI 2 (n=144) (Figure 1). Of the total patients, 128 patients (57.1%) became continent after CESA or VASA (Figure 2). Of the total number of patients, 78% with SUI 1 (coughing and sneezing) became continent after CESA, and 63.6% became continent after VASA (Figure 2). This difference was statistically significant ($p<0.05$).

Of the 161 patients with SUI 2, the continence rate (CR) in patients was 56.2% after CESA and 45.7% after VASA (SUI 2) (Figure 2). However, this difference was not statistically significant ($p>0.05$). Of the 224 patients, 183 patients (81.6%) with SUI were also suffering from urgency symptoms. These patients were classified as MUI 1 or MUI 2 (Figure 3). Of the 183 patients with MUI, 67 patients (36.6%) became continent after CESA or VASA (Figure 3). Eighteen patients of 39 patients (46.1%) with MUI 1 became continent and 49 patients of 144 patients with MUI 2 (34%). This difference was not statistically significant ($p>0.05$). The CR in patients with MUI 1 was 48% after CESA and 42% after VASA (Figure 3), whereas that in patients with MUI 2 was 39% after CESA and 29% after VASA. However, the difference was not statistically significant ($p>0.05$).

The CRs after CESA or VASA in patients with SUI were significantly higher than those in patients with MUI. This finding was observed in all subgroups of SUI as in MUI. The CR after CESA or

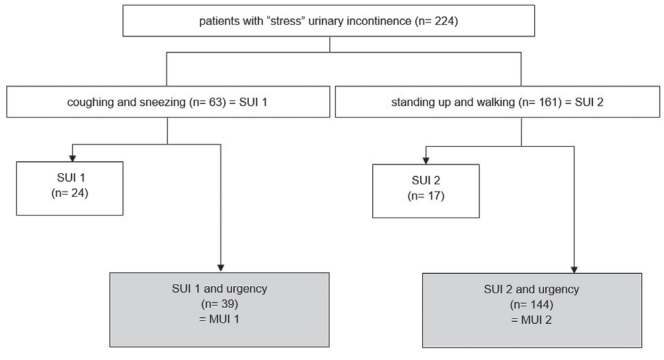


Figure 1. Classification of patients according to their urinary incontinence symptoms
Two hundred and twenty-four patients suffering from stress urinary incontinence (SUI) separated in patients who lose urine during different activities (SUI 1, coughing and sneezing; SUI 2, standing up and walking). Patients with additional urgency urinary incontinence (UUI) were referred to as mixed urinary incontinence (MUI)

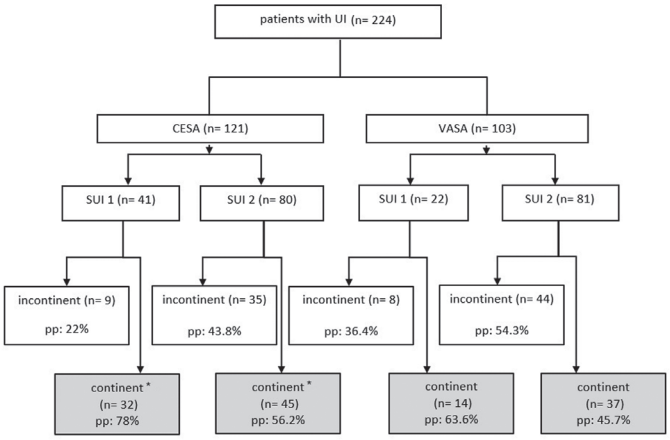


Figure 2. Effect of Cervicosacropexy (CESA) or Vaginosacropexy (VASA) on patients with stress urinary incontinence (SUI)
Patients suffering from SUI were separated in patients who lose urine with coughing and sneezing (SUI 1) or with standing up and walking (SUI 2). Ten patients with missing data (4 with CESA and 6 with VASA) were excluded.
pp: Per protocol, n: Number

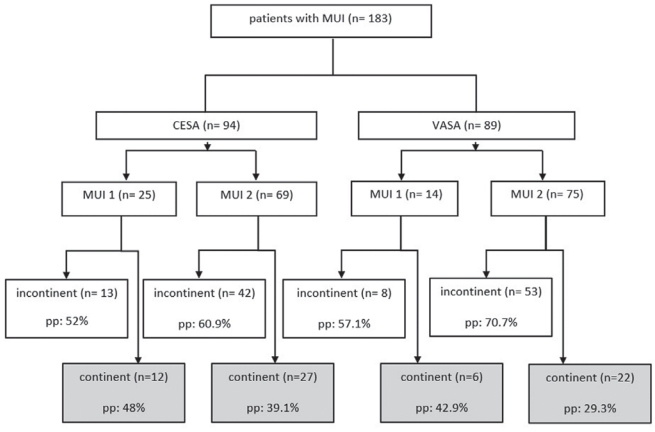


Figure 3. Effects of Cervicosacropexy (CESA) or Vaginosacropexy (VASA) on patients with mixed urinary incontinence (MUI)
Patients suffering from SUI with additional urgency urinary incontinence (UUI) were referred to as mixed urinary incontinence (MUI) and separated in patients who lose urine with coughing and sneezing (MUI 1) or with standing up and walking (MUI 2). Ten patients with missing data (4 with CESA and 6 with VASA) were excluded.
pp: per protocol, n: Number

VASA in patients aged <60 years was 66%, whereas the CR after CESA or VASA in patients aged >60 years was 48.7% (Figure 4), and the difference was statistically significant ($p<0.05$). The CR diminished with increase in age, and the least CR was observed in patients aged more than 70 years (Figure 5).

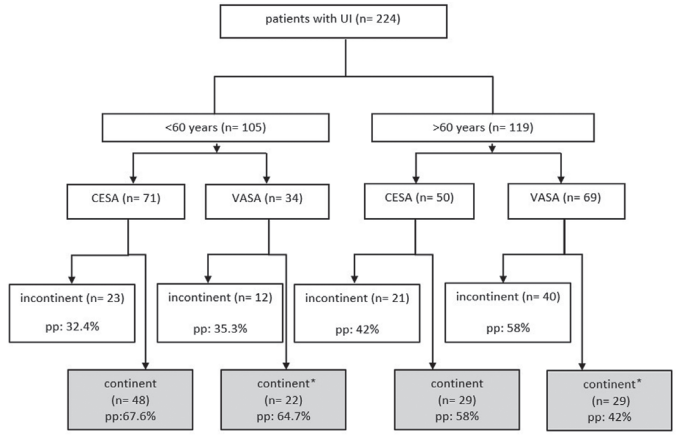
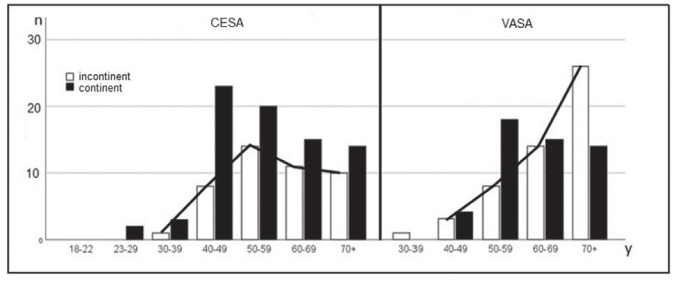


Figure 4. Continence rates (CR) of patients younger or older than 60 years of age at surgery
CESA: Cervicosacropexy; VASA: Vaginosacropexy; pp: Per protocol; n: Number



5. Number of urinary continent / incontinent patients after Cervicosacropexy (CESA) and Vaginosacropexy (VASA) according to different age groups at surgery
CESA: Cervicosacropexy; VASA: Vaginosacropexy

DISCUSSION

The present retrospective analysis of the effects of the apical fixation of the vagina on urinary incontinence led to the reconsideration of the current hypotheses on urinary incontinence in women. The study indicates that CESA and VASA can cure SUI, in addition to their effects on urgency. The elevation and tensioning of the upper vagina after CESA or VASA led to continence in patients having both SUI and MUI.[7] Our previous studies have demonstrated that CESA or VASA can cure UUI.[19,22-25] This finding was explained by the theory that the "urgency" transmitting receptors at the trigone of the bladder base adjacent to the UVJ are stabilized by the elevation or tensioning of the hammock.

However, CESA and VASA were also found to cure SUI, especially SUI during coughing or sneezing which is commonly believed as the indication for a TOT or tension-free vaginal tape. [25,26]

Effects on other "stress" (activity related) incontinence as incontinence when rising from a chair and walking to the toilet were less impressive but also found in about one third of

patients. So far, we have no explanation for that effect of the apical fixation.

The strength of this study lies in the homogeneity of the clinical diagnosis and treatment in all the patients. We excluded patients with history of surgery that could have an influence on urinary continence. A hysterectomy could influence continence because the cervical support of the bladder is removed in this procedure. Therefore, data were separated between patients with a cervix (CESA) and those who had been hysterectomized (VASA).

All the patients underwent apical fixation through CESA or VASA. In CESA, the polyvinylidene difluoride tapes were sutured to the cervical stump (after supracervical hysterectomy) and fixed in front of the S1 and were 8.8 cm long. In VASA, the tapes were sutured to the vaginal stump and were 9.3 cm long. The same lengths of the tapes could be used in all patients because the dimensions of the bony small pelvis are nearly identical in all women.[22]

The continence status was recorded preoperatively and at least two times postoperatively (at discharge and 4 weeks after discharge). The definition of continence was based on the experience and symptoms of the patients after CESA or VASA. All the patients were able to compare the symptoms before and after surgery. According to the standardized interview, the criteria for continence were always the same and reproducible by other investigators. Patients were considered continent, if they admitted that they "do not lose urine anymore! We can watch the News until the end and then go to the toilet without any loss of urine."

The CRs after CESA and VASA were different. More patients became continent after CESA than after VASA. However, the statistical analysis revealed that the difference was significant only in patients with SUI 1.

Significant differences in cure rates were observed in patients with urinary incontinence during different activities. Both CESA and VASA were able to cure more patients with SUI 1 than those with SUI 2, and the difference was statistically significant. In patients with severe "urgency" symptoms, outcomes in patients with MUI 2 were significantly worse compared with those having SUI 2 symptoms alone. Studies have demonstrated that the addition of a TOT can cure approximately 50% of patients who remain incontinent after CESA or VASA. It is not explained; however, why the other patients remain incontinent.

Our data indicated an inverse relation between age and the cure rate in both the patients with SUI and those with MUI. The cure rate in patients aged less than 60 years with SUI symptoms was significantly higher than that in patients aged more than 60 years. Similar findings were observed in patients with MUI.

We hypothesize that urinary incontinence is a pathophysiological continuum. Pressure plays a vital role in incontinence. When the bladder is empty, no "urgency" exists; the "urgency" comes with the filling of the bladder which causes an increase in pressure on the bladder wall and probably on the UVJ and the "urgency" receptors. Incontinence, however, occurs when the patient stands up from the sitting position. In that moment, the counter-pressure of the perineum on the UVJ diminishes, the UVJ opens, and the patient loses urine. A study by Jäger et al. reported that the association between "urgency" and activity-related incontinence is observed in 96% of all patients with UUI.[19] The finding could explain the role of medical treatment in decreasing the urgency symptoms; however, not the incontinence episodes.

According to the International Urogynaecological Association (IUGA), UUI is defined as the complaint of involuntary loss of urine associated with urgency, and SUI is defined as the complaint of the involuntary loss of urine during effort or physical exertion.[30]

Therefore, the IUGA recommended that the term "activity-related incontinence" should be preferred to "SUI" to differentiate SUI from psychological stress.

Thus, according to the recommended definitions of incontinence by the IUGA, all patients with or without MUI were suffering from "activity-related incontinence." The preferred treatment for this type of incontinence is surgical and not medical.

This may explain why a surgical treatment such as CESA and VASA led to continence and disappearance of the "urgency." Thus, the feeling of "urgency" is based on a change in anatomy, which can be repaired by the respective surgical treatment.

CONCLUSIONS

The greatest advantage of this study is its reproducibility. CESA and VASA are the standardized operations that can be performed similarly by every surgeon. Furthermore, the symptoms of urinary incontinence were based on the subjective complaints of the patients. "Urgency" is basically a symptom and can also be evaluated according to our interview method. Therefore, the results presented in this study can be proven or disproven by every surgeon. From the scientific point of view, this is a crucial message.

Contributions

Study design: W.J. and P.M., Data collection: W.J. and S.L., Analysis of Data: A.B., Manuscript writing: W.J.

Ethics

Ethics Committee Approval: This study was approved by the Ethics Committee of the Medical Faculty of the University of Cologne, Germany (approval no: 19-1229).

Informed Consent: It was obtained.

Peer-review: Externally peer-reviewed.

Conflict of Interest: Wolfram Jäger and Sebastian Ludwig receive honoraria from the FEG Textiltechnik mbH, Aachen, Germany. No conflict of the interest was declared by other authors.

Financial Disclosure: Wolfram Jäger and Sebastian Ludwig receive honoraria from the FEG Textiltechnik mbH, Aachen, Germany. The other authors state that they did not receive any financial support for the study and that they have no personal, political or religious interests which interfere with the study.

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A follow-up study confirms day/night enuresis cure in children by squatting-based exercises

ANGEL GARCIA-FERNANDEZ[1], JORGE GARCIA ANDRADE[2], CARLA BECKER[3], PETER PETROS[4]

[1]The National University of Córdoba, Córdoba, Argentina
[2]Centro Urosalud Integral, Quito, Ecuador
[3]Centro De Fisioterapia Uroginecologica Porto Alegre Brasil
[4]Department of Surgery, University of New South Wales Professorial, St Vincent's Hospital, Sydney, Australia (retired)

ABSTRACT

Objective: In 2018, we reported 86% cure of day/night enuresis in a randomized controlled trial of 48 children applying three different squatting-based exercises. All children who were cured were by 4 weeks. A follow-up validation study which also aimed to assess whether singular squatting 10 times twice daily protocol was sufficient to cure day/night enuresis and whether most cures occur by 4 weeks.

Materials and Methods: The study was conducted by three centres, Argentina, Brazil, Equador. Intended protocol: 10 squats twice daily for 4 months. Eligibility criteria were daytime urine leakage plus night-time bedwetting. Exclusion criterion was refusal to sign consent forms. Assessment was by intention to treat, criterion for cure was complete dryness.

Results: When interrupted by the COVID virus, 25 cases had been assessed (ages: 6-11, one aged 17 years). Complete cure: Ecuador 5/8, Brazil 4/5, Argentina 7/12, 64% cure, plus 4 (16%) more than 50% improved, with no further changes noted after 4 weeks. The study were analysed with a McNemar's test, with a null hypothesis of no treatment effect. Small numbers clouded definitive conclusions. Calculating 16/25 cured, the two-tailed p=0.2301; for 20/25 cured or improved, p=0.0051.

Conclusion: The method is easily applicable, costs virtually nothing, does not require special equipment. It compares favourably with other methods such as bedwetting alarms. The results, 64% cure and 16% improvement support the 1st study, and we believe are sufficiently encouraging to recommend adoption by parents and therapists.

Keywords: Day/night enuresis; ligaments; premature micturition; integral theory paradigm

INTRODUCTION

This study began as an attempt to validate a previous randomized controlled trial in 2018 which reported an 86% cure of day/night enuresis in 48 children (34 females, 14 males),[1] a surprising and unexpected result. The 2018 study originated from a question at a scientific meeting, "How can the Integral Theory paradigm[2] be applied to pediatric urology?" Patricia Skilling's squatting-based pelvic floor exercises were discussed.[3] These work by strengthening the three reflex directional muscles which close the urethral tube (continence) and open it for evacuation of urine, Figure 1. Skilling reported greater than 50% improvement in a range of bladder conditions, including frequency, nocturia, urgency, urinary retention, but no cures, Table 1.

Address for Correspondence: Peter Petros, Department of Surgery, University of New South Wales Professorial, St Vincent's Hospital, Sydney, Australia (retired)
E-mail: pp@kvinno.com **ORCID ID:** orcid.org/0000-0002-9611-3258
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Table 1. Skilling data for premenopausal adult women	
Fate of individual symptoms	
Condition	**>50% improvement**
Stress incontinence (n=69)	57 (82%)
Urge incontinence (n=44)	33 (68%)
Frequency only (12%)	10 (83%)
Nocturia (n=32)	29 (90%)
Pelvic pain (n=17)	13 (76%)
Residual urine 202 ml (n=23)	71 ml
n: Number	

The hypothesis for the original day/night enuresis study, was that bedwetting was an uncontrolled micturition caused by weakness or immaturity of the peripheral ligament or muscle control mechanism,[4,5] and that squatting-based exercises may strengthen these to hopefully improve half the children as per Table 1. We hoped for improvement. We did not expect cure.

In the original protocol, the children were treated with 10 squats, 10 bridge exercises twice daily, and fit ball proprioception exercises during the once-a-week clinic review over a 4-month period. Though the treatment course was over a 4-month period, 41/48 had been cured by the end of the first month. Assessment was by intention to treat. The criterion for cure was complete dryness. Fourteen patients had previously had medication treatment (desmopressin: 10, imipramine: 3, oxybutynin: 1), with no significant effect. Nineteen consulted with psychologists. Only some found some degree of impact on their self-esteem. There was no depression. 10% of patients had a history of urinary infections and 68% were considered constipated.[1]

The cure was explained by strengthening the muscles/ligaments of the peripheral bladder control mechanism, Figure 1, thereby preventing activation of the micturition reflex. With reference to Figure 1, three directional muscle forces reflex stretch the vaginal membrane to support the stretch receptors “N” from below. This decreases the afferent impulses which, beyond a critical mass, overcome central control (white arrows) and activate micturition.

The aims of this study were to answer two questions:

1. Is singular squatting 10 times twice daily protocol sufficient to cure day/night enuresis?

2. Do most cures occur by four weeks?

MATERIALS AND METHODS

This report is a follow up study which aimed to assess whether squatting alone was sufficient to cure day/night enuresis. The intended protocol was 10 squats twice daily for 4 months. Recruitment for a planned study of 48 patients began in November 2019 in three different centres, the Integral Institute Centro De Fisioterapia Uroginecologica Porto Alegre Brasil. Recruitment was only from children referred to the various clinics.

Eligibility criteria were night-time bedwetting with or without daytime urine leakage. Exclusion criterion was refusal to sign consent forms. Assessment was done by intention to treat. The criterion for cure was complete dryness, as annotated and signed off by the parent.

The exercises were supervised by the parents. Monitoring was by daily parent diary and weekly review of child plus diary at the clinic. Because of coronavirus disease-19 (COVID-19), only 25 patients were able to be assessed. Consent for publication of unidentified patient data was obtained.

Ethics: Approval of the work plan by the Ethics Committee of CEIS Oulton, Instituto Oulton, affiliation, Faculty of Medical Sciences of the UNC under the supervision of the first author A.F.G. Institutional review board (IRB) approval was also obtained by the ACTA B-345 Registro Provincial De Investigacion En Salud. The trial was IRB approved (ACTA B-345) and registered. (ANZCTR) ACTRN12619000702112.

RESULTS

When interrupted by the COVID-19 virus, 25 cases had been assessed (ages: 6-11, one aged 17 years). Complete cure in Ecuador was in 5/8, in Brazil 4/5, in Argentina 7/12. This represents a 64% cure, plus 4 children (16%) more than 50% improved. As in the first trial,[1] no further improvement in day/night enuresis was noted beyond 4 weeks.

Statistical analysis

Paired binary response data (per-patient presence/absence of a specific sign/symptom before vs after treatment) in the total study cohort were analysed with a McNemar’s test, with a null hypothesis of no treatment effect.

The GraphPad Quickcalcs platform was used for this analysis.

(http://graphpad.com/quickcalcs/mcNemar1/). The sample size was small and gave discordant results depending on whether the four improved cases were included as “cured”:

1. Calculating 16/25 cured.

The two-tailed p-value equals 0.2301. By conventional criteria, this difference is not statistically significant. The p-value was calculated with McNemar’s test with the continuity correction. Chi-squared equals 1.440 with 1 degrees of freedom.

2. Calculating 20/25 cured or improved.

The two-tailed p-value equals 0.0051. By conventional criteria, this difference is statistically significant. The p-value was

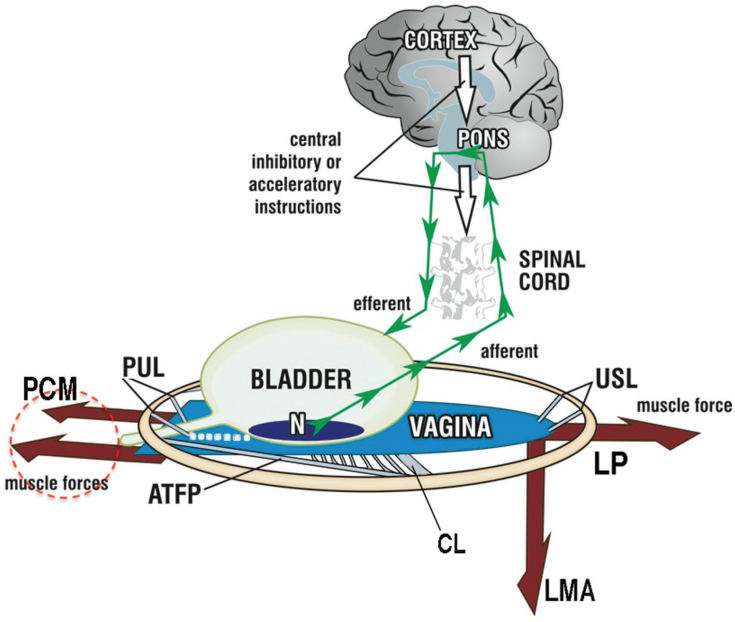

Figure 1. Control of bladder is binary Schematic 3D sagittal view. System in normal closed mode

Cortical control; afferent impulses from stretch receptors "N" are reflexly suppressed cortically (white arrows). When required, the cortex activates the micturition reflex:

Peripheral control is by a musculo-elastic mechanism which responds to cortical efferents (small arrows). Forward, backward, and downward forces (large arrows) combine to stretch the vagina tightly against its supporting ligaments, PUL (pubourethral) and USL (uterosacral), much like the membrane of a drum. The stretched vagina supports the urine column, preventing activation of the stretch receptors "N". This decreases afferent impulses to the cortex. Micturition central control (white arrows) relaxes; PCM (broken circle) relaxes; this allows the posterior muscles (arrows), LP and conjoint LMA to unrestrictedly open out the posterior wall of urethra (white broken lines) just prior to bladder evacuation by global detrusor muscle contraction.

Dysfunction (day/night enuresis). Because the striated muscle forces which activate the peripheral control mechanism contract against PUL and USL, if the muscles (large arrows) are immature, or if the ligaments are weak because of insufficient collagen deposition (again immaturity), the opposite stretching mechanism may not be able to stretch the vaginal membrane sufficiently to support the urine column pressing on "N"; "N" may fire off sufficient afferents to activate micturition during the day (urge incontinence) or at night (enuresis).

CX: Cervix; CL: Cardinal ligament; ATFP: Arcus tendineus fascia pelvis; PCM: Pubococcygeus muscle; LMA: Longitudinal muscle of the anus; LP: Levator plate

calculated with McNemar's test with the continuity correction. Chi-squared equals 7.840 with 1 degrees of freedom.

DISCUSSION

Small numbers clouded definitive conclusions and were too small for valid statistical comparison with the previous study. However, from a practical clinical perspective, 16/25 cure and 50% improvement in four children within 4 weeks was, in our view, sufficiently positive as regards validation and, whether to recommend adoption by parents and therapists. The method is easily applicable, costs virtually nothing, does not require special equipment and in this and the other study,[1] compares very favourably with other methods such as bedwetting alarms.

The small number of patients and results of study did not answer the 2nd question as to whether a singular exercise was as good as the more complex, more labour intensive three exercise regime.[1]

We consider day/night enuresis as an uncontrolled micturition caused by immaturity of peripheral muscle/ligament control which limits afferent impulses to cortex from bladder stretch receptors.[1] We consider that what the exercises did was accelerate the maturation and cure of enuresis which comes about at puberty. Squatting exercises are collagen trophic,[6,7] and we hypothesize the cure came about by strengthening the muscle/ligament complex responsible for preventing activation of the micturition reflex. The well-known cure of enuresis at puberty fits with our hypothesis,[1] of an immature peripheral control mechanism, Figure 1, strengthened by the trophic sex hormones of puberty.

We confirmed that cure, when it occurred, was universally seen by 4 weeks. This raised the question whether some children in the group who were not cured may go onto to have incontinence as adults. The 2nd author (P.P.) has seen many such cases as adults and most seem to respond to a mid-urethral sling which works by reinforcing PUL.[8]

CONCLUSIONS

Though at first glance the results for taking 100% cure as the criterion are seemingly inferior to the three-exercise protocol,[1] the results from squatting only, 64% cure and 16% improvement are sufficiently encouraging to state that this study was confirmatory of the squatting method for cure of day/night enuresis.

Contributions

A.G.F. and P.P. conceptualised the study. A.G.F., J.G.A., C.B. arranged the three studies, collected and analysed of the data. A.G.F. and P.P. wrote and reviewed the manuscript.

Ethics

Ethics Committee Approval: Approval of the work plan by the Ethics Committee of CEIS Oulton, Instituto Oulton, affiliation, Faculty of Medical Sciences of the UNC under the supervision of the first author AFG. Institutional review board (IRB) approval was also obtained by the ACTA B-345 Registro Provincial De Investigacion En Salud. The trial was IRB approved (ACTA B-345) and registered. (ANZCTR) ACTRN12619000702112.

Informed Consent: Consent for publication of unidentified patient data was obtained.

Peer-review: Externally peer-reviewed.

DISCLOSURES

Conflict of Interest: None for A.G.F., J.G.A., C.B. However, P.P. is the co-author of the Integral Theory.

Financial Disclosure: The authors declared that this study received no financial support.

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Editorial Comment

Professor Jacob Bornstein
Editor in Chief of Pelviperineology

The subject of this work, by Garcia-Fernandez A, Becker C and Petros PE, titled “A follow-up study confirms day/night enuresis cure in children by squatting-based exercises” is very interesting, and I believe that it should be disseminated. The study set out to validate a previous randomized controlled trial which gave an unexpected 86% cure rate for day/night enuresis. Our original view was that a larger group of patients was required to increase the substantive value of the work. We communicated this to the authors. Their reply was that there was no prospect of this work continuing possibly for some years because the countries of origin had been devastated by the COVID-19 virus. Under these circumstances, though the numbers are small, because the methodology is so simply repeated and so accessible to even the poorest of countries, we have made an editorial decision to publish it as is, so it can be challenged by other researchers.

Jacob Bornstein

editorinchief@pelviperineology.org

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Efficacy of the mini mesh for reducing prolapse recurrence: comparison of two implant positioning methods

AYELLET NEUMANN KOREN[1], MENAHEM NEUMAN[1,2], JACOB BORNSTEIN[1,2]

[1]Bar Ilan University, Azrieli Faculty of Medicine, Safed, Israel
[2]Department of Obstetrics and Gynaecology, Galilee Medical Center, Nahariya, Israel

ABSTRACT

Objective: We aimed to compare the postoperative complications, cure rates, and patient satisfaction in mini mesh implantation with and without anterior arm fixation to the para vesical fascia for the re-enforcement of the anterior pelvic floor compartment.

Materials and Methods: Thirty female patients diagnosed with symptomatic stage 3 pelvic organ prolapse (POP) of the anterior pelvic floor compartment were operated on by a single surgeon, using the SERATOM PA MR MN mini mesh graft (Serag-Wiessner, Naila, Germany). In thirty other women, serving as a control group, the anterior arms were positioned without fixation, while in the study group anterior arm fixation was added. Surgery complications, patients' satisfaction 3 months after the surgery, POP grade and volume of prolapse, and subjective variables such as a feeling of bulge, pain, and dyspareunia were compared between the two groups.

Results: Significant anatomical and functional improvements were documented in both groups with respect to the objective ($p<0.05$) and subjective ($p<0.01$) criteria, except for pain, dyspareunia, and fecal incontinence. All patients reported high satisfaction.

Conclusion: Surgery with and without fixation led to significant improvement.

Keywords: Mini mesh; pelvic floor reconstruction; pelvic organ prolapse

INTRODUCTION

Pelvic organ prolapse (POP) is a common disorder in women during the reproductive, menopausal, and post-menopausal periods; it is estimated that 50% of all parous women will have an anatomical POP. POP impairs urinary, bowel, and sexual functions as well as self-esteem. While herniation of the anterior pelvic floor compartment is associated with cystocele, that of the posterior pelvic floor compartment is associated with rectocele, enterocele, and uterine prolapse. Approximately 11% of all women are surgically treated for symptomatic POP. However, 30%–65% of the surgically treated patients require repeat prolapse surgery.[1]

Owing to possible complications, the use of a mesh implant in the treatment of POP is controversial. To support the internal pelvic organs, the weakened pelvic fascia is replaced by the synthetic mesh.[2,3] This has been previously shown to be effective and safe with the posterior intra-vaginal slingplasty (PIVS) in the treatment of vaginal apex prolapse. The invasiveness and painful complications of old surgical techniques encouraged Petros et al.[4] to design this new treatment for anatomical restoration. As a forerunner to future mesh design and surgical techniques, the

Address for Correspondence: Jacob Bornstein, Bar Ilan University, Azrieli Faculty of Medicine, Safed, Israel and Department of Obstetrics and Gynecology, Galilee Medical Center, Nahariya, Israel
E-mail: mdjacob@gmail.com **ORCID ID:** orcid.org/0000-0003-1932-5270
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PIVS graft is solely a sling, secured at two ends to the uterosacral ligaments.[5] As will be discussed later, reconstructive POP surgeries frequently involve the implantation of large meshes with wide and deep pelvic dissection; in addition, it bears some inherent hazards due to these implants and the dissection involved.[2] Furthermore, the mesh is secured in place by suturing the mesh arms to the sacrospinous ligament (SSL) and also from the bladder neck to the uterine cervix to achieve anterior compartment support.

Intraoperative complications of vaginal meshes include accidental blood vessel damage, haemorrhage, and visceral (bladder and intestinal) and neural injuries. The postoperative complications include hematomas and infections, overactive bladder (OAB) symptoms, stress urinary incontinence (SUI), vaginal and pelvic pain, and dyspareunia.[3,5,6]

Since vaginal implanted meshes are only covered by the thin vaginal wall (mucosa and underlying fascia) and are also subjected to constant pressure, postoperative mesh displacement and its exposure is troubling and a widespread problem. The mini mesh maintains therapeutic outcomes and reduces the risk of tissue trauma and mesh-related complications by reducing the implant size (being 75% less than the original mesh size) and the number of fixation points.[3,7]

In 2011 and 2008, the Food and Drug Administration (FDA) issued a warning regarding the POP repair technique stating serious adverse events are neither rare nor mild; however, the use of mesh in this POP repair technique does not conclusively improve clinical outcomes. Furthermore, the FDA ordered a continuous evaluation of the effects of using surgical mesh and also noted the need for clinical studies in the field of urogynecology.[8] As a result, the mini mesh was developed to overcome and minimize serious adverse events without compromising effectiveness. Later on, in 2019 the FDA issued an order that remaining manufacturers of transvaginal mesh for apical/anterior compartment prolapse stop selling and distributing their products.[9]

Currently, many of the grafts used in the reconstruction POP are mini meshes, as they have a lower recurrence rate and also simultaneously reduce mesh-related complication rates and severity.[2,7] The mesh examined in this study, augmenting POP repair operation, is similar to that used in the previously reported PIVS technique in terms of positioning and lower mesh size (unlike the large meshes used thereafter). It is currently unclear whether the anterior mini mesh arms should be fixated para vesical or only positioned without fixation. There is a clear lack of evidence-based studies and treatment decisions are largely based on the surgeon's experience and training. This research compares surgical complications and patient satisfaction between patients with fixated mini mesh arms and those only positioned without fixation. We hypothesized that non-fixated anterior mini mesh arms are inferior to the fixated ones, as the non-fixated mesh might not stay in place, leading to an impairment in an appropriate anterior pelvic floor compartment reinforcement and a consecutive cystocele formation, thereby necessitating further corrective operations.

MATERIALS AND METHODS

This was a retrospective, cohort, non-randomized, non-blinded, double arm and dual center study (performed by a single surgeon) involving female patients diagnosed with advanced symptomatic stage 3 anterior POP; the surgeries were performed between 2017 and 2018. The first 30 patients (the control group) were operated using non-fixated mesh arms positioned para vesical, and the subsequent 30 patients (the study group) were operated with para vesical mesh arm fixation to the facia on both sides of the bladder cervix. All patients operated upon during this period were included in the study. Patients with incomplete records were excluded from this study.

All patients received first generation cephalosporin antibiotics intravenously half an hour before surgery, followed by an iodine antiseptic vaginal and surgical field wash. All surgeries were conducted under general anaesthesia. Prior the first surgical incision, 50 ml of saline was injected at the midline of the anterior vaginal wall followed by a longitudinal incision, subfascial lateral dissection toward the pelvic sidewall until the ischiatic spine and then to the mid-portion of the SSL, to which the mesh arms would be fixated to. The other arms were passed through the obturator membrane and those from the bladder neck to the uterine cervix. The two surgical groups differed with respect to the mesh anterior arms sutured (study group) or positioned (control). After the mini mesh was placed and fixated, the vaginal wall was re-sutured in two layers: first the fascia and then the mucosa with running absorbable sutures.

Pre- and postoperative data were obtained for all patients from the medical records and were tabulated and evaluated. According to the instructions for conducting clinical research involving human subjects, this study was approved by the Institutional Research Board (Helsinki committee) at the Galilee Medical Center. Authorization number 0008-18-NHR, on April 11th, 2018. All data collected from the medical records were stored anonymously.

Participants of both groups were treated using the same mini mesh implant, SERATOM PA MR MN® (Serag-Wiessner, Naila, Germany). Furthermore, patients who were diagnosed with

posterior vaginal wall relaxation were concomitantly subjected to posterior colporrhaphy with or without mesh augmentation. Moreover, patients with urinary stress incontinence underwent additional anti-incontinence surgery with sub-mid-urethral slings (SMUS), using TVT- Obturator®, TVT-Abbrevo® (Gynecare, Somerville, USA) or Serasis® (Serag-Wiessner, Naila, Germany). Patients were discharged after overnight hospitalization and were followed up a day, a month, and 3 months later.[10] All procedures were performed by the same surgeon (M.N.).

The age, obstetric history, comorbidities (e.g. hypertension, diabetes mellitus (DM) type 2, gastric esophageal reflux and cardiovascular disease), family history of POP, self-reported urinary tract infection history, and information regarding the previous hysterectomy, POP, or SUI repair were all compared. Furthermore, a physical evaluation was performed early post-op and one-month post-op by the surgeon. Subsequently, objective and subjective variables were measured and recorded pre-operatively and one-month postoperatively. The objective variables included POP severity grade,[10] and volume of prolapse, an objective clinical estimation of the surgeon regarding tissue volume in millilitres protruding out of the vagina.

Additionally, a new measurement of POP severity was proposed; advanced prolapse has been defined as one that protrudes 0.5 litre (L) and over, out of the vagina. Subjective variables included various complaints such as bulge, pain, dyspareunia, voiding problem, OAB symptoms, SUI, UTI, fecal incontinence, and constipation. Information obtained on the operative and postoperative days were included in the operational remarks; complications such as rash and itching, groin pain, fever (>38.5 °C), and need for catheterization as well as patient's reported satisfaction 3 months post-operation were recorded.

Statistical analysis

In addition to descriptive statistical methods [mean ± standard deviation (SD)], Student's t-test and Mann-Whitney U test were used to identify potential differences between the two independent groups of parameters, with and without normal distributions, respectively. Variance analysis of intergroup values was performed using the Kruskal-Wallis test. Additionally, a one-way analysis of variance (ANOVA) test was used for normally distributed data. Spearman's rank correlation coefficient was used to determine potential correlations between multiple groups. The qualitative data were compared using the chi-square test. The results were considered statistically significant based on the 95% confidence interval, and p-values less than 0.05. Z proportion test were used to evaluate the differences between the rates of complications in the literature and those in this study. In total, 56 patients were required to obtain 80% actual power of the study.

RESULTS

In total, 60 patients underwent reconstructive POP surgery for the anterior pelvic floor compartment between July 17th, 2017, and January 5th, 2018; the mean age was 66 years (SD: ±8.77; age range: 41–88 years) and most of the patients were multiparous with a mean of 3.5 labours (SD: ±1.41; range: 1–8 labours). In addition, 13.3% of the patients (n=8) had a history of hysterectomy and 16.7% (n=10) of them had repeated POP surgeries: colpo-sacro-pexy (n=8, 13.3%), colporrhaphy (n=1, 1.7%) and laparoscopic Burch colpo-suspension (n=1, 1.7%). Moreover, 75% of the patients had comorbidities: hypertension (n=19, 31.7%), DM (n=9, 15%), and cardiovascular disease (n=3, 5%). No significant statistical difference in these parameters was found between the two groups. Furthermore, records of familial history of POP was insufficient; therefore, no statistical conclusions could be drawn regarding this potential variable.

Significant statistical improvement ($p<0.05$ and $p<0.01$) was observed in both groups for most of the objective and subjective criteria (Table 1), except for pain, dyspareunia, and fecal incontinence (all mild).

Two patients (3.3%) reported minimal post-op pain; one patient reported one-month post-op groin pain and another reported pain due to a vaginal scar granulation (VAS 1-3). Dyspareunia and faecal incontinence could not be evaluated owing to poor data quality. Of four patients (6.6%) with pre-op dyspareunia, two reported post-op improvement, while the other two had no sexual intercourse during the survey time. Furthermore, of the four patients suffering from faecal incontinence, three reported improvement, which was not statistically significant.

In the control group (para vesical mesh positioning without fixation), all patients reported significant improvement and a complete resolution of symptomatic voiding problems, which was statistically significant ($p<0.05$). On the contrary, the improvement showed by the study group (para vesical mesh fixation to the fascia) was statistically insignificant.

Improvement in both Ba and Bp measurements (objective anterior and posterior POP-Q points)[9] was shown to be statistically significant ($p<0.01$) for both groups, using the Z test (Table 1). Using the Mann-Whitney U test, the statistical significance ($p<0.05$) of the delta Ba improvement was repeatedly demonstrated for the study group, compared to the control group (Table 2).

In total, seven patients (11.7%) from both groups had very advanced prolapse (all had their vaginas bulging out, greater than 0.5 L) and were also prone to complications and recurrence.[11] Five patients (8.3%) were diagnosed with 0.5 L, one patient (1.7%)

Table 1. Improvement in objective and subjective measurements for the study and control groups

	Z	SD	Mean	Z	SD	Mean
Bulge pre-op	5.47**	0.0	3.0	5.39**	0.0	3.0
Bulge post-op for 1 month		0.0	0.0		0.2	0.0
Pain pre-op	0.00	0.0	0.0	1.4	0.0	0.0
Pain post-op for 1 month		0.0	0.0		0.3	0.1
Dyspareunia pre-op	1.0	0.4	0.1	1.3	0.8	0.3
Dyspareunia post-op for 1 month		0.0	0.0		0.4	0.1
Pre-op voiding problem	1.84	0.7	0.3	2.85*	1.2	0.8
1-month post-op voiding problem		0.0	0.0		0.0	0.0
Pre-op OAB Symptoms	3.81**	0.9	1.1	3.48**	1.1	1.7
1-month post-op OAB Symptoms.		0.4	0.1		1.0	0.8
SUI pre-op	2.17*	1.3	0.8	3.46**	1.5	1.2
SUI post-op for 1 month		0.6	0.2		0.0	0.0
Faecal incontinence pre-op	1.41	0.6	0.2	1.41	0.5	0.1
1-month faecal incontinence post-op		0.2	0.0		0.0	0.0
Constipation pre-op	3.41**	0.8	0.6	2.73*	0.7	0.4
Constipation post-op for 1 month		0.0	0.0		0.0	0.0
Ba pre-op	4.77**	1.6	3.2	4.82**	1.2	3.6
Ba post-op for 1 month		0.4	-2.7		0.6	1.9
Bp pre-op	4.75**	1.6	1.0	4.74**	1.7	1.0
1-month Bp post-op		0.7	-2.6		0.9	2.4
C pre-op	4.79**	4.1	2.1	4.79**	3.8	1.7
1-month C post-op		0.6	-5.4		0.6	4.8
POP degree pre-op	5.39**	0.0	3.0	5.39**	0.0	3.0
POP degree post-op for 1 month		0.2	1.0		0.2	1.0

*p<0.05, **p<0.01
POP: Pelvic organ prolapse; study group: Para vesical mesh fixation to the fascia; control group: Para vesical mesh positioning; Pre-op: Pre-operative; Post-op: Post-operative; OAB: Overactive bladder; SUI: Stress urinary incontinence; Ba: The 2/3 point at the anterior vaginal wall; Bp: The 2/3 point at the posterior vaginal wall; SD: Standard deviation; C: Uterine cervix

with 0.75 L, and another (1.7%) with 1.0 L volume bulging out of the vaginal opening. These patients showed improvements in the objective criteria at the one-month postoperative check-up in the clinic; however, six patients still had first-degree POP and one had second-degree POP. No statistical interpretation could be drawn from these data.

Nine patients (15%) had pre-op urinary tract infections (UTI) and three (5%) had post-op UTI. Surgical field fibrosis or the exposure of previous mesh was noted in three patients (5%). Forty-one patients (68.3%) had concomitant anterior and posterior repairs (APR, colporrhaphies), whereas nineteen (31.7%) had both APR and SMUS for SUI. Furthermore, five patients suffered intraoperative bleeding, resulting in a 1.5-3 gr (%) decrease in Hgb; 91.7% of all patients (n=55) had less than 1 gr (%) change in delta haemoglobin (Hgb) (Table 3).

In the control group, two patients (1.3%, respectively) had 2 gr (%) and 3 gr (%) decrease in delta Hgb, respectively. Moreover, one (1.3%) and two patients (2.7%) from the study group had 1.5 gr (%) and 2 gr (%) decrease in delta Hgb, respectively. Similarities were observed between the results comparing the delta Hgb with those of patients who underwent additional APR and APR with trans vaginal tape surgeries (Table 4).

In addition, three APR patients (5%) showed a decrease of 2 gr (%) in the Hgb levels and two APR + SMUS patients (2.7%) showed 1.5 gr (%) decrease. The chi-square test showed no statistical significance associated with the changes in the Hgb levels and the surgical technique used.

Early post-op remarks (one-month follow-up) included three patients (5%) who developed vaginal scar granulation, which was treated with fulguration. On the contrary, late post-op remarks (three-month follow-up) included anticholinergic (n=6, 10 %)

Table 2. Comparison of subjective and objective measurements between groups

Mann-Whitney U	The study group					The control group					
	Percentiles			SD	Mean	Percentiles			SD	Mean	
	75	50	25			75	50	25			
435	3.0	3.0	3.0	0.0	3.0	3.0	3.0	3.0	0.2	3.0	Δ Bulge
420	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.1	Δ Pain
406.5	0.0	0.0	0.0	0.4	0.1	0.0	0.0	0.0	0.5	0.0	Δ Dyspareunia
355.5*	0.0	0.0	0.0	0.7	0.3	0.0	0.0	2.0	1.2	0.8	Δ Voiding problem
431	0.0	1.0	2.0	1.0	1.0	0.0	1.0	2.0	1.1	0.9	Δ OAB symptoms
363	0.0	0.0	3.0	1.6	0.6	0.0	0.0	3.0	1.5	1.2	Δ SUI
450	0.0	0.0	0.0	0.5	0.1	0.0	0.0	0.0	0.5	0.1	Δ Faecal incontinence
380.5	0.0	0.0	1.0	0.8	0.6	0.0	0.0	1.0	0.7	0.4	Δ Constipation
329*	5.8	6.0	7.0	1.6	5.9	5.0	6.0	6.0	1.2	5.6	Δ Ba
410	3.0	3.0	4.3	1.8	3.6	2.0	3.0	5.0	1.7	3.4	Δ Bp
390.5	4.8	6.0	10.3	4.1	7.5	4.0	6.0	7.5	3.7	6.5	Δ C

*p<0.05, Δ: Change from preoperative condition
SD: Standard deviation

Table 3. Delta haemoglobin change according to the trial groups

			Delta Hgb				Total
			<1 gr (%)	1.5 gr (%)	2 gr (%)	3 gr (%)	
Group	Control group	Count	28	0	1	1	30
		Within group, (%)	93.3%	0.0%	3.3%	3.3%	100.0%
		Within delta Hgb, (%)	50.9%	0.0%	33.3%	100.0%	50.0%
	Study group	Count	27	1	2	0	30
		Within group, (%)	90.0%	3.3%	6.7%	0.0%	100.0%
		Within delta Hgb, (%)	49.1%	100.0%	66.7%	0.0%	50.0%
Total		Count	55	1	3	1	60
		Within group, (%)	91.7%	1.7%	5.0%	1.7%	100.0%
		Within delta Hgb, (%)	100.0%	100.0%	100.0%	100.0%	100.0%

Study group: Para vesical mesh fixation to the fascia; Control group: Para vesical mesh positioning; Hgb: Haemoglobin

and beta-2 receptor agonists used (n=1, 1.7%) in the treatment of pre-operative OAB symptoms. In addition, sub-mid-urethral sling implantation was used for the treatment of de novo or aggravated SUI (n=3, 5%); one patient (1.7%) reported minimal coccygeal pain.

Although no statistically significant conclusion was reached, first-day post-op complications were analysed. Subsequently, fifty-four patients (90%) had not suffered any post-op complications. Of all patients in the study group, one (1.3%) needed a 2-day bladder catheterization, another (1.3%) had self-limited mild left groin pain for two weeks; in addition, one patient (1.3%) had mild self-limited perineal rash and itching. However, of all patients in the control group, two (2.7%) needed bladder catheterization for 2 days, one (1.3%) had self-limited fever of unknown origin with a body temperature of 38.5 °C for 2 days and another (1.3%) had mild self-limited left groin pain.

Satisfaction was assessed at the 3-month follow-up (Figure 1). Most of the patients (n=51, 85%), including 90% of the patients in the study group (n=27) and 80% of the patients in the control group (n=24), rated their overall satisfaction as maximal (Figure 1). Eight patients (13%) gave the medium score and only one patient from the control group was dissatisfied and subsequently gave the lowest satisfaction score.

DISCUSSION

The major finding of this study is that both para vesical mesh positioning and para vesical mesh arm fixation can improve most objective and subjective parameters, thereby offering high

Table 4. Delta haemoglobin changes according to the surgery performed

			Delta Hgb				Total
			<1gr (%)	1.5 gr (%)	2 gr (%)	3 gr (%)	
Add. surgery	APR	Count	38	0	3	0	41
		Within add. surgery, (%)	92.7%	0.0%	7.3%	0.0%	100.0%
		Within delta Hgb, (%)	69.1%	0.0%	100.0%	0.0%	68.3%
	APR + TVT	Count	17	1	0	1	19
		Within add. surgery, (%)	89.5%	5.3%	0.0%	5.3%	100.0%
		Within delta Hgb, (%)	30.9%	100.0%	0.0%	100.0%	31.7%
Total		Count	55	1	3	1	60
		Within add. surgery, (%)	91.7%	1.7%	5.0%	1.7%	100.0%
		Within delta Hgb, (%)	100.0%	100.0%	100.0%	100.0%	100.0%

APR: Anterior-posterior repair; TVT: Trans vaginal tape; Hgb: Haemoglobin; Add: Additional

postoperative satisfaction, which was slightly higher in the study group. These results support previous studies, showing that desired outcomes can be achieved using the mini mesh.

Furthermore, the results suggest that "anterior mesh arm fixation" patients had better Ba position (the 2/3 point at the anterior vaginal wall according to the POP-Q) reconstructive outcomes. These slightly better outcomes could be attributed to the nature of the operational procedure of the study group (where mesh was fixated to the para vesical); thus, reinforcing the anatomical structure by keeping the vaginal wall in place. Improvements in either group are of limited significance owing to the relatively small group size.

Both groups showed improved subjective voiding: patients reported no post-operative voiding complaints. Statistical significance was demonstrated in the control group, where all 10 patients with pre-operative voiding had their problems fully resolved. Because the study group had fewer cases (only four patients with pre-op voiding complaints: all of which were resolved), no statistically significant conclusions could be drawn from these data.

Furthermore, no statistically significant differences could be observed for pain, dyspareunia, granulation tissue formation, and faecal incontinence, owing to poor data quality.

Although patients should be informed that anticholinergic medications might be needed for de novo or worsening OAB symptoms, SMUS implantation for SUI, or painkillers for buttock pain, it was noted that the vast majority of patients enjoyed the benefits of mini mesh POP reconstructions with no concerns or complaints.

Moreover, 85% of the patients (90% of the study group and 80% of the control group) were highly satisfied with the procedure. In addition, eight patients comprising five from the control group

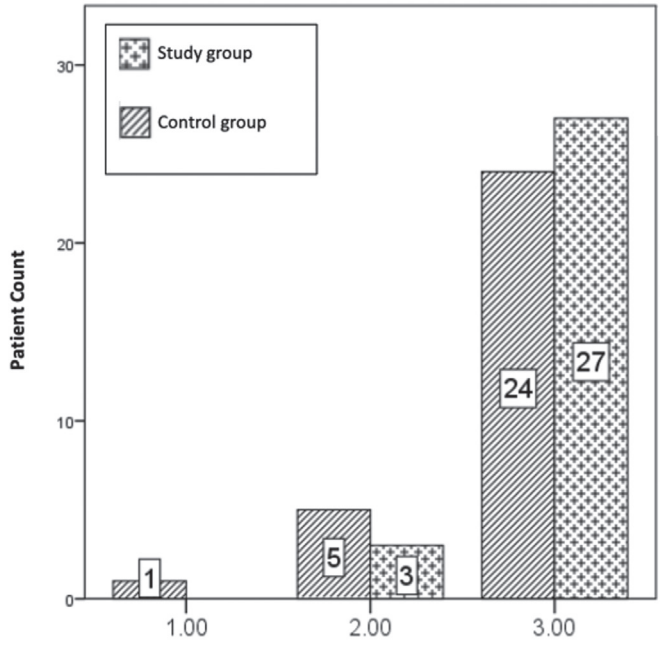

Figure 1. Patient satisfaction according to the trial groups
Study group: Para vesical mesh fixation to the fascia; Control group: Para vesical mesh positioning

and three from the study group were only relatively satisfied. Only one patient from the control group was discontented with the operation performed or its corresponding outcomes; the high patient satisfaction could be a result of the improved cure rate and Ba measure, which underscored the subjective clinical benefits gained by the patients from the surgery.

Advanced POP was estimated by the surgeon as that exceeding a 0.5 L bulging out of the vagina and subsequently and was measured in litres (0.5 L, 0.75 L, and 1.0 L among others). For the first time, the definition as described earlier is being used and may be useful in defining a special and significant subgroup

of patients, who are probably prone to higher operative time, complications and recurrent rates. Seven patients were treated for such extreme prolapse and all of them reported good surgical subjective outcomes, even though in one patient, post-op second-degree POP persisted.

The limitations of this study are the relatively small size of the study groups and the short duration of follow-up. Although additional studies on larger groups including a longer duration of follow-up are needed, the results of this study support the view that fixation of anterior arms to the para vesicle fascia is preferable to positioning only.[12] Furthermore, the results presented here can provide surgeons with valuable decision-making advice in selecting the most appropriate surgical procedure using the mini mesh.

CONCLUSIONS

Mini mesh implantation, with or without anterior arm fixation to the para vesical fascia, led to significant objective and subjective resolution in anterior pelvic floor compartment prolapse. The "anterior mesh arm fixation" resulted in a better POP-Q Ba position.

Authors' contributions

A.N.K.: Project development, data collection and analysis, and manuscript writing, M.N.: Project development, data analysis, and manuscript writing, J.B.: Project development, and manuscript writing.

Ethics

Ethics Committee Approval: Retrospective study.

Informed Consent: Retrospective study.

Peer-review: Externally peer-reviewed.

DISCLOSURES

Financial Disclaimers/Conflict of Interest: MN is affiliated with FEMSelect, Memic, and OORO. ANK and JB report no conflict of interest.

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Anatomy and physiology of anorectum: the hypothesis of fecal retention, and defecation

MICHAEL LEVIN[1,2]

[1]Department of Pediatric Radiology, 1st State Hospital, Minsk, Belarus
[2]Dorot-Netanya Geriatric Medical Center, Israel

ABSTRACT

Continence and defecation are two essential functions of the human body. The normal anatomy of the anorectum is well documented in the literature. The data on the physiology of these processes are controversial and sketchy. The article discusses scientific facts that describe the different aspects of the physiology of anorectum. On this basis, the hypothesis of fecal retention and defecation in the form of successive reflex reactions of the rectum, and pelvic floor muscles, including the internal anal sphincter, external anal sphincter, puborectalis muscle, and levator plates, was proposed. This hypothesis allows for explaining the pathophysiology of functional constipation, fecal incontinence, anorectal malformations, etc.

Keywords: Anal canal length; anal sphincters; defecation; fecal retention; hypothesis physiology anorectum.

INTRODUCTION

Continence and defecation are two essential functions of the human body. Continence is the ability to retain feces until an acceptable time for defecation. Defecation is the evacuation of fecal material from the colon. Both functions involve complex physiologic processes that are not completely understood.[1] The normal anatomy of the gastrointestinal tract is well documented in the literature. The data on the physiology of these processes are controversial and sketchy. For example, muscular contraction is accompanied by energy expenditure and resource depletion. All the known muscles, including the heart, relax after the contraction. During the relaxation, their contractile capacity is recovered. It is still not clear how the anal canal is in the continuous contraction, and which muscles are involved in the act of defecation. It is known that the external anal sphincter (EAS) is responsible for the emergency continence during the increase of abdominal pressure. However, the intensity of contraction promptly decreases after 8-15 seconds.[2,3] It is hard to ascribe the continence to continuous contraction of the internal anal sphincter (IAS).

A clear understanding of the normal physiology of the anorectal zone could significantly improve our approach to such pathological conditions like chronic constipation, fecal incontinence, anorectal malformations, etc.

This work presents a new hypothesis of the continence and defecation, based on analysis of the literature and our own studies.

MATERIALS FOR ANALYSIS

Colon; the continence starts above of the rectum. Only the distal part of the sigmoid colon was available for functional manometric examination. Between the descending and sigmoid colon there

Address for Correspondence: Michael Levin, Department of Pediatric Radiology, 1st State Hospital, Minsk, Belarus; Dorot-Netanya Geriatric Medical Center, Israel
E-mail: nivel70@hotmail.com **ORCID ID:** orcid.org/0000-0001-7830-1944
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is a physiological "colosigmoid sphincter" (CSS) a length of 2.1±0.9 cm. In this zone, the pressure was significantly higher than in the adjacent segments. After a quick inflation of the balloon of large diameter in the descending colon, the decrease of pressure in the CSS was noted. After inflating the same balloon in the sigmoid colon, the pressure in the CSS increases. On the other hand, inflation with a small balloon did not affects the tone of this sphincter. The CSS is involved in a passage of large intestinal contents. CSS retains the feces until it reaches a certain volume.[4] Between the rectum and sigma is located the intestinal segment of 2.8±0.9 cm length with the layer of circular muscle thickened in comparison to the segments above and below it.[5] While the pressure in the sigmoid colon increases, this functional rectosigmoid sphincter (RSS) relaxes. In response to increased pressure in the rectum, its tonus rises.[6] Different reactions of RSS to different volume of the balloon were found. After a quick inflation of the balloon in the sigma with 52.1±3.6 ml of liquid, the tone of the RSS increased but the rectal pressure did not change. After the rapid inflation into the balloon of 86±4.1 ml, the RSS relaxed, and the balloon was dispelled to the rectum. It was accompanied by an increase of the rectal pressure, and the balloon was expelled.[7] Thus, the RSS with CSS prevent the rapid advance of the large volume of the feces from the colon into the rectum. They are the first level of the continence.

Rectum is a reservoir where more dense portions of feces are collected than in the colon, as well as it is involved in the process of defecation by strong contractions.[1] It is in the pelvis retroperitoneally. It starts from the third sacral vertebrae and ends at the level of the pubococcygeal (P-C) line, where it borders on the anal canal. From a functional point of view, the rectum begins caudally to the RSS. While fecal retention, it performs a cumulative function (Figure 1), and during bowel movements, its strong peristaltic wave, which starts from the RSS, expels the stool through the open anal canal. Table 1 shows the normal width of the rectum and the anal canal in patients of different ages after filling the colon with barium at least to the splenic angle.[8,9]

At least starting in the descending colon, small soft fecal boluses are delivered in batches above the CSS, where they coalesce into a single bolus that gradually decreases in volume as fluid is absorbed by the intestinal wall. However, as more portions arrive, the total stool volume reaches a certain level, which causes a rise in pressure. It causes the CSS to open and the peristaltic wave pushes the denser bolus into the sigmoid colon. The same process occurs in the sigmoid and rectum, because of which lumpy dense feces accumulate over the anal canal. Obviously, the same process occurs along the entire length of the colon. In children, the slow movement of the bolus occurs without the participation of sphincters. In adults, in addition to CSS and RSS, 8 more functional sphincters are described. They are not always simultaneous (Figure 2).[10]

Colon sphincters arise during ontogenesis. They manifest as a limited thickening of the circular muscle fibers. As a rule, 2-3 haustras in these places are underdeveloped. At present, it is difficult to determine whether functional sphincters are present in healthy individuals or only in intestinal pathology. It is likely that dyskinesia of these sphincters plays an important role in the development of chronic constipation and diverticula of the left half of the colon.[11]

With or without sphincters the slow peristalsis of the colon, during which fluid is absorbed from the feces, plays a significant

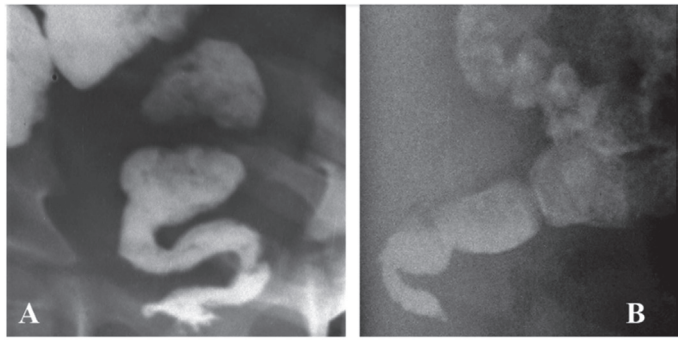

Figure 1. The radiographs of the anorectum of an 8-year-old child performed 24 hours after oral administration of barium (passage). (**A**). Frontal radiograph. (**B**). Lateral radiograph. During the slow promotion across the rectum, the fecal portions decrease in volume and become more contrast (denser) as a result of fluid absorption by the intestinal wall. Most of the feces are in the sigmoid colon.

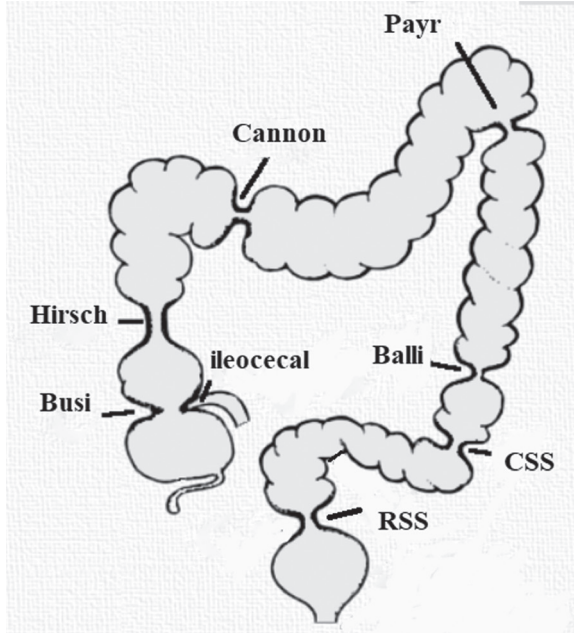

Figure 2. Functional sphincters of the colon
RSS: Rectosigmoid sphincter; CSS: Colosigmoid sphincter

role in long-term fecal retention. The anal canal starts from the P-C line and continues to the anus. Its length is given in Table 1. The anal canal consists of several elements, each of which plays an important role in fecal retention and defecation. In its center is the smooth muscle of the IAS, which is a continuation of the circular layer of the rectum. However, IAS are both morphologically and functionally different from the circular layer of the rectum. Alamovich et al. investigated the normal innervation of the IAS. This study shows that the IAS itself has no autonomous innervation unlike the rest of the digestive tube.[12] During a bowel movement, it opens all along the length, completely and simultaneously. For 24 hours a day, except for a few seconds, during a bowel movement, the anal canal is in a closed position, preventing leaking of the stool and gas. High pressure in the anal canal (25–85 cm H_2O) compared with the pressure in the rectum (2–5 cm H_2O) is the result of contraction of the IAS, puborectalis muscle (PRM), and EAS.[13] It is considered that at rest, the IAS is in a state of partial tetanus and contributes approximately 55% of the anal resting pressure.[14]

Table 1. The normal size of the rectum and anal canal in different ages

Ages	The width of the rectum (cm)	The length of the anal canal (cm)
5 days – 11 months	1.3–3.0 (2.24±0.09)	1.7–2.5 (2.21±0.15)
1 – 3 years	3.0–3.7 (3.21±0.11)	2.3–2.8 (2.55±0.10)
4 – 7 years	3.0–3.9 (3.43±0.14)	2.5–3.6 (3.17±0.14)
8 – 10 years	3.2–4.1 (3.72±0.05)	2.6–3.7 (3.11±0.10)
11 – 15 years	3.6–4.6 (3.95±0.07)	3.1–3.9 (3.43±0.10)
23 – 64 years	3.5–4.8 (3.95±0.21)	3.4–4.2 (4.08±0.07)

Longitudinal fibers between the IAS and EAS consists primarily of smooth muscle fibers that continued from the longitudinal muscle of the rectum. The levator ani muscle (LAM) attached directly to the lateral surface of the longitudinal smooth muscle of the rectum. In the lateral and posterior position, the LAM partially overlapped the EAS.[15]

The IAS is in the center of the pelvic floor muscles, which fan out from it and are attached to the pelvic ring. Muscle complex which forms a pelvic diaphragm is subdivided into four muscles: pubococcygeus, iliococcygeus, coccygeus, and puborectalis, which are located on both sides of the median line. The first three of these four muscles, often called LAM or levator plates, are attached peripherally to the pubic bones, the ischial bones, and to the arcus tendinous, as a thickened part of the obturator fascia. The inner ends of muscle fibers of the LAM are intimately connected with longitudinal muscle and with the deep portion of the EAS on the side and posterior walls of the anal canal.[13,16,17] The PRM is a strong, U-shaped loop of striated muscle that sling the anorectal junction to the posterior aspect of the pubis. Tonic contraction of PRM leads to the appearance of an acute anorectal angle.[16-18] Muscles, in general, have a relatively simple function; they shorten as they contract. Since LAM and PRM have different muscle attachments, they perform different functions. During PRM contraction, the cranial part of the anal canal is pulled forward, resulting in compression of the posterior wall of the anal canal and an acute anorectal angle will occur. Raizada et al.[19] showed that with voluntary contraction, pressures increase significantly in the cranial part of the anal canal that is surrounded by the PRM. They concluded that it is an important mechanism by which PRM contributes to the anal continence mechanism. “Most investigators agree that the PRM is a key component of anal continence mechanism”.[19]

Since the posterior ends of the LAM are attached along the posterior semicircle of the pelvic ring, and the anterior ends are attached to the posterior and lateral walls of the longitudinal muscle and EAS, then during LAM contraction, the posterior and lateral walls of the anal canal are stretched, revealing the anal canal to the width of the rectum, which is accompanied by the disappearance of the anorectal angle.[20,21] Shafik and El-Sibai[22] discovered that the electrical stimulation of the LAM and the PRM by the needle electrode does not change the pressure in the empty rectum. However, when the balloon of 156.6±34.3 ml is inserted - average pressure in the rectum increased to 64.6±18.7 cm H_2O, the need to defecate appeared, and the balloon was expelled.[22] Since electrical stimulation causes muscle contraction, this suggests that defecation accompanied by a contraction, rather than relaxing of the LAM. Li and Guo[23] showed by the use of CT defecography, that the LAM’s main function is to open the genital hiatus and the anus during defecation. Bush et al.[24] studied normal defecation with video proctography or magnetic resonance imaging. They showed that three muscle vectors open the anorectal angle prior to defecation, causing the anorectal luminal diameter to increase to approximately twice its resting size. These vectors are forwards (anterior wall), backward, and downwards (posterior wall). If the effective diameter of the anus is doubled during defecation, the frictional resistance is reduced by a factor of 8. These studies suggest that the opening of the anal canal during defecation is an active process because of the contraction of LAM. However, there is still no consensus regarding the understanding of normal defecation and the role of LAM.[19,25,26]

The EAS is the elliptical cylinder of striated muscle that envelops the entire length of the inner tube of smooth muscle, but it ends

slightly more distal than the IAS. It consists of three parts: deep, superficial, and subcutaneous. The deepest part of the EAS is intimately related to the puborectalis muscle. The anatomy of the anorectal region is presented in the diagram (Figure 3).

In the anal canal activity is the intermittent, transient relaxation of the IAS, which allows to descent of distal rectal contents into the upper anal canal, endowing a perception of their physical nature. This so-called sampling reflex occurs approximately seven times per hour. This reflex can be reproduced under laboratory condition, where rectal distention cause reflex relaxation of the IAS, as well as contraction of the EAS and PRM (anorectal inhibitory reflex).[25]

In an X-ray examination, the anal canal is defined as the contraction zone between barium in the rectum and the radiopaque marker, which is located next to the anus (Figure 4A).

Levin and Troyan[20]. measured the pressure in the anal canal during a barium enema. The penetration of barium into the anal canal in front of the tip of the enema was observed from one to three times. During the appearance of barium in the anal canal, the anal pressure decreased, and after the disappearance of barium, it returned to the basal level. These observations allowed you to draw two conclusions: (1) the expansion of the rectum causes reflex relaxation of IAS with a simultaneous contraction of EAS and PRM; (2) the penetration of barium into the upper part of the anal canal in front of the tip of the enema is the radiological equivalent of the anorectal inhibitory reflex.

The healthy rectum is compliant, i.e. it can accommodate significant volume of stool with little changes in pressure.[25] Musial and Crowell[26] showed an adaptive response of the rectum to distention and its role in the determination of rectal sensory perception thresholds.[24] The rectum, adapting to an ever-increasing volume of contents, relaxes, because of which the pressure in it does not increase. However, adaptability has limitations both in volume and in rectal pressure. With a certain amount of rectal contents, a need for defecation arises, and defecation itself arises when the abdominal wall and the diaphragm are strained, which leads to additional an increase in rectal pressure. Rectal pressure depends on the volume of the feces, and on the tone rectal wall. Sensitive elements in the wall of the rectum are affected by two forces directed towards each other: wall extension with fecal masses and the tone of the rectal wall. The greater the tone of the rectum, the smaller need for the volume of feces, at which a desire for a bowel movement and the possibility of its implementation arises. For example, the high tone of the rectum with diarrhea causes the need for defecation with scanty amounts of feces. The last example proves that sensitive elements in the wall of the rectum do not respond to stretching and changes of their spatial location, but to the rectal pressure. The networks of pacemaker (interstitial cells of Cajal) coordinates the motor function of the rectum.[27]

Contraction of the muscle fibers is a "work" accompanied by energy consumption, without its renewal muscle cannot continue to contract. Following the contraction inevitably the muscle relaxation must arise, during which the muscle restores its capacity for subsequent contraction. The ability of the IAS to prolonged and continuous contraction can be explained by the

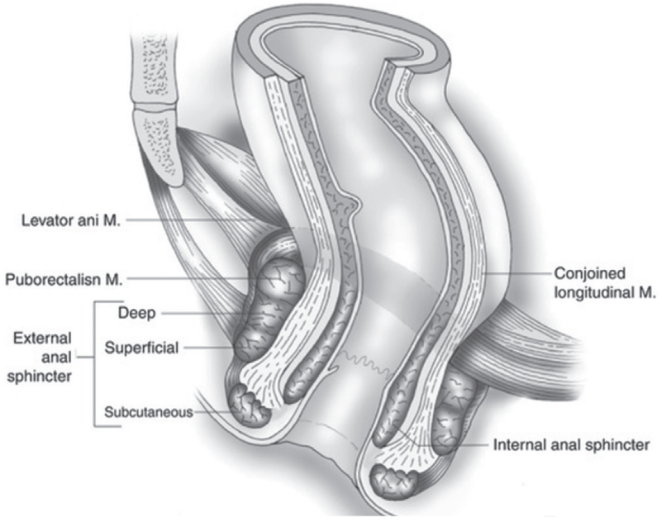

Figure 3. Muscles of the anal canal from an article by Jorge and Habr - Gama[18]

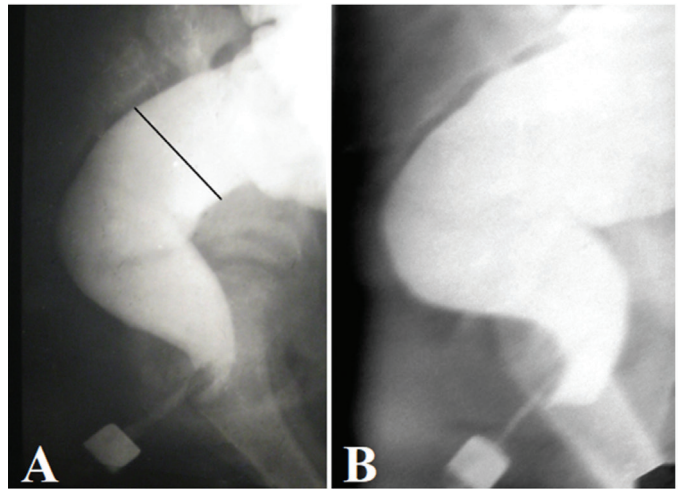

Figure 4. Lateral radiographs of anorectum during a barium enema. (**A**). The true length of the anal canal is equal to the distance between the rectum and the marker, multiplied by a distortion coefficient equal to the ratio of the true diameter of the marker (1.6 cm) to the width of its image on the radiograph. (**B**). During the study, barium penetrates periodically into the anal canal in front of the tip of the enema. At this time, the posterior wall of the anal canal is always pressed against the tip by the contracted PRM. After a few seconds, barium disappears from the anal canal. It is squeezed into the rectum because of a contraction of IAS

PRM: Puborectalis muscle; IAS: Internal anal sphincter

fact that the muscle bundles do not contract simultaneously. It is known that the sheaves of smooth muscle fibers anastomosing with each other forming a tightly knit group of fibers, which operate together.[28] Likely that the different groups of smooth muscle fibers in the IAS are at different stages of recovery of the contractile capacity. At any moment an electrical stimulus that excited from the cells Cajal, leads to a contraction of the groups that are ready to contract. By the next wave of electricity, other groups that have fully restored their capacity are stimulated. This continuous process provides a permanent contraction of the IAS. When there is a need to strengthen the fecal retention, extra-intestinal nerve centers generate a stronger electric potential. This leads to the contraction not only of the muscle fibers group, which is ready to contract but also, the additional groups that are close to this state. The contraction of the larger number of muscle groups leads to increased pressure in the anal canal.

Skeletal muscles are capable of two types of contraction: tonic and mechanical. Tonic prolonged contraction of the LAM, PRM, and EAS explained by postural reflex.[29,30] Each nervous axon has a connection to the muscle fibers scattered throughout the muscle. Therefore, even a small amount of the contracted muscle fibers results in a contraction of the whole muscle. The muscle tone is dependent on the number of fibers participating in the contraction, i.e. from the percentage of axons activating muscle contraction. The prolonged tonic contraction is due to the continuous replacement of the axons activating the different groups of muscle fibers. At a different time, the different groups of the muscle fibers are contracted. At this moment, other muscle fibers restore their contractile potential.

The simultaneous contraction of all muscle fibers leads to a shortening of the muscle and it causes a mechanical movement of the not fixed point of attachment to the fixed point to the bone, such as, for example, the LAM contraction during defecation (Figure 5) and the PRM contraction during anorectal inhibitory reflex. During a mechanical contraction of circular EAS, anal pressure rises sharply. However, the mechanical contraction of striated muscles lasts less than one minute.[31]

There are no voids in the tissues of the pelvic floor. Obviously, during defecation, the anal canal occupies a large volume, not as a result of the relaxation of the sphincters. Only muscle contraction could create this wide channel. And only LAM plates could do this. Thus, the tonic contraction of the LAM provides mechanical support to the rectum and other pelvic floor viscera.[19] It contracts during bowel movements, disclosing the anal canal for passing the stool. The tonic contraction of PRM and EAS together with IAS close the anal canal. Each of these sphincters contributes to the creation of basal anal pressure. Surprisingly, almost all the listed scientific data were published in a book edited by M.M. Henry and M. Swash in 1985.[32]

Using the above scientific data, Levin proposed the hypothesis of the motor function of the anorectum and pelvic floor.[21]

RESULTS

The hypothesis of fecal retention and defecation

Fecal retention: At rest, the IAS and striated muscles of the pelvis floor are in a state of tonic contraction. They help to support the pelvic organs and participate in the continuous

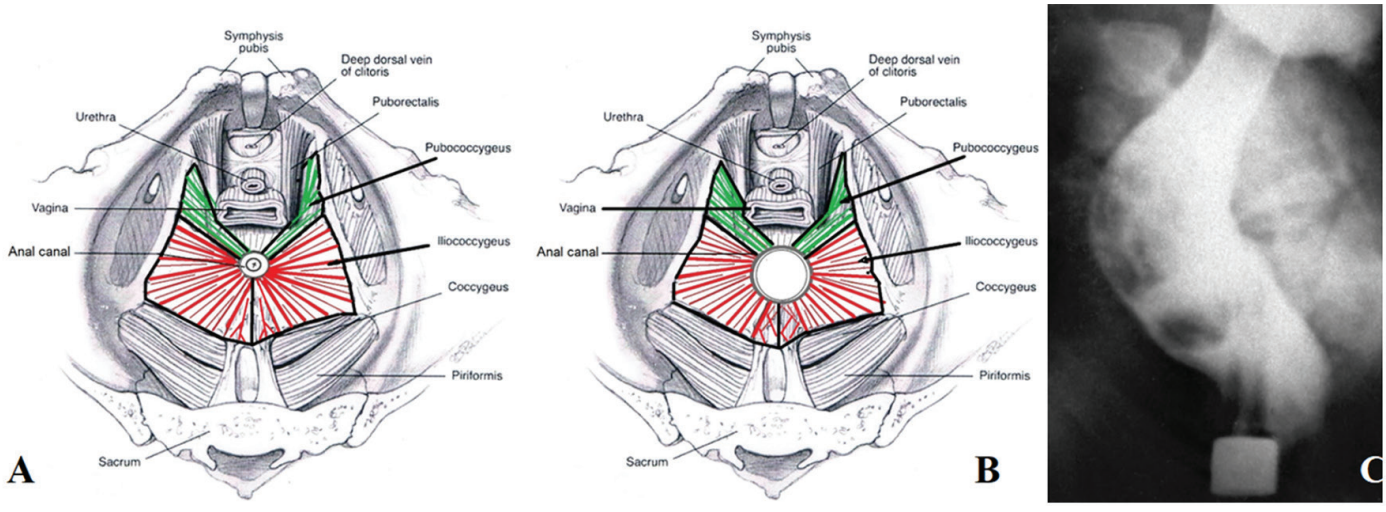

Figure 5. Scheme cross-section of the anorectal region at the level of the deep portion of the EAS. A scheme from the article of Bharucha17 was used. (**A**). At rest anal canal is in a closed state. (**B**). During defecation, the anal canal opened because of the contraction of LAM (pubococcygeus and iliococcygeus). (**C**) Lateral radiography of anorectum of the child during a barium enema. The moment of defecation attempt was recorded. A wide opening of the anal canal is determined. A contrast marker strung on the tip of the enema is located near the anus.
EAS: External anal sphincter; LAM: Levator ani muscle

retention of feces. The pressure in an empty rectum is equal to the intra-abdominal pressure. It is basal rectal pressure (BRP). Its absolute indices are irrelevant, because, firstly, in different articles, they differ significantly from each other, and, secondly, intrarectal catheters distort the true functional characteristics. When the fecal bolus penetrates from the sigmoid colon into the rectum, it stretches the wall of the rectum and rectal pressure increases above the BRP. This pressure we called the threshold pressure of the first order (TP-1). It causes a reflex relaxation of the IAS and contraction of the EAS and PRM. The PRM during contraction pulls forward the upper part of the anal canal. In front, inside the PRM loop the anal pressure decrease because of the IAS relaxation. Between the rectum and anal canal, there is a narrow opening through which the gas and liquid feces can penetrate the upper part of the anal canal. In the mucosa at this level, there are sensors that allow distinguishing the liquid from the gas. The presence of gas is enough to strain the abdominal wall to increase rectal pressure and expel gas through the lower part of the closed anal canal. When the liquid feces penetrate the upper part of the anal canal the tone of the EAS increase, which leads to a contraction of the IAS and crowding out of the fluid from the anal canal into the rectum. During anorectal inhibitory reflex, the formed stool remains in the rectum due to the acute anorectal angle and the narrow hole between the rectum and anal canal. After a few seconds, the rectum adapts to the new rectal volume and relaxes. The rectal pressure drops up to BRP, resulting in the contraction of the IAS and relaxation of the PRM and EAS. After entering the rectum of another bolus of feces this picture (anorectal inhibitory reflex) is repeated. This picture can be observed up to seven per hour. During IAS relaxation, its muscle fibers restore contraction ability. In this period, the fecal retention is performed by the PRM and EAS contraction. During the rise of the intra-abdominal pressure (rise from the spot, cough, etc.), the reflex contraction of all sphincters occurs. The tone of the IAS increases since the electric potential from the center outside the rectum increases the number of contracted muscle bundles.

When the volume of stool in the rectum reaches a certain value, the rectal pressure rises from TP-1 to the threshold pressure of the second-order (TP-2), in which a need for a bowel movement appears. If this need does not coincide with the possibility of its implementation, the rectum continues to relax to a limited extent. At the same time, there is an increase in the tone of the recto-sigmoid sphincter, which prevents the further penetration of feces from the sigmoid colon into the rectum.[33]

Defecation: When the need for a bowel movement coincides with the possibility of its implementation, a straining of the abdominal wall and diaphragm increases, which leads to an increase in the abdominal and rectal pressure from TP-2 to the threshold pressure of the third-order (TP-3). At the rectal pressure TP-3, the reflex defecation takes place: a strong peristaltic wave of the rectum expels stool through the open anal canal. The wide opening of the anal canal is due to the relaxation of the IAS, PRM, and EAS, with a simultaneous contraction of the LAM. Any of the pressure levels depend not only on the volume of feces but also on the tone of the rectum. During the anal canal opening, its wall is stretched at the level of deep and superficial portions of the EAS. Since the subcutaneous portion of the EAS is not connected with LAM it relaxed, but does not stretch (Figure 3). Therefore, during the evacuation of soft feces, it forms a tape, the diameter of which depends on the viscosity of the feces.

Applied physiology

1. Prerequisites for normal bowel movements: a) Normal innervation of all elements of the anal canal and preservation of reflexes. b) The maximum width of the rectum, which forms feces, should not exceed the maximum possible width of the anal canal. c) Normal LAM function is necessary for the wide disclosure of the anal canal, which provides minimal resistance to the movement of feces.

2. This hypothesis allows us to explain the "paradoxical" contraction in PRM during an attempt to defecate in constipated patients. To create pressure that provokes defecation in the wide rectum (megarectum) with a low tone of the rectal wall, the rectal balloon of significantly larger diameter is needed than in the control. The volumes of the rectal balloon that in healthy people create TP-3 pressure and provoke defecation, in patients with obstructive constipation, create TP-1 pressure, causing a contraction in PRM and EAS.

3. Therefore, the key to understanding the pathogenesis of functional constipation is in the expansion of the rectum. Delayed bowel movement leads to an increase in the diameter of the stool. An attempt to defecate causes pain and stops the following attempts. There is a vicious circle, because of which after a while there is a stable expansion of the rectum - megarectum. The rectum forms fecal masses of large diameter difficult to pass through the anal canal. Wide stool stretches the muscles of the pelvic floor, causing stretching and weakening of LAM and PRM, which leads to increased constipation (weakness of LAM) and fecal incontinence (weakness of PRM). This is how descending perineum syndrome develops.

4. Measuring the width of the rectum is the key to determining the cause of constipation and its prognosis.[8,9,11,34-36]

NOTES

The normal anatomy of the gastrointestinal tract is well documented in the literature. The data on the physiology of these processes are controversial and sketchy. Knowledge of the physiology of anorectum allows us to understand the development of pathological processes in this area and apply pathophysiological treatment of chronic constipation, fecal incontinence, etc. The hypothesis presented does not contradict the known scientific facts and can serve as a basis for further research.

Ethics

Ethics Committee Approval: Since this study does not include studies in humans or animals, ethics committee approval was not obtained.

Informed Consent: Since this study does not include studies in humans or animals, informed consent was not obtained.

Peer-review: Externally peer-reviewed.

DISCLOSURES

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VIDEO ARTICLE

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Micturition requires active opening of the posterior urethral wall by directional striated muscles

PETER PETROS

School of Engineering, University of Western Australia

ABSTRACT

The video demonstrates that the current concept of total pelvic floor relaxation preceding micturition is only partly correct. It is only the anterior part of pelvic floor which relaxes. The posterior muscles stretch the bladder/urethral smooth muscle backwards to tension it, prior to active opening of the posterior urethral wall by the downward angulation of the anterior border of levator plate by the conjoint longitudinal muscle of the anus. This action expands the diameter of the urethra, vastly reducing the resistance to flow and therefore, the head of pressure required to be generated by the detrusor to empty the bladder.

Keywords: Micturition video; Integral Theory; active opening; striated muscle

INTRODUCTION

Text adapted from: Petros P, Lynch W, Bush M. Surgical repair of uterosacral/cardinal ligaments in the older female using the tissue Fixation system improves symptoms of obstructed micturition and residual urine. Pelviperineology 2015;34:112-116.

Inability to adequately evacuate the bladder is a major source of repeated urinary infection and pathology.[1] Catheter-associated urinary tract infection (UTI) is the most common nosocomial infection, accounting for >1 million cases in hospitals and nursing homes. The risk of UTI increases with increasing duration of catheterization. In non-institutionalized elderly populations, UTIs are the second most common form of infection, accounting for nearly 25% of all infections with a cost of 1 billion dollars p.a.[1] The traditional view of the mechanism of micturition was described by Messelink et al:[1] "The pelvic floor muscles must relax in order to remove the passive continence mechanisms, thereby favouring normal micturition". A recent Review of voiding dysfunction[2,3] shed little light on the problem. It stated, "There remains a lack of consensus regarding a precise diagnosis and definition of voiding abnormalities in women". The Review's statement of causation[2] was limited to "detrusor underactivity and outflow obstruction which could be either physiological or iatrogenic". Two studies reporting improvement of bladder emptying following cystocele and fascial repair were mentioned, but no anatomical explanations were forwarded as to why.[2] We believe that the answer to these conundra is to be found in urethral resistance to urine flow which is exponentially determined and is instantaneously modified by an external striated muscle mechanism first described in 1990.[4]

Micturition Video: https://www.youtube.com/watch?v=eiF4G1mk6EA&feature=youtu.be

This mechanism, since validated with electromyography and video X-ray studies stretches open the posterior urethral walls during micturition,[5,6] Figure 1 and 2, and is in turn ultimately dependent on competent posterior suspensory ligaments

Address for Correspondence: Peter Petros, School of Engineering, University of Western Australia
E-mail: pp@kvinno.com ORCID: orcid.org/0000-0002-9611-3258
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in the position of the cervix (CX), Figure 1.[5,6] The external opening mechanism, Figure 1 and 2, was described as follows: immediately prior to commencement of voiding, the forward closure vector (m. pubococcygeus) relaxes; relaxation of m. pubococcygeus releases the closure pressure of the hammock on the posterior urethral wall, thereby freeing the posterior vectors (levator plate and the conjoint longitudinal muscle of the anus, arrows, Figure 1, to actively open the urethra prior to detrusor contraction; this causes the urethra to funnel, exponentially lowering the resistance to flow immediately prior to the expulsive action of the detrusor.[6] According to,[4] the keystone of this mechanism is the requirement for firm anchoring points for the downward opening vector, the uterosacral/cardinal ligaments (CL/USL) at CX, Figure 1: the downward opening vector (white arrow, Figure 1) contracts against the CL/USL: if the USL is loose, the vector weakens;[7] the vector cannot open out the posterior urethral wall; the detrusor contracts against an unopened urethra and therefore, a high urethral resistance; a higher detrusor pressure is required for expulsion, Figure 3; the patient will have bladder emptying difficulties because of greatly increased resistance to flow.[8] Resistance to flow is highly sensitive to this opening mechanism, as it is exponentially determined (Poiseuille's Law). For non-laminar flow, it is approximately inversely related to the 4th power of the radius (r).[8] With reference Figure 1, there appears to be almost doubling

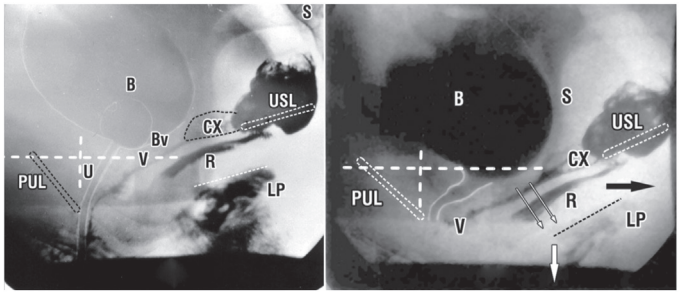

Figure 1. Normal patient. X-rays at rest (left) and during micturition (right), samepatient in sitting position. At rest, slow twitch contractions angulate bladder (B), urethra (U), vagina (V) and rectum (R) around the insertion of the pubourethral ligament (PUL) at midurethra. 10ml radiopaque material has been injected into the levator plate (LP) vagina and rectum. Vertical and horizontal broken lines indicate bony co-ordinates. During micturition (right figure), the urethra has moved backwards from the vertical co-ordinate, suggesting relaxation of the forward vector. Vagina and rectum appear to have been stretch backwards by a backward vector (black arrow). The anterior part of LP has been angulated downwards apparently by the downward vector (white arrow) acting against the CX/USL complex. The backward/downward vectors (thin diagonal arrows) create a diagonal vector force which seems to be pulling open the posterior urethral wall.

B: Bladder; U: Urethra; V: Vagina; R: Rectum; PUL: Pubourethral ligament; LP: Levator plate; CX: Cervix; USL: Uterosacral ligament; S: Sacrum

of the urethral diameter during micturition. The pressure flow relationship as determined by direct laboratory measurement and computer modelling is shown in Figure 3.[8] At a diameter of 3.5 mm, a pressure head of approximately 170 cm H_2O is required to achieve a flow rate of 50 ml/sec, Figure 3. If the urethra can be opened out from 3.5 mm to 6 mm by the proposed external mechanism, the head of pressure required for a 50 ml/sec flow falls to 20 cm H_2O.

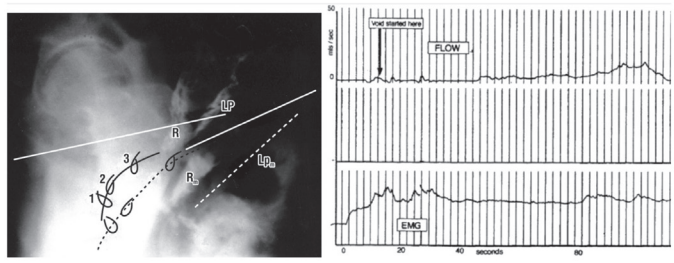

Figure 2. Micturition X-ray superimposed on resting X-ray (left side), patient sitting. Vascular clips have been applied to the midurethra "1". Bladder neck "2" and bladder base "3". Radio-opaque dye has been injected into the levator plate "LP", which has been angulated downwards during micturition, as has the rectum "R", which has 10 ml of barium paste. Broken lines indicate position of organs during micturition. Subscript "m" indicates the position of rectum "R" and levator plate "LP" during micturition. Surface EMG (right side) Surface EMG cylinder placed in the posterior fornix of the vagina simultaneous with uroflowmetry. EMG shows that muscle contraction preceded urine flow.

LP: Levator plate; R: Rectum; EMG: Electromyography

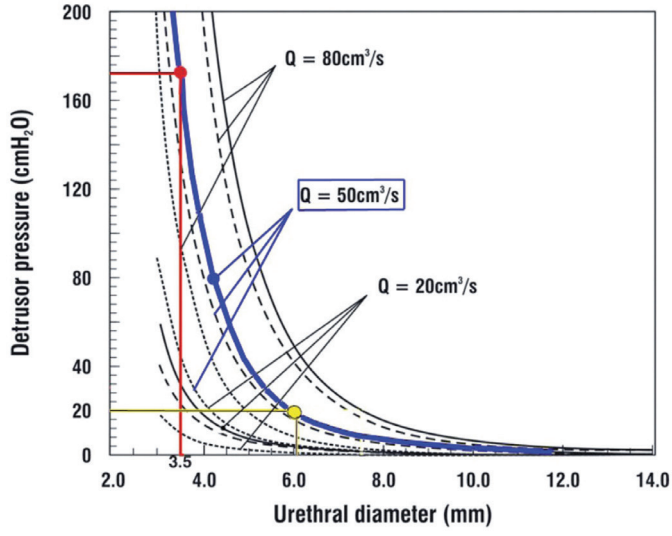

Figure 3. Pressure flow graph - detrusor pressure as a function of urethral diameter for urethral length of 4 cm at flow rates of 20, 50, 80 ml/sec (8). Total resistance to flow (unbroken line) —Frictional component …….. Dynamic component - - - - - -. For a flow rate of 50 ml/sec (blue line), increasing the diameter of the urethra from 3.5 mm to 6 cm, reduces the head of pressure required to empty from approximately 170 cm H_2O to 20 cm H_2O.

Q: Flow (cm^3/s)

Ethics

Peer-review: Externally peer-reviewed.

DISCLOSURES

Conflict of Interest: The author has no conflicts of interest.

Financial Disclosure: The author declared that this study has received no financial support.

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Saturday, 29 May, 2021		
10:00-10:05	**OPENING** **Dr.Menahem Neuman, Dr.Akin Sivaslioglu**	
Session 1		**Moderator: Dr. Peter Petros**
10:05-10:25	Pelvic anatomy with regards to pelvic floor disorders	**Dr. Akin Sivaslioglu**
10:25-10:45	The application of transperineal ultrasonography in incontinence and POP	**Dr. Giulio Santoro**
10:45-11:00	Urodynamic studies: to whom and when?	**Dr. Tolga Guler**
11:00-11:10	The causal link between lax ligaments and gene expression	**Dr. Burcu Kasap**
11:10-11:25	Whom should be treated with which sling for stress UI	**Dr. Menahem Neumann**
11:25-11:45	Coexisting symptoms of over-, underactive bladder, anorectal dysfunctions and pain in women with pelvic organ prolapse - underlying etiology and pathophysiologic pathways	**Dr. Bernhard Liedl**
11:45-12:00	Minislings: how efficient are they?	**Dr. Paulo Palma**
12:00-12:15	**DISCUSSION**	
12:15-13:00	**LUNCH BREAK**	
Session 2		**Moderator: Dr. Naama Marcus**
13:00-13:15	The management of painful bladder syndorme	**Dr. Mehri Mehrat**
13:15-13:30	Application of the integral system to cure of intersititial cystitis and vulvodynia	**Dr. Peter Peros**
13:30-13:45	The management of recurrent SUI after sling surgery	**Dr. Huseyin Cengiz**
13:45-14:00	Sacrocolpopexy: is it still the gold standard?	**Dr. Peter von Theobald**
14:00-14:15	Pectopexy for the treatment of apical prolapse	**Dr. Yakup Kumtepe**
14:15-14:30	Native tissue repair in anterior compartment defects	**Dr. Derya Kilic**
14:30-14:45	How should the posterior compartments defects be managed?	**Dr. Omer Alabaz**
14:45-15:00	Experience with Endofast	**Dr. Naama Marcus**
15:00-15:15	**DISCUSSION**	
15:15-15:30	**BREAK**	
15:30-16:30	**ORAL PRESANTATIONS**	**Moderator: Dr.Yusuf Ustun**

Sunday, 30 May, 2021		
Session 3		**Moderator: Dr. Giuseppe Dodi**
10:00-10:15	Lateral suspension: the technique and to whom?	**Dr. Murat Yassa**
10:15-10:30	Tips and tricks for vaginal hysterectomy	**Dr. Ates Karateke**
10:30-10:45	Meshless device: EnPlace	**Dr. Vincent Lucente**
10:45-11:00	Native tissue repair in prolapse surgery	**Dr. Elvira Bratila**
11:00-11:15	The future of mesh surgery	**Dr. Burghard Abendstein**
11:15-11:30	New minimal invasive method for vaginal apical suspension	**Dr. David Shveiky**
11:30-11:45	Pelvic floor rehabilitation	**PT. Yasemin Irkilata**
11:45-12:00	Sexuality after pelvic floor surgery	**Dr. Sevtap Hamdemir Kilic**
12:00-12:15	**DISCUSSION**	
12:15-13:00	**LUNCH BREAK**	
Session 4		**Moderator: Dr. Menahem Neuman**
13:00-13:15	The management of OASIS	**Dr. Shimon Ginath**
13:15-13:30	vNOTE laparoscpic POP reconstruction	**Dr. Lior Lowenstein**
13:30-13:45	Vulvovaginal reconstruction	**Dr. Eray Caliskan**
13:45-14:00	POP recurrence management	**Dr. Mauro Cervigni**
14:00-14:15	New approach to vulvar pain	**Dr. Jacob Bornstein**
14:15-14:30	The management of obstructed defecation syndrome	**Dr. Darren Gold**
14:30-14:45	Vaginal surgery of large cystocele without mesh: the Plastron	**Dr. Michel Cosson**
14:45-15:00	Self retainig mesh for advanced POP reconstruction	**Dr. Gil Levi**
15:00-15:15	**DISCUSSION**	
15:15-15:30	**BREAK**	
15:30-16:00	**POSTER PRESENTATIONS**	**Moderator: Dr. Peter von Theobald**
16:00-16:30	**TAKE HOME MESSAGES AND CLOSING** **Dr. Peter Petros, Dr. Giuseppe Dodi, Dr. Menahem Neuman, Dr. Bruce Farnsworth, Dr. Peter von Theobald, Dr. Jacob Bornstein, Dr. Naama Marcus, Dr. Akin Sivaslioglu**	

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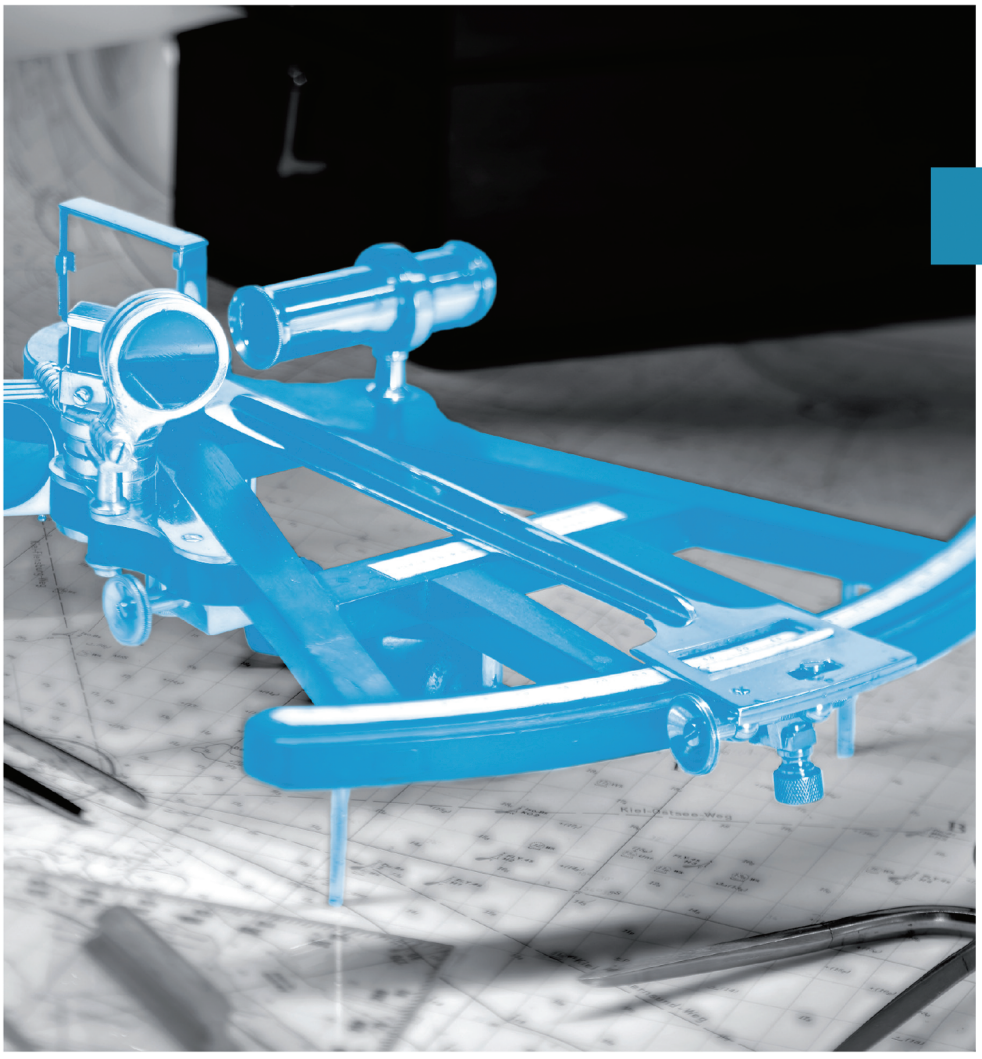

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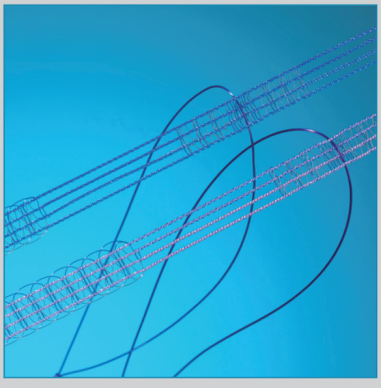

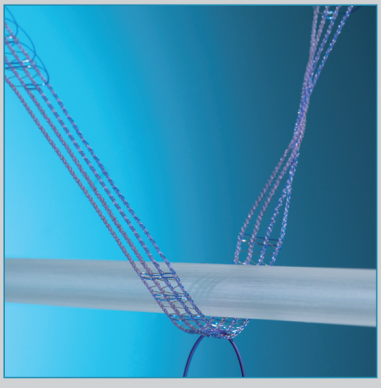

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SERAG-WIESSNER GmbH & Co. KG
Zum Kugelfang 8 - 12
95119 Naila/Germany

+ 49 9282 937-0
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