Plenary 5 - Urogynecology

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Plenary 5 - Urogynecology

Moderators: E. Cristian Campian, Conrad J. Duncan, Bruce S. Kahn

Faculty: Catherine A. Matthews, John R. Miklos, Erinn M. Myers, Guenter K. Noe, Holly E. Richter, Peter L. Rosenblatt

This session provides a range of studies on minimally invasive urogynecologic topics. The session also provides the latest data on new and established treatment options for a variety of urogynecologic conditions.

Learning Objectives: At the conclusion of this course, the clinician will be able to: 1) discuss minimally invasive techniques for urogynecologic conditions; and 2) describe several investigational treatment options for pelvic floor disorders.

Course Outline

11:00  Clinical Characteristics Associated with Successful Use of a Novel Vaginal Bowel Control System for the Treatment of Fecal Incontinence  C.A. Matthews

11:10  A Randomized Trial of Laparoscopic Sacral Colpopexy Versus Laparoscopic Pectopexy for Vaginal and Uterine Prolapse  G.K. Noe

11:20  The 26-Minute Sacral Colpopexy: Do We Really Need Robotic Technology?  J.R. Miklos

11:27  Clinical Efficacy and Safety Evaluation of the Vaginal Control (VBC) System for Treatment of Fecal Incontinence  H.E. Richter

11:37  Laparoscopic Revision of Anterior Mesh Kit Arms for Post-Operative Pelvic Pain  P.L. Rosenblatt

11:44  Equivalence of Two Techniques for Assessing Postoperative Voiding Function – A Randomized Trial  E.M. Myers

12:00  Adjourn
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Grants/Research: Abbvie, Boston Scientific Corp. Inc.
Catherine A. Matthews
Grants/Research: Boston Scientific Corp. Inc.
John R. Miklos
Grants/Research: Allergan, Astellas, Coloplast, Starpharma, United BioSource
Consultant: Coloplast, Endo Evolution, LLC, Gyrus ACMI (Olympus)
Speakers Bureau: Coloplast
Other: Surgical Preceptor: Coloplast, Gyrus ACMI (Olympus)
Erinn M. Myers*
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Consultant: Pelvalon
Other: Royalties: UpToDate

Peter L. Rosenblatt
Grants/Research: Boston Scientific Corp. Inc., Coloplast
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Asterisk (*) denotes no financial relationships to disclose.
Clinical characteristics associated with successful use of a novel Vaginal Bowel Control (VBC) system for the treatment of fecal incontinence

Catherine A Matthews, MD
Associate Professor and Division Chief of Urogynecology and Reconstructive Pelvic Surgery
University of North Carolina

On Behalf of the LIFE Study Investigators:
Catherine A Matthews, MD, Madhulika G Varma, MD, Michelle M Takase-Sanchez, MD, Douglas S Hale, MD, Tressa Muir, MD, Scott Wells, MD, Mary Jannelli, MD, Holly E Richter, PhD, MD.

Disclosures
Grants/Research: Boston Scientific Corp. Inc.

Background

• Fecal incontinence (FI) affects 7-15% of ambulatory women
• Conservative treatment options: Anti-diarrhea agents; biofeedback; passive anal barriers; injectable agents
• Surgical treatment options: Sphincteroplasty; Artificial anal sphincter; Sacral neuromodulation therapy
• Treatment gap for low risk, low cost, high efficacy option

Primary efficacy analysis of VBC system

• The LIFE study demonstrated:
  » High efficacy: 79% (86% per protocol) of patients met treatment success criteria
  » Statistically and clinically significant improvement in symptom-specific QOL
  » No serious adverse events, no unexpected AE’s

Study Objectives

• To evaluate factors that predict successful fitting of the vaginal bowel control device for fecal incontinence
• To assess the interaction between baseline FI characteristics and overall treatment efficacy: Does stool consistency impact device effectiveness?
Methods

• Prospective Cohort Study of women with at least 4 FI episodes over 2 weeks. Primary study outcome was device efficacy (reported separately)

• Secondary Analyses:
  » Data from the subject’s background and pelvic examination were compared across successful and unsuccessful fitting groups.
  » Multivariate, logistic regression analysis was performed.
  » Paired T-tests were used to characterize the difference in FI symptoms from baseline to treatment.

Device Fitting Instructions

• Perform a standard pelvic exam to estimate device size

• Place Insert in the vagina. It should naturally come to rest in the proximal vagina adjacent to the rectum

  » Ask patient to perform a Kegel maneuver to help the Insert settle into the appropriate position.

• Perform a manual vaginal exam to check for a finger’s breadth of clearance between the Insert and the vaginal walls.

• Inflate the Balloon slowly.

• Check for patient comfort, and that there is still about a finger’s breadth of clearance between the device and the vaginal walls

Device Fitting Instructions, cont.

• Perform a rectal exam to evaluate reduction in rectal space. If the balloon protrusion is easily moved with digital pressure, try a larger size.

  » Have the patient perform a mild Valsalva maneuver to ensure device stability.

  » If the device falls below the symphysis into the mid-vaginal plane, and does not retract after the Valsalva, consider a different size device.

  » Have the patient sit up, stand, and walk about the exam room, and try to urinate.

A Properly Fit Device

• Dynamic occlusion above the sphincter complex results in a high efficacy, including across stool presentations.

Results

» 110 women were fit with the VBC Insert.

» 61 entered the ITT cohort and are therefore considered fitting successes.

Fitting Predictors

<table>
<thead>
<tr>
<th></th>
<th>Unsuccessfully Fit</th>
<th>Successfully Fit</th>
<th>p-value* (univariate)</th>
<th>p-value* (multivariate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years; mean (SD)</td>
<td>63.3 (8.7)</td>
<td>60.9 (9.4)</td>
<td>0.16</td>
<td>0.134</td>
</tr>
<tr>
<td>Ethnic origin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body-mass index; mean (SD)</td>
<td>27.3 (5.3)</td>
<td>28.1 (6.6)</td>
<td>0.48</td>
<td></td>
</tr>
<tr>
<td># of Vaginal Births; mean (SD)</td>
<td>2.0 (1.1)</td>
<td>2.1 (1.0)</td>
<td>0.50</td>
<td></td>
</tr>
<tr>
<td>Prior Menopause</td>
<td>36%</td>
<td>63%</td>
<td>0.012</td>
<td>0.262</td>
</tr>
<tr>
<td>Sexual Activity; Y/N</td>
<td>37%</td>
<td>44%</td>
<td>0.19</td>
<td></td>
</tr>
<tr>
<td>Prior Hysterectomy; Y/N</td>
<td>65%</td>
<td>48%</td>
<td>0.029</td>
<td>0.506</td>
</tr>
<tr>
<td>Prior Prolapse Surgery*</td>
<td>33%</td>
<td>8%</td>
<td>0.0006</td>
<td>0.0008</td>
</tr>
<tr>
<td>Vaginal Length, cm; mean (SD)</td>
<td>8.0 (1.1)</td>
<td>8.7 (1.3)</td>
<td>0.0011</td>
<td>0.042</td>
</tr>
<tr>
<td>Degree of Vaginal Atrophy*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tissue Compliance*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Logistic regression. 1Sexually active ≥ 1x/month. 2Includes any vaginal prolapse surgery, excluding hysterectomy. 3Characterized as: none, mild, moderate, severe. 4Characterized as: very compliant, somewhat compliant, and/or many inelastic bands of tissue.
Associated factors with fitting failure

- Shorter vaginal length, vaginal atrophy, and previous prolapse surgery were associated with increased risk of unsuccessful fitting (similar to vaginal pessaries)

Fitting VBC Insert in Atrophic Tissue

- Atrophic tissue may be more likely to limit protrusion of balloon into rectal space instead of conforming, also potentially destabilizing the device

Improvement Seen in All Categories of Bowel Movements

Characteristics of Continent Episodes

Conclusions

- Shorter vaginal length, vaginal atrophy, and previous prolapse surgery were associated with increased potential for unsuccessful fitting.
- This information can be used to counsel patient expectations regarding the VBC fitting experience.
- Successfully fit devices reduced all types of FI episodes and improved continent bowel movements.

References

A Randomized Trial of Laparoscopic Sacral Colpopexy Versus Laparoscopic Pectopexy for Vaginal and Uterine Prolapse

G.K. Noé

Disclosure

I have no financial relationships to disclose.

The Pectopexy is designed as an alternative to sacral colpopexy

Main indication
Central (apical defect)

The Pectopexy and sacral colpopexy form the core of a defect oriented system of pelvic floor repair.

rectocele
entero-cele

methods:
vaginal plastics (classic; ant./post) colposuspension (incontinence and lateral defect)
sacral colpopexy pectopexy vaginal meshes

All compartments get regarded and weighted one by one. Each defect is treated according to its grade and the patients symptoms.
Laparoscopic Colposuspension

short technique video

Sacral- colpo-/cervico-pexy

short technique video sacropexy

S2

without the disadvantages of the limitation of the pelvis with resulting defecation disturbance or ileus

Pectopexy

surgical direction

Pectopexy Fix. Point

vaginal direction

Sacromuscular pectopexy: a new technique of prolapse surgery

Prof. Dr. T. Wedel, Anatomic Institute at the University of Kiel Germany

Pectopexie

lateral fixation method

Laparoscopic pectopexy: a new technique of prolapse surgery

Prof. Dr. T. Wedel, Anatomic Institute at the University of Kiel Germany
Summary

Careful defect diagnostics forms the basis of an optimal treatment!
Symptomatic is important! (less is more)
Choice of the necessary methods!
Broad portfolio of operation techniques to reduce risks and side effects!

The Aim!
Happy patients!!

Thank you for your kind attention!

Post Operative results
prospective, randomised trial Sakropey v. Pectopy

<table>
<thead>
<tr>
<th>N 84</th>
<th>Age</th>
<th>Height</th>
<th>Weight</th>
<th>Hospital stay (days)</th>
<th>OP-dur.</th>
<th>Incontinence</th>
<th>Sexual life</th>
<th>Urethral prolapse</th>
<th>Urethral retraction</th>
<th>Denovo prolapse</th>
<th>Denovo Urgency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sakro</td>
<td>59.95</td>
<td>163</td>
<td>52.75</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pecto</td>
<td>59.06</td>
<td>163</td>
<td>51</td>
<td>44.57</td>
<td>0</td>
<td>1</td>
<td>2,000 days</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

No organ damage >90% Combination interventions

Mean Follow Up 21.3 mo. Pecto-G and 18.9 mo. Sacro-G

<table>
<thead>
<tr>
<th>%79</th>
<th>Rutapase (apical)</th>
<th>Denovo defacement problems %</th>
<th>Denovo incontinence %</th>
<th>Denovo recto-colo defect %</th>
<th>Denovo midline defect %</th>
<th>Denovo Lateral defect %</th>
<th>Denovo Urgency %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sakro 4</td>
<td>5</td>
<td>4.9</td>
<td>9.8</td>
<td>5.3</td>
<td>12.3</td>
<td>17.0</td>
<td></td>
</tr>
<tr>
<td>Pecto 2</td>
<td>1.2</td>
<td>4.8</td>
<td>9.5</td>
<td>5.0</td>
<td>0.0</td>
<td>7.1</td>
<td></td>
</tr>
</tbody>
</table>

Satisfaction – rate: 95.1 v. 97.6% Follow up 1.5-3.1 years

The laparoscopic pectopy is a good alternative to the laparoscopic sacropey. It is equally effective and shows no defecation disorders in the long-term follow-up.

Side effects seem to be low.
Multi-center studies must show the results in daily practice.

The 26-minutes Laparoscopic Sacral Colpopexy
Do We Really Need Robotic Technology?

John R. Miklos, M.D., Robert D. Moore, D.O.
International Urogynecology Associates of Atlanta, Georgia, and Beverly Hills, California

**Study Objective:** To demonstrate the technical steps of a laparoscopic sacral colpopexy (LSC) 2) demonstrate the efficiency of LSC 3) review comparative LSC and robotic assisted sacral colpopexy (RSC) literature and 4) challenge surgeons’ conventional wisdom of RSC.

**Design:** A timed stamped video with a step-by-step explanation of the technique and slides of comparative trials and benefits of robotic surgery are utilized.

**Setting:** Sacral colpopexy remains the gold standard surgical procedure for the treatment of vaginal vault prolapse. It can be performed via laparotomy, laparoscopically with and without the robotic assistance. Robotic technology has been marketed based on unsubstantiated claims including: better visualization, smaller incisions, less blood loss, and greater efficiency. Conventional wisdom suggests that robot assisted laparoscopic surgery is easier and thus faster for the practicing surgeon.

**Intervention:** A timed stamped video of laparoscopic sacral colpopexy in a woman with vaginal vault prolapse is performed in 26 minutes utilizing 14 sutures in the vagina, 2 in the presacral ligament. The stopwatch begins after the placement of the scope in the abdomen and before the placement of the 3 accessory posts and ends with peritoneal closure over the sacral colpopexy mesh.

**Conclusion:** A review of the literature suggests that the average robotic assisted laparoscopic sacral colpopexy takes 260 minutes; the laparoscopic sacral colpopexy average is 200 minutes with the conventional LSC technique realizing a time savings of at least 60 minutes. Our 26 minute LSC supports this finding.
Clinical Efficacy and Safety Evaluation of the Vaginal Bowel Control System for Treatment of Fecal Incontinence

Holly E Richter, PhD, MD
J Marion Sims Professor, Obstetrics and Gynecology
Director, Division of Women’s Pelvic Medicine and Reconstructive Surgery
University of Alabama at Birmingham

On behalf of the LIFE Study Investigators:
Holly E Richter, PhD, MD, Catherine A Matthews, MD, Madhulika G Varma, MD, Michelle M Takase-Sanchez, MD, Douglass S Hale, MD, Douglas Van Drie, MD, Tristi Muir, MD

Disclosures

- Grants/Research: Pelvalon
- Consultant: Pelvalon
- Other: Royalties: UpToDate

Objectives

- At the conclusion of this activity, the participant will be able to:
  - Understand a new therapy for treating fecal incontinence, the Vaginal Bowel Control (VBC) System
  - Describe the effectiveness and safety of the VBC System as demonstrated by the LIFE study

Introduction

- Fecal incontinence (FI), also referred to as accidental bowel leakage (ABL), is a debilitating condition and a significant unmet need in women’s health
- The cause of FI is multifactorial, including congenital, neurologic, and traumatic alterations of the continence mechanism
- Numerous treatments are available for FI but suffer from shortcomings in efficacy, morbidity, cost, and patient compliance

New Paradigm: Vaginal Bowel Control (VBC) System

- A non-surgical treatment option consisting of a vaginal insert and pressure-regulated pump
- Designed to offer a low-risk and easily reversible treatment for FI
- Dynamic control of rectum by the patient

VBC System Components

VBC Insert
- Dual-layer balloon: silicone surface, polyurethane bladder
- Physician customizes pressure, balloon and base size to each patient
- Flexible base composed of silicone and stainless steel

Detachable Inflation Pump
- Regulator sets balloon pressure
- Allows patient to deflate balloon for bowel movements
Trial Design – LIFE Study

Objective
To evaluate the safety and effectiveness of the Vaginal Bowel Control System for the treatment of female fecal incontinence

Design
Multi-center, prospective, open label clinical trial

Sites
6 US sites

Inclusion Criteria
Females, age 19-75 years.
≥4 FI episodes on baseline diary (2/wk); major & minor soiling only

Primary Outcome
Proportion of women obtaining ≥50% reduction of FI episodes

Secondary Outcomes
FIQOL, MMHQ, PGI-I, patient satisfaction

Adverse events

Fitting Period
Period (May repeat)
| 2 weeks | 1 week | 1 month | 2 months |

Treatment Period
Baseline Diary

Optional Treatment Period
Diary

Statistical Analysis

- ITT analysis for primary outcome (1 month); per protocol at 1 and 3 months
- Incidence rates were reported for device-related adverse events
- Means and standard deviations were used to present FI rates and other continuous variables
- Paired t-tests were used to test for differences between baseline and follow-up metrics including average number of FI episodes/week and quality of life scores
- 40 women were needed to achieve significance when a minimum of 40% of subjects met treatment success (50% reduction in FI episodes) providing 80% power at an α = 0.025 using the Exact Binomial Test

Results
Patient Flow

Consented (200)

Screen Failures (Pre-Fitting) (46)

Baseline Diary (154)

Ineligible by Diary: <2 episodes/wk (44)

Entered Fitting Period (110)

Fit Not Achieved and Other Screen Failures (Post-Fitting) (49)

Entered Treatment Period (ITT cohort) (61)

Study Discontinuations (3)

Completed Treatment Period with no major deviations (Per Protocol Cohort) (56)

Completed Optional Treatment Period with analyzable diaries (44)

- Unanalyzable diary (1)
- Lost to follow-up during OTP (3)

Unanalyzable Diaries (2)

Patient Characteristics

N=61

<table>
<thead>
<tr>
<th>Age (years) [mean±SD]</th>
<th>60.8±9.4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethnic origin</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>(45) 74%</td>
</tr>
<tr>
<td>Black</td>
<td>(10) 16%</td>
</tr>
<tr>
<td>Body-mass index ≥30</td>
<td>(18) 30%</td>
</tr>
<tr>
<td>Previous gynecologic surgeries</td>
<td></td>
</tr>
<tr>
<td>Hysterectomy</td>
<td>(29) 48%</td>
</tr>
<tr>
<td>Prior prolapse surgery</td>
<td>(5) 8%</td>
</tr>
<tr>
<td>Prior urinary incontinence surgery</td>
<td>(9) 15%</td>
</tr>
<tr>
<td>Parity (mean±SD [range])</td>
<td>2.1±1.1 (0-4)</td>
</tr>
<tr>
<td>Post-menopause (self-reported)</td>
<td>(51) 85%</td>
</tr>
</tbody>
</table>

Number of fecal incontinence episodes per 2-week period [mean±SD [range]] 11.8±9.1 (4-56)

Outcomes

<table>
<thead>
<tr>
<th>Proportion of Patients Achieving Treatment Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Month Treatment Period</td>
</tr>
</tbody>
</table>
| Intent-to-Treat Cohort  | 78.7% (48/61) (95% CI 66%, 90%)
| Per-Protocol Cohort*    | 85.7% (48/56) (95% CI 74%, 94%)

*5 subjects were excluded from 1 month PP analysis due to non-analyzable diary data (2), exited due to unrelated health issues (2), and withdrew consent (1)
Quality of Life

**FIQOL Subscales**

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Baseline Mean</th>
<th>1 Month Mean</th>
<th>3 Month Mean</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression</td>
<td>1.8</td>
<td>2.0</td>
<td>2.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Coping Behavior</td>
<td>2.8</td>
<td>3.0</td>
<td>3.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Embarrassment</td>
<td>3.5</td>
<td>3.5</td>
<td>3.5</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**MMHQ Subscales**

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Baseline Mean</th>
<th>1 Month Mean</th>
<th>3 Month Mean</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incontinence Impact</td>
<td>40</td>
<td>42</td>
<td>45</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Role Limitations</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Physical Limitations</td>
<td>60</td>
<td>60</td>
<td>60</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Social Limitations</td>
<td>70</td>
<td>70</td>
<td>70</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Personal Relationships</td>
<td>80</td>
<td>80</td>
<td>80</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Emotions</td>
<td>90</td>
<td>90</td>
<td>90</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Sleep/Energy</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Other Secondary Outcomes

- 86% of patients (48/56) reported control of their FI as being “Very much better” (57%) or “Much better” (29%) on the PGI-I question.
- 89% (50/56) were satisfied with their experience using the device (very/somewhat).
- 96% of patients reported the insert to be comfortable (48%) or could not feel it (48%).

Adverse Events:
- No device-related serious adverse events
- Most common: cramping or discomfort: fitting (15%, 16/110), ITT (10%, 6/61), PP (11%, 6/56), extended wear (6%, 4/69)
- 72% (67/93) of AEs occurred in Fitting Period

Conclusions

- VBC System is a new paradigm for treating FI
  - Low-risk and reversible
  - Dynamic control of the rectum
- LIFE study demonstrated
  - High efficacy: 79% (86% per protocol) of patients met treatment success criteria
  - Statistically and clinically significant improvement in symptom-specific QOL
  - No serious adverse events, no unexpected AE’s

Clinical Significance

- VBC System can be tried early in the treatment algorithm without eliminating other treatment options
- The initial fitting procedure, including setting the pressure regulation and rectal occlusion, requires provider and patient training beyond traditional vaginal inserts
- Once successfully fit, a high degree of efficacy and patient satisfaction can be expected
- Longer-term follow-up studies with increased patient experience are planned

Next Generation

- Images and descriptions of Next Generation VBC System

References

Laparoscopic Revision of Anterior Mesh Kit Arms for Post-Operative Pelvic Pain

Peter L Rosenblatt, MD
Mount Auburn Hospital, Cambridge, MA

**Study Objective:** To demonstrate a technique of laparoscopic excision of anterior mesh kit arms.

**Design:** Narrated video presenting a step-by-step explanation of a technique for laparoscopic excision of vaginal mesh.

**Setting:** Community teaching hospital affiliated with a major teaching hospital.

**Intervention:** A laparoscopic approach to removal of anterior mesh arms was performed. The bladder was backfilled with approximately 300 cc of water stained with indigo carmine to outline the superior margin of the bladder. The retropubic space was entered and the vaginal mesh arms were identified and excised.

**Conclusion:** This video demonstrates that a laparoscopic approach to removal of vaginal mesh arms is technically feasible with positive patient outcome.
Equivalence of Two Techniques for Assessing Postoperative Voiding Function – a Randomized Trial

Erinn Myers MD
Division of Female Pelvic Medicine and Reconstructive Surgery
University of North Carolina, Chapel Hill

Disclosure
- I have no financial relationships to disclose
- This study was conducted at the University of North Carolina, Chapel Hill

Objective
At the conclusion of this presentation, the participant will be better able to:
- Articulate the need for postoperative voiding trial
- Discuss retrograde postoperative voiding trial techniques

Background
- Postoperative voiding function is recommended after midurethral sling placement
  - Postoperative voiding dysfunction 19%-37%1-3
- When backfill technique is compared to spontaneous fill
  - Backfill more likely to be effective (61.5% vs 32.1%, p=02)4
  - Backfill is preferred by patients (51.1% vs 44.4%)5

Study Question
- When is the best time to initiate the backfill voiding trail?
  - In the operating room (OR)?
  - In the post-anesthesia care unit (PACU)?

Study Objectives
- Primary
  - To assess whether PACU-fill decreased overall time to discharge compared to OR-fill
- Secondary
  - To determine if OR-fill is equivalent to PACU-fill for voiding function assessment after midurethral sling placement
Inclusion
Women ≥18 years
SUI on urodynamics
Scheduled for midurethral sling

Exclusion
Prior incontinence surgery
Concomitant surgery (except anterior colporrhaphy)
Intraoperative cystotomy

Randomization
OR-fill
PACU-fill
Voiding Trial in PACU

Methods
• Midurethral Sling Procedure
  – Monitored anesthesia care with local anesthetic
  – Cystoscopy performed after sling placement
  – Women were randomized if no trocar injury was identified during cystoscopy

Backfill Techniques
• OR-fill
  – Trocar placement
  – Cystoscopy (300 mL fill)
  – Bladder left filled
  – Foley not replaced
  – Patient transferred to PACU with full bladder
  – Measure void
  – Measure PVR

• PACU-fill
  – Trocar placement
  – Cystoscopy (300 mL fill)
  – Bladder emptied
  – Foley replaced
  – Patient transferred to PACU
  – Backfill with 300 mL NS
  – Foley removed
  – Measure void
  – Measure PVR

Successful void trial = PVR <100 mL

Power Calculation
• Prior study evaluating PACU time for two types of voiding trials after vaginal surgery found a 26 minutes difference between groups
• 29 subjects were needed in each group to be able to reject the null hypothesis with a power of 80% and alpha of .05

<table>
<thead>
<tr>
<th></th>
<th>OR Fill n=30</th>
<th>PACU Fill n=29</th>
<th>p value</th>
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<tbody>
<tr>
<td>Age (yrs)</td>
<td>52 ± 9.7</td>
<td>55 ± 13.1</td>
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</tr>
<tr>
<td>Body Mass Index (kg/m²)</td>
<td>29 ± 6</td>
<td>29 ± 4.7</td>
<td>.78</td>
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<tr>
<td>Bladder Capacity (mL)</td>
<td>599 ± 175</td>
<td>476 ± 245</td>
<td>.07</td>
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<tr>
<td>Post Void Residual (mL)</td>
<td>401 ± 269</td>
<td>299 ± 233</td>
<td>.13</td>
</tr>
<tr>
<td>Anterior Repair (%)</td>
<td>8 (26.7)</td>
<td>6 (20.7)</td>
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<td>Sling Type</td>
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</table>

Duration of Surgery
**Summary**

**• Strengths**
  - Randomized trial
  - Only concomitant procedure was anterior repair

**• Limitations**
  - Unable to assess for reasons PACU time was longer

**Conclusion**

**• Intraoperative bladder filling did not decrease time in PACU compared to traditional bladder filling in PACU**

**• OR-fill and PACU-fill demonstrated similar voiding trial pass rates**

**• Both techniques acceptable options for assessment of bladder function after sling placement**
References


CULTURAL AND LINGUISTIC COMPETENCY

Governor Arnold Schwarzenegger signed into law **AB 1195** (eff. 7/1/06) requiring local CME providers, such as the AAGL, to assist in enhancing the cultural and linguistic competency of California's physicians (researchers and doctors without patient contact are exempt). This mandate follows the federal Civil Rights Act of 1964, Executive Order 13166 (2000) and the Dymally-Alatorre Bilingual Services Act (1973), all of which recognize, as confirmed by the US Census Bureau, that substantial numbers of patients possess limited English proficiency (LEP).

California Business & Professions Code §2190.1(c)(3) requires a review and explanation of the laws identified above so as to fulfill AAGL's obligations pursuant to California law. Additional guidance is provided by the Institute for Medical Quality at [http://www.imq.org](http://www.imq.org).

**Title VI of the Civil Rights Act of 1964** prohibits recipients of federal financial assistance from discriminating against or otherwise excluding individuals on the basis of race, color, or national origin in any of their activities. In 1974, the US Supreme Court recognized LEP individuals as potential victims of national origin discrimination. In all situations, federal agencies are required to assess the number or proportion of LEP individuals in the eligible service population, the frequency with which they come into contact with the program, the importance of the services, and the resources available to the recipient, including the mix of oral and written language services. Additional details may be found in the Department of Justice Policy Guidance Document: Enforcement of Title VI of the Civil Rights Act of 1964 [http://www.usdoj.gov/crt/cor/pubs.htm](http://www.usdoj.gov/crt/cor/pubs.htm).

**Executive Order 13166,”Improving Access to Services for Persons with Limited English Proficiency”,** signed by the President on August 11, 2000 [http://www.usdoj.gov/crt/cor/13166.htm](http://www.usdoj.gov/crt/cor/13166.htm) was the genesis of the Guidance Document mentioned above. The Executive Order requires all federal agencies, including those which provide federal financial assistance, to examine the services they provide, identify any need for services to LEP individuals, and develop and implement a system to provide those services so LEP persons can have meaningful access.

**Dymally-Alatorre Bilingual Services Act** (California Government Code §7290 et seq.) requires every California state agency which either provides information to, or has contact with, the public to provide bilingual interpreters as well as translated materials explaining those services whenever the local agency serves LEP members of a group whose numbers exceed 5% of the general population.

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