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## ORAL PRESENTATION 1

### **Vascular Anatomy of the Presacral Space in Unembalmed Female Cadavers**

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**OBJECTIVES:** To characterize the vascular anatomy of the female presacral space and to correlate these findings to the abdominal sacrocolpopexy.

**MATERIALS AND METHODS:** The vascular boundaries and contents of the presacral space were dissected in 32 unembalmed female cadavers. Distances from the midline of the sacral promontory (MSP) to the closest cephalad and lateral vessels, aortic bifurcation, middle sacral artery and vein, and presacral venous anastomosis were recorded. All middle sacral and venous anastomotic vessels greater or equal to one millimeter were included.

**RESULTS:** Thirty Caucasian and two African American cadaver specimens with a mean BMI of 20.7 kg/m<sup>2</sup> (11.8-33.3 kg/m<sup>2</sup>) were dissected. In 97% of cadavers, the left common iliac vein was the closest cephalad vessel, with a mean distance of 27.5 mm (9.0-51.5 mm) from the MSP. The closest vessel lateral to the MSP was also the left common iliac vein (41%), followed by the right internal iliac artery (24%). The average distance from the MSP to the closest lateral major vessel was 24.3 mm (13.0-34.5 mm). The average distance from the MSP to the aortic bifurcation was 55.5 mm (26.0-89.5 mm). The average distance from the MSP to the caudal venous anastomosis was 30.3 mm (4.0-86.0 mm). A middle sacral artery was present in 100% of cadavers. The average width of this vessel was 1.7 mm (1.0-3.0 mm). In the majority of cadavers (60%), the middle sacral artery was found to the left of the MSP. It was noted to the right of the MSP in 37% of specimens, and crossing the midline in 3% of specimens. The average distance of the middle sacral artery from the MSP was 5.0 mm (0-15.0 mm). A middle sacral vein was not identified in 10% of cadavers; two vessels were noted in 10% of specimens. The mean width of the middle sacral vein was 1.7 mm (0.8-3.8 mm). This vessel was more frequently noted to the right (45%) than to the left (38%) of the MSP. It crossed the midline in 7% of cadavers. The average distance of the middle sacral vein from the MSP was 6.7 mm (0-16.5 mm).

**CONCLUSION:** Anatomic location of the vascular boundaries and contents of the presacral space in reference to the MSP is highly variable. The left common iliac vein was the closest major vessel identified cephalad to the MSP. It is possible that vasodilation of veins from increased volume status and body temperature in the living patient may further reduce the distance of this vessel from the sacral promontory. In addition, identification of veins by palpation is more difficult than that of the arteries and hemorrhage from venous bleeding is more cumbersome to control. Understanding the proximity of the left common iliac vein to the MSP, an area exposed during an abdominal sacrocolpopexy, is essential to avoid injury to this vessel. Middle sacral vessels are variably found on either side of the MSP and vascular anastomosis between the middle and lateral sacral veins are frequently found within 3 cm caudal to the upper border of the sacral promontory. Therefore, careful dissection of the presacral space and good exposure of the anterior longitudinal ligament of the sacrum should minimize potentially life threatening vascular complications.

**Key Words: sacrocolpopexy, anatomy, presacral space, vascular injury**

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ORAL PRESENTATION 2

**A Randomized Trial Comparing Methods of Vaginal Cuff Closure at Vaginal Hysterectomy and the Effect on Vaginal Length**

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<sup>3</sup>*Obstetrics and Gynecology, St. Barnabas Medical Center, Livingston, NJ*

**OBJECTIVES:** To compare the effect of horizontal versus vertical closure of the vaginal cuff during vaginal hysterectomy on vaginal length

**MATERIALS AND METHODS:** Forty-three women were randomized to horizontal (n=23) or vertical (n=20) vaginal cuff closure during vaginal hysterectomy at a community hospital. The primary outcome of vaginal length before and after surgery was compared by the Student t test and the Paired t test.

**RESULTS:** Pre-operatively, mean vaginal lengths in the horizontal and vertical groups were statistically similar (7.76±1.23cm vs 8.28±1.39cm, respectively; p=0.21). Post-operatively, the groups statistically differed (6.63±1.02cm vs 7.93±1.18cm, p<0.001). The mean change in vaginal length was -1.13±1.15cm and -0.35±0.91cm, respectively, (p=0.01). Within group comparisons revealed a statistical difference between pre vs post mean vaginal length in the horizontal group (7.76±1.23cm vs 6.63±1.02cm; p<0.001) and no difference within the vertical group (8.28±1.39cm vs 7.93±1.18cm; p=0.11).

**CONCLUSION:** Closing the vaginal cuff vertically is superior to horizontal closure for the purpose of preserving vaginal length.

**Key Words: vaginal surgery, vaginal hysterectomy, vaginal length**

Disclosure - Consultant: B. Vassallo, Gynecare, Inc., M. Moen, Gynecare, Inc..

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ORAL PRESENTATION 3

**Sensory Nerve Injury After Uterosacral Ligament Suspension**

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**OBJECTIVES:** Uterosacral ligament suspension is a technique commonly performed to suspend the prolapsed vaginal apex. This review describes our experience with the clinical presentation and management of lower extremity sensory nerve symptoms in several subjects after uterosacral ligament suspension

**MATERIALS AND METHODS:** Hospital and office medical records from our two

institutions were reviewed from Jan 2002 - August 2005 and all subjects who underwent uterosacral ligament suspension through a vaginal approach were identified. Records were reviewed and subjects with symptoms of buttock and posterior thigh pain during the 6 week postoperative period were identified. Detailed clinical information was abstracted from the charts of these subjects. Preoperative, intraoperative and postoperative findings were reviewed.

**RESULTS:** Of 169 uterosacral ligament suspensions, we identified 7 subjects with lower extremity pain. Age ranged from 42 to 70 years. Two subjects had a preoperative history of back pain and one of these also had a history of sciatic pain requiring steroid injections. Concurrent procedures included 6 vaginal hysterectomies, 5 anterior repairs, 4 posterior repairs, 2 slings and 1 bilateral salpingo-oophorectomy. All procedures were performed with subjects in high lithotomy position using padded Allen stirrups. Sutures were placed through the both uterosacral ligaments at the level of the ischial spine. Within 24 hours of the surgical procedure, all subjects experienced similar, substantial sharp buttock pain and numbness that radiated down the center of the posterior thigh to the popliteal fossa. Five subjects had pain only in the right thigh, one subject only in the left thigh and one subject in both. Six of seven subjects experienced exacerbation of the pain with walking, standing, or sitting. Neurologic exam documented in six of seven subjects showed no motor deficits and confirmed decreased sensation over the involved dermatome. Pelvic exams were nonspecific in 4 subjects; however, in the other 3 subjects the pain was exacerbated by pulling on the ipsilateral uterosacral suture. In these subjects, the ipsilateral uterosacral ligament suture was removed within 2 days of surgery. These subjects had immediate subjective reduction in their pain and complete resolution of pain by 6 weeks, although the numbness persisted beyond 6 weeks. The remaining 4 subjects were treated with gabapentin and narcotics. Three had resolution of their pain by 12-14 weeks postoperatively and the last subject's pain resolved gradually by 6 months.

**CONCLUSION:** Women undergoing uterosacral ligament suspension are at risk of developing postoperative pain and numbness in a sciatic distribution. These symptoms appear to be related to placement of uterosacral ligament sutures and may be relieved either by prompt removal of the ipsilateral uterosacral ligament suture or with prolonged medical therapy.

**Key Words:** vaginal prolapse, postoperative pain, nerve injury

Disclosure - research grant: Cindy Amundsen, Life-Tech, Inc, Cindy Amundsen, American Medical Systems, Cindy Amundsen, NDI Medical, Cindy Amundsen, Pfizer; consultant : Cindy Amundsen, Allergan.

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#### ORAL PRESENTATION 4

### **Sexual Function, Quality of Life, and Severity of Anal Incontinence Following Anal Sphincteroplasty**

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**OBJECTIVES:** To determine the severity of anal incontinence and its impact on quality of life and sexual function in women following anal sphincteroplasty.

**MATERIALS AND METHODS:** 84 women who underwent anal sphincteroplasty during the years 1993-2004 were mailed validated survey instruments to evaluate health-related quality of life. Questionnaires included the Fecal Incontinence Severity Index (FISI), the Colorectal Anal Impact Questionnaire (CRAIQ), Patient Health Questionnaire (PHQ) to screen for depression with higher scores in each scale reflecting worse disease or impact severity. Also included were the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12 (PISQ-12) and the Medical Outcomes Study Short Form (SF-12) with higher scores reflecting better function. Demographic and perioperative data were obtained from patient charts. Statistical analysis was performed with chi-square, paired t-tests, ANOVA or Pearson's correlations.

**RESULTS:** 59 patients responded to the survey (response rate =70%). Mean age was  $48.1 \pm 11.5$  years and mean length of follow-up was  $5.6 \pm 3.0$  years. Mean FISI score (0-57) was  $23 \pm 15.7$ , with 6 (11%) women being totally continent (group 1), 8 (15%) being incontinent of flatus only (group 2), and 45 (75%) being incontinent of liquid, solid stool or both (group 3). Analysis of medical co-morbidities showed that women with irritable bowel syndrome had a higher mean FISI score compared to women without irritable bowel syndrome ( $28.2 \pm 15.3$  vs.  $19.3 \pm 14.7$ ,  $p=0.04$ ). FISI score correlated with CRAIQ score ( $r = 0.66$ ,  $p < 0.0001$ ) and the physical scale of the SF-12 ( $r = -0.39$ ,  $p = 0.005$ ). The FISI score did not correlate with age, length of follow-up, age at the time of surgery, or procedure type ("end-to-end" vs. "overlapping"). 46 women were sexually active (78%). Sexually active women were younger than those who were not sexually active ( $45.9 \pm 10.6$  vs.  $56.5 \pm 11.5$  years;  $p = 0.002$ ), but they were not different with respect to BMI, FISI score, or procedure type ("end-to-end" vs. "overlapping"). Mean PISQ-12 score was  $34.1 \pm 6.6$  and was significantly correlated with depression as measured by the PHQ ( $r = -0.52$ ,  $p = 0.0002$ ). The PISQ-12 and FISI scores did not correlate and PISQ-12 scores were similar among the three continence groups. None of the individual PISQ-12 items including pain with intercourse or fear of incontinence during intercourse (either urine or stool) were different among the continence groups. Of women who underwent an "overlapping" sphincteroplasty 24% reported that they "always" or "usually" felt pain during intercourse compared to 4% of those having an "end-to-end" sphincteroplasty ( $p=0.04$ ).

**CONCLUSION:** Sexual function as measured by PISQ-12 is not associated with type or severity of anal incontinence. Dyspareunia was more common after an "overlapping" than an "end-to-end" sphincteroplasty. Anal continence rates five years after anal sphincteroplasty are disappointing but similar to previously reported series. 75% of patients have incontinence of liquid or solid stool and these symptoms have a significant impact on physical function and quality of life.

**Key Words:** sexual function, anal sphincteroplasty, quality of life, anal incontinence

Disclosure - Nothing to disclose.

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ORAL PRESENTATION 5

**The Decision to Perform Lymphadenectomy in Advanced Stage Ovarian Cancer: Room for Improvement**

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**OBJECTIVES:** There is limited objective data supporting or refuting the value of lymphadenectomy in patients with advanced stage ovarian cancer. As a result, no clear guidelines exist for the intra-operative management of lymph nodes. This lack of standardization can result in wide differences in surgical practice without sound reason for these differences. To better understand the factors that are important in the decision to perform lymph node assessment (LNA) in ovarian cancer we undertook this study.

**MATERIALS AND METHODS:** All consecutive patients with Stage IIIC or IV epithelial ovarian cancer were included during the 5 year period 1994-1998. Patients who were upstaged to IIIC solely by virtue of lymphatic involvement were excluded as LNA is clearly recommended in the staging of presumably early ovarian cancer. Records were reviewed for specific procedures performed, pathology and overall survival (OS). Simple statistics, univariate and multivariable analysis was performed.

**RESULTS:** 215 patients met inclusion criteria and had sufficient information available from the operative notes to determine the type of LNA performed. Only 89/215 (41.4%) had LNA performed. The subtypes of LNA assessment performed were: 58/89 (65%) underwent complete pelvic (Pe) and para-aortic (Pa) lymphadenectomy (LND) and the remaining 31 (35%) underwent a more limited lymph node sampling (LNS). To first determine the importance of LNA in outcomes, we considered overall survival for the subgroup of patients undergoing LNA. In this group, the performance of radical surgery, LND (vs. LNS) and low RD were all important in univariate analysis. However, only residual disease (RD) was an independent predictor of overall survival. We then determined which factors correlated with the decision to perform LNA. We observed that although multiple factors were significantly correlated with the decision to perform LNA in univariate analysis, only surgeon ( $p<0.001$ ), low RD ( $p=0.004$ ), ASA1/2 ( $p=0.002$ ), and carcinomatosis ( $p=0.01$ ) were important in multivariable analysis. Further, if LNA was performed, the decision to do LND vs. LNS was independently associated with surgeon ( $p<0.001$ ), low RD ( $p=0.002$ ) and patient age  $< 65$  (0.003). In all, surgeon preference appeared to be the most important factor for whether LNA, and extent of LNA. Finally, when considering survival of the subgroup undergoing LNA, we observed a significantly shorter survival for those with lymphatic involvement. However, when considering only those with positive lymph nodes, we observed no survival benefit for those undergoing LND relative to LNS: the only independent predictor of survival was RD.

**CONCLUSION:** The decision to perform LNA in advanced stage ovarian cancer in our series appears based on several intuitively logical factors: low RD, ASA status of the patient. However, the most important factor was individual surgeon preference. We believe the role of LNA and the recommendations for LNA are poorly defined for advanced ovarian cancer. This area represents an opportunity for standardization and improvement in surgical practice of gynecologic oncology.

**Key Words:** surgery, ovarian cancer, lymphadenectomy

Disclosure - Nothing to disclose.

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## ORAL PRESENTATION 6

### **Is Intraoperative Frozen Section Analysis of Pelvic Lymph Nodes Accurate After Neoadjuvant Chemotherapy in Patients With Cervical Cancer?**

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**OBJECTIVES:** Intraoperative frozen section examination of pelvic lymph nodes is frequently used to tailor the extent of lymphadenectomy or select individual treatment strategies in patients with cervical cancer, some of whom may have received neoadjuvant chemotherapy (NACT). NACT can cause necrosis, fibrosis, or keratinization of tumor deposits in extirpated lymph nodes and it is unclear whether intraoperative frozen section analysis of extirpated nodes is accurate after NACT. We analyzed the accuracy of frozen section examination of pelvic lymph nodes in patients after NACT.

**MATERIALS AND METHODS:** We reviewed 134 patients with invasive cervical cancer who underwent surgery including systematic pelvic lymphadenectomy with intraoperative frozen section examination of pelvic lymph nodes. Results of frozen section examination were related to definitive histology and compared between patient groups of NACT and primary surgery.

**RESULTS:** A total of 1670 pelvic lymph nodes were evaluated intraoperatively by frozen section examination and 6689 pelvic lymph nodes were analyzed by final histopathology. We observed 9 false negative cases out of 53 patients with positive lymph nodes (false negative rate 16.9%). After NACT, two false negative diagnoses out of twelve patients with node metastases were recorded (false negative rate 16.7%) (table). No false positive cases were noted.

**CONCLUSION:** NACT does not appear to compromise the diagnostic accuracy of intraoperative frozen section examination of pelvic lymph nodes in patients with cervical cancer.

**Key Words:** cervical cancer, lymph nodes, frozen section, neoadjuvant chemotherapy

Disclosure - Nothing to disclose.

Accuracy of frozen section examination as a diagnostic test for predicting the final node status in patients after NACT and primary surgery of 134 patients with cervical cancer

	NACT (No. of patients)	Primary surgery (No. of patients)
True-positive	10	34
True-Negative	9	72
False-negative	2	7
Sensitivity	83%	83%
Specificity	100%	100%
Positive predictive value	100%	100%
Negative predictive value	82%	91%

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## ORAL PRESENTATION 7

### **Clinical Anatomy and Surgical Skills Training (CASST)**

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**OBJECTIVES:** Resident surgical training is increasingly challenging due to limited work hours, decreased surgical volume, and increasing clinical demands of academic faculty. Innovative, cost effective programs must be developed to teach junior residents anatomy and basic surgical skill (SS). The aim of this program was to develop multicenter, multidisciplinary anatomy and SS training program for junior residents in Ob/Gyn and urology.

**MATERIALS AND METHODS:** We administered a needs assessment on knowledge of basic SS and clinical anatomy to junior residents from 4-residency training programs in Chicago. We then developed 5, 3-hour workshops, including didactics, SS laboratories, and cadaver dissections to teach basic SS and anatomy. A program budget was developed for a single residency program with 6 juniors and compared to the budget for 4 residencies.

Faculty included physicians from gynecology and urology from 3 different academic medical centers. A pre-test was given prior to the first session to assess baseline knowledge. The same test will be administered at the conclusion of the 5th session and at the end of the academic year to help determine short and long term program retention. The needs assessment and some pretest results are presented here.

SPSS (Version 13) was used for data entry and analysis. Chi-square test of association was used for nominal data. Data were considered significant at the .05 level.

**RESULTS:** Thirty-two residents participated in the program. The per-resident cost of the program with 4 participating sites was approximately \$800 for models, cadavers, surgical instruments and supplies. When only 1 site with 6 residents was used, the per-resident cost increased to approximately \$1700.

Ninety-three percent of participants preferred hands-on surgical models or cadavers to didactic lectures. 100% of participants agreed or strongly agreed that they would benefit from more formal training in basic SS before entering the operating room, and 86% thought that prosected cadavers would increase their knowledge of anatomy.

Over half of residents thought their knowledge and/or skills in all areas surveyed (except knot tying) were marginal or poor. A significantly higher percentage of R2s felt their knot tying skills were excellent or adequate ( $p=.009$ ). Urology residents were significantly more likely to report that their knowledge of pelvic anatomy and hysterectomy was poor compared to gynecology residents ( $p=.001$  and  $p=.012$ , respectively).

On pretest assessment 27% could correctly identify 3 branches of the pudendal nerve and 40% accurately described differences between 1st-4th degree perineal lacerations. Only

10% knew the 3 most common sites of ureteral injury during hysterectomy, while another 33% could name 2 sites. 50% selected an appropriate suture type to close fascia, subcutaneous tissues and skin.

**CONCLUSION:** We have developed a unique multicenter, multidisciplinary program to train junior residents in clinical anatomy and surgical skills. By including multiple centers and disciplines, we were able to reduce costs to individual programs and maximize faculty teaching time and effort. Objective outcomes of the program will be assessed at 2 time points to assess short and long term program efficacy.

**Key Words:** surgical education, surgical skills, clinical anatomy

Disclosure - Grant/Research: Kim Kenton, Allergan, Pfizer, Q Med, Life-Tech, Astellas, Elizabeth Mueller, Allergan, Astellas.

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#### ORAL PRESENTATION 8

##### **Is Trans-Obturator Tape as Effective as Tension-Free Vaginal Tape in Patients With a Borderline Maximal Urethral Closure Pressure?**

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**OBJECTIVES:** Few clinical studies compare the trans-obturator tape (TOT) with the tension-free vaginal tape (TVT) and none address whether routine preoperative evaluation of urethral function is warranted. Most TOT failures happen in patients with maximum urethral closure pressure (MUCP)  $\leq 40$  cm H<sub>2</sub>O (Guerette, et al. Int Urogyn J 2005 16(S2): S120 [abstract]). The purpose of this study was to compare TOT to TVT in that population.

**MATERIALS AND METHODS:** Retrospective cohort analysis of fourteen-week outcomes in 145 subjects (TOT=85; TVT=60). All patients had routine urodynamics including urethral pressure profiles preoperatively and fourteen weeks after surgery. All patients had routine cystoscopy at the time of surgery. Outcome variables included urodynamic stress incontinence (USI), subjective stress incontinence, bladder perforations estimated blood loss, and other intraoperative complications. Patients with preoperative MUCP  $\leq 42$  and  $> 42$  cm H<sub>2</sub>O were included in separate sub-analyses of USI outcomes. A new cutpoint was used because initial subanalysis with a cutpoint of 40 cm H<sub>2</sub>O failed to show significance. Student's T-test compared mean baseline characteristics and follow-up times. Pearson  $\chi^2$ -tests of statistical significance and relative risks (RR) were calculated for outcomes.

**RESULTS:** Patients in the TOT and TVT groups did not differ significantly in baseline characteristics or follow-up time. In sub-analysis of patients with a pre-operative MUCP  $\leq 42$  cm H<sub>2</sub>O, USI persisted in 7/44 (16%) patients with TOT and in 1/37 (3%) patients with TVT (RR 5.89; 1.02-33.90, 95%CI). In patients with MUCP  $> 42$  cm H<sub>2</sub>O, USI persisted in 1/41 (2%) patients with TOT and in 1/23 (4%) patients with TVT (RR 0.57; 0.04-8.44, 95%CI). Overall, USI persisted in 8/85 (10%) patients with TOT and 2/60 (3%) patients with TVT (RR 2.85; 0.67-12.07, 95%CI). Subjective complaint of any

stress incontinence after surgery was absent in 52/60 (87%) patients with TVT and 74/85 (87%) patients with TOT (RR 0.97; 0.94-1.01, 95%CI). There was one bladder perforation (2%) with TVT and none with TOT (p=0.41); other intraoperative complications including estimated blood loss also were similar between groups.

**CONCLUSION:** In patients with a MUCP  $\leq$  42 cm H<sub>2</sub>O, the TOT is nearly six times more likely to fail than TVT. Long-term follow-up and randomized controlled trials are needed.

**Key Words:** stress incontinence, transobturator tape, tension-free vaginal tape, maximal urethral closure pressure, urethral pressure profile, surgery

Disclosure - Advisor: Peter Sand, Novasys; Investigator: Peter Sand, Mentor; Investigator, Advisor, Lecturer: Peter Sand, Alza/OrthoMcNeil, Peter Sand, American Medical Systems, Peter Sand, Indevus Pharmaceuticals, Peter Sand, Astellas.

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#### ORAL PRESENTATION 9

##### **The Expectations of Surgical Patients: Are We Talking the Same Language?**

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**OBJECTIVES:** To assess patient expectations of surgical outcome following standardized pre-surgical video presentation of surgical procedures in a randomized trial comparing pubovaginal sling (PVS) and Burch colposuspension.

**MATERIALS AND METHODS:** Participants were randomized to Burch or PVS in an NIH sponsored multi-center trial. Prior to surgery, trial participants watched a video explaining, purpose, risks and benefits as well as the likelihood for eliminating stress incontinence. Preoperatively, a validated questionnaire was used to assess expectations for the effects of surgery on UI-related symptom relief, resolution of current limitations in activity, and change in emotions. The domains were examined on a 5 point Likert-type scale. The expectation score was computed as the average of expectations (0-5) for the resolution of symptoms, limitations or negative emotions reported. Type and severity of incontinence were assessed pre-operatively using the Medical, Epidemiologic and Social Aspects of Aging (MESA) questionnaire, Urinary Distress Inventory (UDI), incontinence impact questionnaire (IIQ), baseline health measures and urodynamic parameters. Bivariate and multivariable associations with expectation were explored using logistic regression analysis.

**RESULTS:** The study included 650 eligible randomized women (age 27-81; mean:51.9). Mean and median expectation scores were 4.4 of 5 and 87% of women had a score >4. Because the scores were highly skewed, women were categorized by score >4 (higher expectations) and < 4 (lower expectations). Symptoms were recorded first followed by expected resolution of the symptom. The most frequent symptoms were urine leakage

(98%) followed by embarrassment (88%). Frequency, reduced physical activity, and urgency were reported by 74%, 72%, and 70% respectively. Limitations on sexual and social activities were reported by less than 44%. Expectation for near or complete improvement was most frequent for urine leakage (98%). Of the 70% of patients reporting urgency, 92% had an expectation of the symptom becoming much better or completely better. Moreover, of the 74% reporting frequency, 83% expected substantial symptom relief. There was no association between expectation and IIQ, urodynamics and baseline health measures. Women who reported a greater impact of their incontinence on the UDI stress subscale had higher expectations. Among women with lower expectations (score less than 4), mean baseline UDI-stress score was 71.8 while among women with high expectations the mean was 79.3 ( $p < 0.01$ ).

**CONCLUSION:** Patients' expectation for the outcome of anti-stress incontinence surgery is uniformly high. Even with standard counseling about expected outcome and benefits of the two procedures patients have expectation regarding resolution of irritative symptoms that are unrealistic and may ultimately impact patient satisfaction.

**Key Words:** surgery, incontinence, patient expectation, patient satisfaction

Disclosure - grant: Veronica T. Mallett, Watson, Yamanouchi, Gynecare, Linda Brubaker, Liley pharmaceuticals.

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#### ORAL PRESENTATION 10

##### **Bowel Symptoms in Women Planning Surgery for Pelvic Organ Prolapse**

C. S. Bradley and .. For the Pelvic Floor Disorders Network

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**OBJECTIVES:** Bowel symptoms are common and often attributed to pelvic organ prolapse (POP). Our objective was to correlate bowel symptoms and level of vaginal descent in women with prolapse.

**MATERIALS AND METHODS:** This analysis used baseline data from the Colpopexy and Urinary Reduction Efforts (CARE) study, a randomized trial of sacrocolpopexy with or without Burch colposuspension in stress continent women with Stages II - IV POP. Participants completed validated questionnaires, including the Colorectal-anal Distress Inventory (CRADI) and the Colorectal-anal Impact Questionnaire (CRAIQ) and underwent Pelvic Organ Prolapse Quantification (POP-Q). POP-Q points Bp, Ba and C assessed descent of the posterior, anterior and apical vagina, respectively. Subject characteristics were compared between prolapse stages using the chi-square test.

**RESULTS:** The CARE trial enrolled 322 women with mean age  $61.3 \pm 10.2$  years and median parity of 3. POP-Q stages included II ( $n=44$ , 13.7%), III ( $n=217$ , 67.4%) and IV ( $n=61$ , 18.9%). Posterior repair had been performed in 71 women (22.0%). When examining individual symptom questions on the CRADI, women with Stages III and IV prolapse tended to have similar levels of symptoms, while women with Stage II prolapse were more symptomatic. (Table) Summary scores for the CRADI (Stage II, median score 58.3; Stage III, score 47.6; and Stage IV, score 48.0;  $p = 0.08$ ) and CRAIQ (Stage II, median score 112.6; Stage III, score 102.3; and Stage IV, score 108.0;  $p = 0.09$ ) showed a similar pattern.

**CONCLUSION:** In conclusion, although bowel symptoms are common in women planning sacrocolpopexy, these symptoms and focused questionnaire scores do not have a linear association with the stage of prolapse in the posterior or other pelvic compartments. We suggest that the CRADI, CRAIQ and POP-Q examination measure complementary, different and not necessarily related aspects of pelvic organ prolapse.

**Key Words: POP-Q, pelvic organ prolapse, bowel dysfunction, anorectal symptoms**

Disclosure - Grant/Research Support: Catherine Bradley, Astellas; Speaker Bureau: Catherine Bradley, Pfizer.

Table

Symptoms	Stage II N=44	Stage III N=217	Stage IV N=61
Splinting	19 (44.2%)	53 (25.1%)	17 (28.3%)
Straining	23 (53.5%)	72 (34.1%)	18 (30.0%)
Incomplete emptying	25 (59.5%)	88 (41.9%)	26 (43.3%)

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#### ORAL PRESENTATION 11

##### **Posterior Vaginal Wall Prolapse Does not Correlate With Fecal Symptoms or Objective Measurements of Anorectal Function**

G. Da Silva, B. Gurland, A. Sleemi and G. Levy

*Maimonides Medical Center, Brooklyn, NY*

**OBJECTIVES:** The purpose of this study is to evaluate the relationship between the degree of posterior vaginal wall prolapse, anorectal symptoms, and physiology.

**MATERIALS AND METHODS:** This is a prospective IRB approved study including all patients evaluated at a Multidisciplinary Pelvic Floor Center by a urogynecologist and colorectal surgeon. A standardized bladder and bowel function questionnaire and POP-Q clinical examination was performed on all patients. Anal physiologic testings (anorectal manometry, transanal ultrasound (US), surface electromyography and pudendal nerve terminal latencies-PNTML) were selectively performed based on bowel symptoms.

Defecography was performed on patients with constipation and to rule out rectal prolapse. Patients were divided into 2 groups based on posterior vaginal wall prolapse Group I: Ap/Bp < -1, and Group II Ap/BP ≥ -1. Patient information was entered into a centralized database and statistical analysis was performed using Fisher's Exact T-test and p value < 0.05 was considered statistically significant.

**RESULTS:** One hundred and thirty-two patients with a mean age of 63 (range: 24-90) years old were evaluated. Sixty-two (47%) in Group I and 70 (52%) in Group II. Overall, obstructive defecation was present in 40.9%, a Wexner fecal incontinence score > 9 in 25%, a feeling of anal blockage in 18.9%, digitation in 12.9 %, evacuation less than 3 BM/week in 7.6 %. Bowel symptoms are summarized in Table 1. Ninety-seven patients underwent physiologic tests. At manometry, both resting (RP) and squeeze pressures (SP)

were significantly higher in patients Group II (RP: 63.1 vs. 36.6, SP 86.3 vs. 51, respectively;  $p < .001$ ). There was no association between rectal capacity, first sensation, urgency and the degree of prolapse. US demonstrated anterior sphincter defect in 21.9% and a perineal body  $< 10$  mm in 67.1% of the patients, with no correlation with the degree of prolapse. There was no association between EMG and PNTML tests results and the degree of prolapse. On defecography, 28% of the patients had concomitant enterocele and 21.3% intussusception, with no correlation with the severity of prolapse.

**CONCLUSION:** Anorectal symptoms do not correlate to the degree of posterior vaginal wall prolapse nor does the presence of prolapse equate to abnormal physiologic studies. However, elevated resting and squeeze sphincter pressures in patients with higher degree of posterior vaginal wall prolapse may help to explain the pathogenesis of posterior wall prolapse. When the sphincter pressures are elevated, a defect in the rectovaginal septum provides a “path of least resistance”.

**Key Words:** posterior vaginal wall prolapse, physiology, anorectal symptoms

Disclosure - Speakers Bureau: Gil Levy, Ortho Pharmaceutical.

symptoms	group I %	group II %	P value
Obstructive Defecation	41.9	40	NS
Wexner Fecal Incontinence Score $>9$	30.6	20	NS
Feeling of anal blockage	17.7	20	NS
anal digitation	12.9	12.9	NS
BM $<3$ /week	11.3	4.3	NS

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## ORAL PRESENTATION 12

### **Rectocele Repair: A Randomized Trial of Three Surgical Techniques Including Graft Augmentation**

M. R. Paraiso, M. D. Barber, T. W. Muir and M. D. Walters

*OBGYN, The Cleveland Clinic Foundation, Cleveland, OH*

**OBJECTIVES:** To compare anatomic and functional outcomes of 3 different surgical techniques for treating rectoceles.

**MATERIALS AND METHODS:** 106 women with stage 2 or greater posterior vaginal wall prolapse were randomized to one of three treatments: traditional posterior colporrhaphy (n=37), site-specific rectocele repair (n=37), or site-specific rectocele repair augmented with a porcine small intestinal submucosa bioengineered collagen matrix (Fortagen™). Subjects underwent a physical examination that included POPQ and completed the Pelvic Floor Distress Inventory-20 (PFDI-20), the Pelvic Floor Impact Questionnaire-7 (PFIQ-7), and the Prolapse and Urinary Incontinence Sexual Questionnaire-12 (PISQ-12) at baseline, 6months, 1 year and 2 years after surgery. Anatomic failure was defined as POPQ point Bp  $> -1$  at one year follow-up. Functional

failure was defined as a worsening in prolapse or colorectal symptoms as assessed by the PFDI-20.

**RESULTS:** Of 106 subjects who enrolled in this study, 105 underwent surgery and 99 subjects (93%) returned for follow-up with a mean follow-up of 16+7 months (range 3.5 to 32 mos.). At baseline, 44 subjects (42%) had stage 2 posterior vaginal wall prolapse; 56 (53%) had stage 3; and 5 (5%) had stage 4. Mean operating time, change in hematocrit, and length of stay were similar between groups. Intraoperative and postoperative complications were infrequent and similar between groups. After one year of follow-up, subjects who received a site-specific repair with graft augmentation had a significantly greater anatomic failure rate (9/27; 33%) than those who received a site-specific repair alone (5/37; 13.5%) or a traditional posterior colporrhaphy (3/33; 9%),  $p=0.035$ . Three percent (1/33) of those in the traditional posterior colporrhaphy group, 5% (2/35) in the site-specific group, and 14% (4/29) in the graft augmentation group had posterior vaginal prolapse to or beyond the hymen at one year,  $p=0.22$ . There were significant improvements in the prolapse and colorectal scales and overall summary scores of the PFDI-20 and PFIQ-7 after surgery in all groups ( $p<.0001$  for each) with no differences between groups. The proportion of subjects with functional failures was 15% (15/99) overall, and not significantly different between groups. At baseline, 64% of subjects were sexually active. Of these, 48% (31/64) complained of dyspareunia prior to surgery. There was no significant change in the rate of dyspareunia one year after surgery and there were no differences between groups. Overall sexual function as measured by the PISQ-12 improved significantly in all groups postoperatively ( $p<.01$ ), with no differences between groups.

**CONCLUSION:** Traditional posterior colporrhaphy and site-specific rectocele repair result in similar anatomic and functional outcomes. Graft augmentation with a porcine-derived acellular collagen matrix does not improve and may worsen anatomic outcomes. All three methods of rectocele repair result in significant improvements in prolapse and bowel symptoms, quality of life, and sexual function with no overall change in the rate of dyspareunia.

**Key Words:** prolapse, vaginal surgery, rectocele, site-specific repair, graft augmentation, posterior colporrhaphy

Disclosure - Consultant: Marie Fidela R. Paraiso, Gynecare and AMS, Mark D. Walters, AMS; Grant/Research Support: Marie Fidela R. Paraiso, Organogenesis, Inc., Matthew D. Barber, Eli-Lilly and AMS.

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## ORAL PRESENTATION 13

### **Histologic Evaluation and Biomechanical Measurements of Implanted Graft Material in a Rabbit Vaginal and Abdominal Model**

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**OBJECTIVES:** The purpose of this study is to describe histologic and biomechanical changes of vaginally and abdominally implanted graft materials (human cadaveric dermal

allograft (Repliform), porcine dermal xenograft (Pelvisoft), porcine collagen coated polypropylene mesh (Pelvitex) and autologous fascia) in New Zealand white rabbits.

**MATERIALS AND METHODS:** Twenty Retired New Zealand Breeder rabbits underwent abdominal and vaginal surgery. Each rabbit had four materials randomly placed in the abdomen and vagina (autologous, Repliform, Pelvisoft, Pelvitex or Pelvisoft). The rabbits underwent harvesting of the graft material at 6 and 12 weeks after implantation. Biomechanical testing on a tensiometer measured the maximum strength of the tissue (Ultimate Stress MPa) and the tissue elasticity (Elastic Modulus MPa). We performed 2-way ANOVA (Sites X Material) to assess magnitude of decline from baseline contributed by sites and materials. Histologic evaluation assessed the extent of inflammatory response, neovascularization, and collagen deposition.

**RESULTS:** Ultimate stress declined from baseline in all materials and was dependent on material used and anatomic site (99% CI,  $P < 0.05$  and 94% CI,  $P = 0.057$ ). The decline in ultimate stress for abdominally implanted materials from baseline were: autologous 0.19 MPa, Pelvisoft 3.54 MPa, Pelvitex 0.96 MPa and Repliform 10.3 MPa. The decline in ultimate stress for each vaginally implanted materials from baseline were: autologous 0.26 MPa, Pelvisoft 3.84 MPa, Pelvitex 4.00 MPa and Repliform 13.1 MPa.

Elastic modulus was found to be dependent on the material (99% CI,  $P < 0.05$ ) but not anatomic site ( $P = 0.73$ ). The decline in Elastic Modulus for abdominally implanted materials from baseline were: autologous 0.29 MPa, Pelvisoft 20.1 MPa, Pelvitex 0.75 MPa and Repliform 25.5 MPa. The decline in elastic modulus for vaginally implanted materials from baseline were: autologous 0.56 MPa, Pelvisoft 18.1 MPa, Pelvitex 0.66 MPa, Repliform 29.0 MPa.

Histologic evaluation noted minimal inflammatory response in autologous and Pelvitex, and moderate to strong inflammatory response in Pelvisoft and Repliform. Minimal neovascularization was noted in all materials. Minimal collagen ingrowth was noted in Repliform and Pelvisoft. Collagen ingrowth was moderate in autologous and Pelvitex but encapsulation was noted in Pelvitex. The histologic findings were not affected by graft site.

**CONCLUSION:** All implanted materials demonstrated a decline in ultimate stress and elastic modulus from baseline. The changes in ultimate stress were affected by the anatomic site, with the vaginally implanted materials showing a greater decline. Autologous and Pelvitex had minimal inflammatory response but the collagen ingrowth differed. Repliform and Pelvisoft showed greater inflammatory response and less collagen ingrowth. Future studies should determine what factors contribute to the host response to graft materials and how they effect graft performance.

**Key Words:** graft material, vagina, rabbit model

Disclosure - Nothing to disclose.

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ORAL PRESENTATION 14

**Can Advanced Stages of Anterior or Posterior Vaginal Wall Prolapse Occur Without Apical Involvement?**

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Brubaker<sup>1,2</sup>

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**OBJECTIVES:** An increasing number of surgical techniques have been developed for anterior vaginal wall prolapse. Some of these techniques address the apex while others may not. Our objective was to determine the associations between the most prolapsed portion of the anterior and posterior vaginal wall and the apex.

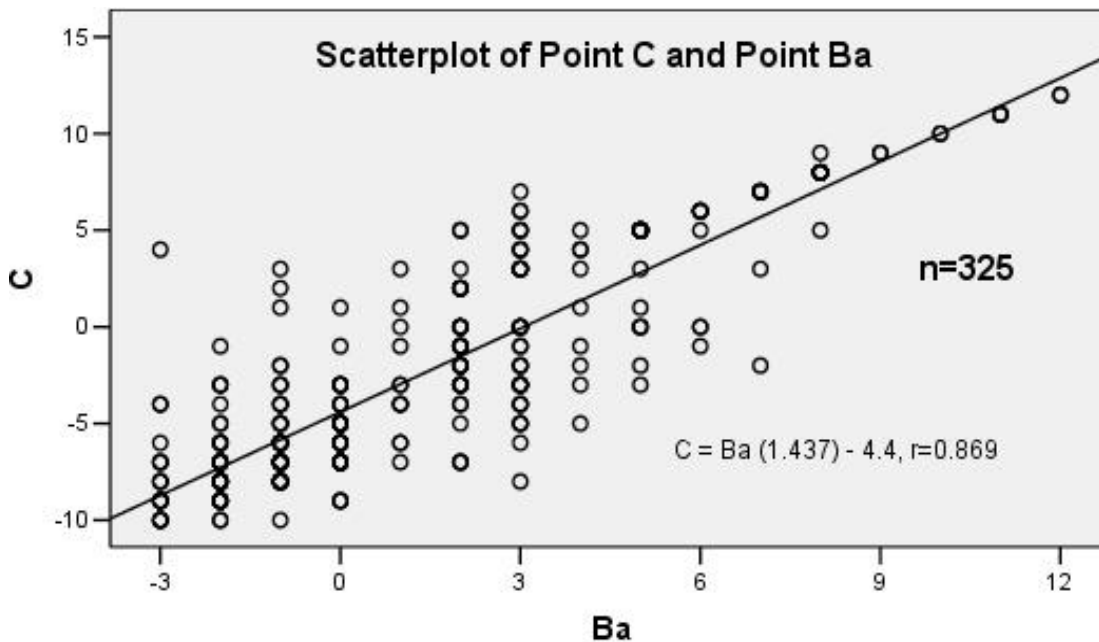
**MATERIALS AND METHODS:** After obtaining IRB approval, we retrospectively reviewed the charts of all new patients who presented to our tertiary care urogynecology practice from January 2004 to February 2005. We extracted demographic data, previous surgical history and physical exam findings including pelvic organ prolapse quantification (POP-Q). POP-Q points Ba, C, and Bp, measured the anterior, apical and posterior segments of the vaginal respectively. Data were analyzed using SPSS version 13 software. Correlations between variables were analyzed using a Spearman's analysis.

**RESULTS:** Three hundred twenty-five women had completed POP-Q measurements that allowed for analysis. The mean age was 60 years and 81% were Caucasian. Thirty-nine percent of the women had a previous hysterectomy. The position of the cervix or vaginal cuff (POP-Q point C) strongly correlated with POP-Q point Ba (most distal position of the anterior wall) ( $r=0.835$ ,  $p<0.001$ ). There was a moderate correlation between the position of the apex and the posterior wall ( $r=0.556$ ,  $p<0.001$ ). The following scatter plot demonstrates the relationship between point C (the cervix or vaginal apex) and point Ba (the most distal portion of the anterior wall). The relationship is strongly linear and using linear regression the following equation can be developed;  $C = Ba (1.4) - 4.4$  ( $r = 0.869$ ). Using this equation we can predict that when the anterior wall is at the hymen (point Ba = 0) the equation calculates C at -4.4. Seventy-five percent of the women in this study had point C at -4 or greater when point Ba was at 0 ( $n=153$ ).

**CONCLUSION:** Anterior vaginal wall prolapse is strongly associated with apical prolapse. Anterior vaginal wall defects that are being surgically repaired often require a concomitant repair of the apical defect.

**Key Words:** anterior prolapse, apical prolapse, posterior prolapse

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#### ORAL PRESENTATION 15

##### **Repair of Obstetrical Vesico-Vaginal Fistulas in Africa**

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**OBJECTIVES:** Objective: Obstetrical fistulas in sub-Saharan Africa result from obstructed labors. Our intent is to report on a series of vesico-vaginal fistula repairs in an ongoing program for repair of obstetrical trauma in Niger, Africa.

**MATERIALS AND METHODS:** Methods: From October 2003 to April 2005, 95 patients presented with vesico-vaginal fistulas and no previous repair. Patients ranged in age from 14 to 51. Their fistulas were variable in location and ranged from 0.5cm to 7cm in size. All patients were offered surgical repair regardless of stage and circumstances. Vaginal repairs were performed in 89 patients (94%). Abdominal transvesical repairs were utilized in 6 patients (6%).

**RESULTS:** RESULTS: After a primary repair, 48 women had complete healing of their fistulas (48/95 = 51%) with 39 women being dry (39/95 = 41%) and 9 having urinary incontinence (9/95 = 9%). Failed fistula repair was noted in 19 (19/95 = 20%) and 28 patients were lost to follow up (28/95 = 29%). If all patients lost to follow up are assumed wet, our failure rate is 49% (47/95). Secondary repairs were performed on 18 of the 19 known failed primary repairs. A second vaginal repair was performed in 15 patients, and an abdominal procedure was undertaken in 3 patients. Healing of the fistulas occurred in 39% (7/18) of surgeries with 3 (17%) women becoming dry and 4 (22%) having urinary incontinence. A second failed surgery occurred in 7 (39%) women and 4 (22%) of patients were lost to follow up. Three of the failed repairs underwent a third surgery with no known successes. A fourth repair was attempted in two patients with one

patient having a successful closure and being dry.

**CONCLUSION:** Conclusions: Success rates for vesico-vaginal fistula repairs have been controversial with questions remaining regarding staging and follow up. Our report confirms the best chance of successful fistula repair, regardless of stage, location or size, is with the initial repair. This series also demonstrates that when all patients appearing with a fistula are included in the reported surgical series, the success rates are less than the impression of reported experiences. We tabulated all patients lost to follow up as failed repairs and wet. While this method, counting patients lost to follow up as wet, is controversial, we feel our data is made more accurate in this manner.

**Key Words:** birth trauma, vesico-vaginal fistulas, urinary incontinence, obstructed labor

Disclosure - Nothing to disclose.

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#### ORAL PRESENTATION 16

##### **A Comparison of Outcomes of Transurethral Versus Suprapubic Catheterization After Urogynecologic Procedures**

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**OBJECTIVES:** To determine if there were any differences in outcomes in patients undergoing urogynecologic procedures when suprapubic or transurethral catheter was used for post-operative bladder drainage.

**MATERIALS AND METHODS:** This was an IRB approved randomized controlled study comparing suprapubic to transurethral catheterization in patients undergoing procedures for pelvic prolapse, or stress urinary incontinence. Patients were included from 1/2002 through 1/2005. A two-sample T-test power analysis was performed and a sample size of 51 and 51 to achieve 93% power to detect a difference was calculated. Ten patients were added to cover for patients in case of loss to follow-up, incomplete records or inability to place catheter. The attending surgeon was the same in all cases. A randomization card was opened in the Operating Room designating whether a transurethral or suprapubic catheter should be placed. A visual analog scale was used for evaluation of postoperative pain. A 16 French Foley was then placed either transurethrally or suprapubically. Extracted data included patient demographics, blood loss, operating room time, incidence of urinary tract infection, pain scores, and length of hospital stay (for patients undergoing procedures requiring a stay). Fishers exact test and Wilcoxon rank sum analysis were used when indicated.

**RESULTS:** One hundred and ten charts were reviewed, and 104 patients were included; 51 in the transurethral group and 53 in the suprapubic group. Demographics were similar in each group relating to age, ethnicity, menopausal status, body mass index, and type of procedure. There were no differences in blood loss, urinary tract infections, length of hospital stay or length of catheterization in either group. There was an increased length of operative time when the suprapubic catheter was placed (mean 11 minutes) but was not statistically significant ( $p = .1$ ). There was a statistical difference in pain perception on a

visual scale, which was significantly less in the supra-pubic group (mild vs. severe)  $p = .01$ .

**CONCLUSION:** There was no significant difference in outcomes for transurethral versus suprapubic catheterization in patients undergoing urogynecologic procedures. Patients did have significantly less pain when a suprapubic catheter was used, and should be considered when undertaking urogynecologic procedures requiring postoperative bladder drainage.

**Key Words:** urogynecologic, transurethral catheter, suprapubic catheter

Disclosure - Nothing to disclose.

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#### ORAL PRESENTATION 17

### **The Role of Pre-Operative Urodynamic Testing in Stress Continent Women Undergoing Sacrocolpopexy: The Colpopexy and Urinary Reduction Efforts (CARE) Randomized Surgical Trial**

A. G. Visco<sup>1</sup>, for the Pelvic Floor Disorders Network<sup>2</sup>

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**OBJECTIVES:** Our objective was to determine, in stress continent women undergoing sacrocolpopexy, whether urodynamics with prolapse reduction predicts postoperative stress incontinence.

**MATERIALS AND METHODS:** 322 stress-continent women with Stage II-IV prolapse underwent standardized urodynamics with water-based transducers. Five prolapse reduction methods were tested, two at each site and both performed for each subject. At sacrocolpopexy (ASC), participants were randomized to Burch colposuspension or no Burch (control). Clinicians were masked to urodynamic results. P-values were computed by two-tailed Fisher's exact test.

**RESULTS:** Preoperatively, 12 of 313 (4%) subjects demonstrated urodynamic stress incontinence (USI) without prolapse reduction. The order of prolapse reduction methods did not affect detection of USI with reduction, 16% with 1st method versus 22% with 2nd. Preoperative detection of USI with prolapse reduction at 300 ml was, in ascending order: pessary, 6% (5 of 88); hand, 16% (19 of 122); swab, 19% (32 of 168); ring forceps, 21% (21 of 98); and speculum, 30% (35 of 118).

As seen in the table below, the Benefit column estimates the decrease in postoperative stress incontinence when the prolapse reduction method is used preoperatively. In evaluating test characteristics of the prolapse reduction methods, the highest benefit was seen with the swab technique, with high positive predictive value (PPV) in controls, followed by low PPV in the Burch group. In addition, incontinence was always lower after negative urodynamic testing.

In the control group, the swab technique of prolapse reduction had the highest positive predictive value for postoperative SUI, and the highest benefit between Burch and control groups.

**CONCLUSION:** In stress continent women with prolapse undergoing sacrocolpopexy, the addition of Burch colposuspension reduced postoperative stress incontinence

symptoms whether or not preoperative urodynamic stress incontinence was diagnosed with reduction testing. However, preoperative USI with prolapse reduction (regardless of method) was associated with a higher likelihood of postoperative stress incontinence, compared to subjects who did not leak with prolapse reduction during urodynamics.

**Key Words: urodynamics, prolapse, CARE Trial, stress incontinence, sacrocolpopexy**

Disclosure - Nothing to disclose.

Prolapse Reduction Method	Stress Leakage at UDS	Control, N (%) Incontinent after ASC Only	Burch, N (%) Incontinent after ASC and Burch	Benefit
Pessary	(-)	19 of 46 (41%)	8 of 37 (22%)	19%
	(+)	1 of 2 (50%)	1 of 3 (33%)	17%
Hand	(-)	18 of 53 (34%)	13 of 50 (26%)	8%
	(+)	4 of 8 (50%)	5 of 11 (45%)	5%
Swab	(-)	22 of 63 (35%)	12 of 63 (19%)	16%
	(+)	11 of 14 (79%)	5 of 18 (28%)	50%
Forceps	(-)	20 of 41 (49%)	5 of 36 (14%)	35%
	(+)	4 of 8 (50%)	3 of 13 (23%)	27%
Speculum	(-)	17 of 42 (40%)	7 of 41 (17%)	23%
	(+)	11 of 20 (55%)	8 of 15 (53%)	2%

#### ORAL PRESENTATION 18

##### **Do Pessaries Improve Lower Urinary Tract Symptoms?**

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<sup>1</sup>Obstetrics and Gynecology, UT Southwestern Medical Center, Dallas, TX; <sup>2</sup>Johns Hopkins Bayview Medical Center, Baltimore, MD; <sup>3</sup>Duke University, Durham, OH; <sup>4</sup>Dartmouth Hospital, Hanover, NH; <sup>5</sup>Victoria General Hospital, Halifax, NS, Canada; <sup>6</sup>Scott & White Clinic, Temple, VA

**OBJECTIVES:** To determine the effects of pessary use on lower urinary tract symptoms in patients with symptomatic pelvic organ prolapse and to compare symptoms in Gellhorn and ring with support users.

**MATERIALS AND METHODS:** This study was a sub-analysis of data collected during a multi-center randomized cross-over trial comparing the Gellhorn and ring with support pessaries in the relief of prolapse symptoms. Subjects with symptomatic pelvic organ prolapse at 6 institutions were randomized to one pessary for three months, followed by the other pessary for 3 months. The Pelvic Floor Distress Inventory (PFDI)

was administered at baseline and after completion of 3 months with each pessary. The urinary scale of the PFDI is divided into 3 subscales: Obstructive/Discomfort, Irritative, and Stress. For this sub-analysis we evaluated pessary effects on urinary symptoms by comparing the baseline subscales with the subscales after 3 months of pessary use. We also calculated the Urinary Distress Inventory score before and after pessary use. Only patients with complete PFDI data after 3 months of pessary use were included. All pessary patients were analyzed as one group. Additionally, analysis was performed comparing urinary symptoms in subjects using the Gellhorn vs. the ring with support. Statistical analysis included paired student's t-test and McNemar chi-square.

**RESULTS:** 134 patients were enrolled in the study and 97 patients completed the first 3 months of the trial and had complete PFDI data. Of the completers, 68% were White, 14% African-American, 14% Hispanic and 3% other. The mean age was 62 years (range 30-89). There was a reduction in urinary symptoms from baseline to 3 months: urinary frequency (49% to 38%,  $p=0.04$ ), urgency (54% to 42%,  $p=0.04$ ), leakage with cough (48% to 38%,  $p=0.03$ ). All 3 urinary subscales, as well as the urinary distress inventory, showed significant reduction in urinary symptoms after 3 months of pessary use. The Obstructive/Discomfort subscale had a baseline mean value of 20.32 which improved to 8.61 after 3 months ( $p<0.0001$ ). The Irritative subscale went from an initial mean of 15.85 to 10.59 ( $p=0.0005$ ). The Stress subscale went from a mean of 15.55 to a mean of 12.24 after pessary use ( $p=0.04$ ). The Urinary Distress Inventory improved from a mean of 51.31 at baseline to 31.45 ( $p<0.0001$ ). There were no significant differences in reduction of urinary symptoms between subjects with the Gellhorn and ring with support pessaries.

**CONCLUSION:** In subjects with symptomatic pelvic organ prolapse who complete 3 months of pessary use with the Gellhorn or the ring with support there is a modest but significant reduction in obstructive, irritative and stress symptoms. Based on this evidence, pessaries should be included in the armamentarium of treatments for symptomatic prolapse patients with lower urinary tract symptoms.

**Key Words:** prolapse, incontinence, pessary, urinary symptoms

Disclosure - Research: K Strobehn, Duramed, Eli Lilly; Research, Consultant: C Amundsen, Life Tech, AMS, NDI Medical, Pfizer, Allergan; Research, Consultant, Advisory Board: GW Cundiff, Cook Ob/Gyn, Bard, Eli Lilly; Research, Speakers Bureau: JI Schaffer, Cook Ob/Gyn, Eli Lilly, GSK, Novartis, Yamanouchi; Research, Speakers Bureau, Consultant, Advisory Bo: AE Bent, Eli Lilly, Q-Med Scand, Cook ObGyn, Gynecare, .

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ORAL PRESENTATION 19

**Randomized Crossover Trial of Ring and Gelhorn Pessaries: Satisfaction Outcomes**

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<sup>2</sup>*Obstetrics and Gynecology, Duke University Medical Center, Durham, NC;*

<sup>3</sup>*Gynecology, Greater Baltimore Medical Center, Baltimore, MD;* <sup>4</sup>*Obstetrics and Gynecology, Scott & White Hospital, Temple, TX;* <sup>5</sup>*Obstetrics and Gynecology, University of Texas Southwestern Medical Center, Dallas, TX*

**OBJECTIVES:** The aim of this randomized crossover trial was to compare patient satisfaction and symptom relief between the ring with support and gelhorn pessaries.

**MATERIALS AND METHODS:** Subjects were women presenting with symptomatic pelvic organ prolapse. They were randomized to one pessary for 3 months. After collection of outcome data, subjects switched to the other pessary for 3 months. They could quit either pessary at any time. Outcome data included a visual analog satisfaction score, and quality of life data using the Pelvic Floor Distress Inventory Pelvic Floor Impact Questionnaire, and Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire . Analysis included paired t-test for continuous data, Chi squared for nonparametric and ordinal data, and logistical regression.

**RESULTS:** Subjects had a mean age of 61 (30-89) and were primarily white, parous, postmenopausal women with 26% on ERT. The majority described their lifestyle as active. The median POPQ stage was 3 ( stg 2=48%, stg 3=42%, stg 4=10%). Prior surgeries included hysterectomy(45%), incontinence surgery(10%), and prolapse surgery(9%). 134 subjects were enrolled with 63 initially randomized to a ring and 71 to a gelhorn. 18 subjects could not be fitted (ring pessary = 7, gelhorn = 5, neither 6), and 56 did not complete one of the 3-month trials. This included 26 who quit the ring pessary (5 moved to gelhorn, and 21 quit the study, 4 to have surgery), while 30 quit the gelhorn pessary (10 moved to the ring, and 20 quit the study, 4 to have surgery). There were an additional 6 subjects lost to follow-up. Subjects who would not wear a pessary for 3 months tended to be younger (57 v. 66,  $p=0.0004$ ) and were less apt to be white ( $p=0.006$ ). 62 subjects had satisfaction scores for both pessaries. There was no difference between the mean satisfaction scores for the ring (6.2, 0-10, sd 4.05) and gelhorn (6.4, 0-10, sd 4.09) yet only 22 (35%) had high satisfaction scores with both pessaries. The 36 (58%) subjects that reported high satisfaction with the ring pessary tended to be older ( $p=0.036$ ), more parous ( $p=0.024$ ), and non-white( $p=0.001$ ). The 39 (63%) who reported a high satisfaction score with the gelhorn pessary were less apt to have had a hysterectomy ( $p=0.035$ ) or prior prolapse surgery ( $p=0.014$ ). The 9 (15%) subjects who were not satisfied with either pessary tended to be white ( $p=0.067$ ), and were more likely to have had prior prolapse surgery ( $p=0.009$ ). Women with stage II prolapse were more likely to report dissatisfaction with either pessary ( $p=0.196$ ).

**CONCLUSION:** While most women (87%) can be fitted with a pessary, the majority of women in this trial (55%) did not use a pessary for 3 months and 7% of women were unsatisfied with either pessary. Younger women and those with prior prolapse surgery are less likely to be satisfied with a pessary. For those who liked pessaries there were clear preferences between the ring and gelhorn. Women reporting high satisfaction with a ring pessary tend to be older and more parous, while women who report high satisfaction with a gelhorn were those without a prior hysterectomy or prolapse surgery.

**Key Words: pelvic organ prolapse, ring pessary, gelhorn pessary, PESSRI trial**

Disclosure - Consultant: Alfred Bent, Lilly; Grant, Consultant: Geoffrey Cundiff, COOK OB/GYN, Lilly, CR BARD.

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ORAL PRESENTATION 20

**Quantification of Levator Ani Cross-Sectional Area Differences between Women**

## **With and Without Prolapse**

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**OBJECTIVES:** An ongoing project has established that women with prolapse are four times more likely to have a major defect detected in MR imaging in the pubic portion of the levator ani (LA) muscle compared to women with normal support. Measurement of cross-sectional area (CSA) perpendicular to muscle fiber direction is the preferred estimate of maximal muscle contraction strength. The present study was undertaken to compare CSA as a function of prolapse status and defect status in the ventral and dorsal components of the pubic portion of the levator ani muscle.

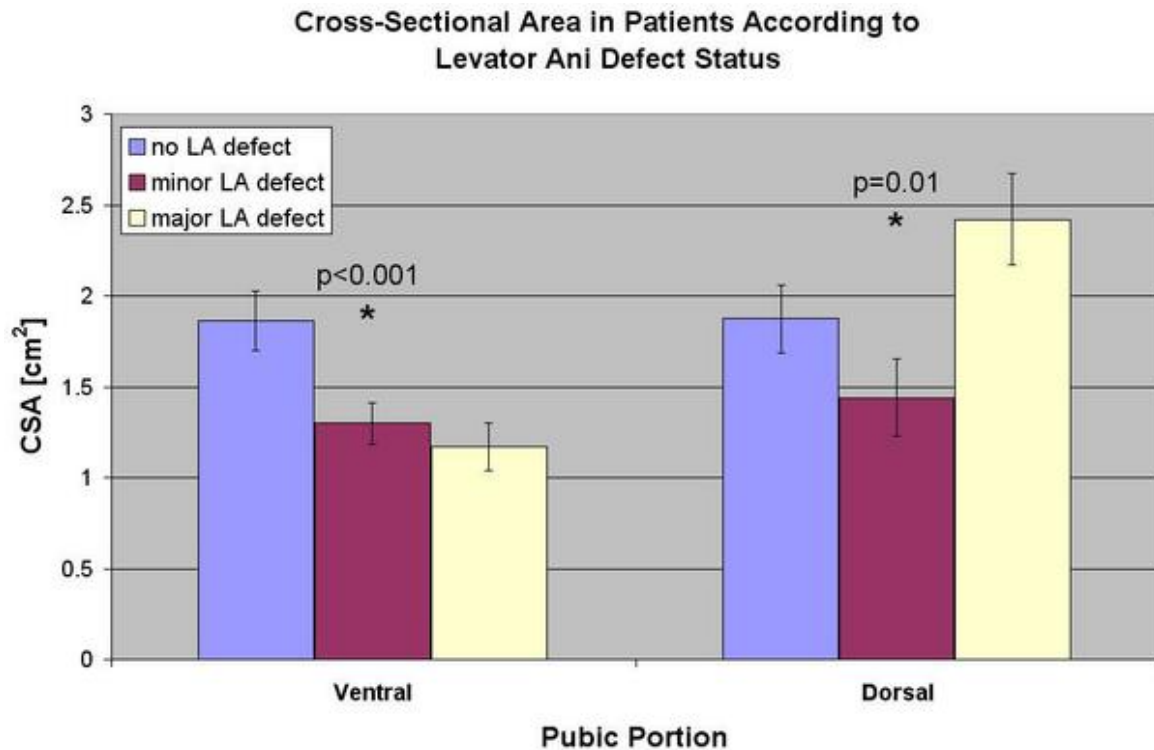
**MATERIALS AND METHODS:** Thirty women with prolapse were selected from an ongoing study with 10 having no levator ani defects, 10 minor, and 10 major defects. The severity of LA defects was established using MR images and a previously validated visual scoring system. A similar group of 30 controls with normal support were selected with 10 patients in each of the three defect status groups. Additionally, groups were age- and parity-matched (mean age: prolapse=61.9±1.6 years, controls=61.3±1.4 years; mean vaginal parity: prolapse=2.7±0.3, controls=3.7±0.4). All patients had pelvic MR scans performed in the supine position. 3-D models of the levator ani muscles were made using 3-D slicer (version 2.1b1) using bi-planar reconstruction (axial and coronal) to reduce partial volume averaging artifacts in individual scan planes. The pubic portion (which includes the pubovisceralis and the puborectalis muscles) of the levator ani muscle was isolated from the iliococcygeal portion. Using I-DEAS®, cross-sections for the pubic portion were measured perpendicular to a fiber direction line from the pubic origin to the middle of the visceral insertion at equally spaced points. CSA from the ventral and dorsal components of the muscle were analyzed separately. One-way analysis of variance was performed.

**RESULTS:** In the ventral component of the muscle, women with major LA defects had 37% smaller CSA and women with minor LA defects had a 30% smaller CSA compared to women with no defects regardless of prolapse status ( $F_{2,57}=9.579$ ,  $p<0.001$ ). In the dorsal component of the muscle, there were significant differences in CSA found according to defect status ( $F_{2,57}=5.53$ ,  $p=0.01$ ). Women with major LA defects had the largest CSA compared to the other defect groups (Fig. 1). For each defect severity level (none, minor, major), there were no significant differences in CSA when women with normal support were compared to women with prolapse.

**CONCLUSION:** 1.) Women with visible LA defects on MR imaging had significantly smaller CSA in the ventral component of the pubic portion of the muscle compared to women with intact muscles. 2.) Dorsally, women with prolapse and severe LA defects have larger levator CSA than women with minor or no defects. Comments: The ventral component of pubic portion of the LA is comprised of the pubovisceralis (which is known to be damaged during birth); in the dorsal component the puborectalis predominates. The finding that women with prolapse and major defects have larger CSA in the dorsal region of the levator ani may be due to an attempt by the puborectal muscle to compensate for birth-induced ventral muscle loss.

**Key Words:** pelvic organ prolapse, levator ani muscle defect, cross-sectional area

Disclosure - Advisory Board: John DeLancey, Eli Lilly; Consultant: John DeLancey, SuRx, Kimberly Clark, Johnson & Johnson, Gynecare,, John DeLancey, Shaw Science, James Ashton-Miller, Johnson & Johnson, BioLogic Engineering, Cybernet , James Ashton-Miller, NFL.



ORAL PRESENTATION 21

**Effect of Hospital Volume on Operative Outcomes Following Urogynecologic Procedures**

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**OBJECTIVES:** To estimate the effect of urogynecologic hospital volume on operative outcomes following urogynecologic procedures.

**MATERIALS AND METHODS:** We conducted a retrospective cohort study utilizing data from the Nationwide Inpatient Sample from 1998-2003. Urogynecologic cases were identified using urogynecologic ICD-9-CM procedure-diagnosis code combinations. Hospital volume was expressed as the average number of urogynecologic cases per year. Hospitals were ranked by volume and then categorized into three groups: low, medium and high volume. These groups were defined by choosing cutoff points for annual hospital volume that most closely sorted the number of patients into three equal groups. Cut-off points were established before outcomes were examined. Outcome measures included in-hospital mortality, peri-operative complications, and non-routine discharges, defined as patients who were not directly discharged home. Patient and hospital

characteristics were abstracted from the database. To adjust for case-mix, comorbidities were compiled into a weighted index based on the Dartmouth-Manitoba method. Descriptive statistics and univariate analyses were performed as appropriate. Multivariable logistic regression was performed to obtain adjusted odds ratios estimating the relative risks of death, complication, and non-routine discharge by hospital volume, adjusting for confounders.

**RESULTS:** There were 315,035 women in our study population and 2,569 hospitals. Overall in-hospital mortality risk was 0.04%, complication risk was 14.4%, and non-routine discharge risk was 1.0%. Low-volume hospitals (LVH) performed <92 cases/year, medium-volume hospitals (MVH) performed 92-185 cases/year, and high-volume hospitals (HVH) performed >185 cases/year. Mortality risk decreased with increasing hospital volume (LVH, 0.02%; MVH, 0.01%; HVH, 0.01%;  $p < 0.05$ ). This inverse relationship was also observed for complications ( $p < 0.01$ ) and non-routine discharges ( $p < 0.01$ ). After adjusting for potential confounders, LVHs were associated with an increased risk of death [LVH, OR 1.77 (1.04, 3.02); MVH, OR 1.08 (0.62, 1.88)] compared to HVHs. Low-volume hospitals were also associated with an increased risk of complications [LVH, OR 1.06 (1.03, 1.10); MVH, OR 1.03 (0.99, 1.10) and non-routine discharges [LVH, OR 1.60 (1.40, 1.85); MVH, OR 1.17 (1.05, 1.29)] compared to HVHs. **CONCLUSION:** The overall risks following urogynecologic procedures are low. However, differences in hospital volume of urogynecologic procedures may contribute to variations in mortality and morbidity risks.

**Key Words:** pelvic floor disorders, morbidity, mortality, hospital volume, urogynecologic surgery

Disclosure - Consultant: Charles R. Rardin, Gynecare; Speaker Bureau: Charles R. Rardin, Pfizer, Charles R. Rardin, Novartis.

Adjusted odds ratios (95% CI) for the effect of hospital volume on outcomes following urogynecologic procedures

Outcome	Hospital Volume		
	Low volume	Medium volume	High volume*
Death	1.77 (1.04, 3.02)	1.08 (0.62, 1.88)	1.00
Complication	1.06 (1.03, 1.10)	1.03 (0.99, 1.10)	1.00
Non-routine discharge	1.60 (1.40, 1.85)	1.17 (1.05, 1.29)	1.00

Adjusted for age, race, number of procedures, comorbidity, and hospital characteristics using multivariable logistic regression. \*Reference group.

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ORAL PRESENTATION 22

**Neuropathic Injury to the Levator Ani Occurs in 1 in 4 Primiparous Women**

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**OBJECTIVES:** We measured levator ani neuromuscular function before and after the first obstetric delivery to identify the location, timing, and mechanism of injury.

**MATERIALS AND METHODS:** Fifty eight primiparous women recruited in the early third trimester underwent concentric needle electromyographic (EMG) exam of the levator ani at four sites (right and left, lateral and medial) during voluntary muscle contraction. Exams were repeated 6 weeks and 6 months post partum. Data were saved digitally and analyzed using a quantitative EMG analysis program to assess muscle function at rest, moderate, and maximal contraction. Turns/amplitude analysis was used, measuring the relationship between density of the muscle recruitment pattern (represented by electrical turns in direction around the baseline) and amplitude of the motor unit potentials in  $\mu\text{V}$ . This method yielded an XY plot of number of turns vs.  $\log(\text{amplitude})$  as previously described.<sup>1</sup> Turns/amplitude data from all 58 subjects at the antepartum visit were pooled to create a normal range through the full muscle effort from rest to maximum contraction. Individual subjects with  $\geq 10\%$  of observed data points outside 95% confidence intervals of the normal range were considered abnormal. We calculated percent outliers for each subject at both 6 weeks and 6 months post partum at each muscle site and assessed relationships between mode of delivery and extent of injury. Appropriate obstetrical and demographic data were collected.

**RESULTS:** Of the 58 subjects, 36 had spontaneous vaginal delivery, 8 operative vaginal delivery, 11 cesarean sections in labor, and 3 elective cesareans without labor. Forty one self identified as Caucasian, 11 African American, and 6 Hispanic or Asian. Body mass index at 6 months post partum was  $26 \pm 5.6 \text{ kg/m}^2$ . Neonatal weight was  $3337 \pm 590 \text{ g}$ . At 6 weeks post partum, 14/58 (24.1%) had EMG evidence of abnormal muscle function with 9 of 14 recovering by 6 months. At 6 months post partum, 17/58 (29.3%) were abnormal, including 12 new injuries that were not evident at 6 weeks. Subjects having cesarean in labor had the greatest proportion of levator injury at 6 weeks, while subjects having vaginal delivery had a slightly greater proportion of injury at 6 months. Subjects having elective cesarean had virtually no injury. Analysis by muscle site showed injury across all sites. Women who had either spontaneous vaginal delivery or cesarean in labor sustained more injury to lateral muscle sites, whereas operative vaginal delivery was associated with greater injury to the medial muscle, particularly on the right.

**CONCLUSION:** Obstetrical delivery is frequently associated with EMG evidence of neuropathic injury to the levator ani both in the early and late post partum period. While some spontaneous recovery occurs, new observations of abnormal muscle at 6 months are consistent with the established mechanism of recovery from a neuropathic injury and emphasize the lengthy time course of muscle repair. Our observed localization of injury indicates that the entire levator ani complex is at risk and that cesarean in labor is not protective.

<sup>1</sup>Nandedkar et al, Muscle Nerve 9(5):423-430.

**Key Words:** electromyography, levator ani, obstetrical delivery

Disclosure - Nothing to disclose.

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ORAL PRESENTATION 23

**Obesity and Retropubic Surgery for Stress Incontinence: Is There Really an Increased Risk of Intra-Operative Complications?**

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**OBJECTIVES:** To evaluate the impact of obesity on length of surgery, blood loss and intra-operative complications in women who underwent retropubic surgery for stress urinary incontinence (SUI).

**MATERIALS AND METHODS:** Of 449 women participating in a multi center randomized trial evaluating antibiotic prophylaxis in women with suprapubic catheters, 250 women underwent retropubic anti incontinence procedures. This is a prospective nested cohort study of these women; 79(32%) of whom were obese (BMI > 30) and 171 (68%) overweight or normal weight (BMI < 30). Data collected included demographic variables, past medical history, physical exam recording prolapse severity and intraoperative and postoperative complications. Data were analyzed with Fisher's Exact for dichotomous variables, t tests for continuous variables and ANOVA for multivariate analysis. Significance was set at P<.05.

**RESULTS:** Obese women undergoing SUI surgery were younger than non-obese women (48.7 vs. 51.9 years, respectively, P < .019), and Hispanic women were more likely to be obese than all other ethnicities (P= 0.005). Severity of anterior, apical or posterior prolapse was similar between groups. (P=NS) The number and type of additional surgeries performed were similar between groups with the exception that obese women were less likely to undergo abdominal apical suspensions (P=.006) or abdominal paravaginal repairs (P=.001); therefore all comparisons are adjusted for the performance of these procedures. Estimated surgical blood loss was greater for obese women (344 vs. 284 P=.027) however, change in hematocrit (preoperative minus postoperative hematocrit) was lower for obese than non-obese women (6.6 vs 7.3, P=0.048). Mean length of surgery was 20 minutes longer in obese women (P=0.024). Length of hospital stay did not vary between groups. (P=NS) Major intraoperative complications were uncommon (14(6%)) with no difference between weight groups. Incidence of postoperative urinary tract infection, wound infections or postoperative major complications were likewise similar between groups (all P >.05).

**CONCLUSION:** In this nested prospective cohort study, retropubic anti incontinence surgery did not increase intra-operative risk for obese patients when compared to non-obese women. Surgery takes longer for obese patients, but blood loss as recorded by change in hematocrit is lower. Major complications were rare and similar between weight groups, as were infectious complications.

**Key Words: obesity, stress urinary incontinence, surgery, complications**

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