Obstetrics and Gynecology International

# New Advances in Urogynecology

Guest Editors: Lior Lowenstein, Peter L. Rosenblatt, Hans Peter Dietz, Johannes Bitzer, and Kimberly Kenton

# New Advances in Urogynecology

Obstetrics and Gynecology

# New Advances in Urogynecology

Guest Editors: Lior Lowenstein, Peter L. Rosenblatt,
Hans Peter Dietz, Johannes Bitzer, and Kimberly Kenton

# Editorial Board

# Contents

Hindawi Publishing Corporation
Obstetrics and Gynecology International
Volume 2012, Article ID 453059, 2 pages
doi:10.1155/2012/453059

*Editorial*

# New Advances in Urogynecology

**Lior Lowenstein,[1,2] Peter L. Rosenblatt,[3] Hans Peter Dietz,[4] Johannes Bitzer,[5] and Kimberly Kenton[6]**

[1] *Department of Obstetrics and Gyenceology, Rambam Health Care Campus, Haifa, Israel*
[2] *Ruth and Baruch Rappaport Faculty of Medicine, Technion—Israel Institute of Technology, Haifa, Israel*
[3] *Division of Urogynecology and Reconstructive Surgery, Mount Auburn Hospital, Harvard Medical School, Cambridge, MA, USA*
[4] *Department of Pelvic Reconstructive Surgery and Urogynaecology, Sydney Medical School Nepean, Penrith, NSW, Australia*
[5] *Department of Obstetrics and Gynaecology, University Hospital Basel, Basel, Switzerland*
[6] *Division of Female Pelvic Medicine and Reconstructive Surgery, Departments of Obstetrics & Gynecology and Urology, Stritch School of Medicine, Loyola University Chicago, Maywood, IL, USA*

Correspondence should be addressed to Lior Lowenstein, lowensteinmd@gmail.com

Received 9 November 2011; Accepted 9 November 2011



Pelvic floor disorders, including urinary incontinence, pelvic organ prolapse (POP), and bowel dysfunction, affect millions of women worldwide resulting in considerable cost and quality of life impact. One-third of all women will suffer from these disorders at some point in their lives [1–5]. Significant research efforts are underway to improve our understanding of the pathophysiology, optimal evaluation, and effective treatment for women with pelvic floor disorders. More than ever before, research is providing meaningful developments into etiologies and novel treatment modalities. Additionally, researchers advance our understanding of improved methods for evaluating treatment outcomes, including patient-reported outcomes. These advances are largely due to the efforts of an increasing number of clinician-scientists who design and conduct high-quality clinical trials and translational studies. In addition to learning more about basic pathophysiology, recent technical advances offer excellent treatment efficacy with reduced morbidity. This work is facilitated by the efforts of multidisciplinary teams composed of a widening group of pelvic floor specialists, including radiologists, physiotherapists, urologists, and urogynecologists. The clinical advances in urogynecology are advancing rapidly and will improve the well-being of millions of women who suffer from pelvic floor disorders.

The main focus of this special issue is on new and existing diagnostic and treatment methods for pelvic floor disorders. The articles summarize current approaches to the treatment of these disorders and look into the future by discussing possible novel interventions for the treatment of pelvic floor dysfunction.

The first paper of this issue, published by a group of clinicians from The Netherlands, explores the association of POP severity and subjective pelvic floor symptoms. As one might expect, presence of POP on exam was associated with patient-reported symptoms of prolapse and voiding dysfunction, but not with urinary incontinence or defecatory symptoms. The second paper evaluates the role of pessary trial in predicting postoperative outcomes of occult stress urinary incontinence. The authors suggest that pessary trial is an effective method to evaluate POP patients for occult stress incontinence, as 20% of patients with occult stress incontinence were identified by pessary trial alone. The third paper presents a comparative study between two common methods to evaluate afferent neural function in the lower urinary tract. The current perception test is becoming increasingly important in diagnosing abnormalities of afferent neural pathways. Since these neurologic problems may contribute to certain pelvic floor disorders, it is important to establish the best methods for these neural changes. The authors conclude that the method of levels is superior to the method of limits when evaluating current perception thresholds in the lower urinary tract. The fourth manuscript reviews a new treatment for stress urinary incontinence, transurethral radio frequency treatment of the bladder neck and

proximal urethra. Radio frequency is thought to reduce funneling of the bladder neck through the denaturation of submucosal collagen, with a resultant reduction in tissue compliance and increased Valsalva leak point pressure. The authors conclude that radio frequency is an effective conservative treatment for stress incontinence with few side effects.

In the fifth paper, from the Cleveland Clinic, an animal model was used to evaluate whether intravenously injected mesenchymal stem cells home to pelvic organs after simulated childbirth injury. The findings of this interesting paper provide evidence that intravenous administration of mesenchymal stem cells may be used as an early intervention to repair injuries to the levator ani muscles and both urethral and ani sphincters, thus preventing future pelvic floor disorders.

The sixth paper presents results of an Israeli survey evaluating trends among Israeli urogynecologists regarding the routine use of mesh. The use of mesh in vaginal prolapse surgery is a hot topic, especially since the last safety notification published by the FDA on July 13, 2011 regarding possible adverse events following the use of vaginal mesh. Ironically, the use of mesh among Israeli urogynecologists increased significantly over the last two years. Though the data regarding the efficacy and safety of vaginal mesh is still lacking, the popularity of this method continues to rise. One possible explanation for this discrepancy is that Israeli physicians practice medicine in an environment characterized by innovation and scientific progress. Until studies with higher levels of evidence prove the efficacy of these treatments, more caution should be advised in the application of this yet unproven technology. The next paper published by Dr. K. T. Downing is a comprehensive review article regarding the progress of treatment of uterine prolapse from ancient times up to the present day. This article is especially relevant for those who are looking for new advances in medicine. As was stated previously by George Santayana, "Those who cannot remember the past are condemned to repeat it."

Last but not least is a paper published by a group of researchers from Spain who evaluated the level of training of residents in obstetrics and gynecology in the management of perineal tears that occur during assisted vaginal delivery. Almost all of the respondents indicated that more training in this specific area is necessary (98%). As Ralph Waldo Emerson once stated, "Skill to do comes of doing."

Finally, in this special issue, the reader will conveniently find a comprehensive summary of the state-of-the-art diagnostic strategies and new advances in urogynecology.

*Lior Lowenstein*
*Peter L. Rosenblatt*
*Hans Peter Dietz*
*Johannes Bitzer*
*Kimberly Kenton*

## References

[1] T. M. Thomas, K. R. Plymat, J. Blannin, and T. W. Meade, "Prevalence of urinary incontinence," *British Medical Journal*, vol. 281, no. 6250, pp. 1243–1245, 1980.

[2] A. H. MacLennan, A. W. Taylor, D. H. Wilson, and D. Wilson, "The prevalence of pelvic floor disorders and their relationship to gender, age, parity and mode of delivery," *British Journal of Obstetrics and Gynaecology*, vol. 107, no. 12, pp. 1460–1470, 2000.

[3] K. Holst and P. D. Wilson, "The prevalence of female urinary incontinence and reasons for not seeking treatment," *New Zealand Medical Journal*, vol. 101, no. 857, pp. 756–758, 1988.

[4] J. V. Jolleys, "Reported prevalence of urinary incontinence in women in a general practice," *British Medical Journal*, vol. 296, no. 6632, pp. 1300–1302, 1988.

[5] S. L. Jackson and T. L. Hull, "Fecal incontinence in women," *Obstetrical and Gynecological Survey*, vol. 53, no. 12, pp. 741–747, 1998.

Hindawi Publishing Corporation
Obstetrics and Gynecology International
Volume 2012, Article ID 798035, 9 pages
doi:10.1155/2012/798035

*Clinical Study*

# Contribution of Primary Pelvic Organ Prolapse to Micturition and Defecation Symptoms

**Annette G. Groenendijk,[1] Erwin Birnie,[2] Jan-Paul W. Roovers,[3] and Gouke J. Bonsel[2,4]**

[1] *Department of Gynecology and Obstetrics, Onze Lieve Vrouwe Hospital, P.O. Box 95500, 1090 HM Amsterdam, The Netherlands*
[2] *Institute of Health Policy and Management, Erasmus Medical Center, P.O. Box 1738, 3000 DR Rotterdam, The Netherlands*
[3] *Department of Gynecology and Obstetrics, Academic Medical Center, University of Amsterdam, P.O. Box 22660, 1100 DD Amsterdam, The Netherlands*
[4] *Department of Obstetrics and Gynecology and Division Obstetrics and Prenatal Medicine, Erasmus MC-Sophia, P.O. Box 2060, 3000 CB Rotterdam, The Netherlands*

Correspondence should be addressed to Annette G. Groenendijk, a.g.groenendijk@olvg.nl

Received 1 April 2011; Accepted 7 July 2011

Academic Editor: Peter L. Rosenblatt



*Objective*. To investigate the contribution of Pelvic Organ Prolapse (POP) to micturition and defecation symptoms. *Method*. Cross-sectional study including 64 women presenting with POP symptoms and 50 controls without POP complaints. Subjects were evaluated using POP-Quantification system, Urinary Distress Inventory, and Defecation Distress Inventory. The MOS SF-36 health survey and the Center for Epidemiological Studies Depression scale were used to measure self-perceived health status and depressive symptoms, respectively. *Results*. POP in terms of POP-Q had a moderate impact on the symptom observing vaginal protrusion (explained variance 0.31). It contributed modestly to obstructive voiding and overactive bladder symptoms (explained variance 0.09, resp., 0.14) but not to urinary incontinence. Constipation was more likely explained by clinical depression than by pelvic floor defects (explained variance 0.13, resp., 0.05). *Conclusion*. Stage of POP and specific prolapse symptoms are associated but such a strong association does not exist between POP and micturition or defecation symptoms.

## 1. Introduction

Pelvic organ prolapse (POP) is a common disorder often associated with symptoms such as a vaginal bulging, pelvic heaviness, bothersome micturition, and defecation symptoms as well as sexual dysfunction, often with a negative impact on quality of life [1, 2]. It is unclear whether the anatomical position of the bladder, bowel, and uterus compromises the bladder and bowel function directly, or whether abnormal anatomy and dysfunction of the pelvic floor share a common etiology. Moreover, it is unclear to what extent micturition and defecation symptoms can be explained by the presence and degree of anatomical abnormalities involved in POP. With the exception of vaginal bulging, none of these symptoms are specific to vaginal prolapse since they also exist in women without POP [3]. Whether or not the symptoms are related to POP is critical to patient management. POP patients in whom defecation symptoms dominate might be primarily referred to the gastroenterologist, but if these patients present with a vaginal prolapse, these patients are usually referred to the gynecologist. The latter commonly offers POP surgery with the correction of the anatomy as well as restoration of the pelvic floor function as treatment aims. This treatment policy assumes a causal rather than indirect relation between POP and these symptoms. However, surgical results frequently are disappointing in terms of pelvic floor function and symptoms [4, 5].

In this study we address the unclear relation between POP and pelvic floor symptoms and compare women who present with symptomatic POP with asymptomatic women. We investigated to what extent bladder and bowel symptoms are related to specific anatomical defects of the pelvic floor or to other factors like patient characteristics (e.g., age,

parity, body weight, educational level) and psychological characteristics.

## 2. Material and Methods

We conducted a cross-sectional study between January 2000 and January 2002 consisting of two groups. The study group consisted of 64 women with symptomatic POP stage 2 or more treated at the gynecology outpatient clinic of the Onze Lieve Vrouwe Hospital. These patients participated in a larger study on the evaluation of the diagnostic work-up of patients with symptomatic primary POP [6–8]. The control group consisted of 35 women who were referred to the gynecology outpatient clinic for other complaints but not seeking medical care for POP and 15 women without gynecological complaints and who were not referred.

Exclusion criteria for both groups were being less than 6 months postpartum, having congenital defects of the urogenital and/or gastrointestinal tract, a fibroid uterus with a size of more than 12 weeks of pregnancy, large ovarian cysts, prolapse surgery and/or hysterectomy in medical history, a poor general condition precluding surgical therapy or insufficient Dutch language proficiency. Patients who visited the general gynecologic outpatient clinic were excluded from the control group if they appeared to have symptoms of pelvic prolapse.

The study was approved by the Medical Ethical Board of the Onze Lieve Vrouwe Hospital.

Standardized medical review and physical examination were carried out during the first visit at the gynecology outpatient clinic of the Onze Lieve Vrouwe Hospital. Stage of POP was assessed using the POP-Quantification (POP-Q) system with the patient sitting 45 degrees upright in a gynecological examination chair while she was instructed to strain forcefully [9]. In agreement with the study of Kahn and colleagues, we used the sum of the anatomic landmarks genital hiatus (gh) and perineal body (pb) as measure for perineal descent [10]. All pelvic examinations were performed by the first author (A. G. Groenendijk). In addition to a standard history review, each patient was invited to complete the following surveys. (1) The MOS SF-36 generic health-related quality-of-life questionnaire was used to measure self-perceived health status [11]. We used the overall physical and mental health summary scores (score range: 0–100, a higher score indicates better health) as indicators of physical and mental health. (2) The Center for Epidemiological Studies Depression scale (CES-D) was used to measure depressive symptoms [12] (scores range: 0 (no symptoms)−60(maximal symptoms); a cutoff score of 16 indicates clinical depression). (3) For the measurement of urogenital and bowel symptoms and symptom-related bother, we used two disease-specific symptom questionnaires. Firstly, the 19-item urinary distress inventory (UDI) consists of five domains: genital prolapse (e.g., feeling and/or seeing a vaginal bulge), urinary incontinence (e.g., urine leakage related to physical activity, coughing, or sneezing and urine leakage related to the feeling of urgency), overactive bladder (e.g., frequency, urgency, and nocturia), obstructive micturition (e.g., feeling of incomplete bladder emptying and difficulties to empty the bladder), and discomfort/pain (e.g., lower abdominal pressure, pain or discomfort lower abdomen, push on the vaginal wall to have bowel movement). Secondly, we used the 15-item defecation distress inventory (DDI) consisting of four domains: constipation, fecal incontinence, painful defecation, and incontinence for gas. The constipation domain was covered by the following items: less than 3 bowel movements a week, in 25% of the time straining at defecation, feeling of incomplete evacuation, sensation of anal blockage, and difficulties with emptying the rectum (manual removal of feces out of the rectum or push on the vaginal wall). Each domain score ranges from 0 to 100, and a higher score indicates more bother of reported symptoms [13, 14]. Both questionnaires have been validated in the Dutch language.

## 3. Analysis

Differences in stage of pelvic organ prolapse, patient characteristics, and reported pelvic floor symptoms between the study and the control group were evaluated using the Student's independent samples $t$-test for Gaussian distributed variables, the nonparametric Mann-Whitney $U$-test for skewed variables, and the chi-square test for nominal/ordinal variables.

The impact of (1) individual risk factors (age, body mass index (BMI), parity, perineal trauma, summary physical health (as proxy for comorbidity), and educational level), alongside (2) specific pelvic floor defects (anterior, middle, and posterior compartment defects) and (3) psychological health status (clinical depression and summary mental health) on the UDI and DDI domain scores (both log transformed) was assessed using multiple linear regression analysis. The resulting beta-coefficients represent the impact on the log UDI or log DDI domain score when the risk factor is changed with one unit of measurement. Adjusted $R^2$ was used as measure of model fit. The change in adjusted $R^2$ was used to quantify the contribution of patient characteristics, psychological health, and specific pelvic floor defects, respectively (in this order, stepwise multiple linear regression analysis).

The post hoc sample size estimation showed that at least 84 patients had to be included in the analysis (power 80%) or alternatively 111 patients (power 90%) (type I error (alpha) = 0.05 (two sided), 13 predictors (see Table 2), effect size = 0.25 corresponding to $R^2 = 0.20$).

SPPS for Windows version 16.0 was used for data management and statistical analysis. A two-sided $P$ value $<0.05$ was considered a statistically significant difference.

## 4. Results

Table 1 depicts the characteristics of the 64 women of the study and the 50 women of the control group. Women in the study group were on average older and had higher parity as compared to the control group. Patients in the study group on average had higher POP stage compared to the control

Table 1: Patient's characteristics.

| Characteristics | Study group ($n = 64$) | Control group ($n = 50$) | $P$ value |
|---|---|---|---|
| *Age (years),* mean (SD) [range] | 56.1 (10.4) [35–77] | 48.9 (8.1) [37–72] | <0.01 |
| *Body Mass Index (BMI),* mean (SD) [range][a] | 25.38 (4.3) [18.4–39.1] | 24.0 (4.3) [18.4–41.3] | 0.99 |
| Educational level | | | 0.68 |
| Primary school/lower vocational education | 22 (34%) | 6 (12%) | |
| Secondary school/high school | 21 (33%) | 23 (46%) | |
| Academic/university | 22 (34%) | 21 (42%) | |
| *Parity* | | | 0.04 |
| 0 | 0 (—) | 4 (8%) | |
| 1 | 15 (23%) | 21 (42%) | |
| 2 | 22 (35%) | 16 (32%) | |
| 3 | 15 (23%) | 8 (16%) | |
| ≥4 | 12 (19%) | 1 (2%) | |
| Overall, mean | 2.3 | 1.6 | |
| Type of delivery | | | 0.36 |
| Vaginal delivery, no forceps or vacuum | 56 (88%) | 40 (80%) | |
| Forceps and/or vacuum | 8 (12%) | 9 (18%) | |
| Caesarian section only | 0 (—) | 1 (2%) | |
| Perineal trauma (per patient) | | | 0.52 |
| No perineal trauma | 16 (25%) | 16 (32%) | |
| Episiotomy or rupture | 48 (75%) | 34 (68%) | |
| POP-Q points, mean (SD)[b] | | | |
| Aa | −0.8 (1.1) | −2.0 (1.2) | |
| Ba | 2.2 (2.2) | −1.9 (1.3) | |
| C | −0.2 (4.1) | −5.7 (1.4) | |
| Gh | 4.1 (1.1) | 2.2 (0.7) | |
| Pb | 2.7 (0.7) | 2.9 (0.6) | |
| Ap | 0.2 (1.4) | −1.6 (1.5) | |
| Bp | 0.3 (1.6) | −1.5 (1.5) | |
| TVL | 8.1 (1.1) | 8.6 (1.1) | |
| POP-Q stage | | | <0.01 |
| Stage I | 0 (—) | 24 (48%) | |
| Stage II | 17 (27%) | 24 (48%) | |
| Stage III | 42 (66%) | 2 (4%) | |
| Stage IV | 5 (8%) | 0 (—) | |
| UDI domains, median (IQR) | | | |
| Prolapse symptoms | 33.3 (45.8) | 0.0 (0.0) | <0.01 |
| Obstructed voiding | 16.7 (33.3) | 0.0 (0.0) | <0.01 |
| Overactive bladder | 27.8 (30.6) | 0.0 (22.2) | <0.01 |
| Discomfort and pain | 22.2 (31.9) | 5.6 (16.7) | <0.01 |
| Urinary incontinence | 13.3 (26.7) | 6.6 (13.3) | <0.01 |
| UDI total | 127.8 (69.1) | 22.2 (35.0) | <0.01 |
| DDI domains, median (IQR) | | | |
| Constipation | 4.7 (17.3) | 0.0 (9.5) | 0.08 |
| Fecal incontinence | 0.0 (13.3) | 0.0 (0.0) | 0.02 |
| Painful defecation | 0.0 (0.0) | 0.0 (0.0) | 0.64 |
| Flatus incontinence | 16.7 (41.7) | 0.0 (33.3) | 0.02 |
| DDI total | 34.5 (67.4) | 21.0 (45.4) | 0.03 |

Table 1: Continued.

| Characteristics | Study group ($n = 64$) | Control group ($n = 50$) | $P$ value |
|---|---|---|---|
| General health (MOS SF36), mean (SD) | | | |
| Summary mental health | 46.3 (14.6) | 50.3 (15.0) | 0.42 |
| Summary physical health | 48.5 (11.3) | 54.3 (11.7) | <0.01 |
| Depression (CES-D) | | | |
| Clinical depression[c] | 23 (36%) | 13 (26%) | 0.52 |

BMI: body mass index; IQR: interquartile range; SD: standard deviation.
[a]BMI of women in the normal population is 18–24 (body mass index = kg/m$^2$).
[b]Point D was not correctly measured in all case and was excluded from the study.
[c]Defined as a CES-D score ≥16.

group (POP III/IV: 74% versus 4%, resp.), and their physical health was significantly worse.

The study group reported significantly more bother from urogenital and bowel symptoms. Significant differences between the groups were found for all UDI domains as well as the flatus and fecal incontinence domains of the DDI. Feeling of vaginal protrusion (50/64 (78%)) and overactive bladder symptoms (45/64 (70%)) were the most frequent and bothersome symptoms in the study group followed by complaints of discomfort and pain. In the control group, the most prevalent and bothersome complaint was urinary incontinence (22/50, 44%). Frequently reported defecation symptoms in both groups were false urge for defecation (27/64 (42%) and 17/50 (34%), resp.), obstructed defecation (29/64 (45%) and 12/50 (24%)), and feeling of incomplete defection (29/64 (45%) and 8/50 (16%), resp.).

Table 2 shows the association between micturition (UDI) and defecation (DDI) scores on the one hand and patient's characteristics, POP-Q scores, and psychological characteristics on the other.

*4.1. Prolapse Feeling.* Pelvic floor defects, dominated by anterior vaginal wall prolapse (Ba) and perineal descent of the pelvic floor (gh + pb), accounted for 31% ($P < 0.001$) of the variance in symptom scores. The impact of clinical depression and summary mental health on prolapse feeling was small (variance explained: 2%, $P = 0.14$). Patient characteristics overall explained 14%. A higher BMI adjusted for other covariables was associated with lower scores of prolapse feeling.

*4.2. Obstructive Voiding.* Voiding problems were associated to specific pelvic floor defects but the overall contribution was modest (9% of explained variance, $P = 0.004$). Voiding problems were predominantly related to patient characteristics, explaining 21% of variance ($P < 0.001$). The relationship between presence of perineal trauma and voiding obstruction was inverse. Patients with better overall physical health had significantly less bother from voiding obstruction, but the impact was small.

*4.3. Overactive Bladder.* Overactive bladder symptoms were mainly related to pelvic floor defects (14% of variance explained, $P = 0.001$), especially to posterior vaginal wall prolapse (point Bp) and to a lesser extent point C. The contribution of patient characteristics was small (7% of variance explained). Only educational level had a significant impact on overactive bladder symptoms, that is, women with lower vocational education had more bother of overactive bladder symptoms.

*4.4. Discomfort and Pain.* Discomfort and pain were mainly related to pelvic floor defects (12% of variance explained), especially posterior vaginal wall prolapse (Bp) and perineal descent of the pelvic floor (gh + pb). However, discomfort and pain scores were also partially explained by patient and psychological characteristics; patients with lower overall physical health and clinically depressed patient showed more discomfort and pain.

*4.5. Constipation.* Constipation was predominantly related to psychological factors (13% of variance explained). Particularly clinically depressed patients reported higher levels of constipation. Constipation was to a lesser extent also related to pelvic floor defects (5% of variance explained, $P = 0.033$); particularly perineal descent (gh + pb) had a significant impact on constipation ($P = 0.03$). Of the patient characteristics only BMI and physical health were significantly related to constipation.

*4.6. Other UDI and DDI Domains.* None of the covariables studied had a significant impact on urinary incontinence (UDI) and fecal incontinence, painful defecation, and incontinence for gas (DDI).

We also examined the association of mild or more severe prolapse with urinary incontinence. In the mild prolapse group (overall POP-Q stages I and II; $n = 65$), the impact of anterior wall prolapse (represented by point Ba) on the UDI domain score (log transformed) with the same predictors as in Table 2 was beta = 2.75, 95%-CI: 0.04 to 1.25 ($P < 0.01$). In the severe prolapse group (overall POP-Q stages III and IV; $n = 49$) we found an inverse but not significant impact of anterior wall prolapse on urinary incontinence: beta= −0.18, 95%-CI: −0.51 to 0.16 ($P = 0.28$).

## 5. Discussion

In this study the association between anatomical and functional abnormalities of the pelvic floor was poor. Anatomical defects and, to a lesser extent, patient characteristics were

Table 2: Multiple linear regression analysis showing the relationship between patient's characteristics, psychological characteristics and anatomical defects at the one hand and pelvic floor symptoms (log scale) at the other hand.

| | $\beta$-coefficient [95%-CI] | $P$ value | Change in $R^2$ adjusted ($P$ value of change) |
|---|---|---|---|
| (i) UDI-prolapse feeling (log scale) | | | |
| *Constant* | 3.28 [−7.17 to 7.29] | 0.11 | |
| *Patient characteristics* | | | 0.14 ($P < 0.01$) |
| Age (years) | 0.00 [−0.03 to 0.04] | 0.80 | |
| BMI | **−1.00 [−0.17 to −0.3]** | **<0.01** | |
| Parity | 0.14 [−0.08 to 0.36] | 0.22 | |
| Perineal trauma | −0.19 [−0.80 to 0.42] | 0.54 | |
| Physical health | −0.02 [−1.13 to 0.25] | 0.28 | |
| Educational level 1[a] | −0.20 [−0.73 to 0.72] | 0.96 | |
| Educational level 2[b] | −0.44 [−1.13 to 0.25] | 0.21 | |
| *Psychological factors* | | | 0.02 ($P = 0.14$) |
| Clinical depression | 0.65 [−0.02 to 1.32] | 0.06 | |
| Mental health | −0.01 [−0.04 to 0.02] | 0.7 | |
| *POP-Q points* | | | 0.31 ($P < 0.01$) |
| Ba | **0.22 [0.04 to 0.39]** | 0.01 | |
| C | 0.04 [−0.07 to 0.15] | 0.51 | |
| Bp | 0.17 [−0.02 to 0.36] | 0.07 | |
| gh + pb | **0.31 [0.05 to 0.58]** | **0.02** | |
| *Full model* | | | 0.47 ($P < 0.01$) |
| (ii) UDI-obstructive voiding (log scale) | | | |
| *Constant* | 4.69 [0.74 to 8.64] | 0.02 | |
| *Patient characteristics* | | | 0.21 ($P < 0.01$) |
| Age (years) | −0.01 [−0.05 to 0.02] | 0.44 | |
| BMI | 0.02 [−0.05 to 0.09] | 0.55 | |
| Parity | 0.16 [−0.07 to 0.38] | 0.17 | |
| Perineal trauma | **−0.95 [−1.56 to −0.35]** | **<0.01** | |
| Physical health | **−0.06 [−0.09 to −0.02]** | **<0.01** | |
| Educational level 1[a] | 0.44 [−0.30 to 1.17] | 0.24 | |
| Educational level 2[b] | −0.22 [−0.91 to 0.46] | 0.52 | |
| *Psychological factors* | | | 0.00 ($P = 0.35$) |
| Clinical depression | −0.35 [−1.01 to 0.32] | 0.30 | |
| Mental health | −0.02 [−0.05 to 0.01] | 0.24 | |
| *POP-Q points* | | | 0.09 ($P < 0.01$) |
| Ba | −0.03 [−0.20 to 0.14] | 0.71 | |
| C | 0.10 [−0.00 to 0.21] | 0.06 | |
| Bp | 0.09 [−0.09 to 0.28] | 0.33 | |
| gh + pb | 0.18 [−0.09 to 0.44] | 0.18 | |
| *Full model* | | | 0.30 ($P < 0.01$) |
| (iii) UDI-overactive bladder (log scale) | | | |
| *Constant* | 3.09 [−0.91 to 7.09] | 0.13 | |
| *Patient characteristics* | | | 0.07 ($P = 0.04$) |
| Age (years) | 0.00 [−0.04 to 0.04] | 0.99 | |
| BMI | −0.01 [−0.08 to 0.06] | 0.85 | |
| Parity | −0.03 [−0.26 to 0.19] | 0.77 | |
| Perineal trauma | −0.33 [−0.94 to 0.28] | 0.28 | |
| Physical health | 0.01 [−0.03 to 0.04] | 0.67 | |
| Educational level 1[a] | **−0.98 [−1.72 to −0.24]** | **0.01** | |

Table 2: Continued.

| | $\beta$-coefficient [95%-CI] | $P$ value | Change in $R^2$ adjusted ($P$ value of change) |
|---|---|---|---|
| Educational level 2[b] | −0.54 [−1.23 to 0.16] | 0.13 | |
| *Psychological factors* | | | 0.00 ($P = 0.49$) |
| Clinical depression | 0.27 [−0.40 to 0.94] | 0.43 | |
| Mental health | 0.001 [−0.03 to 0.03] | 0.97 | |
| *POP-Q points* | | | 0.14 ($P < 0.01$) |
| Ba | −0.02 [−0.15 to 0.19] | 0.80 | |
| C | 0.11 [−0.00 to 0.21] | 0.06 | |
| Bp | **0.24** [ **0.06 to 0.43**] | **0.01** | |
| gh + pb | −0.01 [−0.27 to 0.26] | 0.97 | |
| *Full model* | | | 0.21 ($P < 0.01$) |
| (iv) UDI-discomfort and pain (log scale) | | | |
| *Constant* | 4.93 [0.88 to 7.91] | 0.01 | |
| *Patient characteristics* | | | 0.10 ($P = 0.01$) |
| Age (years) | −0.01 [0.05 to 0.02] | 0.36 | |
| BMI | −0.04 [−0.11 to 0.03] | 0.25 | |
| Parity | 0.09 [−0.11 to 0.29] | 0.36 | |
| Perineal trauma | 0.19 [−0.35 to 0.72] | 0.49 | |
| Physical health | **−0.04** [**−0.07 to −0.01**] | **0.02** | |
| Educational level 1[a] | −0.09 [−0.74 to 0.57] | 0.79 | |
| Educational level 2[b] | −0.18 [−0.79 to 0.43] | 0.56 | |
| *Psychological factors* | | | 0.07 ($P < 0.01$) |
| Clinical depression | **0.73** [**0.14 to1.32**] | **0.02** | |
| Mental health | −0.01 [−0.04 to 0.01] | 0.37 | |
| *POP-Q points* | | | 0.12 ($P < 0.01$) |
| Ba | −0.02 [−0.17 to 0.13] | 0.79 | |
| C | 0.05 [−0.05 to 0.14] | 0.35 | |
| Bp | **0.17** [**0.00 to 0.33**] | **0.05** | |
| gh + pb | **0.24** [**0.00 to 0.47**] | 0.05 | |
| *Full model* | | | 0.29 ($P < 0.01$) |
| (v) DDI-constipation (log scale) | | | |
| *Constant* | 3.32 [−0.08 to 6.71] | 0.06 | |
| *Patient characteristics* | | | 0.06 ($P = 0.07$) |
| Age (years) | 0.00 [−0.03 to 0.03] | 0.99 | |
| BMI | **−0.08** [**−0.14 to −0.02**] | **0.01** | |
| Parity | 0.09 [−0.10 to 0.28] | 0.35 | |
| Perineal trauma | −0.12 [−0.64 to 0.40] | 0.69 | |
| Physical health | **−0.03** [**−0.06 to −0.01**] | **0.02** | |
| Educational level 1[a] | 0.58 [−0.31 to 0.87] | 0.69 | |
| Educational level 2[b] | 0.28 [−0.31 to 0.87] | 0.07 | |
| *Psychological factors* | | | 0.13 ($P < 0.01$) |
| Clinical depression | **0.96** [**0.39 to1.53**] | <0.01 | |
| Mental health | −0.01 [−0.04 to 0.01] | 0.35 | |
| *POP-Q points* | | | 0.05 ($P = 0.03$) |
| Ba | −0.02 [−0.16 to 0.13] | 0.82 | |
| C | −0.08 [−0.17 to 0.02] | 0.10 | |
| Bp | 0.12 [−0.04 to 0.28] | 0.16 | |
| gh + pb | **0.26** [**0.03 to 0.49**] | **0.03** | |
| *Full model* | | | 0.24 ($P < 0.01$) |

[a] Secondary education; reference is primary school/lower vocational education.
[b] Higher professional education; reference is primary school/lower vocational education.

associated with obstructive voiding and overactive bladder but not with urinary incontinence. Any direct association between psychological factors and micturition symptoms appeared absent. Defecation symptoms were unrelated to anatomical abnormalities, patient characteristics, or psychological factors, except for constipation which was associated with psychological factors and, to a lesser extent, with perineal descent. Since the explanatory power of all pelvic floor symptoms was small, it is still unclear which are the main factors that underlie micturition and defecation symptoms.

Some limitations of this study need to be discussed. Firstly, although in agreement with other studies, only few of our patients presented with severe posterior compartment prolapse. As our study group represents an average distribution of vaginal prolapse patients, we do not believe this to be an important drawback. An overrepresentation of patients with severe posterior wall defects is likely to strengthen the relationship between posterior defects and defecation symptoms. Furthermore, forty percent of the women in the control group had a prolapse stage II according to the POP-Q classification system. This high prevalence of mild prolapse is in agreement with epidemiological studies that showed that up to 40% of women over the age of fifty years have mild asymptomatic prolapse [15, 16], which we regard as still a physiologic condition. Secondly, we did not document whether patients or controls had comorbidity. Instead, we used the SF-36 summary physical health dimension as a proxy measure. Probably, this is a more valuable measure to investigate whether pelvic floor function is associated with patient's general health status. Thirdly, since patients and controls had different characteristics, we adjusted for the documented prognostic factors in the multiple regression analysis. We do not think that prognostic incomparability plays an important role as all theoretical prognostic factors were documented in both groups.

Finally, there are two statistical limitations. We did not adjust the type I error level for multiple testing. Furthermore, regression analyses with multiple variables may have introduced multicollinearity or confounding. Multicollinearity did not occur as all bivariate correlations between covariables were <0.80. Removal of the POP-Q points from the regression model showed significant associations between parity and prolapse feeling (beta = 0.4, $P = 0.003$) and between age and fecal incontinence (beta = 0.04, $P = 0.01$). Although associations between covariables might affect the significance of the beta coefficients, they generally do not affect the $R^2$ of the model.

Although POP and urinary incontinence frequently coincided, we found no significant relationship between prolapse and overall urinary incontinence symptoms. An explanation could be that mild prolapse is associated with urinary stress incontinence but severe prolapse is more associated with continence and voiding dysfunction. This theory is supported by our findings from the stratified analysis, showing that mild anterior wall prolapse was found to be significantly associated with urinary incontinence but severe anterior wall prolapse was not.

Furthermore, posterior compartment prolapse was associated with overactive bladder symptoms whereas, in contrast to what one may expect, anterior wall compartment prolapse was not. Only few studies on the relationship between POP and these symptoms are available. Some researchers found a relationship between anterior wall prolapse and overactive bladder symptoms due to outlet obstruction of the bladder [17], while others could not corroborate that association [18]. Our findings are in agreement with the findings of other reports that show that the site of POP and the type of pelvic floor symptoms are not consistently related [19, 20].

Experienced discomfort and pain in the pelvic area appeared to be related to clinical depression but from this study we cannot conclude whether this is a causal relationship or not. Furthermore we found that discomfort and pain symptoms were strongly related to posterior vaginal wall prolaps and perineal descent than to anterior vaginal wall prolapse. Maybe the feeling of pressure on the pelvic floor is caused by invisible structural abnormalities of the posterior compartment like enterocele [21, 22].

Surprisingly, we found no significant effect of age and parity on urogenital and defecation symptoms. One reason may be that the variation of these factors in our population was small, hampering the detection of significant associations. Alternatively, age and parity may have been undetected due to their associations with the respective POPQ points.

Furthermore, we found that a higher BMI was inversely related to prolapse feeling. While the literature supports overweight as a risk factor for pelvic organ prolapse [23], other studies show a protective effect of higher BMI level on pelvic floor injury [24, 25].

Defecation symptoms are frequently reported by women with POP [26] but whether they are the cause or the result of POP is unclear. Researchers report conflicting results about the relationship between the severity of prolapse and bowel symptoms [27, 28]. The association between pelvic floor defects and defecation symptoms in our study appeared to be small to absent. One explanation is that other factors than POP are predominantly responsible for defecation symptoms. The multifactorial pathophysiology of defecation disorders is likely to reduce the contribution of POP, that is, posterior vaginal wall prolapse amongst other factors, for example, occult anorectal anomalies, pelvic floor dyssynergia, endocrine and metabolic factors, and use of medication. The DDI we used to assess the presence of constipation is not valid to determine the symptom's etiology. While outlet obstruction seems responsible for the association between perineal descent and constipation, the association between clinical depression and constipation points to slow transit constipation as the result of different life style.

Another explanation could be that small and mild posterior wall prolapses as frequently found in our study group should be regarded a physiologic condition often present in women without defecation complaints [29] but too small to cause outlet obstruction. Finally, one may question whether POP-Q scores are the best representation of abnormalities of the rectovaginal wall [7, 30] since imaging techniques

(defecography, MRI) can reveal anatomical abnormalities of the posterior compartment that are not represented by abnormal POP-Q scores [31].

Although POP and prolapse symptoms are associated, in our study we did not find a strong relationship between the affected compartment and most of the micturition and defecation symptoms.

An explanation would be that prolapse and pelvic floor symptoms share a common aetiology rather than they have a direct causal relationship. Pathophysiologic concepts that might relate to prolapse and pelvic floor symptoms are collagen disease, abnormally weak pelvic floor muscles due to childbirth and pelvic floor neuropathy [32, 33]. The same neuropathy can obviously cause prolapse and a full range of bladder and bowel symptoms.

The above findings may have important clinical implications. In patients with mild POP who are not bothered by prolapse symptoms, surgical repair as treatment for functional disorders seems ill founded. In such cases, we first recommend conservative management of pelvic floor symptoms. Second, patients scheduled for POP surgery should be informed that coexisting micturition and defecation symptoms are not necessarily the result of POP and these may persist after surgery. The low proportion of explained variation in micturition and defecation symptoms stress the urge to further explore which factors determine the high prevalence of micturition and defecation symptoms in patients who present with POP. Improved insight into these factors may help to optimize the diagnostic work-up and treatment setting in patients with pelvic floor dysfunction.

## References


[1] G. A. Digesu, C. Chaliha, S. Salvatore, A. Hutchings, and V. Khullar, "The relationship of vaginal prolapse severity to symptoms and quality of life," *British Journal of Obstetrics and Gynaecology*, vol. 112, no. 7, pp. 971–976, 2005.

[2] J. E. Jelovsek, C. Maher, and M. D. Barber, "Pelvic organ prolapse," *The Lancet*, vol. 369, no. 9566, pp. 1027–1038, 2007.

[3] R. E. Gutman, D. E. Ford, L. H. Quiroz, S. H. Shippey, and V. L. Handa, "Is there a pelvic organ prolapse threshold that predicts pelvic floor symptoms?" *American Journal of Obstetrics and Gynecology*, vol. 199, no. 6, pp. 683–e1, 2008.

[4] M. A. Kahn and S. L. Stanton, "Posterior colporrhaphy: its effects on bowel and sexual function," *British Journal of Obstetrics and Gynaecology*, vol. 104, no. 1, pp. 82–86, 1997.

[5] R. Milani, S. Salvatore, M. Soligo, P. Pifarotti, M. Meschia, and M. Cortese, "Functional and anatomical outcome of anterior and posterior vaginal prolapse repair with prolene mesh," *British Journal of Obstetrics and Gynaecology*, vol. 112, no. 1, pp. 107–111, 2005.

[6] A. G. Groenendijk, E. Birnie, S. de Blok et al., "Clinical-decision taking in primary pelvic organ prolapse; the effects of diagnostic tests on treatment selection in comparison with a consensus meeting," *International Urogynecology Journal and Pelvic Floor Dysfunction*, vol. 20, no. 6, pp. 711–719, 2009.

[7] A. G. Groenendijk, V. P. van der Hulst, E. Birnie, and G. J. Bonsel, "Correlation between posterior vaginal wall defects assessed by clinical examination and by defecography," *International Urogynecology Journal and Pelvic Floor Dysfunction*, vol. 19, no. 9, pp. 1291–1297, 2008.

[8] A. G. Groenendijk, E. Birnie, G. E. Boeckxstaens, J. P. Roovers, and G. J. Bonsel, "Anorectal function testing and anal endosonography in the diagnostic work-up of patients with primary pelvic organ prolapse," *Gynecologic and Obstetric Investigation*, vol. 67, pp. 187–194, 2009.

[9] R. C. Bump, A. Mattiasson, K. Bo et al., "The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction," *American Journal of Obstetrics and Gynecology*, vol. 175, no. 1, pp. 10–17, 1996.

[10] M. A. Kahn, C. R. Breitkopf, M. T. Valley et al., "Pelvic Organ Support Study (POSTT) and bowel symptoms: straining at stool is associated with perineal and anterior vaginal descent in general gynecologic population," *American Journal of Obstetrics and Gynecology*, vol. 192, pp. 1516–1522, 2005.

[11] R. D. Hays and L. S. Morales, "The RAND-36 measure of health-related quality of life," *Annals of Medicine*, vol. 33, no. 5, pp. 350–357, 2001.

[12] A. T. F. Beekman, D. J. H. Deeg, J. Van Limbeek, A. W. Braam, M. Z. De Vries, and W. Van Tilburg, "Criterion validity of the Center for Epidemiologic Studies Depression scale (CES-D): results from a community-based sample of older subjects in the Netherlands," *Psychological Medicine*, vol. 27, no. 1, pp. 231–235, 1997.

[13] C. H. Van der Vaart, J. R. J. De Leeuw, J. P. W. R. Roovers, and A. P. M. Heintz, "Measuring health-related quality of life in women with urogenital dysfunction: the urogenital distress inventory and incontinence impact questionnaire revisited," *Neurourology and Urodynamics*, vol. 22, no. 2, pp. 97–104, 2003.

[14] H. J. van Brummen, H. W. Bruinse, G. van de Pol, A. P. M. Heintz, and C. H. van der Vaart, "Defecatory symptoms during and after the first pregnancy: prevalences and associated factors," *International Urogynecology Journal and Pelvic Floor Dysfunction*, vol. 17, no. 3, pp. 224–230, 2006.

[15] E. C. Samuelsson, A. Victor, G. Tibblin, and K. F. Svardsudd, "Signs of genital prolapse in a Swedish population of women 20 to 59 years of age and possible related factors," *American Journal of Obstetrics and Gynecology*, vol. 180, no. 2 I, pp. 299–305, 1999.

[16] M. C. P. Slieker-Ten Hove, A. L. Pool-Goudzwaard, M. J. C. Eijkemans, R. P. M. Steegers-Theunissen, C. W. Burger, and M. E. Vierhout, "Prediction model and prognostic index to estimate clinically relevant pelvic organ prolapse in a general female population," *International Urogynecology Journal and Pelvic Floor Dysfunction*, vol. 20, no. 9, pp. 1013–1021, 2009.

[17] M. Basu and J. Duckett, "Effect of prolapse repair on voiding and the relationship to overactive bladder and detrusor overactivity," *International Urogynecology Journal and Pelvic Floor Dysfunction*, vol. 20, no. 5, pp. 499–504, 2009.

[18] M. O. Schimpf, D. M. Sullivan, C. A. LaSala, and P. K. Tulikangas, "Anterior vaginal wall prolapse and voiding dysfunction in urogynecology patients," *International Urogynecology Journal and Pelvic Floor Dysfunction*, vol. 18, no. 7, pp. 721–725, 2007.

[19] A. Miedel, G. Tegerstedt, M. Maehle-Smidt, O. Nyrén, and M. Hammarström, "Symptoms and pelvic floor defects in specific compartments," *Obstetrics and Gynecology*, vol. 112, pp. 851–858, 2008.

[20] R. M. Ellerkmann, G. W. Cundiff, C. F. Melick, M. A. Nihira, K. Leffler, and A. E. Bent, "Correlation of symptoms with location and severity of pelvic organ prolapse," *American Journal of Obstetrics and Gynecology*, vol. 185, no. 6, pp. 1332–1338, 2001.

[21] T. Takahashi, T. Yamana, R. Sahara, and J. Iwadare, "Enterocele: what is the clinical implication?" *Diseases of the Colon and Rectum*, vol. 49, no. 1, pp. S75–S81, 2006.

[22] Q. Chou, A. M. Weber, and M. R. Piedmonte, "Clinical presentation of enterocele," *Obstetrics and Gynecology*, vol. 96, no. 4, pp. 599–603, 2000.

[23] J. Mant, R. Painter, and M. Vessey, "Epidemiology of genital prolapse: observations from the oxford family planning association study," *British Journal of Obstetrics and Gynaecology*, vol. 104, no. 5, pp. 579–585, 1997.

[24] M. M. T. South, S. S. Stinnett, D. B. Sanders, and A. C. Weidner, "Levator ani denervation and reinnervation 6 months after childbirth," *American Journal of Obstetrics and Gynecology*, vol. 200, no. 5, pp. 519–e1, 2009.

[25] P. Baumann, A. O. Hammoud, S. G. McNeeley, E. DeRose, B. Kudish, and S. Hendrix, "Factors associated with anal sphincter laceration in 40,923 primiparous women," *International Urogynecology Journal and Pelvic Floor Dysfunction*, vol. 18, no. 9, pp. 985–990, 2007.

[26] C. J. Klingele, A. E. Bharucha, J. G. Fletcher, J. B. Gebhart, S. G. Riederer, and A. R. Zinsmeister, "Pelvic organ prolapse in defecatory disorders," *Obstetrics and Gynecology*, vol. 106, no. 2, pp. 315–320, 2005.

[27] M. Soligo, S. Salvatore, A. V. Emmanuel et al., "Patterns of constipation in urogynecology: clinical importance and pathophyiologic insights," *American Journal of Obstetrics and Gynecology*, vol. 195, pp. 50–55, 2006.

[28] J. E. Jelovsek, M. D. Barber, M. F. R. Paraiso, and M. D. Walters, "Functional bowel and anorectal disorders in patients with pelvic organ prolapse and incontinence," *American Journal of Obstetrics and Gynecology*, vol. 193, no. 6, pp. 2105–2111, 2005.

[29] P. J. Shorvon, S. McHugh, N. E. Diamant, S. Somers, and G. W. Stevenson, "Defecography in normal volunteers: results and implications," *Gut*, vol. 30, no. 12, pp. 1737–1749, 1989.

[30] A. G. Groenendijk, S. De Blok, E. Birnie, and G. J. Bonsel, "Interobserver agreement and intersystem comparison of the halfway system of baden and walker versus the pelvic organ prolapse-quantitation prolapse classification system in assessing the severity of pelvic organ prolapse," *Journal of Pelvic Medicine and Surgery*, vol. 11, no. 5, pp. 243–250, 2005.

[31] F. M. Kelvin, D. D. T. Maglinte, J. A. Hornback, and J. T. Benson, "Pelvic prolapse: assessment with evacuation proctography (defecography)," *Radiology*, vol. 184, no. 2, pp. 547–551, 1992.

[32] E. S. Lukacz, J. M. Lawrence, R. Contreras, C. W. Nager, and K. M. Luber, "Parity, mode of delivery, and pelvic floor disorders," *Obstetrics and Gynecology*, vol. 107, no. 6, pp. 1253–1260, 2006.

[33] H. P. Dietz, "The aetiology of prolapse," *International Urogynecology Journal and Pelvic Floor Dysfunction*, vol. 19, no. 10, pp. 1323–1329, 2008.

Hindawi Publishing Corporation
Obstetrics and Gynecology International
Volume 2012, Article ID 392027, 5 pages
doi:10.1155/2012/392027

*Clinical Study*

# Ambulatory Pessary Trial Unmasks Occult Stress Urinary Incontinence

**Bilal Chughtai, Sara Spettel, Jonathan Kurman, and Elise De**

*Continence Center, Urological Institute of Northeast New York and Division of Urology, Albany Medical College, Albany, NY 12208, USA*

Correspondence should be addressed to Elise De, ede@communitycare.com

Received 26 April 2011; Revised 14 July 2011; Accepted 25 July 2011

Academic Editor: Lior Lowenstein



*Objective*. We evaluated the use of a one-week ambulatory pessary trial in predicting patients' postoperative outcomes for occult stress incontinence. *Methods*. Patients with anterior vaginal wall prolapse were offered a pessary trial to predict response to reconstruction. We performed a retrospective review of 4 years of cases. All patients underwent a detailed evaluation including videourodynamics with and without pessary reduction. *Results*. Twenty-six patients completed the 1-week pessary trial. Ten (38%) women showing no evidence of stress urinary incontinence (SUI) underwent surgical repair of prolapse without anti-incontinence procedure. None of these patients had SUI postoperatively. Sixteen women (61%) had occult stress urinary incontinence on evaluation and underwent concurrent sling procedure. Three (19%) of these patients were identified by the pessary trial alone. Twenty-five of the 26 patients were without clinical stress incontinence at a mean follow up of 12 months (range 4–37 months). The pessary trial correctly predicted persistent urgency in six patients and persistent frequency in five. No patients with SUI or persistent voiding difficult were missed in a pessary trial. *Conclusion*. An ambulatory pessary trial is an effective, easy, and inexpensive method to approximate anatomic results achieved by surgery under real-life conditions. In our series, 20% of patients with occult SUI were identified by pessary trial alone.

## 1. Introduction

Each year, approximately 200,000 women undergo surgical treatment for pelvic organ prolapse (POP) in the United States [1]. Of these women, approximately 21% included urinary incontinence procedures, for an annual cost of greater than $1 billion for surgical repair of prolapse [2]. The demand for POP repair is expected to increase as the U.S. population ages and life expectancies increase.

The central question in the preoperative evaluation of a patient with POP is to estimate functional outcome once the anatomy is corrected. It is well documented that stress-continent women with advanced POP may develop stress urinary incontinence (SUI) following prolapse reduction [3, 4]. It is thought that correction of the anatomy will unkink or decrease resistance to the urethra, thereby unmasking intrinsic sphincteric deficiency. Regardless of objective outcome of prolapse repair, patient satisfaction with surgery is highly correlated with patient expectations preoperatively [5].

There are no clear guidelines regarding concurrent anti-incontinence procedures during surgical prolapse repair. Some surgeons place a sling or perform a retropubic suspension "prophylactically" at the time of all significant prolapse surgery [6, 7]. Others feel this exposes the patient to additional morbidity without proven benefit [8, 9]. Alternatively, it is extremely discouraging for both the patient and surgeon when a patient develops new-onset SUI after having just undergone a major vaginal reconstruction. An additional anti-incontinence procedure necessitates a repeat trip to the operating room, repeat anesthesia, additional recovery period, and surgery in a previously operated field.

Ideally one could predict the need for anti-incontinence surgery at the time of prolapse reduction in women who do not have stress incontinence preoperatively, as well as predict improvement in other urinary symptoms.

Our study, while not attempting to definitively answer the complex issue of concomitant anti-incontinent surgery during prolapse repair, aims to describe our experience with

an ambulatory pessary trial in addition to preoperative urodynamic testing (UDS). Our primary objective is to determine if an ambulatory pessary trial can identify women with occult stress urinary incontinence before prolapse repair.

There is limited literature examining outcomes with an ambulatory pessary trial. This exercise approximates the anatomic result achieved by surgery under real-life conditions. The trial allows for identification of occult stress incontinence during activities of daily life in the patient's home environment and allows appropriate expectations regarding functional urinary symptoms after surgery. We present the study not as the definitive answer to this controversial surgical question but rather as a tool in the preoperative assessment which we have found clinically useful in our practice.

## 2. Methods

Following Institutional Review Board approval, a retrospective chart review of patients in the Albany Medical Center Division of Urology Clinic and Urodynamic Database was conducted. The electronic medical records of those patients who underwent a pessary trial with a subsequent sling/suspension procedure between June 2005 and February 2009 were identified. All data was tabulated in a deidentified format. Data was collected on patient demographics and the results of urodynamic studies. VUDS data included intra-abdominal, detrusor, and intravesical pressures as well as fill rate at both baseline and maximal capacity. Criteria for inclusion consisted of Baden-Walker grade 2 or higher anterior vaginal wall prolapse and an unresolved diagnostic concern (occult stress incontinence, incomplete emptying, or urge incontinence) and the capacity to retain a pessary.

All patients underwent a detailed history, physical including pelvic exam, including meticulous multichannel VUDS with and without reduction preoperatively. Urodynamic testing was conducted with a Triton Multichannel Urodynamics Monitor (Laborie, Inc., Burlington, Vt, USA) according to the specifications of the ICS [10]. The urodynamic assessment was performed with the patient sitting with SUI evaluated by having the patient cough and perform a Valsalva maneuver at 200 cc and capacity. Vesical leak point pressure was defined as the minimum amount of pressure necessary to produce visible or fluoroscopic urine leakage. Pressure flow studies were conducted as patients voided after reaching functional capacity. Urodynamic stress incontinence was defined as observable urine leakage during valsalva without associated detrusor overactivity.

A split speculum technique with the patient in the lithotomy position was utilized to evaluate the extent of the prolapse for classification according to the Baden and Walker criteria [11]. Urethral hypermobility was defined as a change in the urethral angle between rest and straining of 30 degrees.

Patients who met inclusion criteria were offered a home pessary trial to predict response to reconstruction. The pessary, either Gehrung, donut, or ring, was fitted so it would be large enough to remain in place during periods of increased intraabdominal pressure but loose enough to avoid urethral obstruction. Patients attempted an ambulatory pessary trial for a minimum of one week prior to surgical intervention.

Table 1: Patients demonstrating SUI, UUI, urgency, frequency, and nocturia preoperatively during UDS, pessary trial, and postoperatively.

| | Preoperative clinically | UDS | Ambulatory pessary trial | Postoperative clinically |
|---|---|---|---|---|
| | % (N) | % (N) | % (N) | % (N) |
| SUI | 50 (13) | 23 (6) | 61 (16) | 4 (1) |
| UUI | 85 (22) | 38 (10) | 15 (4) | 23 (6) |
| Urgency | 85 (22) | | 23 (6) | 23 (6) |
| Frequency | 81 (21) | | 19 (5) | 19 (5) |
| Nocturia | 69 (18) | | | 4 (1) |

Table 2: Procedures performed for correction of prolapse and urinary incontinence.

| Procedures | N |
|---|---|
| Colpocleisis—Le Fort | 1 |
| Anterior colporrhaphy | 15 |
| Combined AP colporrhaphy | 5 |
| Colpopexy—abdominal approach | 2 |
| Colpopexy—intravaginal approach | 2 |
| Sling repair | 14 |
| Laparoscopic colpopexy | 1 |

Patients were instructed to note their symptoms with the pessaries in place for the duration of the week, while performing all of their usual activities. Patients were followed with respect to clinical symptoms.

Surgical repair of the prolapse was performed by a single surgeon; an additional anti-incontinence procedure, TOT mid-urethral sling, was performed if SUI was identified preoperatively by the ambulatory pessary trial. All patients received a postoperative examination, systematic interview of voiding symptoms and measurement of postvoid residual (PVR). We do not routinely use postoperative urodynamic evaluation. Outcome was based on patient report of leakage postoperatively.

## 3. Results

Between June 2005 and February 2009, 41 patients accepted the home pessary trial. Of these women, 26 were able to retain their pessary for at least one week; subsequent analysis is based on this subset. The mean age of the study subjects was 65 (range 44 to 80). Twenty-four of the women presented with a cystocele, while 10 had a rectocele. The median cystocele grade was Baden-Walker 2 (range 2–4), while the median rectocele grade was 1.8. The median vault grade was 2 (range 2–4), while the mean degree of urethral hypermobility was 39 (range 0–45). Approximately 62% (16) of the patients had a grade 2 cystocele, while 27% (7) had a grade 3. Only one patient (4%) had a grade 4 cystocele.

Ten (38%) women showed no evidence of SUI by pessary trial, clinical report, VUDS, or physical exam and underwent surgical repair of their prolapse without an

Table 3: Systemic clinic interview.

| |
|---|
| (1) How often do you usually urinate during the day? |
| (2) How many times do you usually urinate during the day? |
| (3) How often do you usually urinate during the night? |
| (4) How many times do you usually urinate at night? (from time you go to bed until time you wake up for the day) |
| (5) What is the reason that you usually urinate? |
| (6) Once you get the urge or desire to urinate, how long can you usually postpone it comfortably? |
| (7) How often do you get a sudden urge or desire to urinate that makes you want to stop what you are doing and rush to the bathroom? |
| (8) How often do you get a sudden urge or desire to urinate that makes you want to stop what you are doing and rush to the bathroom but you do not get there in time? (leak urine or wet pads) |
| (9) How often do you experience urine leakage when you sneeze or cough? |
| (10) How often do you experience urine leakage when you lift and bend? |
| (11) How often do you experience urine leakage when you change positions? |
| (12) How often do you experience urine leakage related to physical activity? |
| (13) How often do you wet yourself, your pads or your clothes without any awareness of how or when it happened? |
| (14) In your opinion how good is your bladder control? |
| (15) How often do you have a sensation of not emptying your bladder completely? |
| (16) How often do you stop and start during urination? |
| (17) How often do you have a weak urinary stream? |
| (18) How often do you push or strain to begin urination? |
| (19) How bothered are you by your bladder symptoms? |

accompanying anti-incontinence procedure. None of these women had stress urinary incontinence postoperatively. No intraoperative complications occurred during the operations, listed in Table 2.

Sixteen (61%) women were found to have occult stress urinary incontinence by pessary trial, clinical report, VUDS, or physical exam and underwent a concomitant vaginal sling procedure (Table 3). Three (19%) of these sixteen were identified by the pessary trial alone; their SUI was not detected with VUDS (Table 1).

The ambulatory pessary trial correctly predicted persistent urgency and persistent frequency in 5 and 6 patients, respectively. Overall, significant decreases in clinical SUI and urge urinary incontinence (UUI) were seen postoperatively (Table 1).

Twenty-five of the 26 patients who qualified for the study were without clinical stress incontinence after surgery at a mean followup of 12 months (range 4–37 months).

There were no patients with occult stress urinary incontinence or persistent voiding difficulty whose symptoms were missed in a successful pessary trial.

## 4. Discussion

Occult SUI is a relatively common occurrence in women with severe pelvic organ prolapse and is critical to identify when planning a surgical repair. Our study confirms this finding, as over 60% of the patients had evidence of SUI, 20% of which was occult and identified by pessary trial only.

The one failure with postoperative SUI occurred in the sling group; although initially dry postoperatively, marked noncompliance with postoperative activity restrictions likely resulted in sling migration. She was later rendered dry by transurethral bulking agent.

Several studies assert that preoperative VUDS with prolapsed reduction is useful for estimating the risk of developing postoperative incontinence [4, 9, 12]. Surgeons adhering to this philosophy will perform an additional anti-incontinence procedure only in those who show urodynamic stress incontinence. Liang et al. reported that none of their 30 patients who were stress-continent during pessary-reduced urodynamic trial developed SUI postoperatively. They concluded that concomitant anti-incontinence surgery is not necessary in this group [12]. Klutke and Ramos found the same results and arrived at a similar conclusion in a retrospective review of 70 patients [13]. Alternatively, patients who do develop incontinence during prolapse-reduced urodynamics are prone to develop stress incontinence postoperatively if an anti-incontinence procedure is not performed concomitantly [14].

However, the study by Visco et al. showed preoperative use of VUDS is not 100 percent sensitive in identifying occult SUI and its sensitivity is also influenced by which reduction method is used [4]. The pessary was found to be the least sensitive method in detection of masked stress incontinence during urodynamic testing, while the speculum was most sensitive [4]. Although commonly used, the vaginal gauze pack was shown in a single institution series to not be particularly successful at unmasking SUI [14]. Although not particularly sensitive for stress incontinence, preoperative pessary testing has been shown to be highly predictive of postoperative voiding function [8]. Reduction by pessary, however, is relatively easy to perform, convenient, and comfortable for most women [9].

In our retrospective review, we confirmed our hypothesis that an ambulatory pessary trial increases the detection rate of SUI. Multichannel VUDS has been shown to detect most cases of occult SUI; however, a certain percentage will be missed, (20% in our study.) We hypothesize that this failure may be due to the nonphysiologic nature of the UDS testing environment and unmasked by both the length of time and different conditions an ambulatory trial allows. In an effort to reduce the hardships of missing occult SUI, we suggest a home pessary trial for women with severe pelvic organ prolapse with no evidence of SUI during VUDS. By having the anti-incontinence procedure performed concurrently with the prolapse repair, women can avoid the risk and significant dissatisfaction associated with an additional operation.

In addition to detecting occult SUI that would most likely otherwise be missed, a home pessary trial confers a number of other benefits. It can help predict persistent incomplete emptying, as well as persistent UUI, thereby providing women with appropriate postoperative expectations. In our trial, none of the patients with either of these two conditions were missed during an ambulatory pessary trial. Rather than trying to address refractory UUI postoperatively, a low-cost, low-morbidity pessary trial can provide the clinician and patient with essential prognostic information.

Our study does contain several limitations, namely, the small sample size, retrospective data collection, reliance on systemic interview rather than standardized pad weight, and limited followup. Also as noted in the results, a significant number of patients were unable to retain for the one-week pessary trial, which does limit its use in preoperative evaluation in patients with perineal relation. Previous studies addressing pessary use report a success rate of 50–71%, depending on patient type and length of trial [15–17]. Although the one-week trial utilized in this study appeared to suffice, the ideal length of a home pessary trial has not been determined. The differences between pessary types could also be a cofounding variable although previous studies found no difference on VUDS between a Smith-Hodge pessary and a ring pessary [18].

Given that the prevalence of pelvic organ prolapse and demand for surgical repair is likely to increase; further research is needed to address the preoperative evaluation with larger study populations, prospective data and extended followup. The need for continued research to define appropriate preoperative evaluation and evaluate results of surgical repair for this common condition is obvious.

## 5. Conclusions

A properly fitted pessary will approximate the anatomic result achieved by surgery during activities of daily life. This reversible trial aids in the decision to perform anti-incontinence procedures and in setting appropriate postoperative expectations regarding urgency and emptying ability. In our series, 20% of patients in our stress incontinent group were identified by pessary trial alone. The pessary is a valuable diagnostic tool, and we suggest a home pessary trial for women with pelvic organ prolapse with no evidence of SUI during VUDS.

## References

[1] S. H. Boyles, A. M. Weber, and L. Meyn, "Procedures for pelvic organ prolapse in the United States, 1979–1997," *American Journal of Obstetrics and Gynecology*, vol. 188, no. 1, pp. 108–115, 2003.

[2] L. L. Subak, L. E. Waetjen, S. Van Den Eeden, D. H. Thom, E. Vittinghoff, and J. S. Brown, "Cost of pelvic organ prolapse surgery in the United States," *Obstetrics and Gynecology*, vol. 98, no. 4, pp. 646–651, 2001.

[3] D. A. Richardson, A. E. Bent, and D. R. Ostergard, "The effect of uterovaginal prolapse on urethrovesical pressure dynamics," *American Journal of Obstetrics and Gynecology*, vol. 146, no. 8, pp. 901–905, 1983.

[4] A. G. Visco, L. Brubaker, I. Nygaard et al., "The role of preoperative urodynamic testing in stress-continent women undergoing sacrocolpopexy: the Colpopexy and Urinary Reduction Efforts (CARE) randomized surgical trial," *International Urogynecology Journal and Pelvic Floor Dysfunction*, vol. 19, no. 5, pp. 607–614, 2008.

[5] E. A. Elkadry et al., "Patient-selected goals: a new perspective on surgical outcome," *American Journal of Obstetrics and Gynecology*, vol. 189, no. 6, pp. 1551–1557, 2003.

[6] S. Raz, N. A. Little, S. Juma, and E. M. Sussman, "Repair of severe anterior vaginal wall prolapse (grade IV cystourethrocele)," *Journal of Urology*, vol. 146, no. 4, pp. 988–992, 1991.

[7] C. A. Cross, R. D. Cespedes, E. J. McGuire, and P. E. Zimmern, "Treatment results using pubovaginal slings in patients with large cystoceles and stress incontinence," *Journal of Urology*, vol. 160, no. 1, pp. 132–134, 1997.

[8] G. Lazarou, R. J. Scotti, M. S. Mikhail, H. S. Zhou, and K. Powers, "Pessary reduction and postoperative cure of retention in women with anterior vaginal wall prolapse," *International Urogynecology Journal and Pelvic Floor Dysfunction*, vol. 15, no. 3, pp. 175–178, 2004.

[9] D. C. Chaikin, A. Groutz, and J. G. Blaivas, "Predicting the need for anti-incontinence surgery in continent women undergoing repair of severe urogenital prolapse," *Journal of Urology*, vol. 163, no. 2, pp. 531–534, 2000.

[10] B. T. Haylen, D. De Ridder, R. M. Freeman et al., "An international urogynecological association (IUGA)/international continence society (ICS) joint report on the terminology for female pelvic floor dysfunction," *Neurourology and Urodynamics*, vol. 29, no. 1, pp. 4–20, 2010.

[11] W. F. Baden and T. A. Walker, "Physical diagnosis in the evaluation of vaginal relaxation," *Clinical Obstetrics and Gynecology*, vol. 15, no. 4, pp. 1055–1069, 1972.

[12] C. C. Liang, Y. L. Chang, S. D. Chang, T. S. Lo, and Y. K. Soong, "Pessary test to predict postoperative urinary incontinence in women undergoing hysterectomy for prolapse," *Obstetrics and Gynecology*, vol. 104, no. 4, pp. 795–800, 2004.

[13] J. J. Klutke and S. Ramos, "Urodynamic outcome after surgery for severe prolapse and potential stress incontinence," *American Journal of Obstetrics and Gynecology*, vol. 182, no. 6, pp. 1378–1381, 2000.

[14] J. P. Gilleran, G. E. Lemack, and P. E. Zimmern, "Reduction of moderate-to-large cystocele during urodynamic evaluation using a vaginal gauze pack: 8-Year experience," *BJU International*, vol. 97, no. 2, pp. 292–295, 2006.

[15] J. L. Clemons, V. C. Aguilar, T. A. Tillinghast, N. D. Jackson, and D. L. Myers, "Risk factors associated with an unsuccessful pessary fitting trial in women with pelvic organ prolapse," *American Journal of Obstetrics and Gynecology*, vol. 190, no. 2, pp. 345–350, 2004.

[16] M. J. Donnelly, S. Powell-Morgan, A. L. Olsen, and I. E. Nygaard, "Vaginal pessaries for the management of stress and mixed urinary incontinence," *International Urogynecology Journal and Pelvic Floor Dysfunction*, vol. 15, no. 5, pp. 302–307, 2004.

[17] L. A. M. Hanson, J. A. Schulz, C. G. Flood, B. Cooley, and F. Tam, "Vaginal pessaries in managing women with pelvic organ prolapse and urinary incontinence: Patient characteristics and factors contributing to success," *International Urogynecology Journal and Pelvic Floor Dysfunction*, vol. 17, no. 2, pp. 155–159, 2006.

[18] T. F. Mattox and N. N. Bhatia, "Urodynamic effects of reducing devices in women with genital prolapse," *International Urogynecology Journal*, vol. 5, no. 5, pp. 283–286, 1994.

Hindawi Publishing Corporation
Obstetrics and Gynecology International
Volume 2012, Article ID 868915, 4 pages
doi:10.1155/2012/868915

*Clinical Study*

# Measuring Urinary Sensation with Current Perception Threshold: A Comparison between Method of Limits and Method of Levels

**Carley Davis,[1] Lior Lowenstein,[1,2] Elizabeth Mueller,[1] Linda Brubaker,[1] and Kimberly Kenton[1]**

[1] *Division of Female Pelvic Medicine and Reconstructive Surgery, Department of Urology, Loyola University Medical Center, USA*
[2] *Department of Obstetrics and Gynecology, Rambam Health Care Campus, 8 Ha'Aliya Street, Haifa 31096, Israel*

Correspondence should be addressed to Lior Lowenstein, lowensteinmd@gmail.com

Received 28 June 2011; Accepted 20 August 2011

Academic Editor: Johannes Bitzer



*Purpose.* To determine the association between the two methods of obtaining current perception thresholds (CPTs) in the lower urinary tract (LUT). *Materials and Methods.* Twenty-one women undergoing pelvic surgery underwent CPT determinations of the urethra. CPTs were measured at 2,000, 250, and 5 Hz (corresponding to A-$\beta$, A-$\delta$, and C fibers, resp.) both pre- and postoperatively. Threshold values were obtained in all patients by using the method of limits and the method of levels. *Results.* CPT values obtained by using the method of levels and the methods of limits were highly correlated at all frequencies before and after surgery ($\rho = 0.93$–$0.99$, $P < 0.0001$). The mean threshold values obtained by the method of levels were significantly lower at all frequencies compared with those obtained by the method of limits. *Conclusions.* Our findings suggest that the method of levels is more sensitive for the detection of CPTs compared to the method of limits.

## 1. Introduction

Given the high-quality evidence supporting the role of afferent innervation in LUT dysfunction, it is essential to validate clinical methods that quantify afferent nerve function. The two most common methods which are currently used to assess CPT's are the method of levels and the method of limits. When reviewing the literature, we found that there have been several studies reporting the normative CPT data in the lower urinary tract [1–6]. Depending on the institution, different techniques and methods are being used to collect this normative data. Based on this established normative data, studies are now focusing on using CPTs in pathologic states [7, 8]. Unless the collection of data is standardized, it will become increasingly difficult to compare or reproduce studies.

Afferent innervation of the lower urinary tract and the vaginal area can be assessed with electrodiagnostic testing. CPT measurement using the Neurometer is a standard technique used to assess the function of afferent sensory nerves [9, 10]. The Neurometer is a constant current stimulator which selectively measures and quantifies different size of sensory nerve populations. Afferent neurons are depolarized by different frequency sine waves depending on their membrane ion channel concentration. This allows differentiation between the major types of afferent neurons based on the frequency of neural stimulation. Large myelinated A-$\beta$ fibers are stimulated at 2000 Hz, smaller myelinated A-$\delta$ fibers are stimulated at 250 Hz, and unmyelinated C fibers are stimulated at 5 Hz.

The Neurometer can be used to obtain CPT's by using either the method of limits or the method of levels. The method of limits uses the manual function of the Neurometer to increase the stimulus until the patient can perceive it for the first time, the upper limit. It is then decreased until the stimulus is no longer perceived, the lower limit. The upper and lower values are averaged to obtain the CPT value. The method of levels uses the automated function of the Neurometer where the patient is put through a series of forced choice tests. True and false stimuli are given in an arbitrary order, and the patient indicates which stimulus is true. If answered correctly, the next presented stimulus is of a lower intensity level. When using the method of levels, the determination of the threshold is based on the lowest

stimulus level which the patient correctly detects 50% of the time.

In the current study, we evaluated the association between the two most commonly used methods for obtaining CPT values in the lower urinary tract.

## 2. Materials and Methods

After approval by our Institutional Review Board, we consecutively enrolled patients from our clinic who were planning on having pelvic reconstructive surgery between September 2006 and May 2007. All women underwent a standardized clinical evaluation including history, physical, and gynecological examination. Our exclusion criteria included: patients with any neurologic disorder or neuropathy, a postvoid residual volume greater than 150 mL with no evidence of pelvic organ prolapse and patients with cognitive impairment. After signing an informed consent, participants underwent CPT testing preoperatively. On postoperative day one or two, the CPT testing was repeated at the patient's bedside.

*2.1. CPT Protocol.* A ring electrode was positioned 1 cm distal to the balloon of a 14 Fr foley catheter which was placed in the subject's urethra. The balloon was inflated and the catheter was pulled snug to assure the electrode was in the urethra. Any residual urine was drained and continued to drain throughout the testing.

Subjects underwent CPT testing in a standardized fashion using a Neurometer CPT device in the dorsal lithotomy position. The 2000 Hz frequency was tested first using the method of limits technique. The amplitude was slowly increased until the stimulus was perceived. This was recorded as the upper limit. The stimulus was turned off until the initial sensation subsided. The same stimulus was then slowly decreased until the patient no longer perceived the stimulus. The last stimulus the patient could perceive was termed the lower limit. The upper and lower limits were averaged to obtain the sensory threshold by the method of limits. The subject was then given a series of forced choice tests by the Neurometer to determine the sensory threshold by the method of levels starting at the lower limit obtained by the method of limits. The Neurometer randomly picks real and false stimuli separated by a 3–5 second rest period. The subject indicated which stimulus was stronger as the intensity was decreased by 0.4 $\mu$A increments. Both the method of limits and the method of levels were then repeated at 250 Hz and 5 Hz.

*2.2. Statistical Analysis.* SPSS for Windows version 16 (Chicago, IL, USA) was used for data management and statistical analysis. CPT values were reported in mA using both the mean and standard deviation. The Wilcoxon Signed Rank was used to compare noncategorical parameters. The correlation between the thresholds obtained by the methods of limits and the method of levels was assessed by Spearman's correlation test. All tests were considered significant at the 0.05 level. No one-sided tests were done.

Table 1: Patient demographics and medical history.

| | |
|---|---|
| Age (years, median) | 61% (31–79) |
| Race/Ethnicity (self-described) | |
| Caucasian | 90% (19/21) |
| Hispanic | 10% (2/21) |
| Hypertension | 33% (7/21) |
| Estrogen treatment | 20% (4/21) |
| Prior prolapse surgery | 15% (3/21) |
| Prior hysterectomy | 52% (11/21) |
| Prior incontinence surgery | 23% (5/21) |
| Blood hypertension | 36.8% (14/38) |
| Depression | 18.4% (7/38) |
| Current surgery | |
| Sacrocolpopexy | 38.1% (8/21) |
| Vaginal Hysterectomy + apical suspension | 24% (5/21) |
| Colpocleisis | 14% (3/21) |
| TVT | 28% (6/12) |
| Suburethral fascial sling | 14% (3/21) |
| Posterior repair | 5% (1/21) |

## 3. Results

Twenty-one women with a mean age of 59 ± 12 years participated in the study. The majority of the patients were Caucasians 90% (19) and the rest were Hispanic. Demographic and medical history information is listed in Table 1.

CPT values obtained by the method of levels were significantly lower at all tested frequencies compared with the values obtained by the method of limits (Table 2). These differences persisted both before and after surgery. Spearman's correlation demonstrated a significantly high correlation between the two methods of threshold evaluation, both before and after surgery at all frequencies (Spearman's rho ranges from 0.92 to 0.99, $P < 0.001$, Table 2).

## 4. Discussion

Our study is the first to evaluate the correlations between the two most common methods of CPT evaluation. Our results demonstrate that the threshold values obtained by the method of levels were persistently lower compared with the values obtained by the method of limits. There was a high correlation between the values obtained by the two different methods at all frequencies. These findings are supported by previous studies that compared the values of thermal threshold levels obtained by the method of levels to the threshold values obtained by the methods of limits. Similar to our findings, the threshold levels obtained by the methods of levels were consistently lower in both normal participants and patients with neuropathic compared with the values obtained by the method of limits [4, 7, 11, 12].

The role of CPT is becoming increasingly important in diagnosing abnormalities of afferent neural pathways which may contribute to pelvic floor disorders. Based on accumulating evidence, it seems likely that in certain pathological

Table 2: Comparison and correlation between threshold levels obtained by methods of levels and methods of limits.

| | Method of levels mean (STD) | Method of limits mean (STD) | †$P$ | Spearman's rho |
|---|---|---|---|---|
| Preoperative (mA) | | | | |
| 2000 Hz | 1.70 (1.19) | 2.09 (1.14) | 0.0001 | .934* |
| 250 Hz | .65 (.37) | .80 (.40) | 0.0001 | .926* |
| 5 Hz | .34 (.34) | .40 (.38) | 0.008 | .934* |
| Postoperative (mA) | | | | |
| 2000 Hz | 2.70 (.17) | 2.95 (1.72) | 0.0001 | .984* |
| 250 Hz | 1.41 (1.12) | 1.60 (1.24) | 0.0001 | .988* |
| 5 Hz | 1.15 (1.60) | 1.32 (1.62) | 0.0001 | .961* |

† Wilcoxon Signed Rank Test; * $P < 0.001$.

states in the pelvis and lower urinary tract, alternate afferent pathways are activated [13–15]. Currently the most common methods used in clinical practice and in published literature are CPT testing and QST using thermal and vibratory stimulation. CPT testing is the most commonly used method to quantify the functional integrity of specific afferent nerve fibers from the periphery to the central nervous system. Normative data for CPT in the LUT has been published in previous studies [1–6]. A review of the literature demonstrates significant variability in the testing equipment as well as inconsistencies in the methods used to obtain the LUT thresholds. The Neurometer device is commonly used in previously published studies [1–6]. This device offers two different, feasible and objective methods to measure LUT sensation. Manufacturer recommendations are that CPT testing with the Neurometer be done using the method of levels rather than the method of limits.

Though CPT threshold evaluation by the method of limits consumes less time, it seems to be less accurate compared with measurements obtained using the method of levels. A possible limitation to the use of the method of limits is the reaction time of the examinee. The reaction time is dependent on the conscious perception of the stimulus, processing of the information and generating an action to indicate a response. During this period of information processing before the subject indicates a response, the stimulus continues to increase or decrease leading to a deviation from the actual perceived stimuli. Another possible limitation to the method of limits technique is the nonstandardized rate of change of the intensity of the CPT stimulus. The examiner determines the rate at which the intensity both increases and decreases adding variability to the technique. The method of levels, being an automated series of forced choice tests, makes this method easy to reproduce and avoids possible inaccuracies due to subject reaction time and examiner variability.

## 5. Conclusion

In order to compare studies of LUT sensation, the method of data collection needs to be standardized. Our data demonstrates a high correlation between the method of limits and the method of levels using the Neurometer. The method of levels resulted in significantly lower CPT values. As a means of standardizing the data collection, we propose that the method of levels, with the above described technique, be instituted as the gold standard in measuring LUT sensory thresholds.

## References

[1] K. De Laet, S. De Wachter, and J. J. Wyndaele, "Current perception thresholds in the lower urinary tract: sine- and square-wave currents studied in young healthy volunteers," *Neurourology and Urodynamics*, vol. 24, no. 3, pp. 261–266, 2005.

[2] H. Kiesswetter, "Mucosal sensory threshold of urinary bladder and urethra measured electrically," *Urologia Internationalis*, vol. 32, no. 6, pp. 437–448, 1977.

[3] J. J. Wyndaele, B. Van Eetvelde, and D. Callens, "Comparison in young healthy volunteers of 3 different parameters of constant current stimulation used to determine sensory thresholds in the lower urinary tract," *Journal of Urology*, vol. 156, no. 4, pp. 1415–1417, 1996.

[4] K. Kenton, E. Fuller, and J. T. Benson, "Current perception threshold evaluation of the female urethra," *International Urogynecology Journal and Pelvic Floor Dysfunction*, vol. 14, no. 2, pp. 133–135, 2003.

[5] K. Kenton, J. Simmons, M. P. FitzGerald, L. Lowenstein, and L. Brubaker, "Urethral and bladder current perception thresholds: normative data in women," *Journal of Urology*, vol. 178, no. 1, pp. 189–192, 2007.

[6] O. Ukimura, S. Ushijima, H. Honjo et al., "Neuroselective current perception threshold evaluation of bladder mucosal sensory function," *European Urology*, vol. 45, no. 1, pp. 70–76, 2004.

[7] A. Cavalcanti Gde, H. Bruschini, G. M. Manzano, L. P. Giuliano, J. A. M. Nóbrega, and M. Srougi, "Urethral sensory threshold and urethro-anal reflex latency in continent women," *International Urology and Nephrology*, vol. 39, no. 4, pp. 1061–1068, 2007.

[8] T. M. Kessler, U. E. Studer, and F. C. Burkhard, "Increased proximal urethral sensory threshold after radical pelvic surgery in women," *Neurourology and Urodynamics*, vol. 26, no. 2, pp. 208–212, 2007.

[9] G. D. Baquis, W. F. Brown, J. T. Capell et al., "Technology review: The Neurometer Current Perception Threshold (CPT)," *Muscle and Nerve*, vol. 22, no. 4, pp. 523–531, 1999.

[10] L. Lowenstein, C. Davis, K. Jesse, R. Durazo-Arvizu, and K. Kenton, "Comparison between sensory testing modalities for

the evaluation of afferent nerve functioning in the genital area," *International Urogynecology Journal and Pelvic Floor Dysfunction*, vol. 20, no. 1, pp. 83–87, 2009.

[11] D. Claus, M. J. Hilz, and B. Neundorfer, "Thermal discrimination thresholds: a comparison of different methods," *Acta Neurologica Scandinavica*, vol. 81, no. 6, pp. 533–540, 1990.

[12] D. Levy, R. Abraham, and G. Reid, "A comparison of two methods for measuring thermal thresholds in diabetic neuropathy," *Journal of Neurology Neurosurgery and Psychiatry*, vol. 52, no. 9, pp. 1072–1077, 1989.

[13] K. Kenton, L. Lowenstein, J. Simmons, and L. Brubaker, "Aging and overactive bladder may be associated with loss of urethral sensation in women," *Neurourology and Urodynamics*, vol. 26, no. 7, pp. 981–984, 2007.

[14] L. Lowenstein, Y. Vardi, M. Deutsch et al., "Vulvar vestibulitis severity—assessment by sensory and pain testing modalities," *Pain*, vol. 107, no. 1-2, pp. 47–53, 2004.

[15] C. L. H. Chan, S. M. Scott, N. S. Williams, and P. J. Lunniss, "Rectal hypersensitivity worsens stool frequency, urgency, and lifestyle in patients with urge fecal incontinence," *Diseases of the Colon and Rectum*, vol. 48, no. 1, pp. 134–140, 2005.

Hindawi Publishing Corporation
Obstetrics and Gynecology International
Volume 2012, Article ID 384234, 6 pages
doi:10.1155/2012/384234

*Review Article*

# Transurethral Radiofrequency Collagen Denaturation for Treatment of Female Stress Urinary Incontinence: A Review of the Literature and Clinical Recommendations

**James Chivian Lukban**

*Division of Urogynecology, Department of Obstetrics and Gynecology, Eastern Virginia Medical School, Norfolk, VA 23507, USA*

Correspondence should be addressed to James Chivian Lukban, lukbanjc@evms.edu

Received 1 May 2011; Revised 25 July 2011; Accepted 8 August 2011

Academic Editor: Peter L. Rosenblatt



Stress urinary incontinence is a prevalent condition in women with a significant negative effect on quality of life. Intervention includes behavioral modification, intravaginal devices, pelvic floor muscle exercises, biofeedback, functional electrical stimulation, and surgical procedures. We will review a new in-office procedure for the treatment of SUI that may serve as a viable nonsurgical option.

## 1. Introduction

Stress urinary incontinence (SUI) is estimated to affect up to 35% of adult women worldwide [1] and 15.7% of community-dwelling women domestically [2]. According to the National Hospital Discharge Survey, there are approximately 100,000 inpatient procedures performed for SUI in the United States annually, with outpatient procedures estimated to exceed 105,000 as per the 2006 National Survey of Ambulatory Surgery [3].

The International Continence Society defines SUI as "the complaint of involuntary leakage of urine upon effort or exertion, or on sneezing or coughing" [4]. In a European sample of 1573 women with urinary incontinence, >80% considered their symptoms to be bothersome, with a negative impact on quality of life as per the Incontinence Quality of Life Questionnaire (I-QOL) [5]. Risk factors for SUI include, but are not limited to, age, parity, history of hysterectomy, forceps delivery, and obesity.

Non-surgical treatment options include behavioral modification, intravaginal devices, pelvic floor muscle exercises, biofeedback, and functional electrical stimulation. In an assessment of 13 systematic reviews on conservative treatment of SUI, Latthe et al. concluded that pelvic floor muscle training (PFMT) was better than no treatment [6]. Nine-to-twelve-month success rates following PFMT with or without biofeedback and/or health education programs range from 52.6% to 74.8% [7–9]. Long-term durability in these patients is likely a function of life-long exercise.

As there is no Food and Drug Administration (FDA) approved medical treatment for SUI, there is a resultant void in terms of invasiveness between conservative therapy and surgical intervention. Urethral bulking agents have shown benefit, however, are indicated for the treatment of SUI due to intrinsic sphincter deficiency (ISD), and are not universally administered in an office setting [10]. Renessa offers an office-based treatment for SUI in the absence of ISD through radiofrequency energy (RF) delivered transurethrally under local anesthesia.

## 2. Pathogenesis of SUI

The pathogenesis of SUI is thought to be the result of urethral hypermobility secondary to a weakening or disruption of the pelvic floor musculature and/or pubourethral ligament, with a subsequent loss of pressure transmission from the bladder to the urethra upon provocation [11, 12]. As most women, independent of continence status, exhibit a measure of hypermobility, Blaivas et al. contend that SUI is dependent

upon the concomitant presence of vesical neck funneling [13]. Ultrasound confirmation of funneling in 111 patients, as reported by Huang and Yang, was associated with a lower maximal urethral closure pressure (MUCP), a smaller area under the urethral pressure profile curve, a lower Valsalva leak point pressure (VLPP), and a larger volume of leakage on pad test [14].

## 3. Transurethral Radiofrequency Mechanism of Action

Transurethral RF treatment of the bladder neck and proximal urethra is thought to reduce funneling through the denaturation of submucosal collagen, with a resultant reduction in tissue compliance. Similar technology has proven effective in the treatment of patients with gastroesophageal reflux disease and fecal incontinence [15, 16]. In a preclinical porcine study employing transurethral RF, Valsalva leak point pressure was higher in the treatment group receiving 24 foci of RF energy at 65°C as compared to controls at 8 weeks ($P = 0.06$) [17].

## 4. Safety of Transurethral Radiofrequency

Transurethral RF collagen denaturation differs from RF ablation in that subnecrotic temperatures are employed, resulting in collagen remodeling as opposed to necrosis [17]. Additionally, treated foci are microscopic, avoiding gross tissue destruction. In the aforementioned animal study by Edelstein, none of the 30 treated animals demonstrated obstruction or stricture within the proximal urethra or bladder neck. Histopathology after sacrifice revealed, most commonly, focal chronic inflammation within the submucosa 1-2 mm beneath the epithelium, with evidence of fibroplasia and vascular proliferation [17] (Figure 1). Created are localized regions of denatured collagen at each focus, approximately 200 $\mu$ in diameter [23].

## 5. The Renessa Device

Renessa is an FDA-approved device which includes an RF generator, a sterile single-use 21 F transurethral probe, foot pedal, probe interface cable, and standard AC power cord (Figure 2). Low-power RF energy is delivered through four partially insulated 23-gauge nickel-titanium needle electrodes deployed from the probe shaft into the submucosa of the bladder neck and proximal urethra (Figure 3). Tissue temperatures are measured automatically. Impedance is also reported prior to energy delivery to ensure appropriate contact between electrodes and tissue. Irrigation of the mucosa with sterile water occurs transurethrally throughout the duration of the procedure to prevent overheating of the mucosa and submucosa. Energy is delivered to a total of thirty-six sites circumferentially.

## 6. Procedure Description

The radiofrequency probe is inserted until the tip is within the bladder lumen. The balloon is then insufflated with

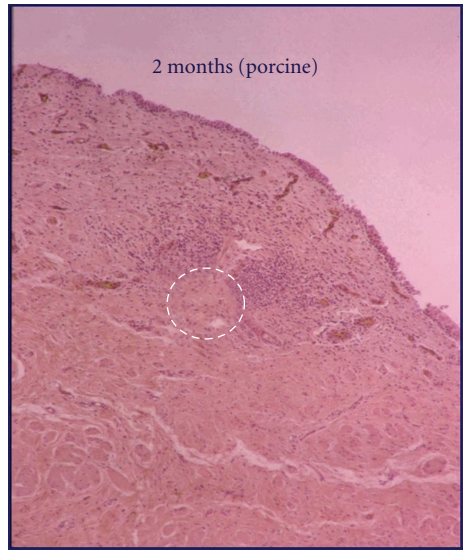


Figure 1: Porcine bladder neck posttreatment with Renessa. histologic image (hematoxylin and eosin) of porcine bladder outlet at 8 weeks following radiofrequency collagen remodeling. Denatured collagen is surrounded by focal chronic inflammatory cells.

Figure 2: Renessa equipment.

10 cc of water. To treat the bladder neck, the electrodes are deployed first, and gentle traction along the previously determined urethral axis is applied (approximately 1/2 pound of force with the operator's index and middle fingers). The screen will display impedance upon initial pedal pressure. If all electrodes read less than 300 ohms, the pedal is pressed again to begin radiofrequency delivery. During treatment, the four electrodes traverse the mucosa

Table 1: Summary of Renessa clinical studies.

| Study (year) | Design | Patients (number) | Mean age (range) | Follow-up (months) | Measures | Outcomes | Adverse events (% incidence) |
|---|---|---|---|---|---|---|---|
| Sotomayor and Bernal (2005) [18] | Pilot clinical trial with sequential enrollment into 1 of 4 groups based on number of submucosal foci.<br>Group 1–24<br>Group 2–36<br>Group 3–48<br>Group 4–60 | 41 | 47.6 (34–81) | 12 | I-QOL<br>IEF | I-QOL—incidence of ≥10 point score improvement.<br>Group 1: 63%<br>Group 2: 44%<br>Group 3: 70%<br>Group 4: 67%<br>Mean scores showed significant improvement for Groups 2–4.<br>IEF—incidence of ≥50% reduction.<br>Group 1: 63%<br>Group 2: 67%<br>Group 3: 70%<br>Group 4: 89% | Urgency (22)<br>Dysuria (8) |
| Appell et al. (2006) [19] | Randomized sham-controlled trial. | 173 (110 Treated) (63 Sham) | 50 (22–76) | 12 | I-QOL<br>LPP (cm $H_2O$) | I-QOL—incidence of ≥10 point score improvement.<br>Treated: 48%<br>Sham: 44% ($P = 0.7$)<br>LPP—mean ± SD<br>Treated: 13.2 ± 39.2<br>Sham: −2.0 ± 33.8 ($P = 0.02$) | AE (Rx, Sham incidence)<br>Wet OAB (10, 9.5)<br>Dysuria (9.1, 1.6)<br>Dry OAB (7.3, 3.2)<br>UTI (4.5, 4.8)<br>Asymptomatic DO (1.8, 6.3)<br>Retention (0.9, 0)<br>Hematuria (0.9, 0)<br>Hesitancy (0, 1.6) |
| Appell et al. (2007) [20] | Retrospective followup of 12-month RCT | 21 (Treated) | 52.2 (39.0–65.4) | 36 | I-QOL<br>IEF | I-QOL—mean improvement: 12.7 points<br>IEF—incidence of ≥50% reduction: 56% | No new AE's |
| Elser et al. (2009) [21] | Prospective single-arm study | 136 (ITT) | 47.0 (26.0–87.0) | 12 | I-QOL<br>IEF<br>UDI-6<br>PGI-I<br>PWT | I-QOL—incidence of ≥10 point score improvement: 50.3%<br>Mean scores showed significant improvement ($P < 0.0001$)<br>IEF—incidence of ≥50% reduction: 50%<br>UDI-6—mean scores showed significant improvement ($P < 0.0001$)<br>PGI-I—improvement: 49.6% ("very much" 14.4%, "much" 14.4%, "a little" 20.8%)<br>PWT—≥50% reduction: 69% (45% < 1 gram) | Dysuria (5.2)<br>Retention (4.4)<br>Pain (2.9)<br>UTI (2.9)<br>Increased leakage (0.7) |
| Elser et al. (2010) [22] | Prospective single-arm study | 136 (ITT) | 47.0 (26.0–87.0) | 18 | I-QOL<br>IEF<br>UDI-6<br>PGI-I | I-QOL—incidence of ≥10 point score improvement: 47.8%<br>Mean scores showed significant improvement ($P < 0.0001$)<br>IEF—incidence of ≥50% reduction: 46.7%<br>UDI-6—mean scores showed significant improvement ($P < 0.0001$)<br>PGI-I—improvement: 50.4% ("very much" 9.6%, "much" 15.2%, "a little" 25.6%) | No new AE's |

I-QOL: Incontinence quality of life instrument, IEF: incontinence episode frequency, LPP: leak point pressure, SD: standard deviation, Rx: treated group, AE: adverse event, OAB: overactive bladder, UTI: urinary tract infection, DO: detrusor overactivity, RCT: randomized controlled trial, UDI-6: urogenital distress inventory, PGI-I: patient global impression of improvement, PWT: pad weight test, and ITT: intent to treat.

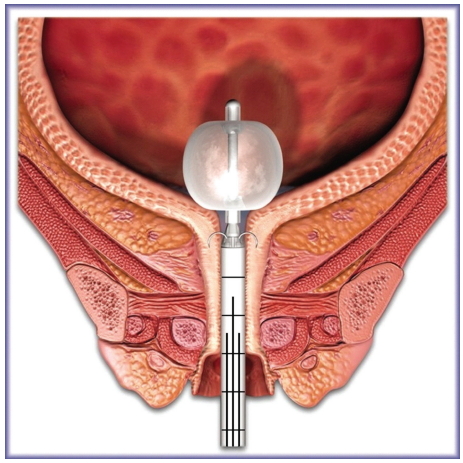

Figure 3: Probe with electrodes deployed delivering treatment.

Figure 4: Probe with markings.

and rest within the submucosa. Energy is delivered for a 60-second cycle while sterile room temperature water simultaneously irrigates the mucosa to prevent thermal injury. The submucosa immediately surrounding the four tips is heated and maintained at 65 degrees Celsius for a minimum of 30 seconds. The electrodes are withdrawn, and the probe shaft is repositioned after the first treatment cycle, first 30 degrees to the right, and then 30 degrees to the left of midline for cycles 2 and 3, respectively. Markings to guide such rotation are in the form of longitudinal lines on the probe shaft (Figure 4). The bladder neck receives a total of 12 discrete foci of denaturation.

To treat the proximal urethra, the same steps are carried out; however, traction is placed on the probe prior to deployment of the electrodes. Three cycles of energy are delivered to the proximal urethra followed by another 3 cycles just distal to the initial site, achieved with a slightly greater degree of traction. Thus, the proximal urethra receives a total of 24 foci of denaturation.

## 7. Clinical Recommendations for Office-Based Lower Urinary Tract Anesthesia

The safe and effective administration of topical and local anesthesia must be fully considered, as it is essential for the successful completion of Renessa in the office. Wells and Lenihan reported on the feasibility of in-office anesthesia in patients undergoing transurethral radiofrequency treatment, employing preprocedure diazepam with a bilateral periurethral block using a total of 10 cc of 2% lidocaine [24]. Thirty-three women completed a visual analog scale (0 = no pain, 10 = terrible pain) immediately prior to discharge. Overall, 42% of patients rated their pain as 0, with a mean pain score of 1.4 ± 1.8. The following is a summary of the anesthetic regimen we currently employ.

*7.1. Preprocedure Oral Regimen.* The patient is instructed to take an anxiolytic such as diazepam 5–10 mg and a nonsteroidal such as ibuprofen 800 mg about 30–60 minutes before the procedure.

*7.2. Periurethral and Bladder Neck Topical Anesthesia.* The introitus is prepared with povidone iodine. A 6-inch catheter is placed, and the bladder is drained. A negative urine dip is confirmed. Five cc of 2% xylocaine jelly is then infused into the catheter as it is withdrawn. EMLA cream is placed on a cotton swab and inserted transurethrally to rest at the bladder neck. The resting urethral angle with swab in place is determined by a goniometer to direct the orientation of the Renessa probe during treatment.

A small aliquot of EMLA cream is also applied adjacent to the urethral meatus at 3 and 9 o'clock in preparation for injection of local anesthesia at these sites. Experience with the safety and efficacy of EMLA on the labia has been previously demonstrated [25].

*7.3. Periurethral and Bladder Neck Injection Anesthesia.* After 10 minutes, a periurethral block is performed with a total of 10 cc of 1% xylocaine using a 22 gauge, 1 1/4" needle introduced at the previously anesthetized 3 and 9 o'clock sites. The needle is buried to the hub (to ensure anesthesia of the bladder neck) along the urethral axis as determined by the cotton swab present within the urethra. It should be noted that the proximal urethra and bladder neck are well vascularized, circumscribed by a pampiniform plexus of veins. It is therefore essential that prior to injecting xylocaine, one aspirates the syringe to reduce the possibility of intravascular injection. Anesthetic is infused at each site in two aliquots −3 cc at the bladder neck followed by 1/2 cm withdrawal, aspiration and reinjection of the remaining 2 cc's. If additional anesthesia is required during treatment,

another 5 cc of 1% xylocaine may be administered as above on either side.

*7.4. Intravesical Bladder Neck Anesthesia.* Immediately after periurethral and bladder neck injection, intravesical anesthesia of the bladder neck is carried out. The cotton swab within the urethra is removed, and a red rubber catheter is placed to drain any residual urine. The bladder is retrograde filled with 30 cc of 1% xylocaine. The patient then stands or sits upright to ensure contact between the intravesical xylocaine and bladder neck. After 10 minutes, the bladder is drained completely, filled with 30 cc of sterile water at room temperature (to cool tissue during treatment), and the catheter removed. Complete evacuation of intravesical anesthesia is suggested, as xylocaine absorption may be significantly increased in highly vascularized traumatized areas such as the bladder neck and proximal urethra following treatment with Renessa.

*7.5. Postprocedure Oral Regimen.* Patients are given a prescription for phenazopyridine 200 mg three times a day for three days to provide lower urinary tract analgesia. The administration of postprocedure antibiotics may be at the discretion of the physician.

## 8. Clinical Data

A summary of prospective trials employing Renessa is presented in Table 1 [18–22]. Inclusion criteria common to all studies were SUI and urethral hypermobility, with exclusion of those with a history of previous anti-incontinence surgery and those with primary urge-associated leakage in the presence of mixed incontinence. In the Appell and Elser trials, patients with a LPP of <60 cm $H_2O$ on urodynamics were not eligible for participation [19, 21].

Regarding 12 to 18 month efficacy, patients treated with low-energy RF to 36 submucosal foci exhibited a ≥10 point score reduction in I-QOL ranging from 44% to 50.3%, and a ≥50% reduction in IEF ranging from 46.7% to 67%. An I-QOL score improvement of ≥10 points has been shown to correlate with patient perception of improvement as being "much better," a ≥25% reduction in IEF, and a ≥25% reduction in stress pad weight [26]. Although no statistically significant difference was observed by Lenihan et al. between treatment and sham groups regarding a ≥10 point improvement in I-QOL, a subanalysis of patients deemed to have moderate-to-severe SUI determined that 74% of those receiving treatment versus 50% of those receiving sham achieved such improvement ($P = 0.03$) [27]. Additionally, outcomes in this population were independent of menopausal status.

Patients treated with transurethral RF collagen denaturation experienced rare long-term sequelae. No serious AE's were reported in any of the aforementioned clinical trials, and no difference was seen in the incidence of AE's between treatment and sham groups.

## 9. Discussion

Renessa represents an office intervention for SUI that is safe and is without significant AE's or known long-term negative effects. Safety has been confirmed in animal studies with no evidence of posttreatment urethral obstruction or stricture formation. The putative mechanism of decreased funneling may be supported by both animal and human data in which LPP was found to improve following RF treatment [17, 19].

Efficacy of transurethral collagen denaturation appears to be within range of that of PFMT. Alewijnse et al. reported 1-year success following PFMT (with randomization of 129 patients to PFMT alone versus PFMT plus one of three health education programs), citing a ≥50% improvement in IEF in 74.8% (64.4% by intent to treat) of patients overall [7].

In terms of actual number of leaks, Elser et al. reported a reduction in median weekly IEF from a 15.0 (1.0 − 245.0) to 7.5 (0.0 − 140.0) at 12 months ($P = 0.0026$) [21]. This is in line with data from the Alewijnse trial in which was reported a reduction in mean weekly IEF from 22.9 ± 24.1 to 7.8 ± 12.2 at 12 months ($P < 0.001$). In a large RCT of 530 patients randomized to individual or group PFMT, Janssen et al. reported similar data at 9 months, with a reduction in mean weekly IEF from 16.3 ± 15.8 to 8.6 ± 15.5 and from 14.4 ± 15.3 to 6.1 ± 10.5 for the individual and group patients, respectively, [8].

Eighteen-month data following Renessa shows improvements at 12 months to be durable [22]. This may be an advantage over PFMT, as durability following pelvic floor muscle rehabilitation may be wholly dependent upon continued therapy.

We chose not to compare our data to bulking agents, as Renessa is indicated for SUI and not ISD. Additionally, as transurethral RF treatment is in-office, we did not compare such therapy to surgical anti-incontinence data.

## 10. Conclusion

Radiofrequency collagen denaturation is a safe, nonsurgical, and in-office procedure for the treatment of female SUI, providing an improvement in quality of life. Such therapy may represent an alternative to PFMT or for those who have failed such treatment.

## 11. Coding

The current procedural terminology code (CPT) for the Renessa procedure is 53860.

## References

[1] K. Luber, "The definition, prevalence, and risk factors for stress urinary inconitinence," *Reviews in Urology*, vol. 6, supplement 3, pp. S3–S9, 2003.

[2] I. Nygaard, M. D. Barber, K. L. Burgio et al., "Prevalence of symptomatic pelvic floor disorders in US women," *Journal of the American Medical Association*, vol. 300, no. 11, pp. 1311–1316, 2008.

[3] K. A. Cullen, M. J. Hall, and A. Golosinskiy, *Ambulatory Surgery in the United States, 2006*, National Health Statistics Reports, United States Department of Health and Human Services, 2009.

[4] P. Abrams, L. Cardozo, M. Fall et al., "The standardisation of terminology in lower urinary tract function: report from the standardisation sub-committee of the International Continence Society," *Urology*, vol. 61, no. 1, pp. 37–49, 2003.

[5] S. Papanicolaou, S. Hunskaar, G. Lose, and D. Sykes, "Assessment of bothersomeness and impact on quality of life of urinary incontinence in women in France, Germany, Spain and the UK," *BJU International*, vol. 96, no. 6, pp. 831–838, 2005.

[6] P. M. Latthe, R. Foon, and K. Khan, "Nonsurgical treatment of stress urinary incontinence (SUI): Grading of evidence in systematic reviews," *BJOG*, vol. 115, no. 4, pp. 435–444, 2008.

[7] D. Alewijnse, J. F. M. Metsemakers, I. E. P. E. Mesters, and B. Van den Borne, "Effectiveness of pelvic floor muscle exercise therapy supplemented with a health education program to promote long-term adherence among women with urinary incontinence," *Neurourology and Urodynamics*, vol. 22, no. 4, pp. 284–295, 2003.

[8] C. C. M. Janssen, A. L. M. Lagro-Janssen, and A. J. A. Felling, "The effects of physiotherapy for female urinary incontinence: individual compared with group treatment," *BJU International*, vol. 87, no. 3, pp. 201–206, 2001.

[9] P. Aukee, P. Immonen, D. E. Laaksonen, P. Laippala, J. Penttinen, and O. Airaksinen, "The effect of home biofeedback training on stress incontinence," *Acta Obstetricia et Gynecologica Scandinavica*, vol. 83, no. 10, pp. 973–977, 2004.

[10] http://www.cigna.com/customer_care/healthcare_professional/coverage_positions/medical/mm_0206_coveragepositioncriteria_injectable_bulking_agents_stress_incont.pdf.

[11] A. R. B. Smith, G. L. Hosker, and D. W. Warrell, "The role of partial denervation of the pelvic floor in the aetiology of genitourinary prolapse and stress incontinence of urine. A neurophysiological study," *British Journal of Obstetrics and Gynaecology*, vol. 96, no. 1, pp. 24–28, 1989.

[12] R. C. Lovegrove-Jones, Q. Peng, M. Stokes, V. F. Humphrey, C. Payne, and C. E. Constantinou, "Mechanisms of pelvic floor muscle function and the effect on the urethra during a cough," *European Urology*, vol. 57, no. 6, pp. 1101–1110, 2010.

[13] J. G. Blaivas, L. J. Romanzi, and D. M. Heritz, "Urinary incontinence: pathophysiology, evaluation, treatment overview, and nonsurgical management," in *Cambell's Urology*, P. C. Walsh, A. B. Retik, E. D. Vaughan, and AJ Wein, Eds., pp. 1007–1043, W.B. Saunders, Philadelphia, 7th edition, 1998.

[14] W. C. Huang and J. M. Yang, "Bladder neck funneling on ultrasound cystourethrography in primary stress urinary incontinence: a sign associated with urethral hypermobility and intrinsic sphincter deficiency," *Urology*, vol. 61, no. 5, pp. 936–941, 2003.

[15] T. Takahashi, S. Garcia-Osogobio, M. A. Valdovinos, C. Belmonte, C. Barreto, and L. Velasco, "Extended two-year results of radio-frequency energy delivery for the treatment of fecal incontinence (the secca procedure)," *Diseases of the Colon and Rectum*, vol. 46, no. 6, pp. 711–715, 2003.

[16] R. E. Lutfi, A. Torquati, and W. O. Richards, "The endoscopic radiofrequency approach to management of GERD," *Current Opinion in Otolaryngology and Head and Neck Surgery*, vol. 12, no. 3, pp. 191–196, 2004.

[17] P. S. Edelstein, "A preclinical study of nonsurgical radiofrequency collagen remodeling for the treatment of stress urinary incontinence," *Expert Review of Medical Devices*, vol. 3, no. 6, pp. 743–748, 2006.

[18] M. Sotomayor and G. F. Bernal, "Twelve-month results of nonsurgical radiofrequency energy micro-remodeling for stress incontinence," *International Urogynecology Journal and Pelvic Floor Dysfunction*, vol. 16, no. 3, pp. 192–196, 2005.

[19] R. A. Appell, S. Juma, W. G. Wells et al., "Transurethral radiofrequency energy collagen micro-remodeling for the treatment of female stress urinary incontinence," *Neurourology and Urodynamics*, vol. 25, no. 4, pp. 331–336, 2006.

[20] R. A. Appell, G. Singh, I. W. Klimberg et al., "Nonsurgical, radiofrequency collagen denaturation for stress urinary incontinence: retrospective 3-year evaluation," *Expert Review of Medical Devices*, vol. 4, no. 4, pp. 455–461, 2007.

[21] D. M. Elser, G. K. Mitchell, J. R. Miklos et al., "Nonsurgical transurethral collagen denaturation for stress urinary incontinence in women: 12-month results from a prospective long-term study," *Journal of Minimally Invasive Gynecology*, vol. 16, no. 1, pp. 56–62, 2009.

[22] D. M. Elser, G. K. Mitchell, J. R. Miklos et al., "Nonsurgical transurethral collagen denaturation for stress urinary incontinence in women: 18-month results from a prospective long-term study," *Neurourology and Urodynamics*, vol. 29, no. 8, pp. 1424–1428, 2010.

[23] *Data on file*, Novasys Medical, Inc, Newark, Calif, USA.

[24] W. G. Wells and J. P. Lenihan, "Use of in-office anesthesia during non-surgical radiofrequency collagen denaturation for stress urinary incontinence," *Current Medical Research and Opinion*, vol. 23, no. 6, pp. 1279–1284, 2007.

[25] M. Mansell-Gregory and B. Romanowski, "Randomised double blind trial of EMLA for the control of pain related to cryotherapy in the treatment of genital HPV lesions," *Sexually Transmitted Infections*, vol. 74, no. 4, pp. 274–275, 1998.

[26] D. L. Patrick, M. L. Martin, D. M. Bushnell, I. Yalcin, T. H. Wagner, and D. P. Buesching, "Quality of life of women with urinary incontinence: Further development of the incontinence quality of life instrument (I-QOL)," *Urology*, vol. 53, no. 1, pp. 71–76, 1999.

[27] J. P. Lenihan, T. Tomsen, M. Smith et al., "Comparison of the quality of life after nonsurgical radiofrequency energy tissue micro-remodeling in premenopausal and postmenopausal women with moderate-to-severe stress urinary incontinence," *American Journal of Obstetrics and Gynecology*, vol. 192, no. 6, pp. 1995–2001, 2005.

Hindawi Publishing Corporation
Obstetrics and Gynecology International
Volume 2012, Article ID 612946, 7 pages
doi:10.1155/2012/612946

*Research Article*

# Pelvic Organ Distribution of Mesenchymal Stem Cells Injected Intravenously after Simulated Childbirth Injury in Female Rats

**Michelle Cruz,[1] Charuspong Dissaranan,[2] Anne Cotleur,[3] Matthew Kiedrowski,[4] Marc Penn,[5] and Margot Damaser[6,7]**

[1] *Department of Biomedical Engineering, The Cleveland Clinic, Euclid Avenu ND20, Cleveland, OH 44195, USA*
[2] *Department of Urology, The Cleveland Clinic, 9500 Euclid Avenue Q100, Cleveland, OH 44195, USA*
[3] *Department of Neuroscience, The Cleveland Clinic, 9500 Euclid Avenue NC30, Cleveland, OH 44195, USA*
[4] *Department of Stem Cell Biology & Regenerative Medicine, The Cleveland Clinic, 9500 Euclid Avenue NE30, Cleveland, OH 44195, USA*
[5] *Departments of Cardiovascular Medicine and Stem Cell Biology and Regenerative Medicine, The Cleveland Clinic, 9500 Euclid Avenue NE30, Cleveland, OH 44195, USA*
[6] *Departments of Biomedical Engineering, Urology, and Stem Cell Biology and Regenerative Medicine, The Cleveland Clinic, 9500 Euclid Avenue ND20, Cleveland, OH 44195, USA*
[7] *Advanced Platform Technology Center, Louis Stokes Cleveland VA Medical Center, Cleveland, OH 44106, USA*

Correspondence should be addressed to Margot Damaser, damasem@ccf.org

Received 8 April 2011; Accepted 26 June 2011

Academic Editor: Johannes Bitzer



The local route of stem cell administration utilized presently in clinical trials for stress incontinence may not take full advantage of the capabilities of these cells. The goal of this study was to evaluate if intravenously injected mesenchymal stem cells (MSCs) home to pelvic organs after simulated childbirth injury in a rat model. Female rats underwent either vaginal distension (VD) or sham VD. All rats received 2 million GFP-labeled MSCs intravenously 1 hour after injury. Four or 10 days later pelvic organs and muscles were imaged for visualization of GFP-positive cells. Significantly more MSCs home to the urethra, vagina, rectum, and levator ani muscle 4 days after VD than after sham VD. MSCs were present 10 days after injection but GFP intensity had decreased. This study provides basic science evidence that intravenous administration of MSCs could provide an effective route for cell-based therapy to facilitate repair after injury and treat stress incontinence.

## 1. Introduction

During the second stage of vaginal delivery, pressure of the fetal head on the pelvic floor causes direct trauma to the pelvic muscles, pelvic floor organs including the urethra, and the nerves that innervate them [1]. These injuries can lead to development of pelvic floor disorders (PFDs), including pelvic organ prolapse, stress urinary incontinence (SUI) and fecal incontinence. Available treatment options for SUI and fecal incontinence include fluid and dietary manipulation, electrical stimulation, physiotherapy, and pessaries or vaginal cones [2–4]. Surgery remains the mainstay of treatment for severe cases of SUI and fecal incontinence as well as for pelvic organ prolapse. The lifetime risk of undergoing surgery for PFD has been estimated as 11% [5]. Although several therapeutic options exist, no current therapy is able to fully correct the underlying pathophysiology.

Stem cells have been investigated in both animal and clinical studies as a potential treatment for SUI and have been demonstrated to improve both function and anatomy [6–11]. Most of these studies utilized autologous muscle-derived progenitor cells injected into the urethra to treat SUI and have demonstrated their potential for clinical utility; however, long-term outcomes are not yet available [12]. After vaginal delivery, the pelvic organs, their innervating nerves, and connective tissue in the region are injured, which later

can lead to PFD. These diffuse injuries in multiple organs may not be successfully treated with local administration of stem cells to the urethra.

Hematopoetic and mesenchymal stem cells (MSCs) migrate or home to sites of injury following gradients of chemokines, such as stromal derived factor 1 (SDF1) and (C-C motif) ligand 7 (CCL7), previously called MCP-3 [13]. Once localized to tissues, they can differentiate into different tissue types and produce paracrine and growth factors [14]. Animal models in several fields have been utilized to demonstrate MSC homing and resultant facilitation of functional improvement with a variety of injury models, including cardiac injury [15, 16], renal failure [17], and skin wounds [18], demonstrating the clinical potential of this cell population.

Simulation of childbirth injury in female rats by distending the vagina has become a standard method of modeling the maternal injuries of childbirth and results in symptoms of SUI [19–22]. A simulated childbirth injury is used because in all animals, including nonhuman primates, the baby's head to birth canal ratio is much smaller than it is in humans, implying that vaginal birth is most traumatic humans [23]. We have previously demonstrated that CCL7 and one of its receptors CCR1 are upregulated in the urethra after simulated childbirth injury, indicating a potential for MSC homing to pelvic organs [24]. The goal of the current study was to determine to which organs MSCs injected intravenously will home after simulated childbirth injury in female rats. Although functional studies are left to a follow-up study, these organs are presumed to be the same ones in which the cells would have the greatest therapeutic potential. Once demonstrated in a basic science preclinical model, intravenously delivered MSCs may serve as an effective route to deliver stem cells to facilitate repair after childbirth injury and treat PFD.

## 2. Methods

*2.1. Stem Cell Harvest and Culture.* Bone marrow from a donor female Sprague-Dawley rat was used to create cultured MSC adapting the methods of Lennon & Caplan [25]. In brief, the rat was euthanized and the femur and tibia were harvested. The bones were cleaned and both ends were removed for aspiration of marrow by flushing with Dulbeco's Modified Eagle Medium-Low Glucose solution supplemented with 12% Fetal Bovine Serum and 1% Anti-Anti (Invitrogen, Carlsbad, CA) containing penicillin, streptomycin, and amphotericin. The cells were centrifuged and washed then plated (passage 0). Every other day the media was changed and, after reaching confluency (80–100%), the cells were passaged using Trypsin-EDTA. At passage 3 cells were incubated with Intracellular adhesion molecule I (ICAM-1) antibody (10 $\mu$L/1 $\times$ $10^6$ cells) for 30 min at room temperature in the dark to select for MSC. Cells were sorted via flow cytometry, and ICAM+ cells were collected under sterile conditions. These MSC were transfected with pCCLsin.ppt.hPGK.GFP.pre (a generous gift from the Cossu Lab) which uses a human PGK promoter to constitutively express green fluorescent protein (GFP). After reaching confluency, cells were resorted under sterile conditions and GFP-positive (GFP+) cells were collected. Cells were grown to passages 15-16 before being injected in rats.

*2.2. Vaginal Distention (VD).* All experimental procedures were approved by the Institutional Animal Care and Use Committee of the Cleveland Clinic. Age-matched virgin female Sprague-Dawley rats (240265 g) underwent either a simulated childbirth injury by vaginal distension (VD; $n$ = 11) or sham VD ($n$ = 11). VD was performed as we have done previously [24]. In brief, each rat was anesthetized, a modified 10Fr Foley catheter was inserted into the vagina and the balloon was inflated to 3 mL for 4 hours. Sham VD consisted of catheter insertion for 4 hours without balloon inflation. 1 hour after injury, the animals were anesthetized with isoflurane and sodium nitroprusside was administered via the lateral tail vein at 1 mg/kg for 1 minute. Immediately following, 2 million GFP-labeled MSCs in 1 mL of saline were injected via the lateral tail vein.

*2.3. Fluorescent Imaging.* Four or 10 days after VD or sham VD, a sham VD and VD pair were anesthetized and imaged simultaneously *in vivo* for visualization of GFP+ cells using a supercooled charge-coupled camera in a light tight box. Immediately afterward the urinary bladder, urethra, vagina, rectum, and levator ani muscles were harvested from each animal and imaged similarly *ex vivo*. Total fluorescent flux (photons/second/cm$^2$/steradian) in a region of interest selected around each organ from *ex vivo* imaging was calculated. Values from VD animals were normalized to that of the paired sham VD animal which was imaged simultaneously.

*2.4. Flow Cytometry.* To validate quantitative values of flux from *ex* vivo imaging, we processed the tissues and analyzed individual cells by flow cytometry. After organs were imaged *ex vivo* they were minced into 1 mm pieces and dissociated with a collagenase/DNase (2 mg/mL collagenase I, 120 units/mL Dnase I; Worthington Biochemical Co., Lakewood, NJ) mixture for 4 hours until a single cell suspension was obtained. Control organs were harvested from rats that have not received MSC and were processed identically to the experimental groups. Each cell suspension was incubated with DRAQ5 (BioStatus Limited, London UK), a nuclear stain and fixed overnight in 1% formalin with FACS buffer (1xPBS, 25 mM HEPES, 1% inactivated FBS, .1% sodium azide, 1 mM EDTA). The samples were then permeabilizied (FACS buffer + 0.2% saponin), blocked (Perm buffer + 4% heat inactivated FBS), and stained with rabbit Ant-GFP Alexa Fluor 488 antibody (Invitrogen, Carlsbad, CA). Cells were then incubated for 20 min in Perm buffer centrifuged and resuspended in FACS buffer and filtered through a 30 $\mu$m filter. Labeled cells were maintained on ice prior to flow cytometric analysis.

The LSRII flow cytometer (BD, Franklin Lakes, NJ) was calibrated before each experiment using LinearFlow (Invitrogen) fluorescent intensity standards to ensure uniform fluorescent detection throughout the study. Although cells isolated from different organs required FSC/SSC cytometer adjustments, all samples within an organ group were collected with similar scatter profiles.

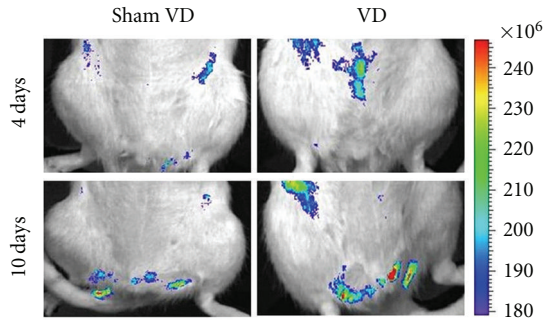


Figure 1: Examples of *in vivo* fluorescence images for GFP+ mesenchymal stem cells 4 and 10 days after vaginal distension (VD) and sham VD. The colored scale represents total fluorescent flux (photons/second/cm$^2$/steradian).

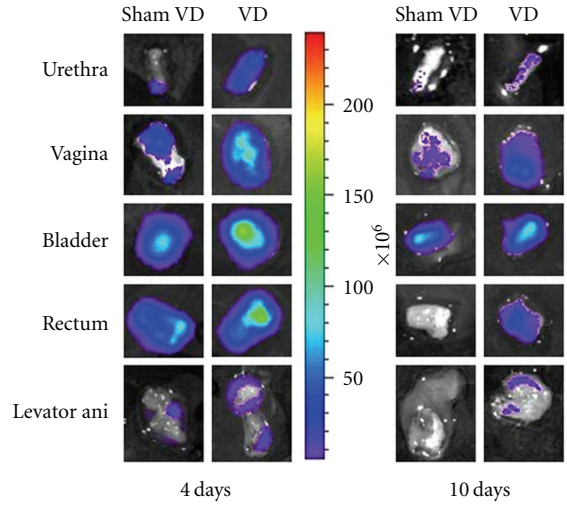


Figure 2: Examples of *ex vivo* fluorescence images for GFP+ mesenchymal stem cells in the urethra, vagina, bladder, rectum, and levator ani 4 and 10 days after vaginal distension (VD) and sham VD. Each column contains organs taken from a single animal. The colored scale represents total fluorescent flux (photons/second/cm$^2$/steradian).

For each control organ 10,000 events were collected to obtain baseline values and 200,000 events were collected from each sample. Analysis was done using FlowJo 9.1 (Treestar, Ashland, OR). Events were initially gated on Forward Scatter Width (FSC-W) and Forward Scatter Area (FSC-A) to obtain a singlet population. Additional gating on DRAQ5 fluorescent intensity versus Side Scatter Area (SSC-A) minimized inclusion of noncellular events in the analysis. Finally, DRAQ5+ events were analyzed for the presence of GFP+ cells and results were compared between Sham and VD using uniform gating within each organ group.

*2.5. Data Analysis.* Quantitative values are presented as mean ± standard error of the mean. Statistical comparisons were made using a Student's $t$-test with $P < 0.05$ indicating a significant difference between groups. *In vivo* imaging data was analyzed qualitatively.

## 3. Results

*In vivo* imaging demonstrated evidence of GFP+ MSCs in the pelvic region both 4 and 10 days after VD (Figure 1). However, due to the proximity of the pelvic organs, it was impossible to utilize *in vivo* imaging to determine which of the pelvic organs contained more MSCs at these time points.

Four days after VD, relative flux of fluorescence imaged *ex vivo* in the urethra (2.9 ± 0.7; $P < 0.01$), vagina (2.0 ± 0.4; $P = 0.03$), rectum (3.4 ± 1.4; $P = 0.02$) and levator ani (1.9 ± 0.4; $P = 0.01$) was significantly greater than after sham VD (defined as 1; Figures 2 and 3). Ten days after VD, relative flux of fluorescence was significantly greater after VD (1.6 ± 0.2; $P < 0.01$) than after sham VD (defined as 1) only in the urethra. At this time point, a trend towards significance was present in relative flux for the levator ani (1.9 ± 0.6; $P = 0.07$) and vagina (2.4 ± 0.9; $P = 0.07$) after VD compared to sham VD. There was no significant difference in relative flux in the urinary bladder between VD and sham VD either 4 or 10 days after injury. Similarly, there was no significant difference in relative flux in the rectum between VD and sham VD 10 days after injury (Figures 2 and 3).

There was a significant decrease in total flux from 4 to 10 days after sham VD for the vagina ($P = 0.02$), levator ani ($P = 0.02$), and rectum ($P < 0.01$), as well as a trend towards significant decrease after sham VD from 4 to 10 days in the urethra ($P = 0.05$), and bladder ($P = 0.07$; Figure 4). There was a significant decrease in total flux from 4 to 10 days after VD in the urethra ($P = 0.03$), rectum ($P < 0.01$), and levator ani ($P < 0.01$). There was a trend towards a significance decrease in total flux from 4 to 10 days after VD in the vagina ($P = 0.07$) and bladder ($P = 0.09$).

Flow cytometry results for all organs at both timepoints were highly variable in scatter properties, background autofluorescence, and in DRAQ5 staining; therefore no statistically significant differences between groups could be determined.

## 4. Discussion

Vaginal childbirth can cause injury to pelvic organs, pelvic floor muscles, and the pudendal nerve, among other structures, which can lead to PFD [1]. Two-thirds of women who have delivered vaginally experience at least one type of PFD [26]. Symptoms of these disorders can cause social and sexual isolation, restriction of employment, and reduced quality of life [27]. Symptoms often do not develop until years after the original injury [28] suggesting that although some repair may occur after childbirth, it is imperfect and insufficient in the long term.

Cell-based therapy is gaining attention as a potential treatment, particularly for SUI [29, 30]. Preclinical investigations in animal models have utilized stem cells obtained from adipose tissue [6, 31], bone marrow [32], or muscle [33, 34]. Initial clinical studies have reported improvement in SUI after an autologous injection of stem cells directly into the urethra [8, 12]. Some of the preclinical studies utilize simulated childbirth injury models involving pregnant rats [6, 35, 36] and others do not [21, 24, 37–39]. Although

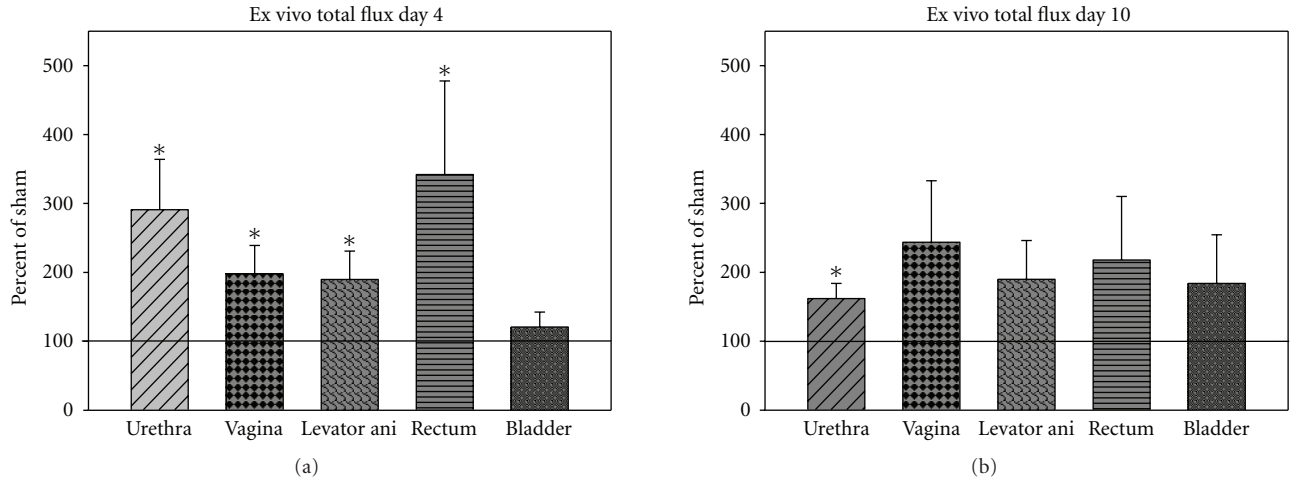


Figure 3: Relative fluorescent flux measured *ex* vivo (a) four days and (b) ten days after vaginal distension (VD) normalized to total fluorescent flux in paired animals that underwent sham VD simultaneously. Values are displayed as mean ± standard error of 5-6 animals/group as a percent of the sham VD values. ∗ denotes a statistically significant difference compared to sham VD ($P < 0.05$).

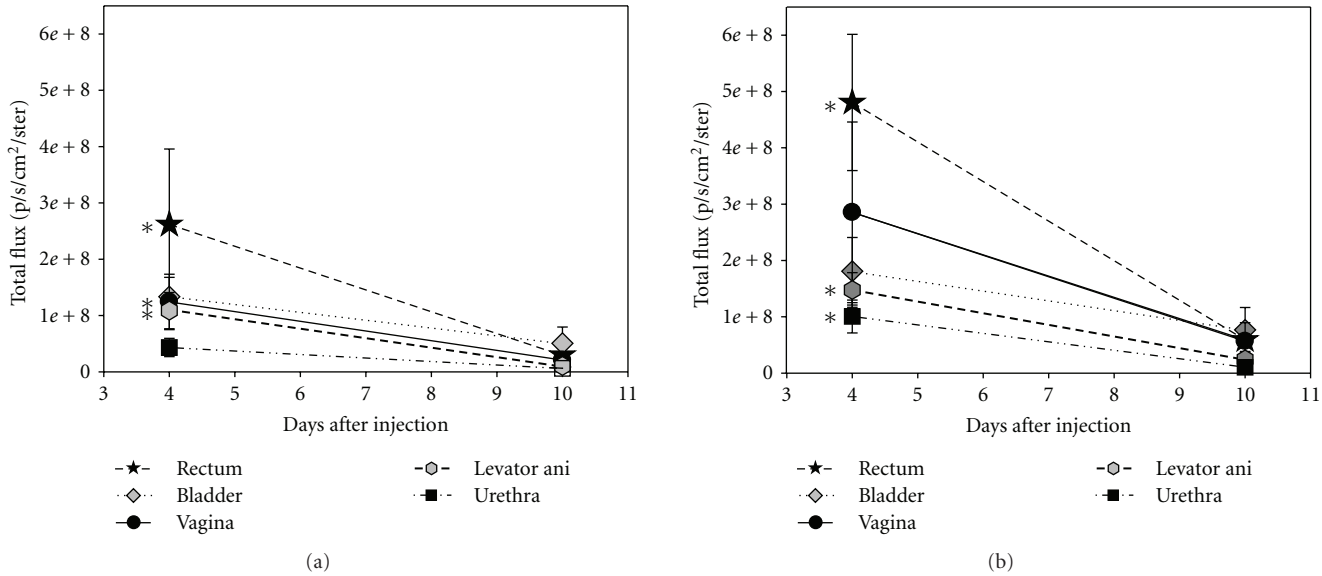


Figure 4: Total fluorescent flux 4 and 10 days after (a) sham vaginal distension and (b) vaginal distension (VD). Values are displayed as mean ± standard error of 5-6 animals/group. ∗ denotes a statistically significant difference compared to the same organs 10 days after sham VD or VD ($P < 0.05$).

different investigators utilize different outcome measures, making comparisons difficult; the overall results are quite similar and indicate that the urethra and vagina sustain significant injury to muscles, connective tissue, innervation, and vascularization [19].

Intravenous administration is less invasive than periurethral or intraurethral injections and has been shown to be an effective route to deliver stem cells and facilitate functional improvement in cardiac ischemia [40] and ischemic stroke [41] models. Additionally, intravenous administration allows the stem cells to home to and target the multiple organs that are damaged during childbirth injury compared with a direct injection that would potentially treat the target organ only. Lin et al. demonstrated that intravenously delivered adipose-derived stem cells can migrate to the urethra after simulated childbirth injury and improve urethral function [6]. However, an investigation of the migration, or homing, of the cells to different pelvic organs was not made.

While there are several different methods of labeling and tracking infused cells, GFP is commonly used, in part because differentiation of MSC does not alter GFP expression [42]. *In vivo* imaging in our study showed a strong GFP signal in the pelvic region after VD, indicating the presence of GFP+ MSC in the structures of the pelvic region. *In* vivo

fluorescence was not as prominent in the pelvic region after sham VD, likely because of reduced homing after sham VD compared to VD, leading to lower fluorescence in the pelvic region, coupled with the depth of pelvic organs underneath the pelvic bone. Nonetheless, our results indicate that GFP-labeled MSCs are potentially useful for the monitoring of cell migration, homing, engraftment, and survival of transplanted MSCs in pelvic organs.

*Ex vivo* imaging demonstrated that allogenic MSCs migrated to the urethra, vagina, levator ani muscles, and rectum to a greater extent after VD than after sham VD, confirming that tissue injury plays an important role in homing of MSCs to the pelvic organs since these tissues have previously been shown to incur greater damage after VD than sham VD [37, 43]. The vagina and urethra have been studied to the greatest extent after VD since they demonstrate the greatest damage [6, 19, 37, 43]. Our data suggests that damage to the levator ani and rectum ought to be investigated as well.

After injury, peripheral tissues release chemokines that cause mobilization and attract MSCs to engraft in the tissue via a cytokine gradient [14]. We have previously reported that CCL7, a known stem cell homing cytokine, is upregulated in rat urethra and vagina but not in the rectum or bladder immediately following VD [38]. We also found a positive relationship between duration of VD and the subsequent expression of CCL7 and its receptor, CCR1, in the urethra [24]. In contrast to this previous work, the current study demonstrated that MSC also home to the rectum after VD, suggesting that there are other factors as yet undiscovered that may play a significant role in the homing of MSC to pelvic organs after VD.

Hypoxia of tissues has been previously shown to upregulate cytokines that attract MSC and play a significant role in MSC homing [44]. Although our previous work demonstrated significant hypoxia in the bladder after VD [37], the current study did not show any increase in homing of MSC to the bladder after VD compared to sham VD. Interestingly, the previous work also demonstrated hypoxia of the bladder after sham VD [44]. It is possible that the homing of MSC to the bladder after sham VD was sufficiently high so no difference was demonstratable compared to VD.

The significant reduction in total fluorescent flux by 10 days after VD in all organs is indicative of a significant reduction in MSC, which may have been due to cell death. Poor viability of MSC after cell transplantation in myocardium has previously been reported [45, 46]. Anoikis, a loss of cell to matrix adhesion resulting in a reduction of repression of apoptotic signal [47], may have been occurring in these cells after transplantation. Future research will be designed to investigate the fate of cells that home to pelvic organs after VD. Despite their low survival rate, we have demonstrated in a parallel study, that MSCs infused intravenously facilitate a rapid improvement of urethral function after VD, likely via a paracrine mechanism of action [48].

We performed flow cytometry to validate the *ex vivo* imaging results and quantify the number of GFP+ MSC engrafted in each organ. However, despite careful gating and backgating of subpopulations on multiple parameters to ensure authenticity, the results showed high variability in scatter and fluorescent properties among controls and samples within each organ group, indicating that our current technique was not sufficient at preserving the cells. Flow cytometry has been previously utilized to determine that 1–5% of the cells in the heart are MSCs after an intravenous MSC infusion [15], which has been confirmed by other methods as well [40, 49]. Although it is likely that fewer than 2% of total cells were MSCs in the urethra after VD in our study, due to the smaller size and lower vascularization of this organ, it is possible that with technical improvements we could detect these cells. Future work will be focused on improving these techniques.

One potential limitation of our animal model is that it relies on stem cell homing after an acute simulated childbirth injury although SUI and other PFD manifest and are treated years after the original injury. The cell-based therapies we investigated could be administered soon after delivery in women who are at highest risk for development of PFD such as women with genetic predispositions [50–52] or those with postpartum SUI [30, 53, 54]. The latter is most intriguing because the cell-based therapy may both treat their postpartum SUI and prevent later recurrence of SUI. In addition, it may be possible to induce homing a long time after injury or increase homing after an acute injury via genetic modification of stem cells to express a greater number of homing ligands [55]. Furthermore it may be possible to administer electrical stimulation to the paravaginal region, which has been shown *in vitro* to induce cell migration of neural stem cells [56], human-induced pluripotent stem cells [57], and adipose-derived MSCs [58]. Further research utilizing preclinical animal models will be needed to initiate clinical trials of these therapies.

Although we investigated stem cell homing after simulated childbirth injury, it has been shown that potentially stem cells do not necessarily need to home to injured tissue to improve function [59]. Therefore, it is possible that MSCs could accelerate recovery at sites distant from those where cells migrate or home, suggesting a systemic paracrine effect of the cells. Further research is needed to determine the mechanism of homing and accelerated recovery with cell-based therapies.

## 5. Conclusion

We conclude from this study that MSC preferentially home to the urethra, vagina, levator ani, and rectum after simulated childbirth injury, providing evidence that intravenous administration of MSCs could be a potentially effective method of delivering cell-based therapies after vaginal childbirth injury.

## Conflict of Interests

The authors have no real or potential conflict of interest with the results of this study.

## Acknowledgments

The authors would like to thank Giulio Cossu's Lab at San Raffaele Hospital for the pCCLsin.ppt.hPGK.GFP.pre Vector

used in this experiment. This study was prepared with financial support from the State of Ohio. The content reflects the views of the authors and does not purport to reflect the views of the State of Ohio. This award continues to support the commercialization of innovative therapies and technologies at the Center for Stem Cell and Regenerative Medicine at Case Western Reserve University, Cleveland, Ohio. Financial support was also obtained from the Cleveland Clinic, the Department of Veterans Affairs, and the National Science Foundation (Grant no. 0755263). This work was also made possible by the Case Western Reserve University/Cleveland Clinic CTSA Grant from the NIH/National Center for Research Resources (UL1 RR024989).

## References

[1] C. E. Turner, J. M. Young, M. J. Solomon, J. Ludlow, and C. Benness, "Incidence and etiology of pelvic floor dysfunction and mode of delivery: an overview," *Diseases of the Colon & Rectum*, vol. 52, no. 6, pp. 1186–1195, 2009.

[2] P. Santos, A. Rodrigues, M. Girao, M. Sartori, L. Oliveira, and R. A. Castro, "Comparative study of pelvic floor functional electrical stimulation and vaginal cone in the treatment of women with stress urinary incontinence," *International Urogynecology Journal*, vol. 19, pp. S30–S31, 2008.

[3] D. Vickers and G. W. Davila, "Kegel exercises and biofeedback," in *Pelvic Floor Dysfunction*, D. Steven, G. Wexner, D. W. Davila, and G. M. Ghoniem, Eds., pp. 303–310, Springer, London, UK, 2009.

[4] L. C. M. Berghmans, H. J. M. Hendriks, K. Bo, E. J. Hay-Smith, R. A. de Bie, and E. S. C. V. van Doorn, "Conservative treatment of stress urinary incontinence in women: a systematic review of randomized clinical trials," *British Journal of Urology*, vol. 82, no. 2, pp. 181–191, 1998.

[5] M. F. Fialkow, K. M. Newton, G. M. Lentz, and N. S. Weiss, "Lifetime risk of surgical management for pelvic organ prolapse or urinary incontinence," *International Urogynecology*, vol. 19, no. 3, pp. 437–440, 2008.

[6] G. Lin, G. Wang, L. Banie et al., "Treatment of stress urinary incontinence with adipose tissue-derived stem cells," *Cytotherapy*, vol. 12, no. 1, pp. 88–95, 2010.

[7] D. S. Dave, V. Gunther-Lopez, R. Zhang et al., "Periurethral injection of autologous adipose-derived stem cells with hepatocyte growth factor-impregnated PLGA microspheres for treatment of stress urinary incontinence in an animal model," *Neurourology and Urodynamics*, vol. 27, no. 2, p. 109, 2008.

[8] S. Herschorn, L. Carr, C. Birch et al., "Autologous muscle-derived cells as therapy for stress urinary incontinence: a randomized, blinded trial," *Neurourology and Urodynamics*, vol. 29, no. 2, p. 307, 2010.

[9] J. J. Lim, J. B. Jang, J. Y. Kim, S. H. Moon, C. N. Lee, and K. J. Lee, "Human umbilical cord blood mononuclear cell transplantation in rats with intrinsic sphincter deficiency," *Journal of Korean Medical Science*, vol. 25, no. 5, pp. 663–670, 2010.

[10] Y. Xu and Y. Song, "Transplantation of muscle-derived stem cell plus fibrin glue restores urethral function in a pudendal nerve-transected rat model," *Neurourology and Urodynamics*, vol. 28, no. 7, pp. 822–823, 2009.

[11] X. H. Zou, Y. L. Zhi, X. Chen et al., "Mesenchymal stem cell seeded knitted silk sling for the treatment of stress urinary incontinence," *Biomaterials*, vol. 31, no. 18, pp. 4872–4879, 2010.

[12] L. K. Carr, D. Steele, S. Steele et al., "1-year follow-up of autologous muscle-derived stem cell injection pilot study to treat stress urinary incontinence," *International Urogynecology Journal*, vol. 19, no. 6, pp. 881–883, 2008.

[13] V. Sordi, "Mesenchymal stem cell homing capacity," *Transplantation*, vol. 87, no. 9, pp. S42–S45, 2009.

[14] Z. J. Liu, Y. Zhuge, and O. C. Velazquez, "Trafficking and differentiation of mesenchymal stem cells," *Journal of Cellular Biochemistry*, vol. 106, no. 6, pp. 984–991, 2009.

[15] R. A. Boomsma, P. D. Swaminathan, and D. L. Geenen, "Intravenously injected mesenchymal stem cells home to viable myocardium after coronary occlusion and preserve systolic function without altering infarct size," *International Journal of Cardiology*, vol. 122, no. 1, pp. 17–28, 2007.

[16] W. Jiang, A. Ma, T. Wang et al., "Intravenous transplantation of mesenchymal stem cells improves cardiac performance after acute myocardial ischemia in female rats," *Transplant International*, vol. 19, no. 7, pp. 570–580, 2006.

[17] M. Morigi, M. Introna, B. Imberti et al., "Human bone marrow mesenchymal stem cells accelerate recovery of acute renal injury and prolong survival in mice," *Stem Cells*, vol. 26, no. 8, pp. 2075–2082, 2008.

[18] M. Sasaki, R. Abe, Y. Fujita, S. Ando, D. Inokuma, and H. Shimizu, "Mesenchymal stem cells are recruited into wounded skin and contribute to wound repair by transdifferentiation into multiple skin cell type," *Journal of Immunology*, vol. 180, no. 4, pp. 2581–2587, 2008.

[19] A. Hijaz, F. Daneshgari, K. D. Sievert, and M. S. Damaser, "Animal models of female stress urinary incontinence," *Journal of Urology*, vol. 179, no. 6, pp. 2103–2110, 2008.

[20] A. S. Lin, S. Carrier, D. M. Morgan, and T. F. Lue, "Effect of simulated birth trauma on the urinary continence mechanism in the rat," *Urology*, vol. 52, no. 1, pp. 143–151, 1998.

[21] I. Kamo, Y. Kaiho, T. W. Canon et al., "Functional analysis of active urethral closure mechanisms under sneeze induced stress condition in a rat model of birth trauma," *Journal of Urology*, vol. 176, no. 6, pp. 2711–2715, 2006.

[22] D. D. Rahn, J. F. Acevedo, and R. A. Word, "Effect of vaginal distention on elastic fiber synthesis and matrix degradation in the vaginal wall: potential role in the pathogenesis of pelvic organ prolapse," *American Journal of Physiology*, vol. 295, no. 4, pp. R1351–R1358, 2008.

[23] W. R. Trevathan, *Human Birth: An Evolutionary Perspective*, Aldine de Gruyter, New York, NY, USA, 1987.

[24] H. M. Wood, M. Kuang, L. Woo et al., "Cytokine expression after vaginal distention of different durations in virgin Sprague-Dawley rats," *Journal of Urology*, vol. 180, no. 2, pp. 753–759, 2008.

[25] D. P. Lennon and A. I. Caplan, "Isolation of rat marrow-derived mesenchymal stem cells," *Experimental Hematology*, vol. 34, no. 11, pp. 1606–1607, 2006.

[26] I. Kepenekci, B. Keskinkilic, F. Akinsu et al., "Prevalence of pelvic floor disorders in the female population and the impact of age, mode of delivery, and parity," *Diseases of the Colon & Rectum*, vol. 54, no. 1, pp. 85–94, 2011.

[27] K. Davis and D. Kumar, "Pelvic floor dysfunction: a conceptual framework for collaborative patient-centred care," *Journal of Advanced Nursing*, vol. 43, no. 6, pp. 555–568, 2003.

[28] L. Viktrup, "The risk of lower urinary tract symptoms five years after the first delivery," *Neurourology and Urodynamics*, vol. 21, no. 1, pp. 2–29, 2002.

[29] A. Staack and L. V. Rodríguez, "Stem cells for the treatment of urinary incontinence," *Current Urology Reports*, vol. 12, pp. 41–46, 2011.

[30] L. M. Dolan, G. L. Hosker, V. T. Mallett, R. E. Allen, and A. R. B. Smith, "Stress incontinence and pelvic floor neurophysiology 15 years after the first delivery," *BJOG: An International Journal of Obstetrics and Gynaecology*, vol. 110, no. 12, pp. 1107–1114, 2003.

[31] G. S. Jack, R. Zhang, M. Lee, Y. Xu, B. M. Wu, and L. V. Rodríguez, "Urinary bladder smooth muscle engineered from adipose stem cells and a three dimensional synthetic composite," *Biomaterials*, vol. 30, no. 19, pp. 3259–3270, 2009.

[32] Y. Kinebuchi, N. Aizawa, T. Imamura, O. Ishizuka, Y. Igawa, and O. Nishizawa, "Autologous bone-marrow-derived mesenchymal stem cell transplantation into injured rat urethral sphincter," *International Journal of Urology*, vol. 17, no. 4, pp. 359–368, 2010.

[33] T. W. Cannon, J. Y. Lee, G. Somogyi et al., "Improved sphincter contractility after allogenic muscle-derived progenitor cell injection into the denervated rat urethra," *Urology*, vol. 62, no. 5, pp. 958–963, 2003.

[34] H. Strasser, R. Marksteiner, E. Margreiter et al., "Transurethral ultrasonography-guided injection of adult autologous stem cells versus transurethral endoscopic injection of collagen in treatment of urinary incontinence," *World Journal of Urology*, vol. 25, no. 4, pp. 385–392, 2007.

[35] J. Resplande, S. S. Gholami, T. M. Graziottin et al., "Long-term effect of ovariectomy and simulated birth trauma on the lower urinary tract of female rats," *Journal of Urology*, vol. 168, no. 1, pp. 323–330, 2002.

[36] K. D. Sievert, M. E. Bakircioglu, T. Tsai, S. E. Dahms, L. Nunes, and T. F. Lue, "The effect of simulated birth trauma and/or ovariectomy on rodent continence mechanism. Part I: functional and structural change," *Journal of Urology*, vol. 166, no. 1, pp. 311–317, 2001.

[37] M. S. Damaser, C. Whitbeck, P. Chichester, and R. M. Levin, "Effect of vaginal distension on blood flow and hypoxia of urogenital organs of the female rat," *Journal of Applied Physiology*, vol. 98, no. 5, pp. 1884–1890, 2005.

[38] L. L. Woo, A. Hijaz, M. Kuang, M. S. Penn, M. S. Damaser, and R. R. Rackley, "Over expression of stem cell homing cytokines in urogenital organs following vaginal distention," *Journal of Urology*, vol. 177, no. 4, pp. 1568–1572, 2007.

[39] W. Zhao, C. Zhang, C. Jin et al., "Periurethral injection of autologous adipose-derived stem cells with controlled-release nerve growth factor for the treatment of stress urinary incontinence in a rat model," *European Urology*, vol. 59, no. 1, pp. 155–163, 2011.

[40] N. Nagaya, T. Fujii, T. Iwase et al., "Intravenous administration of mesenchymal stem cells improves cardiac function in rats with acute myocardial infarction through angiogenesis and myogenesis," *American Journal of Physiology*, vol. 287, no. 6, pp. H2670–H2676, 2004.

[41] L. Perasso, C. E. Cogo, D. Giunti et al., "Systemic administration of mesenchymal stem cells increases neuron survival after global cerebral ischemia in vivo (2VO)," *Neural Plasticity*, vol. 2010, Article ID 534925, 5 pages, 2010.

[42] M. T. Harting, F. Jimenez, and C. S. Cox, "Isolation of mesenchymal stem cells (MSCs) from green fluorescent protein positive (GFP+) transgenic rodents: the grass is not always green(er)," *Stem Cells and Development*, vol. 18, no. 1, pp. 127–135, 2009.

[43] H. Q. Pan, J. M. Kerns, D. L. Lin, S. Liu, N. Esparza, and M. S. Damaser, "Increased duration of simulated childbirth injuries results in increased time to recovery," *American Journal of Physiology*, vol. 292, no. 4, pp. R1738–R1744, 2007.

[44] R. Das, H. Jahr, G. J. V. M. van Osch, and E. Farrell, "The role of hypoxia in bone marrow-derived mesenchymal stem cells: considerations for regenerative medicine approaches," *Tissue Engineering—Part B*, vol. 16, no. 2, pp. 159–168, 2010.

[45] C. Toma, M. F. Pittenger, K. S. Cahill, B. J. Byrne, and P. D. Kessler, "Human mesenchymal stem cells differentiate to a cardiomyocyte phenotype in the adult murine heart," *Circulation*, vol. 105, no. 1, pp. 93–98, 2002.

[46] T. Freyman, G. Polin, H. Osman et al., "A quantitative, randomized study evaluating three methods of mesenchymal stem cell delivery following myocardial infarction," *European Heart Journal*, vol. 27, no. 9, pp. 1114–1122, 2006.

[47] H. Song, B. W. Song, M. J. Cha, I. G. Choi, and K. C. Hwang, "Modification of mesenchymal stem cells for cardiac regeneration," *Expert Opinion on Biological Therapy*, vol. 10, no. 3, pp. 309–319, 2010.

[48] C. Dissaranan, B. Gill, M Cruz et al., "Intravenous mesenchymal stem cells facilitate recovery from stress urinary incontinence after childbirth injury," *Neurourology and Urodynamics*, vol. 30, no. 2, p. 235, 2011.

[49] I. M. Barbash, P. Chouraqui, J. Baron et al., "Systemic delivery of bone marrow-derived mesenchymal stem cells to the infarcted myocardium: feasibility, cell migration, and body distribution," *Circulation*, vol. 108, no. 7, pp. 863–868, 2003.

[50] P. Norton and I. Milsom, "Genetics and the lower urinary tract," *Neurourology and Urodynamics*, vol. 29, no. 4, pp. 609–611, 2010.

[51] M. H. Kerkhof, L. Hendriks, and H. A. M. Brolmann, "Changes in connective tissue in patients with pelvic organ prolapse—a review of the current literature," *International Urogynecology Journal*, vol. 20, no. 4, pp. 461–474, 2009.

[52] M. P. Wu, "Regulation of extracellular matrix remodeling associated with pelvic organ prolapse," *Journal of Experimental and Clinical Medicine*, vol. 2, no. 1, pp. 11–16, 2010.

[53] I. Diez-Itza, M. Arrue, L. Ibañez, A. Murgiondo, J. Paredes, and C. Sarasqueta, "Factors involved in stress urinary incontinence 1 year after first delivery," *International Urogynecology Journal*, vol. 21, no. 4, pp. 439–445, 2010.

[54] C. MacArthur, C. M. A. Glazener, P. D. Wilson, R. J. Lancashire, G. P. Herbison, and A. M. Grant, "Persistent urinary incontinence and delivery mode history: a six-year longitudinal study," *BJOG: An International Journal of Obstetrics and Gynaecology*, vol. 113, no. 2, pp. 218–224, 2006.

[55] D. Sarkar, P. K. Vemula, W. Zhao, A. Gupta, R. Karnik, and J. M. Karp, "Engineered mesenchymal stem cells with self-assembled vesicles for systemic cell targeting," *Biomaterials*, vol. 31, no. 19, pp. 5266–5274, 2010.

[56] L. Li, Y. H. El-Hayek, B. Liu et al., "Direct-current electrical field guides neuronal stem/progenitor cell migration," *Stem Cells*, vol. 26, no. 8, pp. 2193–2200, 2008.

[57] J. Zhang, M. Calafiore, and Q. Zeng, "Electrically guiding migration of human induced pluripotent stem cells," *Stem Cell Reviews and Reports*. In press.

[58] K. E. Hammerick, M. T. Longaker, and F. B. Prinz, "In vitro effects of direct current electric fields on adipose-derived stromal cells," *Biochemical and Biophysical Research Communications*, vol. 397, no. 1, pp. 12–17, 2010.

[59] A. Shabbir, D. Zisa, G. Suzuki, and T. Lee, "Heart failure therapy mediated by the trophic activities of bone marrow mesenchymal stem cells: a noninvasive therapeutic regimen," *American Journal of Physiology*, vol. 296, no. 6, pp. H1888–H1897, 2009.

Hindawi Publishing Corporation
Obstetrics and Gynecology International
Volume 2012, Article ID 672356, 4 pages
doi:10.1155/2012/672356

*Clinical Study*

# Is Mesh Becoming More Popular? Dilemmas in Urogynecology: A National Survey

**Alexander Condrea,[1,2] Itamar Netzer,[3] Shimon Ginath,[1,2] Joseph Eldor-Itskovitz,[3] Abraham Golan,[1,2] and Lior Lowenstein[3]**

[1] *Edith Wolfson Medical Center, 62 HaLohamim Street, P.O. Box 5, Holon 58100, Israel*
[2] *Sackler Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel*
[3] *Department of Obstetrics and Gynecology, Ruth and Bruce Rappaport Faculty of Medicine, Technion-Israel Institute of Technology, Rambam Health Care Campus, 6 Ha'Aliya Street, P.O. Box 9602, Israel*

Correspondence should be addressed to Lior Lowenstein, lowensteinmd@gmail.com

Received 14 July 2011; Revised 13 September 2011; Accepted 19 September 2011

Academic Editor: Kimberly Kenton



The use of vaginal mesh in pelvic organ prolapse (POP) repair surgery has become more common in recent years. The purpose of the current study was to evaluate the common practice of Israeli urogynecologists, and to determine whether surgical practice has changed over the last two years. *Methods*. In 2009 and again in 2011, a survey was mailed to all urogynecologists affiliated with an academic institute in Israel. The survey consisted of 7 Likert-scale items and 3 open questions; the latter inquired about preferred type of surgery in three clinical scenarios. *Results*. Of 22 practitioners, 15 responded to the survey. The number of urogynecologists who reported using vaginal mesh for the repair of primary POP increased from 47 to 67% from 2009 to 2011. The number who would not use vaginal mesh in POP repair of elderly patients dropped from 60 to 3%. Finally, for the treatment of a 35-year-old patient with stage III uterine prolapse who desired to preserve fertility, 13% recommended the used vaginal mesh in 2009 compared with 47% in 2011. *Conclusion*. A survey of practitioners shows that the use of vaginal mesh for the repair of primary and recurrent pelvic organ prolapse has become more common among Israeli urogynecologists.

## 1. Introduction

The use of vaginal mesh in pelvic organ prolapse repair surgery has recently become more common [1]. A number of prolapse repair mesh devices have been designed by different companies and marketed extensively as a minimally invasive approach to pelvic floor repair. A Cochrane Collaboration review entitled "*Surgical management of pelvic organ prolapse in women,*" and based on 3773 patients in 40 trials, was published in 2010 [2]. The authors concluded that abdominal sacral colpopexy is associated with a lower rate of recurrent vault prolapse (RR 0.23, 95% CI 0.07–0.77) and dyspareunia (RR 0.39, 95% CI 0.18–0.86) than vaginal sacrospinous colpopexy, though the latter was found to have a shorter operating time. The use of mesh or graft inlays at the time of anterior vaginal wall repair was found to reduce the risk of recurrent anterior wall prolapse. Standard anterior repair was associated with more anterior compartment failures on examination than was polypropylene mesh repair as an overlay (RR 2.14, 95% CI 1.23 to 3.74) or armed transobturator mesh (RR 3.55, 95% CI 2.29 to 5.51) [2]. However, due to the paucity of peer-reviewed manuscripts, the authors advised relating to this procedure with caution. Reliable long-term data on the effect of vaginal mesh in pelvic organ prolapse surgery is particularly lacking.

Subsequent to a metaanalysis of the use of vaginal mesh in pelvic organ prolapse repair surgery, the Society

of Gynecologic Surgeons Systematic Review Group (SGS-SRG) issued two publications, "*Clinical practice guidelines on vaginal graft use*" [3] and "*Graft use in transvaginal pelvic organ prolapse repair, a systematic review*" by Sung et al. [4]. The objective of the former was to establish guidelines regarding the employment of synthetic grafts or native tissue repair in POP repair [3]. Weak evidence was found for the superiority of native tissue repair in anterior vaginal wall repair, when compared with biologic graft (4 trials). Weak evidence was also found for the superiority of native tissue repair in anterior vaginal wall repair, when compared with absorbable synthetic graft (2 trials) [3]. Moreover, weak evidence was found for nonabsorbable synthetic mesh improving anatomic outcomes of anterior vaginal wall repair, albeit with significant tradeoffs in regard to the risk of adverse events (2 trials). Regarding the superiority of native tissue repair for posterior prolapse versus absorbable synthetic graft or biologic graft, evidence was also weak (3 trials). Finally, no comparative studies were found that addressed the use of biologic grafts in multiple compartment repair compared with native tissue repair; the use of absorbable synthetic graft in multiple compartment vaginal wall repair compared with native tissue repair, or the use of nonabsorbable synthetic graft in multiple compartment repair compared with native tissue repair [3]. In conclusion, the authors noted that while the data supporting a lower rate of prolapse recurrence in graft use is limited, physicians should nevertheless consider and communicate to patients the seemingly improved durability of the procedure in the face of potential adverse events [4].

Due to the insufficient evidence, from a medical-legal point of view, the best course of action regarding the use of vaginal mesh in POP is a matter of debate. Some advocate that distinct informed consent be obtained for the use of vaginal mesh [5]. However, in a letter to the editor, Ann Weber states, "obtaining informed consent from patients for vaginal mesh placement during prolapse surgery cannot be achieved in light of the current dearth of data regarding risks and benefits [6]," and suggests that such procedures be regarded as "experimental."

Despite the paucity of peer-reviewed studies on the use of vaginal mesh in pelvic floor prolapse repair, professional interest seems on the rise in recent years. A search of the PubMed database for the keywords "vaginal mesh" yields 118 articles published in 2009, 98 in 2010, and 53 as of July 2011, in all languages. These include randomized trials, basic science (e.g., ultrasound, histology, and animal models), case reports, retrospective series, guidelines, professional surveys, and reviews.

The purpose of the current study was to evaluate the common practice of Israeli urogynecologists, and to evaluate trends in the practice of pelvic organ prolapse repair during the last two years.

## 2. Materials and Methods

An electronic survey was mailed to all fellowship-trained urogynecologists affiliated with an academic institute in Israel, in 2009 and again in 2011. The survey consisted of 7 Likert-scale score items and 3 open questions. Possible responses to the 7-point Likert-score questions ranged from "none of the time" to "all of the time." Subjects included general mesh use; mesh use in light of comorbidity (diabetes, menopause, and stress urinary incontinence); and considerations of other factors (sexual activity, fertility). See The appendix for the full questionnaire. The open questions inquired about preferred type of surgery in three clinical scenarios. Participants were instructed not to consider financial factors in their decision making. Surveys were mailed back anonymously.

## 3. Statistical Analysis

SPSS for Windows version 18 (SPSS, Inc., Chicago, IL) was used for data management and statistical analysis. The chi-square test was used for comparison between dependent groups of categorical variables. All tests were considered significant at the .05 level. All tests were 2 sided.

## 4. Results

The response rate of those who answered both in 2009 and 2011 was 68% (15/22). An increase in the number of urogynecologists who reported "frequently" or "almost always" using vaginal mesh for the repair of primary POP increased from 47 to 67%. Similarly, for recurrent POP, the number who would use vaginal mesh increased from 80 to 93%. For women older than 70 years, 60% of urogynecologists in 2009 compared with 33% in 2011 stated that they will rarely or never use meshes for POP repair.

Regarding a case of a 55-year-old sexually active woman with uterine prolapse stage III, there was no change in the practice of the surveyed urogynecologists, with none of the participants choosing to perform abdominal or laparoscopic surgery, instead participants recommended vaginal hysterectomy and apical suspension with or without graft insertion. Regarding an 80-year-old healthy women with procidentia, only 13% chose to perform colpocleisis in 2009 compared with 47% in 2011 ($P < 0.001$). Finally, regarding the case of a 35-year-old patient with stage III uterine prolapse who desired to preserve fertility, 2 (13%) recommended Manchester surgery with the insertion of vaginal mesh in 2009 while 7 (47%) recommended the use of mesh in 2011, with only one of them recommending Manchester surgery ($P < 0.001$).

## 5. Discussion

This survey shows an increasing trend in the use of vaginal mesh for pelvic organ prolapse (POP) repair by Israeli pelvic floor surgeons over the last two years. This was apparent for

primary and recurrent POP repair, as well as for POP repair in patients presenting with concomitant disease, menopause, or lifestyle considerations. Importantly, in women desiring preservation of fertility, there appears to be a marked increase in the use of mesh in hysteropexy, which may reflect on increase in documentation of favorable results pertaining to pregnancy [7, 8]. The reported increase in the use of colpocleisis may result from current training of physicians, and increased caution by urogynecologists regarding possible mesh complications in the elderly population.

The use of vaginal meshes in POP repair has increased in Israel despite the lack of randomized controlled trials supporting such use, and despite seemingly unresolved legal complications regarding the extent of patients' consent. The latter issue is not merely a technicality—long-term stability and risks of complications from these procedures are as yet unknown. Nevertheless, the reasons for the growing popularity of vaginal mesh are varied. First, Israeli surgeons practice medicine in an environment characterized by innovation and scientific progress, exemplified by Israel's reputation as a world leader of biotechnological research and development. Second, the boon of new mesh products, accompanied by powerful marketing efforts, has made a wide array of vaginal mesh products available to surgeons. Third, experience and mastery of the use of vaginal meshes may alleviate previous reservations in favor of the new technology. Fourth, and perhaps of prime importance, the ease of use of the new mesh products, along with physicians' own experience about better durability in POP repair with mesh compared with native tissue, is making them lucrative for most gynecologists.

The use of a nonvalidated questionnaire is a limitation of the current study. Further, its anonymity precluded assessment of such characteristics of urogynecologists as number of years in practice and place of training. Most importantly, we have no data regarding the number of vaginal mesh procedures that were actually performed by each gynecologist, which may constitute a reporting bias on the part of the respondents.

## 6. Conclusion

The survey reported herein demonstrates a recent increase in the popularity of vaginal mesh use for the repair of pelvic organ prolapse among Israeli urogynecologists.

Randomized controlled trials of the use of vaginal mesh for POP repair are needed to determine optimal indications for their use. In the meantime, caution should be advised in the application of this yet unproven technology [4].

## Appendix

### Survey Questionnaire

Questions 1–3 pertain to women referred due to stage 3 prolapse of at least one compartment.

| | Always | | | | | Never |
|---|---|---|---|---|---|---|
| | 5 | 4 | 3 | 2 | 1 | 0 |
| (1) Use of vaginal mesh in primary POP repair | 5 | 4 | 3 | 2 | 1 | 0 |
| (2) Use of vaginal mesh in recurrent POP repair | 5 | 4 | 3 | 2 | 1 | 0 |
| (3) Would you use a vaginal mesh in a patient who is disinterested in sexual intercourse? | 5 | 4 | 3 | 2 | 1 | 0 |
| (4) Would you use a vaginal mesh in women over 70 years of age? | 5 | 4 | 3 | 2 | 1 | 0 |
| (5) Do you consider insulin dependent diabetes mellitus a contraindication to vaginal mesh use? | 5 | 4 | 3 | 2 | 1 | 0 |
| (6) In a menopausal patient with a stage III prolapse of one vaginal wall and stage II uterine prolapse, would you prefer to *preserve* the uterus? | 5 | 4 | 3 | 2 | 1 | 0 |
| (7) In a menopausal patient with stage I uterine prolapse and stage III elongation of uterine cervix, would you prefer to preserve the uterus? | 5 | 4 | 3 | 2 | 1 | 0 |

(8) A healthy, physically, and sexually active 55 year old. Diagnosis: stage III uterine prolapse, stage III cystocele, gaping introitus, stress urinary incontinence.
Your choice of procedure: .....

(9) A healthy 80-year-old patient who is not sexually active. Diagnosis: total prolapse.
Your choice of procedure: .....

(10) A 35-year-old woman desiring preservation of fertility. Diagnosis: stage III uterine prolapse, stage II cystocele, stage II rectocele (pessary treatment failed).
Your choice of procedure: .....

## References


[1] B. Feiner, J. E. Jelovsek, and C. Maher, "Efficacy and safety of transvaginal mesh kits in the treatment of prolapse of the vaginal apex: a systematic review," *International Journal of Obstetrics and Gynaecology*, vol. 116, no. 1, pp. 15–24, 2009.

[2] C. Maher, B. Feiner, K. Baessler, E. J. Adams, S. Hagen, and C. M. Glazener, "Surgical management of pelvic organ prolapse in women," *Cochrane Database of Systematic Reviews*, vol. 4, Article ID CD004014, 2010.

[3] M. Murphy, "Clinical practice guidelines on vaginal graft use from the society of gynecologic surgeons," *Obstetrics and Gynecology*, vol. 112, no. 5, pp. 1123–1130, 2008.

[4] V. W. Sung, R. G. Rogers, J. I. Schaffer et al., "Graft use in transvaginal pelvic organ prolapse repair: a systematic review," *Obstetrics and Gynecology*, vol. 112, no. 5, pp. 1131–1142, 2008.

[5] S. J. Mucowski, C. Jurnalov, and J. Y. Phelps, "Use of vaginal mesh in the face of recent FDA warnings and litigation," *American Journal of Obstetrics and Gynecology*, vol. 203, no. 2, pp. 103.e1–103.e4, 2010.

[6] A. M. Weber, "Informed consent cannot be obtained for use of vaginal mesh," *American Journal of Obstetrics and Gynecology*, vol. 204, no. 3, article e6, 2010.

[7] M. Hefni and T. El-Toucky, "Uterine prolapse in young women," *Bailliere's Best Practice and Research*, vol. 25, no. 2, pp. 157–165, 2010.

[8] B. Ridgeway, A. C. Frick, and M. D. Walter, "Hysteropexy: a review," *Minerva Ginecologica*, vol. 60, no. 6, pp. 509–528, 2008.

Hindawi Publishing Corporation
Obstetrics and Gynecology International
Volume 2012, Article ID 649459, 9 pages
doi:10.1155/2012/649459

*Review Article*

# Uterine Prolapse: From Antiquity to Today

**Keith T. Downing**

*Division of Female Pelvic Medicine and Reconstructive Surgery, Department of Obstetrics & Gynecology and Women's Health, Albert Einstein College of Medicine/Montefiore Medical Center, Bronx, NY 10461, USA*

Correspondence should be addressed to Keith T. Downing, kdowning@montefiore.org

Received 2 June 2011; Revised 26 August 2011; Accepted 26 August 2011

Academic Editor: Hans Peter Dietz



Uterine prolapse is a condition that has likely affected women for all of time as it is documented in the oldest medical literature. By looking at the watershed moments in its recorded history we are able to appreciate the evolution of urogynecology and to gain perspective on the challenges faced by today's female pelvic medicine and reconstructive surgeons in their attempts to treat uterine and vaginal vault prolapse.

"*He who cannot render an account to himself of at least three thousand years of time, will always grope in the darkness of inexperience*"
Goethe, Translation of Panebaker

## 1. Introduction

This special issue provides urogynecologists with the opportunity to explore recent advances that have and will continue to propel our subspecialty forward. Simultaneously, it provides us with the opportunity to look back and appreciate the landmark moments that have led us to our current state of affairs. It is with this spirit, mindful of Goethe's words, that this paper will focus its attention on a brief history of the management of uterine prolapse.

## 2. Antiquity to the Common Era

Uterine prolapse is an ailment that has seemingly affected women for all of time. In fact, the problem of uterine prolapse and its potential treatment is described in the oldest documented medical literature, the Egyptian Papyri, where it is written, "of a woman whose posterior, belly, and branching of her thighs are painful, say thou as to it, it is the falling of the womb," (Kahun papyrus ca. 1835 B.C.E.) [1]. The Ebers papyrus goes on to recommend "to correct a displaced womb: with oil of earth (petroleum) with fedder (manure) and honey; rub the body of the patient," (Ebers papyrus ca. 1550 B.C.E.) [2].

Over one thousand years later, during the time of Hippocrates (c. 460–377 B.C.E.) and the subsequent generations that he influenced, the prevailing medical thought was that the uterus acted as an animal unto itself. This concept led to treatments such as fumigation, in which pleasant fumes would be placed at a woman's head and vile ones near her prolapsed womb, in order to stimulate the uterus to retreat. Polybus, a pupil of Hippocrates (and his son-in-law), wrote in his noted text "On Diseases of Women," of other therapies for uterine prolapse including the application of an astringent to the womb followed by placement of a vinegar soaked sponge, or halved pomegranate. If these measures failed, women were subjected to succussion—the practice of tying a woman upside down by her feet to a fixed frame and bouncing her repeatedly until her prolapse reduced then leaving her bed bound for three days with her legs tied together [3].

However, a gradual shift in medical thought began to occur toward the end of the Hippocratic era. Medicine slowly began to free itself from the influence of theurgy. By the first century C.E. Soranus, the most notable gynecologist of antiquity, would rebuke the Hippocratic approaches to treating uterine prolapse. He considered fumigation nonsensical, regarded the use of pomegranates as bruising, and deemed

succussion unbearable. Instead, in his monumental treatise, "Gynecology," Soranus prescribed the following: "... bathe the prolapsed part of the uterus with much lukewarm olive oil, and make a woolen tampon corresponding in shape and diameter to the vagina and wrap it in very thin clean linen... one should dip it briefly in vinegar... acacia juice... or wine, and apply it to the uterus and move the whole prolapsed part, forcing it up gently until the uterus has reverted to its proper place and the whole mass of wool is in the vagina" [4]. Yet, despite this therapeutic advance, outdated notions about the uterus would persist. As late as the second century C.E., prominent Greek physician Aretaeus the Cappadocian, in his "Causes and Indications of Acute and Chronic Diseases," still described the uterus as, "an animal within an animal" [5].

Despite Soranus's vast knowledge of obstetrics and gynecology, female pelvic anatomy remained poorly understood. Physicians of the age commonly referred to the uterus as mater (Latin for mother) or hystera (Greek for womb) in the plural form, believing the uterus consisted of more than one chamber [3]. Had it not been for Rome's prohibition on the use of human cadavers, this belief might have been dispelled by the work of Galen, the Rome based physician and anatomist. However, Galen was left to extrapolate his understanding of human anatomy from dissections and vivisections of lower animals in which the finding of uterine horns was commonplace [3].

The Mediaeval era brought about a return to theurgy, and medicine, including the management of uterine prolapse, regressed. It was during the Middle Ages that fantastical concepts regarding female pelvic anatomy emerged. The seven cells doctrine was one such concept. It stated that the uterus consisted of seven compartments, three on each side and one in the middle and posited that female fetuses developed on the left, male fetuses on the right, hermaphrodites in the middle [6]. Beliefs from the Hippocratic era resurfaced and as late as 1603, a text by Roderigo de Castro advised that the prolapsed uterus, "be attacked with a red-hot iron as if to burn, whereupon fright will force the prolapsed part to recede into the vagina" [3]. While the practice of medicine during the Middle Ages left much to be desired, in the middle of the fifteenth century changes in the way people thought about art and philosophy would soon lead to new ways of thinking in medicine.

The Renaissance grew out of Florence where a collection of artists and intellectuals began to focus on the works and ways of the classical age. This led to a renewed attention to the beauty of nature, including the human form [7]. Artists took part in private anatomic dissections to advance their training, something physicians of that time had yet to do in a consistent way [3]. Unfortunately, drawings by master artists such as Leonardo di Vinci did not receive notice by the physicians of the era, but the works of others would. In the early sixteenth century, Berengario da Carpi, professor at Bologna and Pavia, would produce drawings of the female uterus and would be the first to state clearly that the uterus consisted of one cavity [3, 6]. Two decades later Andreus Vesalius, professor of anatomy at Padua, with the aid of his illustrator, John of Calcar, would produce his epochal, "De Corporis Humani Fabrica." In this work, Vesalius would reproduce an accurate description of the entire female genital tract including the ligaments of the uterus [6]. With this accomplishment, Vesalius and his disciples lifted the veil that had obscured the intricacies of the female genitourinary tract, ultimately helping physicians to better understand female pelvic floor anatomy.

## 3. Evolution of the Pessary

By the close of the sixteenth century, the management of uterine prolapse became more firmly rooted in the use of pessaries. Pessaries would evolve from lint balls or halved fruit soaked in vinegar to something closer to their modern form. This shift was largely due to the inventiveness of France's royal surgeon, Ambroise Paré. Paré devised oval shaped pessaries of brass and waxed cork. He attached thread to them to facilitate their removal, while others were to be worn with belts to help them remain in situ [8]. In the eighteenth century, Henrick van Deventer, who started his career as a goldsmith, made pessaries of various shapes and sizes out of waxed cork or wood, and metals such as silver and gold [9]. By the mid-nineteenth century, pessary use had become quite common. Yet, alternative methods of managing prolapse were still prescribed. These included the use of astringents such as tannin and alum; cold sitz baths, surf bathing, and sea-water douches; postural exercises; Brandt's "uterine gymnastics" which embodied anointing, massage, and manual replacement of the prolapsed parts; leeching; torsion of the uterus; attempts to produce fibrosis of the surrounding tissues by the introduction of gonorrheal exudates into the vagina or the deliberate induction of pelvic peritonitis [10].

Hugh Hodge of Philadelphia (who was concerned with ailments he believed to be caused by uterine retroversion) was a major proponent of pessary use. He shared the sentiments of many gynecologists in the United States and abroad when, in 1860, he proclaimed pessary use to be the "sine qua non" for the treatment of uterine displacements [11]. He put forth the following as the ideal qualities for a pessary: it should be made of incorruptible material, maintain the normal uterine position, allow for natural movement, be worn without pain, and not excite leucorrhea or menorrhagia [12]. The first of these, to be incorruptible, came to pass in 1844 when Charles Goodyear was granted U.S. patent no. 3,633 for the invention of vulcanized rubber [13]. Before then, pessaries had consisted of wax, wood, leather, glass, and metal. Now a material could be used that resisted decomposition. This ultimately led to the development of Hodge's eponymous lever pessary and was followed by an explosion in the number and variety of pessaries put to use by gynecologists. It was said in those years that fortunes were made by two groups of gynecologists: those who inserted pessaries and those who removed them (a bit reminiscent of vaginal mesh use today) [12].

However, not everyone in the profession was so keen on pessary use. In 1866, during his satirical presidential address to the New Hampshire State Medical Society, W. D. Buck commented, "The Transactions of the National Medical Association for 1864 has figured one hundred and

twenty-three different kinds of pessaries, embracing every variety, from a simple plug to a patent threshing machine, which can only be worn with the largest hoops. They look like the drawings of turbine water-wheels, or a leaf from a work on entomology. Pessaries, I suppose, are sometimes useful, but there are more than there is any necessity for. I do think that this filling the vagina with such traps, making a Chinese toy-shop of it, is outrageous" [14]. Despite this sentiment, pessaries would remain popular throughout the eighteen hundreds. However, with the discoveries in asepsis by Lister and anesthesia by Morton, paired with advances in suture materials and surgical instruments, surgery would soon replace the pessary as the predominant method of treating uterine prolapse.

## 4. The Rise of Surgery

The surgical management of uterine prolapse has been recorded as far back as the second century C.E. Soranus advised, "cutting off the black part," when the prolapsed uterus became gangrenous [4]. Similarly, Berengario claimed he witnessed his father, a surgeon, remove a prolapsed uterus by scalpel asserting that not only had the patient survived, but also she was able to resume coitus. He later claimed to have achieved the same outcome using strong twine as an ecraseur [3]. Later, the prominent seventeenth century Dutch gynecologist Hendrik van Roonhuyse reported a case in which he extirpated a prolapsed uterus after multiple attempts by other caregivers had failed to adequately restore the organ (previously placed pessaries made of cork and wax had led to ulcerations, pain, foul discharge, putrefaction, and fever). The patient was reported to have survived, but van Roonhuyse provided no details of his surgical technique or of an anesthetic used, if any [3]. In these early reports it remains unclear whether "hysterectomy" meant removal of the cervix, the cervix and a portion of the uterus, or the uterus in total.

During the mid to late 19th century, opening the peritoneum for any indication remained a risky endeavor and was largely reserved for cases of presumed gynecologic malignancy [15]. Consequently, surgical attempts to treat uterine prolapse consisted of efforts such as narrowing the vaginal vault (by colporrhaphy or the application of cautery or astringents), performing a perineorrhaphy or infibulation, or offering cervical amputation [10]. However, as the 19th century progressed, notable advances would take place. In 1877, the Frenchman LeFort—influenced by the works of German gynecologists such as Hegar, Simon, and Spiegelberg, who had the idea of occluding the vaginal introitus to restrain uterine prolapse—described the principle of partial colpocleisis, the operation that has borne his name since [16]. In 1886, Olshausen reported performing a laparotomy solely for the purpose of uterine ventrofixation [17]. In 1899, Watkins and Wertheim separately reported on the use of uterine interposition to treat uterine prolapse [12]. Although, by the end of the nineteenth century there were several treatments for uterine prolapse, the ability to achieve durable repairs remained elusive due to a limited understanding of female pelvic floor anatomy.

## 5. Mechanisms of Uterine Support

In 1895, while practicing in Berlin, Alwin Mackenrodt published his comprehensive, and accurate, description of the female pelvic floor connective tissue. In regard to what have become known as the Cardinal or Mackenrodt ligaments he remarked: "This whole ligamentous apparatus appears so excellent and extensive that it is quite surprising that it has not been recognized previously" [12]. Shortly thereafter, Fothergill, building upon the work of his senior colleague, the prominent Manchester obstetrician gynecologist Archibald Donald, recognized the importance of the Cardinal ligaments to uterine support and perfected what became known as the Manchester-Fothergill surgery. Fothergill's procedure involved dissecting the bladder off the lower uterine segment followed by plication of the parametrial and paravaginal tissue at the anterior aspect of the cervix, thus effectively shortening the uterine supports. He would combine the aforementioned steps with an anterior and posterior colporrhaphy and perineoplasty to keep recurrence in check [12, 18] and later would advocate cervical truncation as part of the surgery [19]. Fothergill would become a vociferous proponent of the belief that the parametrial (and paravaginal) fascia was the key structure to maintaining uterine support [20]. Referring to Peter Thompson's research on the comparative morphology of the levator ani muscles in tailed apes and man [21], he considered the levator ani muscles withered muscle bodies no longer required to carry out their original function (tail movement) and therefore deemed them inadequate supports for the uterine body. He remarked, "Injuries to the perineum and levator ani doubtless straighten and widen the road from the pelvic cavity to the exterior. But if the organs remain firmly attached above, no mere enlargement of the opening below will make them come down." To bolster his thesis, Fothergill was fond of noting, "The true supports of the uterus can be seen at vaginal hysterectomy… Let him incise… round the cervix, and… freely divide the posterior attachments...Next let the operator deliver the fundus… this affords another proof that the broad and round ligaments have no value as suspenders… the uterus still remains fixed by the tissue known as the parametrium, and by this alone. Until this is divided… the organ is… as completely supported as before an incision was made" [20].

In 1934, Bonney published, "The Principles that Should Underlie All Operations for Prolapse." Using basic analogies such as an in-turned finger of a rubber glove and the securing of stove piping in a metal box, Bonney was able to convey the manner in which the pelvic viscera are supported [22]. These concepts would later be refined by DeLancey and described as levels of fascial supports: level I: proximal suspension; level II: lateral attachments; level III: distal fusion [23].

In 1936, Mengert, inspired by 1858 cadaveric data from Legendre and Bastien, published a simple but influential study in which cadaveric uteri were subjected to traction with a 1 kg weight while structures attached to the uterus were severed in various sequences. The uterine descent observed after incising the parametrial tissues reinforced Mackenrodt's anatomic research and Fothergill's clinical observation,

suggesting the parametrial and paravaginal tissues (i.e., cardinal and uterosacral ligaments) were the primary support structures for the uterus [24].

However, Mackenrodt and Fothergill were not lone voices. In 1907, a gynecologist, Josef Halban, and anatomist, Julius Tandler, professors at the famed Vienna Medical School [25], published Anatomie und Atiologie der Genitalprolapse beim Weibe [26]. Their thesis on uterine support was quite contradictory to Mackenrodt and Fothergill's. Halban and Tandler maintained that the pelvic fascia was like a spider's web, able to bear the proper weight of the spider, but incapable of supporting a greater, abnormal burden [27]. Thus, it was the levator ani muscles that were essential to maintaining uterine support. Like Fothergill, they too turned to the comparative anatomic work of Peter Thompson but drew a different conclusion. Consistent with a prime tenet of the Vienna School, form follows function [25], Halban and Tandler viewed the functional adaptation of the levator ani muscles from their tail wagging purpose to that of maintaining pelvic floor support as evidence they were not superfluous muscle bodies (otherwise they would have regressed with the tail), but significant [28]. Others who were sympathetic to Halban and Tandler's thesis would point to the observation of large prolapses in patients with maldeveloped pelvic floor muscles from spina bifida, to the work of Goff, who asserted that the "fascia" described in vaginal plastic procedures was the "loosely arranged areolar type," as well as the work of Berglas and Rubin, who demonstrated the complete absence of ligamentous material in the endopelvic fascia [27, 29, 30]. In time, pelvic floor surgeons would recognize the importance of both structures [31] influencing new approaches to repair uterine prolapse.

## 6. Vaginal Hysterectomy and Vault Prolapse

Vaginal hysterectomy was first performed and developed in attempts to treat cervical and uterine malignancies [15]. The first vaginal hysterectomy for uterine prolapse was reported by Choppin, of New Orleans, in 1861. The surgery was conducted under chloroform and the removal of the uterus, after it was dissected away from the bladder and rectum, was excised using "Chassaignac's Ecraseur." A little more than a month after the surgery, Choppin presented the patient to the class of the New Orleans School of Medicine, the patient holding the specimen in hand [32]. Choppin's success was a rarity. However, as the new century arrived this fact would change. By 1915, Mayo would publish his technique for vaginal hysterectomy [33], as would Bissell, in 1918, coupling his technique of vaginal hysterectomy with an anterior and posterior colporrhaphy [34]. The rapid rise of surgery for the correction of uterine prolapse in the early twentieth century left one American gynecologist to write in 1923, "Gynecology has become so predominantly a surgical specialty... the young gynecologist of today frequently has no conception of what the pessary is meant to do and he is apt to be even irritated at the suggestion that such an implement should be accorded at least a modest position in his armamentarium" [35]. In the spring of 1937, at the sixty-second Annual Meeting of the American Gynecological Society, Baer and his colleagues reported on the type of operations performed for uterine prolapse in 1928 compared to those performed in 1937. They noted that by the latter date vaginal hysterectomy had become the predominant operation, replacing interposition [36]. Modifying the surgical methods established by Mayo, and others, McCall, in 1957, published his technique of obliterating the cul-de-sac of Douglas to cure an enterocele and prevent subsequent vault prolapse [37]. By the mid-twentieth century, vaginal vault prolapse had become a recognized sequela of hysterectomy. Thus, in 1965, Symmonds and Sheldon were able to report on the number of posthysterectomy vaginal vault prolapse cases they had observed at the Mayo Clinic [38].

Surgical attempts to correct posthysterectomy vault prolapse were made as early as the nineteen twenties. In 1927, Miller described a technique to reduce vault prolapse that amounted to a bilateral, transperitoneal iliococcygeus suspension (or, depending upon the actual depth of suture placement, a bilateral sacrospinous fixation) [39]. Others would follow with modifications of established procedures such as ventrofixation [40], with or without the use of a biograft [41, 42]. However, it was Arthure and Savage from Charing Cross Hospital in London who would make the most lasting impact on the repair of apical defects. They recognized that vault prolapse could occur after abdominal or vaginal hysterectomy, total or subtotal: hysterectomy alone would not cure uterine prolapse. They analyzed the surgical techniques used at the time and noted the faults of each. In 1957, they published their surgical technique of sacral hysteropexy believing it to be a better anatomic repair that would prove to have superior durability and less risk of enterocele formation. The description they provided, save the use of a graft, is nearly identical to the abdominal sacrocolpopexy performed today (they even noted the importance of keeping the repair tension free while using the sacral promontory as a fixation point) [43].

Long before the sacral promontory had been considered a fixation point for correcting apical prolapse, Zweifel of Germany, in 1892, commented on his attempts to correct uterovaginal prolapse by using silkworm sutures to unilaterlly affix the upper vagina to the sacrotuberous ligament

[44]. The use of the sacrotuberous ligament to anchor vault prolapse was not attempted again until another German, J. Amreich, in the 1950s, reported on his experience using a transgluteal (Amreich I) and transvaginal (Amreich II) approach to a vaginal-sacrotuberal fixation [44]. Two other German gynecologists, Sederl and Richter, avoided the difficult-to-access sacrotuberous ligament in favor of the sacrospinous ligament, while attempting to repair vault prolapse transvaginally [45, 46]. Richter's operative success popularized his technique across Europe and also stimulated the interest of two American gynecologists, Randall and Nichols. In 1971, Randall and Nichols reported the surgical outcomes of 18 patients who underwent transvaginal sacrospinous fixation for vault prolapse performed over the previous four years. They found the operation restored the normal vaginal depth and felt it to be an effective operation in women with vault prolapse and in those who were found

to have insufficient uterosacral or cardinal ligament strength at the time of vaginal hysterectomy [47].

Since Randall and Nichols' 1971 publication, the procedure has changed little [48, 49]. The most notable modifications have been related to instrumentation: the introduction of the Miya Hook [50], the Shutt needle driver [51], and the Laurus needle driver, presently known as the Capio (Boston Scientific, Natick, MA) [52]. Other reported surgical approaches to correct vault and advanced uterine prolapse include the iliococcygeus fixation (first described by Inmon) [53], endopelvic fascia fixation [54, 55], coccygeous muscle fixation [56], high uterosacral ligament suspension [57, 58], and levator myorrhaphy [59]. Thus, upon exiting the twentieth century, it had been the effort and ingenuity of a multitude of accomplished surgeons, attempting to prevent and correct vaginal vault prolapse, which led to many of the surgical techniques presently used to correct advanced apical prolapse. Notably, of the surgeries established in the nineteenth century, only the LeFort colpocleisis has endured.

## 7. Quantifying Prolapse

In October 1995, the International Continence Society formally adopted the document that would introduce the Pelvic Organ Prolapse Quantification (POP-Q) to the larger gynecology community. This document, three years in the making, and validated in six centers in Europe and the United States, would replace Baden-Walker and other descriptive measures as the means to objectively report findings of pelvic organ prolapse [60]. Subsequently, the POP-Q has become the standard means by which to report pelvic organ prolapse in the international literature and has been increasingly embraced by physicians in their clinical practices [61]. However, the POP-Q is not without its potential confounders [62, 63]. Thus, both clinicians and clinical investigators have turned to the various imaging modalities that allow for in situ evaluation of the female pelvic organs and their supporting structures.

Imaging pelvic floor anatomy can be traced back to Berglas and Rubin's method of levator myography in which they injected radio-opaque dye into the levator ani muscles, vagina, and endocervix, revealing by X-ray that the vagina did not rest at a steep incline, but rather lie almost horizontal, parallel to the levator plate [64]. Since that time, both magnetic resonance imaging (MRI) and sonography have advanced notably to better visualize the pelvic floor. Hedvig Hricak first described female pelvic anatomy by MRI in 1983 [65]; however, he was most concerned with its ability to differentiate benign versus malignant conditions involving the pelvic organs [66]. Yang and colleagues, in 1991, would introduce dynamic MRI. This would allow MR images to be taken during valsalva [67]. Further, 2D and 3D MRI has been used in research studies to evaluate levator ani status in women with and without pelvic floor disorders [68, 69].

The most recent advances in MRI technology, such as HASTE (half-Fourier-acquisition single shot turbo spin echo technology), FISP (fast imaging with steady-state free precession), and TSE (turbo spin-echo), allow for the fast acquisition of images simultaneously in all three compartments (anterior, central, and posterior), making MRI a valuable option to aid in the evaluation of pelvic floor disorders, including prolapse. Already, MRI is replacing fluoroscopy as the means to perform defecography studies in some institutions, and it continues to be evaluated in research protocols investigating its potential role in the clinical evaluation of pelvic organ prolapse [70].

Although MRI is fascinating technology, it has its flaws: exams are performed in the supine position, it does not allow for patient biofeedback during imaging, it may not be tolerated well by some patients, and it is costly. As an alternative, sonography which has been utilized to aid in evaluating the urogynecologic patient since the mid-1980s has the advantage of lower cost, relative ease of use, minimal patient discomfort, shorter study durations, and wide availability [71, 72]. The advent of 3D/4D sonographic imaging has improved the clinical utility of pelvic floor sonography, and the transperineal/translabial approach has made it more patient friendly. Dietz and colleagues have reported 3D/4D sonography to be more accurate than physical exam in detecting levator muscle injuries and that sonographic injuries to the levator muscles are associated with pelvic organ prolapse, including apical prolapse [73, 74]. Sonography has also been used to image vaginal mesh implants, as it is able to readily detect mesh size and position (as opposed to MRI or CT) [75].

## 8. Apical Prolapse Surgery in the 21st Century

Two major shifts have occurred in the surgical management of apical prolapse in current practice: the introduction of vaginal mesh and that of advanced endoscopic surgery.

Graft use in pelvic reconstructive surgery can be traced back to the early 1900s [76]. In 1955, Moore and colleagues reported the use of tantalum mesh in the repair of cystoceles [77]. The concept that pelvic organ prolapse is a type of hernia, comparable to other fascial defects, made attractive the idea of replacing weakened fascia of the pelvic floor with a more reliable biologic or synthetic material. Over the intervening years, a number of auto-, allo-, and xenografts have been used with this intent in pelvic floor repairs. However, the success general surgeons achieved using polypropylene mesh in the correction of incisional hernias significantly influenced the use of this mesh by pelvic floor surgeons (type I monofilament, macroporous polypropylene mesh becoming the standard) [78]. Additionally, the success of the tension-free transvaginal tape (TVT) mid-urethral sling with its facility of use, clinical effectiveness, and marketability as an all-inclusive "kit" demonstrated the potential for mesh to improve surgical outcomes and opened a market in women's health care medical device manufacturers could exploit. In 2001, Petros introduced the infracoccygeal sacropexy (Intravaginal Slingplasty Tunneler, Tyco, USA) as a novel means to transvaginally correct vault prolapse using polypropylene mesh [79]. Petros' mesh was multifilament and complications due to perirectal abscesses and fistula formation led to its removal from the market. However, since that time, a steady stream of mesh "kits" have been

engineered by medical device makers and have made their way into the hands of many pelvic floor surgeons for the purpose of correcting apical and other forms of prolapse. Yet controversy has and continues to surround the use of vaginal mesh particularly as its acceptance in clinical use has outpaced the development of well-designed clinical trials [80]. In 2006, the French Health Authorities (HAS) reported that mesh for transvaginal repair of pelvic organ prolapse should be limited to clinical research [81]. In 2008, the US Food and Drug Administration (FDA) issued a warning regarding the use of mesh for prolapse and incontinence repair [82], repeating that warning in 2011, although narrowing it to vaginal mesh used to correct pelvic organ prolapse (not for anti-incontinence procedures or when used abdominally) [83]. These warnings stemmed from concerns over mesh erosion through the vagina, pain, infection, bleeding, dyspareunia, organ perforation, and urinary problems. While many of these complications are common to all pelvic floor repairs, mesh erosion and some types of organ perforation are surely unique to mesh and the trocars used for its placement. Presently, with respect to apical prolapse, no published, well-designed, randomized controlled trials have established the superiority of vaginal mesh over native tissue repairs [84]. This is beginning to change with respect to the anterior compartment [85].

What the future holds for vaginal mesh in pelvic organ prolapse repairs is uncertain. Nevertheless, while biomaterials improve and the subspecialty weighs the appropriate indications for their use, advances in endoscopic repairs for apical prolapse surge forth.

It has been the efforts of many physicians from the global scientific community that have brought forth the modern state of laparoscopy in gynecologic surgery. The pioneering works of Georg Kelling, Hans Christian Jacobaeus, John C. Ruddock, Janos Verees, and Kurt Semm all deserve further mention; however, a discussion of their contributions is beyond the scope of this paper [86–88].

The recent advances in endoscopic technology have been remarkable, and they have allowed urogynecologists to make endoscopic surgery a primary tool in their surgical armamentarium. It has been of great benefit to patients that what many believe to be the most durable apical prolapse repair, abdominal sacrocolpopexy, is achievable via minimally invasive approaches [89]. Presently, a debate exists regarding what method of sacrocolpopexy (straight sticks versus robotic assisted) should become the predominant technique taught and performed by urogynecologist in light of differences in cost, patient safety, surgeon training, and surgical outcomes. Well-designed studies have started to shed light on this issue [90, 91], but it is a conversation that is only beginning. And yet, in the shadow of that debate gynecologists are already reporting their early experiences with single incision laparoscopic surgery (SILS, or LESS—laparoendoscopic single-site surgery) and natural orifice transluminal endoscopic surgery (NOTES) [92, 93]. Whether these new surgical approaches will be amenable to performing safe and timely apical and other prolapse repairs remains to be seen. Nevertheless, a SILS sacrocolpopexy has been reported [94].

## 9. Conclusion

Uterine prolapse is an age-old condition the treatment of which has evolved over thousands of years. It is a condition from which many women have suffered and that many physicians have attempted to treat. The slow historical progress of the field and the challenges that we face today in treating uterine prolapse reflect the very intricacies of this disorder that fascinate and inspire us. Today, not only do urogynecologists reap the benefits gleaned from the developments over the ages, but also from the advances in modern technology. We are now positioned to more effectively evaluate and treat this condition and to enhance our understanding of its causes through the pursuit of novel research.

## References

[1] W. J. S. McKay, *The History of Ancient Gynaecology*, Balliere, Tindal and Cox, London, UK, 1901.

[2] C. P. Bryan, *Ancient Egyptian medicine : The Papyrus Ebers*, Ares Publishers, Chicago, Ill, USA, 1974.

[3] J. V. Ricci, *The Genealogy of Gynaecology: History of the Development of Gynaecology Throughout the Ages, 2000 B. C.-1800 A. D*, 1950.

[4] Soranus and O. Temkin, *Soranus' Gynecology*, Johns Hopkins University Press, Baltimore, Md, USA, 1991.

[5] F. Adams, *The Extant Works of Aretaeus*, Nabu Press, Cappadocian, Turkey, 2010.

[6] H. Speert, *Iconographia Gyniatrica; A pictorial History of Gynecology and Obstetrics*, F. A. Davis, Philadelphia, Pa, USA, 1973.

[7] E. H. Gombrich, *A little History of the World*, Yale University Press, New Haven, Conn, USA, 2005.

[8] A. Paré, *The Workes of That Famous Chirurgion Ambrose Paré*, Richard Cotes and Willi Du-Gard, London, UK, 1649.

[9] H. van Deventer, *The Art of Midwifery Improved*, E. Curll, London, UK, 1716.

[10] J. V. Ricci, *One Hundred Years of Gynaecology 1800–1900 : A Comprehensive Review of the Specialty During Its Greatest Century with Summaries and Case Reports of All Diseases Pertaining to Women*, The Blakiston Company, Philadelphia, Pa, USA, 1945.

[11] H. L. Hodge, *On Diseases Peculiar to Women, Including Displacements of the Uterus*, Blanchard and Lea, Philadelphia, Pa, USA, 1860.

[12] H. Speert, *Obstetric and Gynecologic Milestones: Essays in Eponymy*, Macmillan, New York, NY, USA, 1958.

[13] C. Goodyear, Inventor. Improvement in India-Rubber Fabrics. US patent 36331844.

[14] W. D. Buck, "A raid on the uterus," *New York Medical Journal*, vol. 5, p. 464, 1867.

[15] R.. Pichevin, "Vaginal hysterectomy," *The British Gynaecological Journal*, vol. 11, 1985.

[16] L. LeFort, "Nouveau Procédé pour la guérison du prolapsus utérin," *Bulletin générale de Therapeutic*, vol. 92, pp. 337–344, 1877.

[17] R. M. V. Olshausen, "Ueber ventrale Operation bei Prolapsus und Retroversio uteri," *Zentralblatt fur Gynakologie*, vol. 13, 1886.

[18] L. A. Emge and R. B. Durfee, "Pelvic organ prolapse: four thousand years of treatment," *Clinical Obstetrics and Gynecology*, vol. 9, no. 4, pp. 997–1032, 1966.

[19] W. E. Fothergill, "Anterior colporrhapy and amputation of the cerix combined as a single operation for use in the treatment of genital prolapse," *American Journal of Surgery*, vol. 29, p. 161, 1915.

[20] W. E. Fothergill, "The supports of the pelvic viscera: a review of some recent contributions to pelvic anatomy, with a clinical introduction," *Proceedings of the Royal Society of Medicine*, vol. 1, pp. 43–60, 1908.

[21] P. Thompson, "On the levator ani, or ischio-anal muscle of ungulates, with special reference to its morphology," *Journal of Anatomy and Physiology*, vol. 33, part 3, pp. 423–433, 1989.

[22] V. Bonney, "The principles that should underlie all operations for prolapse," *The Journal of Obstetrics and Gynecology of the British Empire*, vol. 41, no. 5, pp. 669–683, 1934.

[23] J. O. DeLancey, "Anatomic aspects of vaginal eversion after hysterectomy," *American Journal of Obstetrics and Gynecology*, vol. 66, no. 6, part 1, pp. 1717–1728, 1992.

[24] W. F. Mengert, "Mechanics of uterine support and position. I. Factors influencing uterine support (an experimental study)," *American Journal of Obstetrics and Gynecology*, vol. 31, no. 5, pp. 775–782, 1936.

[25] E. Lesky, *The Vienna Medical School of the 19th Century*, Johns Hopkins University Press, Baltimore, Md, USA, 1976.

[26] J. Halban, *Anatomie und Aitologie der Genitalprolapse beim Weibe*, Wilhelm Braumuller, Leipzig, Germany, 1907.

[27] R. H. Paramore, "The supports-in-chief of the female pelvic viscera," *Proceedings of the Royal Society of Medicine*, vol. 1, no. 4425, pp. 195–214, 1908.

[28] J. Halban and J. Tandler, "The anatomy and etiology of genital prolapse in women: the supporting apparatus of the uterus," *Obstetrics and gynecology*, vol. 15, pp. 790–796, 1960.

[29] B. H. Goff, "An histologic study of the perivaginal fascia in a nullipara," *Journal of Surgery, Gynecology and Obstetrics*, vol. 52, pp. 32–42, 1931.

[30] B. Berglas and I. C. Rubin, "Histologic study of the pelvic connective tissue," *Journal of Surgery, Gynecology and Obstetrics*, vol. 97, no. 3, pp. 277–289, 1953.

[31] R. F. Porges, J. C. Porges, and G. Blinick, "Mechanisms of uterine support and the pathogenesis of uterine prolapse," *Obstetrics and Gynecology*, vol. 15, pp. 711–726, 1960.

[32] S. Choppin, "Removal of the uterus and its appendages in a case of procidentia uteri, by means of the Ecraseur," *Southern Journal of the Medical Sciences*, p. 841, 1866.

[33] C. H. Mayo, "Uterine prolapse associated with pelvic relaxation," *Journal of Surgery, Gynecology and Obstetrics*, vol. 20, p. 257, 1915.

[34] D. Bissell, "Total hysterectomy, per vaginam, lapping of the anterior vaginal wall fascia and the approximation of the cardinal ligaments, for the cure of extreme procidentia uteri of long standing," *The American Journal of Obstetrics and Diseases of Women and Children*, vol. 77, 1918.

[35] E. Novak, "The vaginal pessary: its indications and limitations," *Journal of the American Medical Association*, vol. 80, no. 18, pp. 1294–1298, 1923.

[36] J. L. Baer, R. A. Reis, and R. M. Laemle, "Prolapse of the uterus-shifting trends in treatment," *American Journal of Obstetrics and Gynecology*, vol. 34, no. 5, pp. 827–839, 1937.

[37] M. L. McCall, "Posterior culdeplasty; surgical correction of enterocele during vaginal hysterectomy; a preliminary report," *Obstetrics and gynecology*, vol. 10, no. 6, pp. 595–602, 1957.

[38] R. E. Symmonds and R. S. Sheldon, "Vaginal prolapse after hysterectomy," *Journal of Obstetrics and Gynecology*, vol. 25, pp. 61–67, 1965.

[39] N. F. Miller, "A new method of correcting complete inversion of the vagina," *Journal of Gynecology and Obstetrics*, vol. 44, pp. 550–554, 1927.

[40] L. Brady, "An operation to correct genital prolapse following vaginal panhysterectomy," *American Journal of Obstetrics and Gynecology*, vol. 32, no. 2, pp. 295–299, 1936.

[41] G. E. Ward, "Ox fascia lata for reconstruction of round ligaments in correcting prolapse of the vagina," *Archives of Surgery*, vol. 36, no. 1, pp. 163–170, 1938.

[42] G. A. Williams and A. C. Richardson, "Transplantation of external oblique aponeurosis: an operation for prolapse of the vagina following hysterectomy," *American Journal of Obstetrics and Gynecology*, vol. 64, no. 3, pp. 552–558, 1952.

[43] G. E. Arthure and D. Savage, "Uterine prolapse and prolapse of the vaginal vault treated by sacral hysteropexy," *The Journal of Obstetrics and Gynaecology of the British Empire*, vol. 64, no. 3, pp. 355–360, 1957.

[44] P. Zweifel, *Vorlesungen über Klinische Gynäkologie*, Hirschwald, 1892.

[45] J. Sederl, "Surgery in prolapse of a blind-end vagina," *Geburtshilfe Frauenheilkd*, vol. 18, no. 6, pp. 824–828, 1958.

[46] K. Richter, "The surgical anatomy of the vaginaefixatio sacrospinalis vaginalis. A contribution to the surgical treatment of vaginal blind pouch prolapse," *Geburtshilfe und Frauenheilkunde*, vol. 28, no. 4, pp. 321–327, 1968.

[47] C. L. Randall and D. H. Nichols, "Surgical treatment of vaginal inversion," *Obstetrics and Gynecology*, vol. 38, no. 3, pp. 327–332, 1971.

[48] H. A. Winkler, J. E. Tomeszko, and P. K. Sand, "Anterior sacrospinous vaginal vault suspension for prolapse," *Obstetrics and Gynecology*, vol. 95, no. 4, pp. 612–615, 2000.

[49] R. Kearney and J. O. L. DeLancey, "Selecting suspension points and excising the vagina during Michigan four-wall sacrospinous suspension," *Obstetrics and Gynecology*, vol. 101, no. 2, pp. 325–330, 2003.

[50] F. S. Miyazaki, "Miya Hook ligature carrier for sacrospinous ligament suspension," *Obstetrics and Gynecology*, vol. 70, no. 2, pp. 286–288, 1987.

[51] T. R. Sharp, "Sacrospinous suspension made easy," *Obstetrics and Gynecology*, vol. 82, no. 5, pp. 873–875, 1993.

[52] L. R. Lind, J. Choe, and N. N. Bhatia, "An in-line suturing device to simplify sacrospinous vaginal vault suspension," *Obstetrics and Gynecology*, vol. 89, no. 1, pp. 129–132, 1997.

[53] W. B. Inmon, "Pelvic relaxation and repair including prolapse of vagina following hysterectomy," *The Southern Medical Journal*, vol. 56, pp. 577–582, 1963.

[54] L. E. Phaneuf, "Inversion of the vagina and prolapse of the cervix following supracervical hysterectomy and inversion of the vagina following total hysterectomy," *American Journal of Obstetrics and Gynecology*, vol. 64, no. 4, pp. 739–745, 1952.

[55] R. E. Symmonds and J. H. Pratt, "Vaginal prolapse following hysterectomy," *American Journal of Obstetrics and Gynecology*, vol. 79, no. 5, pp. 899–909, 1960.

[56] W. N. Thornton Jr. and W. A. Peters, "Repair of vaginal prolapse after hysterectomy," *American Journal of Obstetrics and Gynecology*, vol. 147, no. 2, pp. 140–148, 1983.

[57] G. R. Seigworth, "Vaginal vault prolapse with eversion," *Obstetrics and Gynecology*, vol. 54, no. 2, pp. 255–260, 1979.

[58] B. L. Shull, C. Bachofen, K. W. Coates, and T. J. Kuehl, "A transvaginal approach to repair of apical and other associated sites of pelvic organ prolapse with uterosacral ligaments," *American Journal of Obstetrics and Gynecology*, vol. 183, no. 6, pp. 1365–1374, 2000.

[59] G. E. Lemack, P. E. Zimmern, and D. S. Blander, "The levator myorraphy repair for vaginal vault prolapse," *Urology*, vol. 56, no. 6, supplement 1, pp. 50–54, 2000.

[60] R. C. Bump, A. Mattiasson, K. Bo et al., "The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction," *American Journal of Obstetrics and Gynecology*, vol. 175, no. 1, pp. 10–17, 1996.

[61] W. Auwad, R. M. Freeman, and S. Swift, "Is the pelvic organ prolapse quantification system (POPQ) being used? A survey of members of the International Continence Society (ICS) and the American Urogynecologic Society (AUGS)," *International Urogynecology Journal and Pelvic Floor Dysfunction*, vol. 15, no. 5, pp. 324–327, 2004.

[62] A. Reich, F. Kohorst, R. Kreienberg, and F. Flock, "Influence of bladder volume on pelvic organ prolapse quantification results," *Gynecologic and Obstetric Investigation*, vol. 70, no. 2, pp. 82–86, 2010.

[63] A. K. Orno and H. P. Dietz, "Levator co-activation is a significant confounder of pelvic organ descent on Valsalva maneuver," *Journal of Ultrasound in Obstetrics and Gynecology*, vol. 30, no. 3, pp. 346–350, 2007.

[64] B. Berglas and I. C. Rubin, "Study of the supportive structures of the uterus by levator myography," *Journal of Surgery, Gynecology and Obstetrics*, vol. 97, no. 6, pp. 677–692, 1953.

[65] H. Hricak, C. Alpers, L. E. Crooks, and P. E. Sheldon, "Magnetic resonance imaging of the female pelvis: initial experience," *American Journal of Roentgenology*, vol. 141, no. 6, pp. 1119–1128, 1983.

[66] H. Hricak, "MRI of the female pelvis: a review," *American Journal of Roentgenology*, vol. 146, no. 6, pp. 115–1122, 1986.

[67] A. Yang, J. L. Mostwin, N. B. Rosenshein, and E. A. Zerhouni, "Pelvic floor descent in women: dynamic evaluation with fast MR imaging and cinematic display," *Radiology*, vol. 179, no. 1, pp. 25–33, 1991.

[68] J. O. L. DeLancey, R. Kearney, Q. Chou, S. Speights, and S. Binno, "The appearance of levator ani muscle abnormalities in magnetic resonance images after vaginal delivery," *Obstetrics and Gynecology*, vol. 101, no. 1, pp. 46–53, 2003.

[69] K. Singh, M. Jakab, W. M. N. Reid, L. A. Berger, and L. Hoyte, "Three-dimensional magnetic resonance imaging assessment of levator ani morphologic features in different grades of prolapse," *American Journal of Obstetrics and Gynecology*, vol. 188, no. 4, pp. 910–915, 2003.

[70] C. A. Woodfield, B. S. Hampton, V. Sung, and J. M. Brody, "Magnetic resonance imaging of pelvic organ prolapse: comparing pubococcygeal and midpubic lines with clinical staging," *International Urogynecology Journal and Pelvic Floor Dysfunction*, vol. 20, no. 6, pp. 695–701, 2009.

[71] E. I. Kohorn, A. L. Scioscia, P. Jeanty, and J. C. Hobbins, "Ultrasound cystourethrography by perineal scanning for the assessment of female stress urinary incontinence," *Obstetrics and Gynecology*, vol. 68, no. 2, pp. 269–272, 1986.

[72] E. M. Grischke, H. P. Dietz, P. Jeanty, and W. Schmidt, "A new study method: the perineal scan in obstetrics and gynecology," *Ultraschall in der Medizin*, vol. 7, no. 4, pp. 154–161, 1986.

[73] H. P. Dietz and C. Shek, "Validity and reproducibility of the digital detection of levator trauma," *International Urogynecology Journal and Pelvic Floor Dysfunction*, vol. 19, no. 8, pp. 1097–1101, 2008.

[74] H. P. Dietz and J. M. Simpson, "Levator trauma is associated with pelvic organ prolapse," *International Journal of Obstetrics and Gynaecology*, vol. 115, no. 8, pp. 979–984, 2008.

[75] R. Tunn, A. Picot, J. Marschke, and A. Gauruder-Burmester, "Sonomorphological evaluation of polypropylene mesh implants after vaginal mesh repair in women with cystocele or rectocele," *Ultrasound in Obstetrics and Gynecology*, vol. 29, no. 4, pp. 449–452, 2007.

[76] A. John and H. W. J. Rock, *TeLinde's Operative Gynecology*, Lippincott Williams & Wilkins, Philadelphia, Pa, USA, 9th edition, 2003.

[77] J. Moore, J. T. Armstrong, and S. H. Wills, "The use of tantalum mesh in cystocele with critical report of ten cases," *American Journal of Obstetrics and Gynecology*, vol. 69, no. 5, pp. 1127–1135, 1955.

[78] R. W. Luijendijk, W. C. J. Hop, M. P. van den Tol et al., "A comparison of suture repair with mesh repair for incisional hernia," *New England Journal of Medicine*, vol. 343, no. 6, pp. 392–398, 2000.

[79] P. E. Papa Petros, "Vault prolapse II: restoration of dynamic vaginal supports by infracoccygeal sacropexy, an axial day-case vaginal procedure," *International Urogynecology Journal and Pelvic Floor Dysfunction*, vol. 12, no. 5, pp. 296–303, 2001.

[80] A. Gomelsky, D. F. Penson, and R. R. Dmochowski, "Pelvic organ prolapse (POP) surgery: the evidence for the repairs," *British Journal of Urology*, vol. 107, no. 11, pp. 1704–1719, 2011.

[81] Haute Autorité de Santé, "ÉValuation Des Implants De Renfort Posés Par Voie Vaginale Dans Le Traitement Des Prolapsus Génitaux," 2006, http://www.has-sante.fr/portail/upload/docs/application/pdf/synthese_implant__prolapsus_voie_vaginale.pdf

[82] US Food and Drug Administration, "FDA public health notification: serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse and stress urinary incontinence," in *US Food and Drug Administration*, 2008.

[83] US Food and Drug Administration, "FDA Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse," 2011, http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm.

[84] C. Maher, B. Feiner, K. Baessler, E. J. Adams, S. Hagen, and C. M. Glazener, "Surgical management of pelvic organ prolapse in women," *Cochrane Database of Systematic Reviews*, vol. 4, Article ID CD004014, 2010.

[85] D. Altman, T. Vayrynen, M. E. Engh, S. Axelsen, and C. Falconer, "Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse," *The New England Journal of Medicine*, vol. 364, no. 19, pp. 1826–1836, 2011.

[86] G. S. Litynski and V. Paolucci, "Origin of laparoscopy: coincidence or surgical interdisciplinary thought?" *World Journal of Surgery*, vol. 22, no. 8, pp. 899–902, 1998.

[87] J. K. Ruddock, "Peritoneoscopy," *Journal of Surgery, Gynecology and Obstetrics*, vol. 65, no. 6, 1937.

[88] T. A. Stellato, "History of laparoscopic surgery," *Surgical Clinics of North America*, vol. 72, no. 5, pp. 997–1002, 1992.

[89] I. E. Nygaard, R. McCreery, L. Brubaker et al., "Abdominal sacrocolpopexy: a comprehensive review," *Obstetrics and Gynecology*, vol. 104, no. 4, pp. 805–823, 2004.

[90] J. P. Judd, N. Y. Siddiqui, J. C. Barnett, A. G. Visco, L. J. Havrilesky, and J. M. Wu, "Cost-minimization analysis of robotic-assisted, laparoscopic, and abdominal sacro-colpopexy," *Journal of Minimally Invasive Gynecology*, vol. 17, no. 4, pp. 493–499, 2010.

[91] J. M. M. Tan-Kim, A. Shawn, K. M. Luber et al., "Robotic-assisted and laparoscopic sacrocolpopexy: comparing operative times, costs and outcomes," *Female Pelvic Medicine and Reconstructive Surgery*, vol. 17, no. 1, pp. 44–49, 2011.

[92] P. F. Escobar, D. Starks, A. N. Fader, M. Catenacci, and T. Falcone, "Laparoendoscopic single-site and natural orifice surgery in gynecology," *Fertility and Sterility*, vol. 94, no. 7, pp. 2497–2502, 2010.

[93] S. Uppal, M. Frumovitz, P. Escobar, and P. T. Ramirez, "Laparoendoscopic single-site surgery in gynecology: review of literature and available technology," *Journal of Minimally Invasive Gynecology*, vol. 18, no. 1, pp. 12–23, 2011.

[94] E. Drapier, "Transumbilical single port laparoscopic sacrocolpopexy using standard instruments," 2011, http://www.websurg.com/ref/doi-vd01en3384.htm.

Hindawi Publishing Corporation
Obstetrics and Gynecology International
Volume 2012, Article ID 316983, 7 pages
doi:10.1155/2012/316983

*Clinical Study*

# Management of Obstetric Perineal Tears: Do Obstetrics and Gynaecology Residents Receive Adequate Training? Results of an Anonymous Survey

**A. Cornet,[1] O. Porta,[2] L. Piñeiro,[2] E. Ferriols,[2] I. Gich,[3] and J. Calaf[2]**

[1] *Department of Obstetrics and Gynaecology, Viladecans Hospital, Avenue Gavà 38 Viladecans, 08840 Barcelona, Spain*
[2] *Department of Obstetrics and Gynaecology, Hospital of the Hdy cross and Saint Paul, Mas Casanovas 90, 08025 Barcelona, Spain*
[3] *Department of Epidemiology, Hospital of the Hdy cross and Saint Paul, Mas Casanovas 90, 08025 Barcelona, Spain*

Correspondence should be addressed to A. Cornet, aricucut@hotmail.com

Received 16 March 2011; Revised 22 May 2011; Accepted 25 May 2011

Academic Editor: Hans Peter Dietz



*Background/Aim*. To evaluate the obstetrics and gynaecology residents' perspective of their training and experience in the management of perineal tears that occur during assisted vaginal delivery. We hypothesised that residents would perceive room for improvement in their knowledge of pelvic floor anatomy and the training received in tears repair. *Design*. Descriptive cross-sectional study. *Population/Setting*. Seventy-two major residents from all teaching hospitals in Catalonia. *Methods*. A questionnaire was designed to evaluate experience, perception of the training and supervision provided. *Results*. The questionnaire was sent to all residents ($n = 72$), receiving 46 responses (64%). The participants represented 15 out of the 16 teaching hospitals included in the study (94% of the hospitals represented). Approximately, 52% of residents were in their third year while 48% were in their fourth. The majority of them thought that their knowledge of pelvic floor anatomy was poor (62%), although 98% felt confident that they would know when an episiotomy was correctly indicated. The survey found that they lacked experience in the repair of major degree tears (70% had repaired fewer than ten), and most did not carry out followup procedures. *Conclusion*. The majority of them indicated that more training in this specific area is necessary (98%).

## 1. Introduction

Obstetric anal sphincter injury (OASI) is said to occur in approximately 1–4% of all deliveries, although the true incidence may be substantially higher [1]. Followup has shown anal incontinence (AI) symptoms in up to 57% of those who undergo primary repair [2]. Longterm followup of such symptomatic patients shows a high prevalence of women with AI after OASI [3]. Women with OASI are twice as at risk of suffering AI six-month postpartum [4]. However, about 60–80% of women who suffer an obstetric anal sphincter injury but have a good external anal sphincter (EAS) repair remain asymptomatic at twelve months. Most women who remain symptomatic describe incontinence of flatus or faecal urgency [5]. Although AI is not a life-threatening condition, it may affect women psychologically and physically [6, 7].

There is no other moment in a woman's life when pelvic floor structures are more vulnerable than during childbirth. DeLancey et al. [8] showed the association between delivery and injuries caused to the levator ani muscles, and Hendrix et al. [9] has ascertained the increase in the risk of pelvic organ prolapse after vaginal delivery. But the strongest data suggesting a causal relationship between childbirth and levator trauma is provided by ultrasound studies comparing pelvic floor structures before and after childbirth [10, 11]. If professionals practising in the labour ward are made more aware of the risk to pelvic floor structures during delivery, they are more likely to adopt the appropriate preventive measures.

Various studies suggest that the degree of knowledge of obstetrics and gynaecology specialists in the repair of perineal injuries, specifically those involving the anal sphincter, is limited. According to Fernando et al. [12] and

McLennan et al. [13], the training given to obstetrics and gynaecology residents on this subject is insufficient. Furthermore, these studies show the positive effect of introducing specific training actions [14–17]. Evaluating this situation for gynaecology residents and future specialists is of great relevance, since measures can be taken during their training period which aim to maximise aptitudes and, thereby, allow residents to undertake a more comprehensive and safer professional practice. At this point in time, no specific formal training regarding OASI management is contemplated in the educational programme of residents in Catalonia.

We hypothesised that there was room for improvement in the knowledge of pelvic floor anatomy for obstetrics and gynaecology residents in Catalonia (a region in the north-east of Spain with approximately eight million inhabitants), and that residents had poor experience in repairing third and fourth degree perineal tears, and insufficient knowledge of the risk that their obstetric manoeuvres entailed for the female pelvic floor.

The aim of this research was to verify the validity of this hypothesis through a questionnaire explicitly designed for this purpose. If shown to be valid, the hypothesis will reveal the need for specific training actions to be formally implemented.

## 2. Material and Methods

A descriptive cross-sectional study was designed. The population included in the sample consisted of third and fourth year obstetrics and gynaecology residents in Catalonia. First and second year residents were not included, as complex tears are usually repaired by experienced residents (i.e., third and fourth year residents). A questionnaire was designed containing 40 items, which was reviewed by three senior doctors and pelvic floor pathology experts that had no connection with our centre—although this was not formally validated. The questionnaire was divided into five blocks: affiliation, anatomy, episiotomy, perineal tears, and teaching (Table 4).

The study took place between October 2007 and January 2008. We sent out 72 questionnaires by e-mail to all residents in their third and fourth year with the endorsement of the *Acadèmia de Ciències Mèdiques de Catalunya i Balears*. Emphasis was also placed on information received through our contact with residents and associate physicians from the hospitals involved. The number of residents per year differs from one hospital to the next, with as many as seven residents in the bigger hospitals to one resident in the smaller ones. There are 16 hospitals with residency programmes in Catalonia, and all of them were included. The sample was constituted by 12-male residents and 60-female residents (there are more female than male students at medical schools and, consequently, there are more female than male residents in several specialties). Participants remained anonymous—although mention was made of the hospital of origin—and all responses were treated confidentially. A Microsoft Excel database was created with all the variables as dichotomous except those of the affiliation and variables 18 and 19 (ordinal from 0 to 5) and 20 (ordinal with three possibilities).

Three variables from the original questionnaire were modified for the statistical analysis. First, a new dichotomous variable denominated "deliveries per resident" (<1000 deliveries/resident, >1000 deliveries/resident) was created in the affiliation block, calculated according to the discrete quantitative variable of "number of deliveries/year" for each hospital and the discrete quantitative variable of "number of residents per year in that hospital." Also, the average quantitative variable of "number of residents/year" of that first block was converted into a dichotomous variable ($\leq$2 residents/year, >2 residents/year). Finally, in the tears block, the discrete quantitative variable 20 was converted into an ordinal variable (Table 4).

Frequency tables were calculated for each variable, with confidence intervals of 95% for some of the variables of each block which were considered outstanding and representative. In addition, aggregate index rates were calculated for each block. Finally, cross-data from Student's $t$ test was used to compare each rate on the basis of other variables, facilitating the standard and mean deviation. All analyses were done using the SPSS statistical package (V15.0).

The variables that were considered representative of each block were as follows.

*Anatomy.* Question 6 was selected as representative of the block since it evaluated each resident's subjective perception of his/her knowledge of pelvic floor anatomy.

*Episiotomy.* Questions 12 and 15 could reflect that a restrictive policy for episiotomy may promote the learning of its indications.

*Tears.* Questions 18 and 19 would be useful in comparing how self-confident the residents felt when repairing tears versus major surgery (caesarean section). Complementing this question, question 20 reflects the frequency in which residents were confronted with these kinds of tear. As explained above, this variable was converted into a dichotomous variable to facilitate the statistical analysis.
Questions 21, 22, and 23 were useful to analyse how well residents knew the definition of major tears, but we considered questions 18 and 19 more relevant for showing how insecure they felt when it came to repairing them.

*Teaching.* Questions 25 and 26 were selected because they reflected the morbidity associated with perineal tears.

Questions 24, 31, and 33 were the most representative in terms of the evaluation of teaching.

Participants were not asked to provide informed consent, and they voluntarily participated after having received written information regarding the purposes of the study. No compensation was provided for completing the survey. The study was revised and approved by the Institutional Ethics Committee.

## 3. Results and Discussion

*3.1. Results.* We received 46 questionnaires out of the 72 (64%) sent out to all third and fourth year residents,

Table 1: Demographics of participants.

| | Total | % |
|---|---|---|
| Received questionnaires | 46/72 | 64% |
| Represented teaching hospitals | 15/16 | 94% |
| Third year residents | 24/46 | 52% |
| Fourth year residents | 22/46 | 48% |
| Female residents | 37/46 | 80% |
| Male residents | 9/46 | 20% |

representing 15 out of the 16 teaching hospitals in Catalonia participating in the study (94% of hospitals). There were 24 (52%) in their third year while the remaining 22 (48%) were in their fourth. There were 37 (80%) females against 9 (20%) males (Table 1). Aggregate index rates calculated for each block are shown in Table 2.

No significant differences were found in the comparison carried out between the variables of each block when crossed with the affiliation variables. We found no systematic differences between the mean scores of each block, depending on year of residence, level of hospital, number of residents per hospital, or number of deliveries per resident (Table 3).

About 28 (62%) answered that their knowledge of pelvic floor anatomy was inadequate (95% CI: 45.4–74.9). Moreover, 45 (98%) of respondents thought they knew when an episiotomy was indicated (95% CI: 88.5–99.9). In 37 (80%) of the centres a restrictive policy for episiotomy was used (95% CI: 66.1–90.6).

Of the Catalan residents, 32 (70%) had repaired less than 10 third or fourth degree perineal tears (95% CI: 54.2–82.3). We observed significant differences with regard to how residents graded their self-confidence in the execution of a caesarean section and in the repair of a third or fourth degree tear. Residents were asked to grade their level of self-confidence when confronted with a caesarean section or a complex tear in an ordinal-ranked 0–5 scale. They graded the c-section with an average score of 4.41 (SD 0.65) and the complex tear with an average of 3.26 (SD 0.9), respectively, ($P < 0.001$).

During their first perineal tear, 42 (91%) were supervised (95% CI: 79.2–97.6). About 33 (72%) did not conduct clinical followup after a tear (95% CI: 57.0–82.0), although 41 (89%) said "they did know the risk of urinary or faecal incontinence on the basis of whether the delivery is spontaneous or instrumental (95% CI: 79.2–97.6)". Finally, 42 (91%) thought that it was necessary to receive more theoretical training (95% CI: 79.2–97.6), and 45 (98%) thought there was a need for a theoretical-practical course on pelvic floor anatomy and on the repair of its injuries (95% CI: 88.5–99.9).

*3.2. Discussion.* This study provides information concerning how residents view their training in the repair of obstetric perineal trauma and looks at how they practice, how they are supervised, and how they followup patients. Before this study, there was a perceived deficit in the current training of residents in pelvic floor repair at the time of vaginal delivery as there are no formal, written educational objectives in the residency programme. It seemed important to objectively demonstrate this perceived deficit, so that this information might help revise what is currently being taught in resident training. The results indicate that actions such as practical workshops or the objective evaluation of skills should be carried out to reinforce residents' training in this area, in all teaching hospitals in Catalonia.

There are no differences in the assessments done by third and fourth year residents, and there are no discrepancies between second and third level hospitals. Neither were there differences whether the number of residents in the hospital was equal to, less than 2 or more than 2 or whether the number of deliveries per resident was more than 1000 or less (Table 3).

We have no explanation for why no questionnaire was received from one of the 16 hospitals.

The majority of residents think they do not have sufficient knowledge of pelvic floor anatomy. However, they feel confident in knowing when an episiotomy is required. This could be partly due to the fact that 80% of the participating hospitals use episiotomy in a restrictive manner.

We observed a clear difference in the self-confidence that residents show in the performance of a caesarean section when compared with the repair of a third or fourth degree perineal tear. On the one hand, the incidence of third degree tears in Catalonia is about 0-1% [18] underlining the high probability that many tears are underdiagnosed, although the cumulative incidence of AI postpartum in the same area is 4.5% (95% CI 3.1–5.9) [18]. On the other hand, according to an international study on cesarean rates worldwide, the reported incidence of caesarean section in Southern Europe is about 24% [19]. The rate in Spain was about 18% in 1999, approaching 21% in 2004 [20]. Since the incidence of c-section is much higher than that of third and fourth degree tears, not surprisingly residents feel far more confident in performing the c-section when confronted with the repair of a complex tear. This result is of high clinical significance. It is important to note, when explaining this result, that 70% of the residents have repaired less than 10 third or fourth degree tears, even though the number of caesarean sections carried out by each of them is far higher.

Although residents claim that they know the consequences that a particular damage to the pelvic floor might entail for a patient, it is alarming that nearly 72% admit that they do not regularly followup women during the postpartum period. This fact suggests that even teachers and seniors have a limited understanding of the real problem [21]. In our region, it is common that puerperae make their postpartum check at one month after delivery with their midwife or gynaecologist in their corresponding primary care centre. Many hospitals do not yet have strong pelvic floor units. Consequently, the puerperae coming from these hospitals are still visited in their primary care centres at one month after their delivery, whatever their complications might have been. Thus, being aware of the implications of these injuries, it is of the utmost importance that a guideline is designed in all hospitals that ensures the followup of these patients. The followup is aimed at providing them with

Table 2: Aggregate index rates calculated for each block of questions. Higher scores indicate better results.

| | Anatomy questions | Episiotomy questions | Tear questions | Teaching questions |
|---|---|---|---|---|
| Valid participants | 46 | 45 | 46 | 44 |
| Lost participants | 0 | 1 | 0 | 2 |
| Mean score | 3,17 | 4,29 | 3,19 | 10,79 |
| Median's score | 3,00 | 4,00 | 3,00 | 11,00 |
| SD | 1,48 | 0,84 | 0,96 | 1,68 |
| Minimum score | 1,00 | 2,00 | 1,00 | 6,00 |
| Maximum score | 6,00 | 5,00 | 5,00 | 14,00 |

Table 3: Mean scores per block. Higher scores indicate better results (mean ± SD). There were no significant differences in anatomy, knowledge of episiotomy, or knowledge of perineal tears between 3rd and 4th year residents, residents from different hospital levels, number of residents per hospital, or number of deliveries per resident. *Level III hospitals are referral hospitals.

| | Year of residence | | Hospital level* | | Residents per hospital | | Deliveries per resident | |
|---|---|---|---|---|---|---|---|---|
| | 3rd | 4th | II | III | 1 or 2 | >2 | <1000 | ≥1000 |
| Anatomy Questions | 3.46 ± 1.61 | 2.86 ± 1.28 | 2.85 ± 1.57 | 3.30 ± 1.45 | 3.16 ± 1.63 | 3.10 ± 1.30 | 2.92 ± 1.32 | 3.48 ± 1.63 |
| Episiotomy Questions | 4.30 ± 0.76 | 4.27 ± 0.93 | 4.00 ± 1.08 | 4.41 ± 0.71 | 4.30 ± 0.91 | 4.30 ± 0.80 | 4.16 ± 0.99 | 4.45 ± 0.60 |
| Tear questions | 3.04 ± 1.04 | 3.36 ± 0.85 | 2.92 ± 1.04 | 3.30 ± 0.92 | 2.62 ± 0.57 | 3.19 ± 0.93 | 3.28 ± 0.98 | 3.09 ± 0.94 |
| Teaching Questions | 11.00 ± 2.02 | 10.57 ± 1.21 | 10.46 ± 2.02 | 10.93 ± 1.53 | 10.67 ± 1.71 | 10.90 ± 1.70 | 10.56 ± 1.85 | 11.04 ± 1.46 |
| Total | 21.86 ± 3.90 | 21.00 ± 2.49 | 20.23 ± 3.92 | 21.97 ± 2.87 | 20.75 ± 3.43 | 21.44 ± 2.81 | 20.78 ± 3.46 | 22.20 ± 2.95 |

a good recovery from the morbidity, together with information and counselling for future pregnancies.

Although the majority of the residents were supervised on their first repair, they believe that increased theoretical-practical training is still necessary. As recommended by other international societies [22], we strongly believe that it is important that part of the workload of subspecialists in urogynaecology at each hospital is devoted to active involvement in obstetrics. This may be appropriate in terms of preventing pelvic floor dysfunction on the labour ward through the education of residents and midwives, and by being present to help diagnose and treat anal sphincter injuries when they occur. Complementary to this, as shown by some authors, the implementation of tools that allow for the structured assessment of technical skills for the repair of fourth degree tears may be useful [23, 24]. We think that efforts should be made to regularly include such tools as a part of the residents' education programme in Catalonia.

Not many surveys have been conducted which address this particular aspect of an obstetrics and gynaecology resident's education programme. Other surveys have shown that the urogynaecology training of general obstetrics and gynaecology residents should be revised and improved [25, 26], and some of the urogynaecology abilities queried in such surveys may be similar to an obstetric anal sphincter repair (i.e., posterior colporrhaphy, anal sphincteroplasty). Although most of these surveys have been conducted in English speaking countries, whose health care systems are different from that of Spain, their results are consistent with those of our own study, indicating that the Catalan residents' needs may be similar to those of residents in other countries.

As the incidence and prevalence of faecal incontinence in Catalonia and Spain are similar and parallel to those published in the international literature [27], and, due to its cultural proximity, we believe that our results may also be representative of the situation in the rest of Spain.

One of the limitations to this study was the sample size, which poses a problem regarding the statistic power needed to obtain statistically significant differences when crossing the affiliation data with the different items. In order to expand the sample size, it may be necessary to extend the survey to a national level, thereby allowing more significant conclusions to be drawn. Nonetheless, the population of Catalonia may be sufficiently representative of the rest of Spain to at least conclude that the lack of confidence when dealing with major perineal tears may be applicable nationwide.

Furthermore, we should have taken certain measures to ensure greater participation in the questionnaire, since 64% participation may be below what is considered acceptable for a survey to support a valid study.

Based on the results of our study, it appears that a thorough discussion and debate on residents' education and the prevention of pelvic floor dysfunctions caused by obstetric trauma should be undertaken by scientific societies in Spain.

## 4. Conclusions

According to the results of the 46 questionnaires received, it can be concluded that there is a need to improve the training of residents in the management of perineal injuries during

Table 4: Questionnaire.

| | | | | |
|---|---|---|---|---|
| Affiliation (mark with a cross) | | | | |
| 1 | Year of residence | R3 | R4 | |
| 2 | Hospital | Level II | Level III | |
| 3 | Number of births/year (2006) | | | |
| 4 | Number of residents/year | | | |
| 5 | Gender | Male | Female | |
| Evaluation on the knowledge of anatomy (mark with a cross) | | | | |
| 6 | Do you think you have adequate knowledge of the pelvic floor anatomy? | YES | NO | |
| 7 | Do you know the name of the various muscles of the pelvic floor? | YES | NO | |
| 8 | Are you able to recognize the various muscles of the pelvic floor during digital vaginal examination? | YES | NO | |
| 9 | Are you able to identify the tendinous arc of the anus levator during digital vaginal examination? | YES | NO | |
| 10 | Can you identify the sciatica spines during digital vaginal examination? | YES | NO | |
| 11 | Do you know the path of the pudenda nerve, and are you able to inject the anaesthetics in it? | YES | NO | |
| Evaluation on the knowledge of episiotomy (mark with a cross) | | | | |
| 12 | Do you know when an episiotomy would be indicated? | YES | NO | |
| 13 | Are you familiar with the suture of the various types of episiotomy (medial, medial lateral)? | YES | NO | |
| 14 | Do you know when the medial episiotomy is counter indicated? | YES | NO | |
| 15 | Does your centre apply a selective policy for episiotomy? | YES | NO | |
| 16 | Do you think a selective policy for episiotomy is positive? | YES | NO | |
| Evaluation on the knowledge of the perineal tears (mark with a cross or rate from 0 to 5) | | | | |
| 17 | Do you know the definition of grades III and IV perineal tears? | YES | NO | |
| Classification of perineal tears grade I: affects the vaginal mucosa and the connective tissue; grade II: affects the underlying muscles in addition; grade III: anal sphincter rupture; grade IV: affects the rectal mucosa | | | | |
| 18 | Do you feel able to carry out a C-section? (rate from 0 to 5) | | | |
| 19 | Do you feel able to repair a grade III or IV perineal tear? (rate from 0 to 5) | | | |
| 20 | How many grade III or IV perineal tears have you repaired? | 0–10 | 10–20 | >20 |
| 21 | Can you distinguish between a grade III and a grade IV perineal tear during the usual practice? | YES | NO | |
| 22 | Do you know more than one technique to repair an anal sphincter injury? | YES | NO | |
| 23 | Do you know when prophylactic antibiotics should be administered after a tear? | YES | NO | |
| Evaluation on teaching (mark with a cross) | | | | |
| 24 | Do you feel competent when repairing a perineal tear? | YES | NO | |
| 25 | Do you usually followup on a puerpera who has suffered a grade III or IV perineal tear after discharge (followup, pain level, sexual and anal dysfunctions)? | YES | NO | |
| 26 | Do you know if there is any difference in the risk of urinary and faecal incontinence after birth (due to mechanical lesion) depending on whether the birth is spontaneous or instrumental? | YES | NO | |
| 27 | Do you know if any of the instruments (spatules, forceps, vacuum pads) have higher associated risk or are their risks equivalent? | YES | NO | |
| 28 | Did you have a teaching assistant help during your suture in your first perineal tear repair? | YES | NO | |
| 29 | Did an assistant supervise/help you on subsequent occasions? | YES | NO | |
| 30 | Or did a major resident, in the absence of assistants? | YES | NO | |

Table 4: Continued.

| Evaluation on teaching (mark with a cross) | | | |
|---|---|---|---|
| 31 | Do you think that you received adequate supervision when faced with a grade III or IV perineal tear? | YES | NO |
| 32 | Do you think you can teach a minor resident to repair a grade III or IV perineal tear, in practice? | YES | NO |
| 33 | Have you received formal training on pelvic anatomy or on the repair f perineal lacerations, within your training programme? | YES | NO |
| 34 | Have you received theoretical training in any clinical session, videos, articles offered by any assistant? | YES | NO |
| 35 | Have you read books, articles related to pelvic anatomy, perineal tears, episiotomy, surgical techniques for repairs, and so forth? | YES | NO |
| 36 | Have you received any theoretical-practical training with corpses? | YES | NO |
| 37 | Do you think you need to receive more supervision by an assistant or major resident to repair grade III or IV perineal tears? | YES | NO |
| 38 | Do you think you need more theoretical training on it? | YES | NO |
| 39 | Do you think a theoretical-practical course on the anatomy of he pelvic floor and the repair of its lesions would be useful? | YES | NO |
| 40 | Would you give the same replies if you reread the questions after some minutes? | YES | NO |

delivery and postpartum followup. This may be achieved by including theoretical and practical courses to reinforce pelvic anatomy and suture skills, and creating units to followup patients that are affected by complicated tears.

## Acknowledgments

The authors express their most sincere thanks to all the residents who participated in this survey or who encouraged others to do so, and to all associate physicians who helped to distribute it. Their special thanks also go to the *Acadèmia de Ciències Mèdiques de Catalunya i Balears* (Academy of Medical Sciences of Catalonia and the Balearic Islands) for their collaboration.

## References

[1] D. E. Fenner, B. Genberg, P. Brahma, L. Marek, and J. O. L. DeLancey, "Fecal and urinary incontinence after vaginal delivery with anal sphincter disruption in an obstetrics unit in the United States," *American Journal of Obstetrics and Gynecology*, vol. 189, no. 6, pp. 1543–1550, 2003.

[2] H. Gjessing, B. Backe, and Y. Sahlin, "Third degree obstetric tears: outcome after primary repair," *Acta Obstetricia et Gynecologica Scandinavica*, vol. 77, no. 7, pp. 736–740, 1998.

[3] K. Haadem, S. Ohrlander, and G. Lingman, "Long-term ailments due to anal sphincter rupture caused by delivery—a hidden problem," *European Journal of Obstetrics and Gynecology and Reproductive Biology*, vol. 27, no. 1, pp. 27–32, 1988.

[4] D. Borello-France, K. L. Burgio, H. E. Richter et al., "Fecal and urinary incontinence in primiparous women," *Obstetrics & Gynecology*, vol. 108, no. 4, pp. 863–872, 2006.

[5] "The management of third and fourth degree perineal tears," RCOG Green-top Guideline no. 29, March 2007.

[6] A. L. O'Boyle, J. D. O'Boyle, B. Calhoun, and G. D. Davis, "Pelvic organ support in pregnancy and postpartum," *International Urogynecology Journal*, vol. 16, no. 1, pp. 69–72, 2005.

[7] D. A. Patel, X. Xu, A. D. Thomason, S. B. Ransom, J. S. Ivy, and J. O. L. DeLancey, "Childbirth and pelvic floor dysfunction: an epidemiologic approach to the assessment of prevention opportunities at delivery," *American Journal of Obstetrics and Gynecology*, vol. 195, no. 1, pp. 23–28, 2006.

[8] J. O. L. DeLancey, R. Kearney, Q. Chou, S. Speights, and S. Binno, "The appearance of levator ani muscle abnormalities in magnetic resonance images after vaginal delivery," *Obstetrics & Gynecology*, vol. 101, no. 1, pp. 46–53, 2003.

[9] S. L. Hendrix, A. Clark, I. Nygaard, A. Aragaki, V. Barnabei, and A. McTiernan, "Pelvic organ prolapse in the women's health initiative: gravity and gravidity," *American Journal of Obstetrics and Gynecology*, vol. 186, no. 6, pp. 1160–1166, 2002.

[10] H. P. Dietz and V. Lanzarone, "Levator trauma after vaginal delivery," *Obstetrics & Gynecology*, vol. 106, no. 4, pp. 707–712, 2005.

[11] K. L. Shek and H. P. Dietz, "Intrapartum risk factors for levator trauma," *BJOG*, vol. 117, no. 12, pp. 1485–1492, 2010.

[12] R. J. Fernando, A. H. Sultan, S. Radley, P. W. Jones, and R. B. Johanson, "Management of obstetric anal sphincter injury: a systematic review & national practice survey," *BMC Health Services Research*, vol. 2, no. 1, article 1, p. 9, 2002.

[13] M. T. McLennan, C. F. Melick, S. L. Clancy, and R. Artal, "Episiotomy and perineal repair: an evaluation of resident education and experience," *The Journal of Reproductive Medicine*, vol. 47, no. 12, pp. 1025–1030, 2002.

[14] K. M. Groom and S. Paterson-Brown, "Can we improve on the diagnosis of third degree tears?" *European Journal of Obstetrics Gynecology and Reproductive Biology*, vol. 101, no. 1, pp. 19–21, 2002.

[15] V. Andrews, R. Thakar, A. H. Sultan, and C. Kettle, "Can hands-on perineal repair courses affect clinical practice?" *British Journal of Midwifery*, vol. 13, pp. 562–565, 2005.

[16] A. H. Sultan, M. A. Kamm, and C. N. Hudson, "Obstetric perineal trauma: an audit of training," *Journal of Obstetrics and Gynaecology*, vol. 15, no. 1, pp. 19–23, 1995.

[17] R. Thakar, A. H. Sultan, R. Fernando, A. Monga, and S. Stanton, "Can workshops on obstetric anal sphincter rupture

change practice?" *International Urogynecology Journal*, vol. 12, no. 3, p. S5, 2001.

[18] M. Solans-Domènech, E. Sánchez, and M. Espuña-Pons, "Urinary and anal incontinence during pregnancy and postpartum: incidence, severity, and risk factors," *Obstetrics & Gynecology*, vol. 115, no. 3, pp. 618–628, 2010.

[19] A. P. Betrán, M. Merialdi, J. A. Lauer et al., "Rates of caesarean section: analysis of global, regional and national estimates," *Paediatric and Perinatal Epidemiology*, vol. 21, no. 2, pp. 98–113, 2007.

[20] S. Cabré, M. A. Rodríguez, A. Vela, M. Borràs, and J. M. Lailla, "Incidencia de cesáreas: evolución, causas. Análisis de 17 años," *Progresos de Obstetricia y Ginecología*, vol. 45, no. 5, pp. 192–200, 2002 (Spanish).

[21] H. P. Dietz, "Pelvic floor assessment," *Fetal and Maternal Medicine Review*, vol. 20, no. 1, pp. 49–66, 2009.

[22] S. Jha, R. Freeman, P. Toozs-Hobson, and D. Richmond, "Urogynaecology training in the UK: past, present and future," *International Urogynecology Journal*, vol. 20, no. 4, pp. 377–380, 2009.

[23] N. Y. Siddiqui, K. J. Stepp, S. J. Lasch, J. M. Mangel, and J. M. Wu, "Objective structured assessment of technical skills for repair of fourth-degree perineal lacerations," *American Journal of Obstetrics & Gynecology*, vol. 199, no. 6, pp. 676.e1–676.e6, 2008.

[24] S. Siddighi, S. D. Kleeman, M. S. Baggish, C. M. Rooney, R. N. Pauls, and M. M. Karram, "Effects of an educational workshop on performance of fourth-degree perineal laceration repair," *Obstetrics & Gynecology*, vol. 109, no. 2, part 1, pp. 289–294, 2007.

[25] M. O. Schimpf, D. M. Feldman, D. M. O'Sullivan, and C. A. LaSala, "Resident education and training in urogynecology and pelvic reconstructive surgery: a survey," *International Urogynecology Journal*, vol. 18, no. 6, pp. 613–617, 2007.

[26] C. J. Sultana, K. Kenton, E. Ricci, and R. G. Rogers, "The state of residency training in female pelvic medicine and reconstructive surgery," *International Urogynecology Journal*, vol. 18, no. 11, pp. 1347–1350, 2007.

[27] G. Lacima and M. Espuña, "Patología del suelo pélvico," *Gastroenterologia y Hepatologia*, vol. 31, no. 9, pp. 587–595, 2008 (Spanish).