Plenary 5 – Urogynecology

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Professional Education Information

Target Audience
This educational activity is developed to meet the needs of residents, fellows and new minimally invasive specialists in the field of gynecology.

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Plenary 5 – Urogynecology

Moderators: Cheryl B. Iglesia and Bruce S. Kahn
Faculty: John R. Miklos, Erinn M. Myers, Melissa Pendergrass, Suran R. Ramphal, Douglas Van Drie, Ming-Ping Wu

This session will include reviews of several submissions related to urogynecology including: 1) the need for screening patients for uterine pathology prior to laparoscopic sacrocolpopexy at the time of supracervical hysterectomy; 2) a description and review of a technique for laparoscopic transperitoneal extravesical vesico-vaginal fistula repair as well as, 3) laparoscopic repair of uterogential fistulas; 4) 12 month results for an adjustable sling for the treatment of SUI; 5) The utility of a web-based interactive educational tool for counseling patients with POP; 6) review of risk factors for and procedures performed in repeat surgery for SUI.

Learning Objectives: At the conclusion of this course, the clinician will be able to: 1) Reduce the risk of unanticipated uterine neoplasia at the time of supracervical hysterectomy; 2) consider further exploration of laparoscopic repair of VVF; and 3) counsel patients more effectively prior to surgery for POP.

Course Outline

11:00 Unanticipated Pathology in the Uterine Specimen at the Time of Robotic Sacrocolpopexy M. Pendergrass

11:10 Laparoscopic Non-O’Connor Transperitoneal Extravesical Vesicovaginal Fistula Repair in 41 Patients: A Descriptive Technique and Feasibility Study J.R. Miklos

11:20 Feasibility of Laparoscopic Repair of Urogenital Fistulae S.R. Ramphal

11:30 Twelve-Month Results for an Adjustable Single Incision Sling in the Treatment of Female Stress Urinary Incontinence D. Van Drie

11:40 Interactive Web-Based Tool for Pelvic Organ Prolapse: Impact on Patient Understanding and Provider Counseling E.M. Myers

11:50 The Choice of Repeat Surgeries after Failed Primary Surgeries for Female Stress Urinary Incontinence, 1997-2010: A Population-based Nation-wide Descriptive Study M-P Wu

12:00 Closing Remarks/Adjourn
PLANNER DISCLOSURE
The following members of AAGL have been involved in the educational planning of this workshop and have no conflict of interest to disclose (in alphabetical order by last name).
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Viviane F. Connor
Consultant: Conceptus Incorporated
Kimberly A. Kho*
Frank D. Loffer, Executive Vice President/Medical Director, AAGL*
Linda Michels, Executive Director, AAGL*
M. Jonathan Solnik*
Johnny Yi*

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FACULTY DISCLOSURE
The following have agreed to provide verbal disclosure of their relationships prior to their presentations. They have also agreed to support their presentations and clinical recommendations with the “best available evidence” from medical literature (in alphabetical order by last name).
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Grants/Research: Boston Scientific, Karl Storz
Consultant: Karl Storz
Speakers Bureau: Avbie, Johnson & Johnson, Shionogi, Warner Chilcott
John R. Miklos
Consultant: Coloplast
Speakers Bureau: Coloplast
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Stock Ownership: Holstor, T-DOC, LLC
Erinn M. Myers*
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Douglas Van Drie
Grants/Research: Coloplast
Consultant: Coloplast
Speakers Bureau: Astellas
Other: Preceptor: Medtronic
Ming-Ping Wu*

Asterisk (*) denotes no financial relationships to disclose.
Unanticipated pathology in the uterine specimen at the time of robotic sacrocolpopexy

Melissa Pendergrass, M.D. - MIGS Fellow, Legacy Health

I have no financial relationships to disclose.

Objectives

1) Measure the prevalence of unanticipated gynecologic pathology at the time of hysterectomy with robotic sacrocolpopexy

2) Identify predictive risk factors for having unanticipated gynecologic pathology at the time of robotic hysterectomy with sacrocolpopexy

Background

Women have an 11% - 19% lifetime risk of undergoing surgery for pelvic organ prolapse and/or urinary incontinence

Robotic sacrocolpopexy gaining popularity

47% of women underwent a concomitant hysterectomy

Many reconstructive surgeons now prefer LSH to TLH in order to decrease the risk of mesh complications, specifically erosion

Background

Current endometrial screening models are from the abnormal uterine bleeding population

No screening recommendations in asymptomatic patient population

Rates of abnormal uterine pathology reported in literature = 0.2 – 2.6%

Materials and Methods

Cross-sectional prevalence study

Four large metropolitan based community hospitals in Portland, Oregon; March 2010 and March 2012

Inclusion criteria: women undergoing a hysterectomy at the time of sacrocolpopexy using the DaVinci surgical robot

Exclusion criteria: known cases of pre-malignant or malignant uterine/cervical pathology, and known adnexal masses

Chart review of patient demographics, operative and pathology reports
**Demographic data**

- 119 patients
  - 88 LSH
  - 31 TLH

**Results**

- 7 cases of abnormal pathology
  - 3 CAEH
  - 4 endometrial cancer

The prevalence of unanticipated uterine pathology was 6% (95% CI 1%-10%)

**Discussion**

- Escalating concern for mesh erosion
- Increasing rates of LSH with RA SCP
- Risk of morcellating unanticipated uterine pathology
- Management dilemma for patient and physician

**Conclusion**

This study exposes a possible need for pre-operative screening of asymptomatic women who are undergoing a robotic hysterectomy and sacrocolpopexy. This may be particularly true for those with risk factors such as obesity and diabetes.
References


LAPAROSCOPIC NON-O’CONOR TRANSPERITONEAL EXTRAVESICAL VESICOVAGINAL FISTULA REPAIR IN 41 PATIENTS: A DESCRIPTIVE TECHNIQUE & FEASIBILITY STUDY

JOHN R MIKLOS MD & ROBERT D MOORE DO
ATLANTA UROGYNECOLOGY ASSOCIATES
ATLANTA GA

DISCLOSURE
Consultant: Coloplast
Stockholder: T-DOC, LLC, HolstOR
Speakers Bureau: Coloplast
Other: Preceptor: Coloplast, Cook Medical, Gyrus ACMI Olympus, SurgiQuest

OBJECTIVE
• Differentiate between O’Conor & transperitoneal extravesical non – cystotomy
• Apply the steps of a transperitoneal extravesical VVF repair
• Recognize the feasibility of this approach
• Summarize the current literature regarding this technique

O’Conor Technique
• First Described -1950¹
• Abdominal approach
• Bivalve the bladder
• GOLD STANDARD

TRANSPERITONEAL EXTRAVESICAL VVF TECHNIQUE
• 1998- Von Theobold²
  - Bladder only????
• 1999- Miklos et al³
  - Vagina & bladder
• 1999-Miklos⁴
  - VUF w/o cystotomy
• 2005-Sotelo et al⁵
  - N=15  Cure=93%

Materials & Methods
• Retrospective Chart Review
• Primary or Recurrent VVF
• Laparoscopic Repair
• Atlanta Urogynecology Associate Surgeon
  - (JRM & RDM)
Material & Methods

- Age
- Etiology of VVF
- Number of previous repairs
- Length of Hospital Stay
- EBL
- Intraoperative or Postoperative Complications
- Success or Failure (cystoscopy/urogram/…)

Material & Methods

- 98% (40/41) – No omental flap
- 100% Suprapubic catheter
- 14 days - Average SP catheter
- 100% Antibiotics (p.o.) post operatively

RESULTS

- Age 46.7 (range 31-73)
- 41 VVF
  - 95% (39/41) Hysterectomy
  - No cancer or radiation patients
- 10 Recurrent VVF (25%)**
  - 1—— 3 previous failures
  - 3——2 previous failures
  - 6——1 previous failure
- ** 3 of the recurrent fistulas were after omental flaps

RESULTS

- Hospital stay -1.2 DAY (1-3) Hospital stay
- EBL–70 mL (5-200mL)
- 98% (40/41) Cure Rate
  - 1 failure repaired via open technique
  - 100% (10/10) cure – recurrent VVF
  - 100% (3/3) cure - recurrent VVF - omental flap
- No complications
- No laparotomies
Conclusion

Transperitoneal Extravesical (Non Cystotomy) VVF repair without omental flaps:

1. Acceptable cure rates
2. Primary or recurrent VVF
3. Can be performed successfully on failed VVF w/omental flaps
4. Require less trauma to the bladder wall
5. Safe & viable technique for the skilled laparoscopist

REFERENCE SLIDE

LAPAROSCOPIC REPAIR OF UROGENITAL FISTULAE

SURAN RAMPHAL

Disclosure

I have no financial relationships to disclose.

INTRODUCTION

Fistulae

- One of the most difficult clinical conditions encountered by pelvic surgeons.
- Most common cause in developed countries is iatrogenic
  - anxious patient and referring physician
- Incidence of 0.2-2.5%
- 90% occur after hysterectomy

SURGICAL APPROACH

SURGERY IS THE GOLD STANDARD

- Abdominal
- Vaginal
- Combined

Success repair – 75-97%

7 CASES

- 5 cases of laparoscopic repair following TAH
- 2 cases with vesico-uterine fistula following caeserean section

ABDOMINAL APPROACH

- Inadequate vaginal exposure and access
- Close proximity to ureters
- Multiple fistula
- Associated gynecological pathology

LAPAROSCOPY

- Minimally invasive
- Shorter hospital stay
- Quicker recovery time
- Minimal scars
- Magnification and more precise surgery
- Better access to pelvic pathology
• Ages – 41, 47, 55, 41, 38
• BMI – 31.2, 32.4, 28, 33, 34’1
• Average surgical time – 147 min (130-170)
• 3 way foleys catheter – kept in for 21 days
• Prophylactic antibiotics at surgery
• Nitrofurantoin for duration of catheterization
• Stents removed at 6 weeks in outpatient clinic
• Average hospital stay – 12 days (8 - 21)
• 6 months – one failure. Successfully repaired with an extraperitoneal approach
• No complications
UTEROVAGINAL FISTULA

• Ages 30 and 32
• Both had 2 previous c/s
• Incontinence occurred 1 and 2 months after C/S BUT diagnosis made 12 and 14 months
• Both had dysmenorrhea
• Regular periods but no cyclical haematuria
• No irritative bladder symptoms

SURGICAL MANAGEMENT

• Cystoscopy with ureteric stents inserted
• Bladder was densely adherent to the uterus
• Uterine curette for manipulation
• Bladder dissected of uterus
• Bladder repaired with vicryl 2.0 (2 layers)
• Uterine incision repaired
• Surgical time – 130 and 140 minutes
• 6 months – both patients were continent

Laparoscopic transperitoneal extravesical repair of vesicovaginal fistula

Abstract
Introduction and hypothesis: Laparoscopic repair of vesicovaginal fistula (VVF) has been recently reported. We present our experience of laparoscopic transperitoneal extravesical repair of VVF.

Methods: Nineteen patients with supratrigonal VVF were included. Patients with malignant neoplasms and recurrent fistula were excluded. Laparoscopic transperitoneal extravesical repair was done using forceps to suture the bladder, closed longitudinally, while the vagina was closed transversely, with tacks of resorbable material. The bladder was drained by a urethral catheter for 3 weeks. The mean operative time was 171.4 ± 18.3 mm. There was no conversion to open in all patients. Mean blood loss was 1101 ± 27 mg. No urinary or postoperative complications occurred. Mean hospital stay was 31.1 days. A mean follow-up of 39.3 ± 9.3 months all patients were cured.

Conclusion: Laparoscopic transperitoneal extravesical repair of VVF is a safe and effective minimally invasive procedure for treatment of VVF.

Early laparoscopic repair for supratrigonal vesicovaginal fistula

• 13 patients
• Average age 37.2 years
• All had previous abdominal hysterectomies
• All the fistulae were supratrigonal
• Surgery – 2-4 weeks after initial surgery
• Conversion to laparotomy in one d/t adhesions
• Vicryl 2.0 sutures – both vaginal and bladder repair
• Omental graft
• Discharged on day 5, foleys removed day 15
• At 21 months- one failure
CONCLUSION

• Laparoscopic VVF repair following hysterectomies and laparoscopic uterovesical fistula repair following caeserean sections are feasible and associated with good surgical outcome.

• Careful patient selection

• Specialized units
Twelve-month results for an adjustable single incision sling in the treatment of female stress urinary incontinence

Douglas M. Van Drie, M.D.
Director, Female Pelvic Medicine & Urogynecology Institute of Michigan
Grand Rapids, MI
Chairman, Spectrum Health Department of Obstetrics and Gynecology
Clinical Professor, Department of Obstetrics and Gynecology
Michigan State University College of Human Medicine

Disclosure
- Grants/Research Support: Coloplast
- Consultant: Coloplast
- Speakers Bureau: Astellas
- Other: Preceptor: Medtronic

Objectives:
- Present 12 month data on the Altis Sling
- Review Altis helical inside out single incision adjustable design
- Discussion of the 12 month efficacy and safety data

Study Objective and Design
Objective: Evaluate the efficacy and safety of a novel adjustable Altis® Single Incision Sling (SIS) for the treatment of stress urinary incontinence (SUI).

Design: Prospective Investigational Device Exemption study with two years follow-up.

Study Setting and Enrollment
Setting: 17 sites (16 US and 1 CA)
Patients: 113 women with diagnosed SUI Implanted between December 2010 – January 2012
No more than 25% of patients implanted at any site

Interventions: Implant of single incision sling

Altis Single Incision Sling System
- 7.75cm length
- Size 1 PP monofilament suture
- Helical inside-out approach
- Ergonomic with visual cue
- Tip leads into the membrane
- Anchors have semi-flexible tines designed for secure retention in tissue
- Dynamic anchor allows for intraoperative bi-directional tensioning and adjustability
Primary and Secondary Endpoints

Primary Endpoint
- Improvement > 50% measured by the 24-hour pad weight at 6 months

Secondary Endpoints
- Pad weight improvements over baseline at all other timepoints
- Cough stress test in the standing and lithotomy positions
- Assessment of subject Quality of Life (QoL)
- Patient Global Impression of Improvement (PGI-I)
- Assessment of device and procedure related adverse events

Inclusion and Exclusion Criteria

Inclusion
- Female ≥ 18 years of age
- Confirmed SUI through CST or urodynamics
- Has failed 2 non-invasive incontinence therapies for > 6 months
- Is able and willing to participate

Exclusion
- Neurogenic or urge predominant incontinence
- Active urogenital infection
- Pelvic organ prolapse stage II or greater
- Atonic bladder or post-void residual consistently >100 cc
- Prior surgical incontinence treatment
- Pregnant or desire to become pregnant
- Planning to undergo concomitant pelvic floor prolapse procedure

Baseline and Procedural Characteristics

Age: 54.5±14.0 (range: 25.3, 89.3)

Pre-operative Procedure Location
- Pre-op antibiotics 97.3% (110/113) In-patient hospital 59.3% (67/113)
- Pre-op estrogen 25.7% (29/113) ASC 23.9% (27/113)

Stress Urinary Incontinence History
- In-office 16.8% (19/113)
- Hypermobility 81.4% (92/113)

Anesthesia
- General 52.2% (59/113)
- Spinal 2.7% (3/113)

Baseline and 12 Month UDI-6 and IIQ-7 Scores

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Mean ± SD</th>
<th>Median</th>
<th>Range</th>
<th>95% CL</th>
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</thead>
<tbody>
<tr>
<td>UDI-6 at Baseline</td>
<td>55.8±18.8</td>
<td>55.5</td>
<td>16.7, 99.9</td>
<td>52.0, 59.1</td>
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<td>UDI-6 at 12 months</td>
<td>9.9±13.2</td>
<td>5.6</td>
<td>0.0, 66.6</td>
<td>7.3, 12.5</td>
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<tr>
<td>IIQ-7 at Baseline</td>
<td>54.3±25.4</td>
<td>57.0</td>
<td>4.0, 99.0</td>
<td>49.6, 59.0</td>
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<td>IIQ-7 at 12 months</td>
<td>8.2±18.1</td>
<td>0.0</td>
<td>0.0, 99.0</td>
<td>4.7, 11.7</td>
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Baseline and 12 Month UDI-6 and IIQ-7 Scores

Quality of Life Scores at Baseline and 12 Months

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<tr>
<th>Endpoint</th>
<th>Mean Reduction ±SD</th>
<th>Median</th>
<th>Range</th>
<th>95% CL</th>
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<tbody>
<tr>
<td>UDI-6*</td>
<td>45.8±20.3</td>
<td>44.4</td>
<td>-11.1, 94.4</td>
<td>41.8, 49.5</td>
</tr>
<tr>
<td>IIQ-7*</td>
<td>47.0±26.3</td>
<td>47.0</td>
<td>-9.5, 99.9</td>
<td>41.6, 52.1</td>
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*Statistically significant change from baseline to 12 months, p <0.0001

Efficacy Endpoints

Post-hoc Analysis at 12 Months

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<th>Endpoint</th>
<th>Success</th>
<th>Lower 95%CL</th>
<th>p-value*</th>
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<tr>
<td>Pad Testing1</td>
<td>90.1%</td>
<td>85.2%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Cough Stress Test2</td>
<td>90.1%</td>
<td>85.2%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>UDI-6 Score3</td>
<td>89.3%</td>
<td>84.3%</td>
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<tr>
<td>IIQ-7 Score3</td>
<td>90.3%</td>
<td>85.5%</td>
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<td>PGI-I4</td>
<td>89.3%</td>
<td>84.3%</td>
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*Percent of subjects with ≥ 50% reduction in pad weight
1Percent of subjects with negative cough stress test
2Percent of subjects with ≥ 50% reduction in UDI and IIQ Score
3Percent of subjects with responses of "Very much better" or "Much better"
4Observed success rate is greater than the performance goals of 50% for pad weight, UDI, and IIQ and 66% for CST

QOL Outcomes Results: 12 months

Quality of Life Score Reduction from Baseline to 12 Months

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<tr>
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<td>-9.5, 99.9</td>
<td>41.6, 52.1</td>
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</table>

*Statistically significant change from baseline to 12 months, p <0.0001

Baseline Quality of Life Scores at Baseline and 12 Months

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<tr>
<th>Endpoint</th>
<th>Mean ± SD</th>
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<td>UDI-6</td>
<td>55.6</td>
<td>54.3</td>
<td>55.6</td>
<td>55.6</td>
</tr>
</tbody>
</table>

*Statistically significant change from baseline to 12 months (p-value <0.0001)
Adverse Events- 12 month review

- 11 device-related events were reported in 8 study subjects:
  - One (0.9%) case of each:
    - Urinary retention
    - UTI
    - Decreased urine stream
    - Dyspareunia
    - Inflammation
    - Worsening OAB
    - Voiding dysfunction
  - Four (3.5%) mesh extrusions
- No unanticipated device effects (UADEs)
- 3 serious adverse events (SAEs) were reported

Conclusion

- Twelve month data support that the Altis SIS for the treatment of SUI is safe and effective.
- We will continue to follow these patients through 2 years.
Interactive Web-based tool for Pelvic Organ Prolapse: Impact on Patient Understanding and Provider Counseling

Erinn Myers MD
Division of Urogynecology and Reconstructive Pelvic Surgery
University of North Carolina at Chapel Hill

Disclosures

• I have no financial relationships to disclose.

Objectives

At the conclusion of this presentation, the participant will be better able to:

• Use available web-based technology to educate patients on their pelvic anatomy
• Provide patients with individualized counseling
• Integrate a consistent tool for counseling without prolonging the time of the visit

Background

• Pelvic organ prolapse is common.¹
• Patient understanding of pelvic anatomy is frequently limited.²
• Clear communication of physical exam findings to the patient at the time of evaluation is essential.³-⁴
• Improve patient understanding with technology ⁷-⁸
• Few studies have evaluated the use of interactive educational multimedia to facilitate an interactive counseling session.

Study Objective

• Primary
  • To compare standard counseling (SC) with SC + iPad™ for effect on patient satisfaction with understanding of prolapse

• Secondary
  • Assess patient anxiety
  • Feasibility of use
  • Provider satisfaction
Methods

- Primary outcome: Change between pre-visit and post-visit patient satisfaction with understanding of presenting bulge symptoms
  - Responses from the Likert Scale Questionnaires were dichotomized for analysis.
  - 90 patients required to achieve a power of 80% with an alpha of 0.05 to detect a 30% difference between the groups.

Demographics

<table>
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<tr>
<th></th>
<th>SC</th>
<th>SC + iPad™</th>
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<tbody>
<tr>
<td>n=44</td>
<td></td>
<td>n=46</td>
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<tr>
<td>Age (years)</td>
<td>60.7 ± 11.9</td>
<td>59.1 ± 14.1</td>
<td>.6</td>
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<td>Education (years)</td>
<td>14 ± 2.5</td>
<td>14 ± 2.4</td>
<td>1.0</td>
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<tr>
<td>BMI (kg/m²)</td>
<td>29.5 ± 8.8</td>
<td>27.9 ± 6.5</td>
<td>.3</td>
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POP-Q

<table>
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<td>Aa</td>
<td>-.5 (-2, 2)</td>
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<td>Ba</td>
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<tr>
<td>C</td>
<td>-5 (-6.2, 2)</td>
<td>-5 (-6.1)</td>
</tr>
<tr>
<td>D</td>
<td>-5 (-7.4, 4)</td>
<td>-5 (-7.5, 4)</td>
</tr>
<tr>
<td>Ap</td>
<td>-1 (-2, 0)</td>
<td>-1.5 (-2, -5)</td>
</tr>
<tr>
<td>Bp</td>
<td>-1 (-2, 0)</td>
<td>-1.5 (-2, 0)</td>
</tr>
<tr>
<td>GH</td>
<td>4.5 (3.5, 5)</td>
<td>4 (3.5)</td>
</tr>
<tr>
<td>PB</td>
<td>3 (2.5, 3.5)</td>
<td>3 (3.4)</td>
</tr>
<tr>
<td>TVL</td>
<td>9 (6.5, 9)</td>
<td>9 (8, 10)</td>
</tr>
</tbody>
</table>

Patient Understanding of Bulge Symptoms Before and After Counseling

<table>
<thead>
<tr>
<th></th>
<th>SC</th>
<th>SC + iPad™</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Understanding of Bulge Symptoms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Before</td>
<td>50</td>
<td>43.5</td>
</tr>
<tr>
<td>After</td>
<td>95.5</td>
<td>97.8</td>
</tr>
<tr>
<td>p=.50</td>
<td>p=0.001</td>
<td>p&lt;0.001</td>
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</tbody>
</table>

Patient Anxiety Regarding Bulge Symptoms Before and After Counseling

<table>
<thead>
<tr>
<th></th>
<th>SC</th>
<th>SC + iPad™</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety Before</td>
<td>65.9</td>
<td>73.9</td>
</tr>
<tr>
<td>Anxiety After</td>
<td>31.8</td>
<td>28.3</td>
</tr>
<tr>
<td>p=.40</td>
<td>p&lt;0.001</td>
<td>p=.70</td>
</tr>
</tbody>
</table>

Provider Results

- Total time in counseling (p=.40)
  - 9.5 minutes – SC
  - 8.9 minutes – SC + iPad™

- All Providers (n=9)
  - iPad™ was easy to use
  - Would incorporate it into practice
Conclusion

- Patient counseling with or without iPad™
  - Increased patient satisfaction
  - Decreased patient anxiety
- The iPad™ web-based tool
  - Consistent counseling tool
  - Provides each patient with an individualized visual representation of her anatomy
  - Easily integrated into counseling session
  - Did not increase counseling time

References

The choice of repeat surgeries after failed primary surgeries for female stress urinary incontinence:
A population-based nation-wide follow-up descriptive study

Ming-Ping Wu, MD, PhD
Division of Urogynecology and Pelvic Floor Reconstruction, Department of Obstetrics and Gynecology, Chi Mei Foundation Hospital, Tainan, Taiwan

Objective

• To identify the choices of repeat surgeries after failed primary surgeries for stress urinary incontinence (SUI) among different surgical types.
• Material and methods
  – Women who had National Health Insurance (NHI) in Taiwan
  – identified repeat surgery, follow-up 4 years
  – Variables,
    – primary SUI surgical types, patient age, surgeon age and gender, specialty, hospital accreditation levels and ownership.
    – the choice of either same- or different-repeat surgical types, and same- or different-specialty or surgeon.

Result 1

• Reoperation rate: 2.70% (394/14613), with an incidence rate of 42.99 per 10,000 person year (PY).
  – Injection procedures had highest reoperation rate, as compared with RPU, PVS, MUS, vaginal procedure, (p-value all <0.0001).
  – The reoperation rate was higher in MUS > RPU and PVS.
• The intervals between primary and repeat surgery
  – Shortest in injection, followed by PVS, vaginal procedure, MUS, and RPU.

Disclosure

• I have no financial relationships to disclose.

Abbreviation

• RPU: retro-pubic urethropexy operations (ICD-9 code 59.5)
  • Marshall-Marchetti-Krantz procedure or Burch colposuspension
  • Laparotomy (open) or laparoscopy (LSC)
• PVS: traditional pubovaginal sling (ICD-9 code 59.4)
• MUS: mid-urethral sling operations (ICD-9 code 59.79)
• Vaginal procedure
  • Kelly (ICD-9 code 59.0): urethral-vaginal junction plication operations
  • Needle (ICD-9 code 59.8): bladder neck needle suspension and para-urethral suspension operations
• Injection (ICD-9 code 59.72): operations to inject an implant into the urethra/bladder neck

1. The reoperation rates among different primary surgical types for female stress urinary incontinence

<table>
<thead>
<tr>
<th>Surgical types</th>
<th>Primary</th>
<th>Repeat</th>
<th>Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. (%)</td>
<td>Person Year</td>
<td>No. (%)</td>
</tr>
<tr>
<td>RPU</td>
<td>6237</td>
<td>42.68</td>
<td>30826.66</td>
</tr>
<tr>
<td>RPU open</td>
<td>5245</td>
<td>(35.89)</td>
<td>25922.62</td>
</tr>
<tr>
<td>RPU LSC</td>
<td>892</td>
<td>(6.79)</td>
<td>4954.84</td>
</tr>
<tr>
<td>PVS</td>
<td>2423</td>
<td>16.58</td>
<td>15934.74</td>
</tr>
<tr>
<td>MUS</td>
<td>4527</td>
<td>30.98</td>
<td>22170.25</td>
</tr>
<tr>
<td>Vaginal</td>
<td>1238</td>
<td>8.47</td>
<td>6082.91</td>
</tr>
<tr>
<td>Kelly</td>
<td>617</td>
<td>(4.22)</td>
<td>3027.84</td>
</tr>
<tr>
<td>Needle</td>
<td>621</td>
<td>(4.25)</td>
<td>3055.07</td>
</tr>
<tr>
<td>Injection</td>
<td>188</td>
<td>1.29</td>
<td>692.41</td>
</tr>
<tr>
<td>Total</td>
<td>14613</td>
<td>(100)</td>
<td>91648.74</td>
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</tbody>
</table>

*per 10,000 person year

2-1. The comparison of variables for the primary with repeat surgeries for stress urinary incontinence

<table>
<thead>
<tr>
<th>Primary</th>
<th>Repeat</th>
<th>Adjusted HR (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. (%)</td>
<td>No. (%)</td>
</tr>
<tr>
<td>RPU open</td>
<td>5245</td>
<td>35.89</td>
</tr>
<tr>
<td>RPU LSC</td>
<td>992</td>
<td>6.79</td>
</tr>
<tr>
<td>PVS</td>
<td>2423</td>
<td>16.58</td>
</tr>
<tr>
<td>MUS</td>
<td>4527</td>
<td>30.98</td>
</tr>
<tr>
<td>Vaginal</td>
<td>1238</td>
<td>8.47</td>
</tr>
<tr>
<td>Injection</td>
<td>188</td>
<td>1.29</td>
</tr>
<tr>
<td>Patient</td>
<td>140</td>
<td>9.84</td>
</tr>
<tr>
<td>age</td>
<td>40-59</td>
<td>8751</td>
</tr>
<tr>
<td>≥60</td>
<td>4555</td>
<td>31.17</td>
</tr>
<tr>
<td>Surgeon</td>
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<td>3827</td>
</tr>
<tr>
<td>age</td>
<td>40-49</td>
<td>7047</td>
</tr>
<tr>
<td>≥50</td>
<td>3759</td>
<td>25.59</td>
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<tr>
<td>Surgeon</td>
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<td>745</td>
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<tr>
<td>gender</td>
<td>Male</td>
<td>13868</td>
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</table>
The comparison of variables for the primary with repeat surgeries for stress urinary incontinence

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Primary</th>
<th>Repeat</th>
<th>Adjusted (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gyn</td>
<td>11841</td>
<td>81.03</td>
<td>240 2.03</td>
</tr>
<tr>
<td>Urol</td>
<td>2711</td>
<td>18.55</td>
<td>150 5.53</td>
</tr>
<tr>
<td>Others</td>
<td>61</td>
<td>0.42</td>
<td>4 6.56</td>
</tr>
<tr>
<td></td>
<td>11513</td>
<td>100</td>
<td>394 2.87</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Accreditation</th>
<th>Primary</th>
<th>Repeat</th>
<th>Adjusted (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Center</td>
<td>9625</td>
<td>65.87</td>
<td>268 2.73</td>
</tr>
<tr>
<td>Regional</td>
<td>2711</td>
<td>18.55</td>
<td>150 5.53</td>
</tr>
<tr>
<td>Local</td>
<td>61</td>
<td>0.42</td>
<td>4 6.56</td>
</tr>
<tr>
<td></td>
<td>14613</td>
<td>100</td>
<td>394 2.87</td>
</tr>
</tbody>
</table>

Result II

- The adjusted hazard ratio (HR) of reoperation was highest in injection — (HR 23.16) compared with RPU, or (HR 13.56) with PVS.
- MUS also had higher HR, — (HR 1.68) as compared with RPU, or (HR 1.59) with PVS.
- Other variables, patient age, surgeon age and gender, hospital accreditation levels and ownership were not significant.
- Urologists had higher reoperation rate, as compared with gynecologists (HR 1.80).

The choice of repeat surgery after failed primary surgery for stress urinary incontinence

<table>
<thead>
<tr>
<th>Repeat</th>
<th>RPU open</th>
<th>RPU LSC</th>
<th>MUS</th>
<th>Vaginal</th>
<th>Injection</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>RPU open</td>
<td>38(39.58)</td>
<td>17(17.40)</td>
<td>21(21.50)</td>
<td>43(44.79)</td>
<td>2(2.08)</td>
<td>96</td>
</tr>
<tr>
<td>RPU LSC</td>
<td>4(28.57)</td>
<td>11(7.14)</td>
<td>17(13.33)</td>
<td>16(11.37)</td>
<td>2(1.39)</td>
<td>51</td>
</tr>
<tr>
<td>MUS</td>
<td>14(27.45)</td>
<td>11(1.96)</td>
<td>17(33.33)</td>
<td>16(11.37)</td>
<td>1(1.96)</td>
<td>51</td>
</tr>
<tr>
<td>vaginal</td>
<td>9(29.03)</td>
<td>0(0.00)</td>
<td>11(33.33)</td>
<td>11(33.33)</td>
<td>1(3.33)</td>
<td>31</td>
</tr>
<tr>
<td>injection</td>
<td>0(0.00)</td>
<td>0(0.00)</td>
<td>1(1.56)</td>
<td>1(1.56)</td>
<td>0(0.00)</td>
<td>31</td>
</tr>
<tr>
<td>Total</td>
<td>85(21.57)</td>
<td>3(0.76)</td>
<td>48(12.18)</td>
<td>10(2.54)</td>
<td>7(1.79)</td>
<td>394</td>
</tr>
</tbody>
</table>

4. The choice of either same-type or different-type repeat surgery after failed primary surgery

<table>
<thead>
<tr>
<th></th>
<th>Same-type</th>
<th>Different type</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>RPU</td>
<td>110</td>
<td>204 (85.00)</td>
<td>36 (15.00)</td>
</tr>
<tr>
<td>RPU open</td>
<td>96</td>
<td>38 (39.58)</td>
<td>58 (60.42)</td>
</tr>
<tr>
<td>RPU LSC</td>
<td>14</td>
<td>7 (50.00)</td>
<td>7 (50.00)</td>
</tr>
<tr>
<td>Sling</td>
<td>51</td>
<td>17 (33.33)</td>
<td>34 (66.67)</td>
</tr>
<tr>
<td>MUS</td>
<td>138</td>
<td>91 (65.94)</td>
<td>47 (34.06)</td>
</tr>
<tr>
<td>vaginal</td>
<td>31</td>
<td>16 (50.00)</td>
<td>15 (50.00)</td>
</tr>
<tr>
<td>injection</td>
<td>64</td>
<td>62 (96.88)</td>
<td>2 (3.13)</td>
</tr>
<tr>
<td>Total</td>
<td>394</td>
<td>214 (54.31)</td>
<td>180 (45.69)</td>
</tr>
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</table>

5. The choice of either same-or-different-specialty, same-or-different-surgeon

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Same-specialty</th>
<th>Different-specialty</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gynecology</td>
<td>240 (85.00)</td>
<td>36 (15.00)</td>
<td>0.001</td>
</tr>
<tr>
<td>Urology</td>
<td>120 (80.00)</td>
<td>30 (20.00)</td>
<td>0.001</td>
</tr>
<tr>
<td>Others</td>
<td>4 2 (50.00)</td>
<td>2 (50.00)</td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>394 326 (82.74)</td>
<td>68 (17.26)</td>
<td>0.001</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Same-surgeon</th>
<th>Different-surgeon</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gynecology</td>
<td>240 (53.51)</td>
<td>118 (45.17)</td>
<td>0.001</td>
</tr>
<tr>
<td>Urology</td>
<td>105 (70.00)</td>
<td>45 (30.00)</td>
<td>0.001</td>
</tr>
<tr>
<td>Others</td>
<td>4 1 (25.00)</td>
<td>3 (75.00)</td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>394 228 (57.87)</td>
<td>166 (42.13)</td>
<td>0.001</td>
</tr>
</tbody>
</table>

The distributions of SUI surgeries among different specialties, 2000-2006

- Gynecologist: 9.27%
- Urologist: 4.91%
- Others: 11.48%
- Vaginal: 9.27%
- Injection: 6.34%
- MUS: 27.48%
- PVS: 13.11%
- RPU: 37.99%
Discussion

• Failed primary surgeries for SUI remain a concern – 2.7% and 42.99/10,000 person year.
• Reoperation is the “tip of the iceberg” of surgical failure
  – The reported reoperation rates surely underestimated the failure rates
  – Taken into consideration of the choice of more conservative modalities
• MUS was the most commonly used as repeat SUI surgeries 42.89%.

References

Cultural and Linguistic Competency

Governor Arnold Schwarzenegger signed into law **AB 1195** (eff. 7/1/06) requiring local CME providers, such as the AAAGL, 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 AAAGL'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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