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Two-Year Outcomes After Surgery for Stress Urinary Incontinence in Older Compared to Younger Women

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Abstract

Precis—Women 65 years and older have similar perioperative adverse events and length of stay, but lower subjective and objective cure rates after stress incontinence surgery than younger women.

Objective—To estimate if perioperative and postoperative outcomes after Burch colposuspension or pubovaginal sling for stress urinary incontinence (SUI) differed with age.

Methods—This study was a prospective secondary analysis of the Stress Incontinence Surgical Treatment Efficacy Trial. Baseline characteristics, adverse events, and 2-year outcomes of women at least 65 years old were compared to those younger than 65 utilizing chi-square and t-tests. Multivariable analyses were performed, including age and outcomes that differed between age groups on univariable analysis, adjusting for variables that differed by age group at baseline and by surgical treatment group.

Results—Six-hundred fifty-five women were included in analyses of perioperative events and 520 for 2-year outcomes. Mean age ($\pm$ SD) was 69.7($\pm$ 3.7) years in the older group and 49.4($\pm$ 8.2) in the younger group. Older women had slightly longer time to normal activities (50 versus 42 days, $p=0.05$), but there was no difference in time to normal voiding (14 versus 11 days, $p=0.42$). Older women were more likely to have a positive stress test at follow-up (OR 3.7, 95% CI 1.70-7.97, $p=.001$), less subjective improvement in stress (8 point lesser decrease, 95%CI: 1.5-14.1, $p=0.02$), and urge incontinence (7 point lesser decrease, 95% CI 1.5-12.2, $p=0.01$) by the Medical and Epidemiologic Social Aspects of Aging questionnaire, and were more likely to undergo surgical retreatment for SUI (OR 3.9, 95% CI 1.30-11.48). Perioperative adverse events and length of stay did not differ between groups.

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Conclusion—Older women undergoing surgery for stress incontinence can expect to do as well as younger women with respect to perioperative outcomes, but experience 2-year outcomes that are worse.

Clinical Trial Registration—ClinicalTrials.gov, www.clinicaltrials.gov, NCT00064662

Introduction

Pelvic floor disorders, including urinary incontinence, fecal incontinence, and pelvic organ prolapse, increase in prevalence as women age. (1) Over 200,000 surgeries are performed each year for the treatment of pelvic floor disorders with many of these procedures being performed on the older woman. (2) With the aging U.S. population, the estimated demand for care of pelvic floor disorders is projected to increase by 45 percent over the next 30 years. (1)

Despite a pressing need for data on surgical outcomes in older women, there is a relative paucity of such information in the literature. This may be because older patients are often specifically excluded from clinical trials in this area. For example, Bugeja et al. reported that one third of original research papers in major medical journals excluded elderly patients without justification. (3)

The data that do exist on surgical outcomes in older patients are somewhat mixed. Previous studies looking at risk factors for failure or the effect of age on outcomes for both the Burch colposuspension and fascial sling suggest that cure rates are lower and that there is an increased risk for postoperative storage symptoms, voiding dysfunction, and urinary tract infections in older women (4-10). In a review of medical records on 226 women undergoing surgery for incontinence at a large referral center, women over the age of 70 had a higher risk of complications when compared to younger women (11). Conversely, a chart review of 267 patients over age 75 who underwent urogynecologic surgery found that the overall perioperative morbidity rate in older women was low (12).

The objective of this study was to estimate, in a well-characterized randomized cohort of women, if older women differed from younger women with respect to perioperative and postoperative outcomes up to 24 months after undergoing Burch colposuspension or pubovaginal sling for treatment of stress urinary incontinence (SUI).

Materials and Methods

This is a planned, analysis of data from the Stress Incontinence Surgical Treatment Efficacy Trial (SISTEr) (13). Subjects were enrolled from February, 2002 to June 2004. Eligibility requirements included documented pure or predominant SUI symptoms for at least three months, a positive standardized urinary stress test, and planned SUI surgery. There was no upper age limit in recruitment of adult women for the study. Details of the SISTEr study methods have been published previously (14) and are briefly outlined here. All study procedures were approved by the institutional review board of each participating clinical center and the Biostatistical Coordinating Center with written informed consent obtained from all women prior to enrollment.

Women were randomized in the operating room after anesthesia induction with the use of a permuted-block randomization schedule with stratification according to clinical site to receive a Burch colposuspension or an autologous rectus fascial sling. Because these procedures are frequently performed in conjunction with pelvic prolapse surgery, abdominal and vaginal approaches for both pelvic prolapse repair and hysterectomy were permitted. Baseline assessment included a complete medical history, physical examination, urodynamic evaluation and patient symptom survey. Follow-up data were collected by interview and clinical

examination perioperatively, and at 6 weeks, 3, 6, 12, 18 and 24 months postoperatively. Factors assessed at baseline included age, race, body mass index (BMI), previous incontinence surgery, number of vaginal deliveries, total number of medications used regularly, menopausal/hormone replacement therapy (HRT)/smoking status, pelvic organ prolapse by stage, Q-tip angle, diabetes, and history of frequent urinary tract infections.

Incontinence severity was measured at each visit and included urge and stress symptom scores using the validated Medical Epidemiological and Social Aspects of Aging questionnaire (MESA) (15), number of incontinence episodes on 3-day voiding diary, 24-hour pad test, stress test, and condition specific quality of life scores including the Urogenital Distress Inventory (UDI) and Incontinence Impact Questionnaire (IIQ) (16). Urodynamic data were collected at baseline and 24 months post surgery or at the time of surgical retreatment if that occurred before 24 months. Factors measured included: demonstrated stress incontinence, valsalva leak point pressures (VLPP's), presence of detrusor overactivity, and voiding dysfunction. Sexual function was characterized using the Pelvic Organ Prolapse and Incontinence Sexual Function Questionnaire (PISQ) (17).

Perioperative factors measured were length of hospital stay and adverse events including urinary retention, urinary tract and wound infections, as well as medical complications. Postoperative measures included: treated and untreated de novo or persistent urge incontinence as measured by MESA, voiding dysfunction, pelvic organ prolapse or further pelvic surgery for any reason after Burch or sling.

Overall treatment failure was defined as retreatment for SUI (including behavioral or surgical therapies) at any time, and/or self-report of SUI by the MESA questionnaire (response of sometimes or often), and/or positive stress test (leakage on examination during cough or valsalva at a standardized bladder volume of 300 mL or capacity), and/or greater than 15 gram pad weight on 24 hour pad test and/or incontinence episodes by 3-day bladder diary any time 6 months after surgery. The primary outcome was determined at 24 months. 655 women were included in the perioperative event analysis and 520 women were included in the analyses of 2 year follow-up outcomes. The 520 women included 491 who completed 24 months of the study and data from 29 women who underwent surgical retreatment prior to 24 months. Although we planned to include only women with 24-month follow-up, there were a disproportionate number of older women who had surgical retreatment prior to 24 months. Exclusion of these women with less successful outcomes would have biased the comparison of 2-year outcomes between age groups in favor of the older women. For women who had received surgical retreatment prior to the 24-month visit, their last measures before treatment were used.

For factors associated with age we compared women younger than 65 years to those 65 years and older. Perioperative and postoperative events and outcomes were evaluated comparing the two age groups. Univariable analyses were carried out using cross-classification and the chi-square test for categorical factors and the t-test for comparison of means of continuously measured factors.

To further evaluate post-operative outcomes associated with age group, we used multivariable methods to control for treatment group and other covariables. For stress test, a categorical outcome measure, we used multiple logistic regression analysis. For continuous outcome measures we used least squares multiple linear regression analysis. For all analyses, we first computed the analysis including age group, treatment group and their interaction. If the interaction effect was not statistically significant we removed it from the analysis. We then added covariates that were found to be significant in bivariate analyses and other variables

thought to possibly be clinically significant. A 5% significance level was used. Analyses were performed using SAS Version 9.1 (SAS Institute, Inc. Cary, NC).

Results

A total of 655 women with an age range of 27 to 81 years were enrolled and randomized in the SISTER Trial. Eighty-one women (12%) were 65 years or older. Baseline demographic, clinical characteristics and operative data presented by age group are shown in Table 1. The mean age of the younger cohort was 49.4 ± 8.2 years and that of the older cohort was 69.7 ± 3.7 years. The two age groups differed significantly with regard to education, income, number of vaginal deliveries and smoking status. As expected, the older age group used significantly more medications and a greater percentage were on hormone replacement therapy. A greater percentage of older women had stage 3 or 4 pelvic organ prolapse and had a lower mean straining angle on Q-tip test. The baseline VLPP's were also significantly lower for the women in the older age group. The older age group reported less distress due to urinary symptoms as measured by the UDI and lower incontinence impact as measured by the IIQ. A lower percentage of the older group was sexually active, but sexually active women in the older group had slightly higher (better) PISQ scores. Women in the older and younger age groups had similar rates of concomitant surgical procedures.

Following surgery, the two age groups did not differ with respect to length of stay, readmissions within 6 weeks, time to return to normal voiding or presence of voiding dysfunction (Table 2). Older women had a slightly longer time to return to normal activities, 50 days versus 42 days ($p=.05$). Adverse event rates are also shown in Table 2. There were no differences in adverse events rates between age groups.

Univariable analyses of outcomes are presented in Table 3. Older women were more likely to undergo surgical retreatment for stress incontinence (14%) than younger women (4%). A significantly smaller percentage of older women had a negative stress test at 24-month follow-up (71% versus 84%). The mean improvement in MESA stress score and UDI score was significantly smaller for women in the older group. Outcome measures that did not differ between age groups included improvement in pad weight, incontinence episodes per day on diary and MESA urge score. There were no significant differences in urodynamic changes at 24 months compared with baseline including non-invasive uroflowmetry, post-void residual volume determination, cystometry and pressure flow studies.

We computed multivariable analyses for selected outcomes controlling for treatment group, income, number of prescription medications, number of vaginal deliveries, menopausal/HRT status, pelvic organ prolapse stage, and baseline levels of UDI, IIQ, stress index and urge index (Table 4). The interaction between age group and treatment group was not statistically significant in any model. When treatment group and other covariables were controlled, the association between older age and a negative stress test and improvement in the MESA stress score remained. Older women were more likely to have a positive stress test at follow-up (OR 3.7, 95% CI: 1.70 - 7.97, $p=.001$), less improvement in stress incontinence (8 point lesser decrease on the MESA, 95% CI: 1.5 to 14.1, $p=0.02$), less improvement in urge incontinence symptoms (7 point lesser decrease on the MESA, 95% CI 1.5 to 12.2, $p=0.01$) and were more likely to undergo surgical retreatment for SUI (OR 3.9, 95% CI 1.30-11.48). Conversely, the difference between age groups in improvement in UDI was decreased and no longer statistically significant when covariates were controlled (10 point greater decrease, 95% CI: -4.6 to 24.0, $p=0.18$).

There were no differences in multivariable analyses for all other 24-month outcomes between the two age groups, including satisfaction with treatment.

Discussion

Older women did not differ from younger women in most perioperative outcomes after undergoing stress incontinence surgery with or without concomitant prolapse surgery. These outcomes included length of stay, readmissions within 6 weeks, total number of patients with serious adverse events and number of adverse events, despite the probability of more medical comorbidities in the older women as measured indirectly by their increased number of prescription medications. However, at 24 months postoperatively, older women were more likely to have a positive stress test, less improvement in subjective assessment of stress and urge incontinence symptoms and a higher rate of surgical retreatment as compared to younger women whether they had a Burch colposuspension or pubovaginal sling.

We had previously reported that age was not a risk factor for stress specific or non stress failure in the SISTEr trial (18). This was based on composite outcomes where stress failure was defined as any self report of urinary incontinence (UI) as measured by the MESA questionnaire and/or a positive stress test and/or retreatment for SUI, and non stress failure was defined as a positive 24-hour pad test and/or any incontinence episodes on a 3-day voiding diary with none of the 3 criteria for stress failure. In this current planned secondary analysis, we sought to characterize more fully, the individual components of these composite outcome measures as they differ by age group. Other studies of older women have shown that effective detrusor contractility, bladder capacity, ability to withhold voiding, and urethral closure pressure decline with increasing age (5,19) and detrusor hyperactivity with impaired contractile function and irritative bladder symptoms tend to increase (20), thus predisposing older women to the potential risk of adverse surgical outcomes. In our study, the older women overall had lower baseline valsalva leak point pressures than the younger women which may have influenced their outcomes, although whether they had a Burch colposuspension or pubovaginal sling did not influence these findings.

Very few studies exist comparing perioperative morbidity between older and younger women in the setting of pelvic floor surgery. In one recent study comparing perioperative morbidity and 12 month outcomes of older (≥ 70 years of age) and younger (< 70 years) women undergoing sacrocolpopexy for pelvic organ prolapse, where roughly half the subjects received a Burch colposuspension, there were also no significant differences by age group in any perioperative complication rates (21). However, in that study, length of stay was significantly increased in the older women (3.1 ± 1.0 vs 2.7 ± 1.5 days, $p=0.02$) whereas in our study there was no significant difference in length of stay. This may reflect more vaginal-only surgery in our study whereas all subjects in the other report had an abdominal incision.

A recent review of SUI surgery outcomes (4) found less improvement in urinary tract symptoms for older women in three studies with the tension-free vaginal tape (TVT) procedure (22-24) as well as decreased satisfaction (24). Our study showed equal satisfaction between the age groups despite lower objective and subjective cure rates in the older women. A prospective cohort study of 196 women following colposuspension also showed outcomes that varied by age group. Continence based on clinical symptomatology, demonstration of stress incontinence, and limited post-operative urodynamics, was achieved in 93.1% (162/179) of younger women (< 70 years) compared to 77.3 % (17/179) of older women (> 70 years), $p=0.02$ (8). Post-operative voiding dysfunction after colposuspension as determined by need for prolonged catheterization has also been reported to be increased as women age affecting 12% of those less than 50 years of age, 25% of those 50-64 years and 50% of those 65 years and older (9). This was partially attributed to impaired detrusor function in the older women. Our results differed in not showing a difference by age.

Traditionally, the pubovaginal sling has been associated with high continence rates but sometimes this success is offset by increased voiding dysfunction, storage symptoms and need for surgical revision (25-27). As the older woman has an increased risk of voiding dysfunction, there has been historic reluctance to perform them in this age group (28). In our study there was no difference in voiding dysfunction between younger and older patients whether they had a Burch colposuspension or pubovaginal sling. A recent report utilized Medicare claims data to measure the effect of patient age on outcomes of sling surgery for stress urinary incontinence (6). Women were stratified for analysis at age 75 and multivariable analyses were conducted to identify the independent effects of patient age and comorbidities on outcomes. One year after surgery, overall outcomes in younger women (aged 65-74) were significantly better than in older women with respect to postoperative urge incontinence (20.0% versus 12.6%), treatment failure (10.5% versus 7.2%) and outlet obstruction (10.5% versus 6.6%).

Limitations of our study include not having geriatric specific measures of functional status such as Activities of Daily Living, Instrumental Activities of Daily Living and Life Space Assessment in order to characterize the potential change in functional status with surgery. Strengths include multiple sites, standardization of surgical techniques, a robust sample size, 24 months of follow-up and subjective characterization of the cohorts using validated questionnaires as well as objective outcomes. Many other studies have been limited by small numbers of older women and short-term follow-up (11).

In conclusion, our findings suggest that women over 65 years of age contemplating surgery for stress urinary incontinence, with or without concomitant prolapse surgery, can expect to do as well as younger women with respect to their surgical experience, voiding function, and patient satisfaction, but may face somewhat lower subjective and objective cure rates. Whether these findings will be similar in the newer midurethral sling procedures is an area of active interest and research. As the number of older women seeking care for this debilitating condition continues to increase, it is imperative that we are able to adequately counsel them with respect to their risks and benefits of surgery, especially with respect to issues of continued symptoms and need for subsequent treatment.

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Table 1
Selected Characteristics of Sample at Baseline by Age

Characteristics	Less than 65 years old N=574	65 years and older N=81	p value
DEMOGRAPHIC CHARACTERISTICS			
Racial and ethnicity group - N (%)			0.41
Hispanic	67 (11.7)	5 (6.2)	
Non-Hispanic White	416 (72.6)	64 (79)	
Non-Hispanic Black	40 (7)	4 (4.9)	
Non-Hispanic Other	50 (8.7)	8 (9.9)	
Marital Status - N (%)			0.85
Married/Living as Married	391 (68.1)	56 (69.1)	
Not Married	183 (31.9)	25 (30.9)	
Education - N (%)			0.0005
High School or less	198 (34.5)	27 (33.3)	
Some post-HS training	242 (42.2)	20 (24.7)	
Baccalaureate or more	134 (23.3)	34 (42.0)	
Household Income - N (%)			0.0001
<\$20,000	104 (19.5)	12 (18.5)	
\$20,000 - \$49,999	143 (26.9)	35 (53.8)	
\$50,000 - \$79,999	116 (21.8)	9 (13.8)	
\$80,000 +	169 (31.8)	9 (13.8)	
Self Rated Health - N (%)			0.31
Excellent	125 (21.9)	21 (25.9)	
Very Good	206 (36.1)	33 (40.7)	
Good	156 (27.3)	22 (27.2)	
Fair	72 (12.6)	4 (4.9)	
Poor	12 (2.1)	1 (1.2)	
Number of medications taken - mean (SD)			
Prescription Medications	2.9 (2.8)	4.4 (2.5)	<0.0001
Over-the-Counter Medications	1.4 (2.0)	2.5 (2.1)	<0.0001
RISK FACTORS FOR INCONTINENCE			
BMI [†] - mean (SD)	30.1 (6.3)	29.3 (5.2)	0.22
Vaginal Deliveries - mean (SD)	2.5 (1.5)	3.3 (1.8)	0.0004
Prior Hysterectomy - N (%)	169 (29.4)	32 (39.5)	0.07
Prior Prolapse Surgery - N (%)	10 (1.7)	3 (3.7)	0.21 ^a
Prior Incontinence Surgery - N (%)	80 (13.9)	13 (16)	0.61
Smoking Status - N (%)			0.0004
Never Smoked	311 (54.2)	44 (54.3)	
Former Smoker	171 (29.8)	36 (44.4)	
Current Smoker	92 (16)	1 (1.2)	
Menopausal Status - N (%)			<0.0001
Post-menopausal on HRT	168 (29.3)	55 (67.9)	
Post-menopausal not on HRT	207 (36.1)	26 (32.1)	
Pre-menopausal	198 (34.6)	0 (0)	
CLINICAL CHARACTERISTICS			
Quality of Life			
Total UDI Score [*] - mean (SD)	152.7 (48.9)	138.5 (45.1)	0.01
Total IIO Score [*] - mean (SD)	176.0 (100.4)	138.9 (101.7)	0.002
PISO Score [*] - mean (SD)	31.4 (7)	34.6 (6.4)	0.02
Sexually active in the last 6 months - N (%)	421 (74.1)	29 (35.8)	<0.0001
Pad test weight in grams - mean (SD)	42.53 (80.3)	50.7 (72.8)	0.39
Incontinence episodes/day - mean (SD)	3.2 (2.9)	3.27 (3.2)	0.84
MESA Urinary Incontinence symptom score [‡]			
Stress index - mean (SD)	71.9 (16.9)	69.6 (17.3)	0.24
Urge index - mean (SD)	35.5 (21.9)	39.0 (19.9)	0.17
Prolapse Stage [§] - N (%)			0.01
Stage 0/1	143 (24.9)	19 (23.5)	
Stage 2	347 (60.5)	40 (49.4)	
Stage 3 or 4	84 (14.6)	22 (27.2)	
Q-Tip test in degrees - mean (s.d.)			
Resting angle	15.61 (18)	14.1 (15)	0.41
Straining angle	61.01 (18.6)	54.6 (15.7)	0.003
Delta = strain - rest angles	45.39 (18.6)	40.5 (14.5)	0.008

Characteristics	Less than 65 years old N=574	65 years and older N=81	p value
URODYNAMIC MEASURES			
Urodynamic stress incontinence - N (%)			0.21
Yes	511 (89)	73 (90.1)	
No	55 (9.6)	5 (6.2)	
Invalid study	8 (1.4)	3 (3.7)	
VLPP ^{//} ≤ 60 cm/H ₂ O - N (%)	84 (22.2)	22 (44.0)	0.0015
Δ VLPP [¶] ≤ 60 cm/H ₂ O - N (%)	227 (60.1)	38 (76.0)	0.03
Detrusor overactivity - N (%)	50 (8.8)	10 (12.7)	0.27
OPERATIVE VARIABLES			
Surgical Randomization			0.87
Burch Procedure - N (%)	289 (50.3)	40 (49.4)	
Sling Procedure - N (%)	285 (49.7)	41 (50.6)	
Concomitant Surgery [#] - N (%)			
None	235 (40.9)	40 (49.4)	0.33
Prolapse surgery with anterior vaginal wall repair, +/- other repair	113 (19.7)	17 (21)	
Prolapse surgery without anterior vaginal wall repair (includes posterior wall, apex)	185 (32.2)	21 (25.9)	
Other non-prolapse surgery ^{**}	41 (7.1)	3 (3.7)	

^a Fisher's Exact Test

* UI denotes urinary incontinence, UDI Urogenital Distress Inventory, IIQ Incontinence Impact Questionnaire, PISQ. Pelvic Organ Prolapse and Incontinence Sexual Function Questionnaire (PISQ score was obtained only in women who were sexually active), SD standard deviation

[†] BMI, body mass index: weight (kg) relative to square of height (m²)

[‡] UI Symptom scores: Sum of responses to 9 items for stress symptoms and 6 items for urge symptoms on the Medical, Epidemiological and Social Aspects of Aging questionnaire. Response categories for each item 0 = "never" to 3 = "often." Stress and urge subscale scores were converted to a 100 point "index" for easier comparison

[§] Prolapse staging is based on the methods of the Pelvic Organ Prolapse Quantification System.

^{//} VLPP: valsalva leak point pressure: vesical pressure at time of leakage.

[¶] Δ VLPP: delta valsalva leak point pressure: vesical pressure at time of leakage minus baseline vesical pressure.

[#] Concomitant prolapse repairs included anterior vaginal wall repair (anterior colporrhaphy and paravaginal repairs), posterior colporrhaphy, apical suspension procedures (sacrospinous ligament suspension, uterosacral ligament suspension or sacrocolpopexy), enterocele repair and hysterectomy.

^{**} Other concomitant surgery included anal sphincter repair, tubal ligation, abdominoplasty.

Table 2Perioperative Characteristics and Adverse Events^a by Age, Severity^b and Organ System

	Age <65 years (N=574)	Age ≥65 years (N=81)	p value ^c
Length of Stay in days - mean (SD)	2.0 (2.8)	1.9 (1.0)	0.54
Time to return to normal voiding in days - mean (SD)	11.4 (24.6)	13.8 (24.9)	0.42
Time to return to normal activities in days - mean (SD)	50.2 (33.0)	42.5 (32.8)	0.05
	# of Events (# of Unique Patients)	# of Events (# of Unique Patients)	
Readmissions within 6 weeks	23 (23)	1 (1)	0.34
Voiding Dysfunction	44 (44)	10 (10)	0.19
Serious Adverse Events^d			
Genitourinary	43 (38)	9 (8)	0.35
Pelvic Pain	2 (2)	0 (0)	1.0
Vascular/hematologic: bleeding	3 (3)	1 (1)	0.41
Wound-surgical intervention	24 (22)	0 (0)	0.10
Gastrointestinal	2 (2)	0 (0)	1.0
Pulmonary: respiratory distress requiring intubation	1 (1)	0 (0)	1.0
Anesthetic complication: laryngospasm requiring reintubation	1 (1)	0 (0)	1.0
Total Number of Serious Adverse Events	76	10	
Patients^e with Event (%)	66 (11%)	8 (10%)	0.85
Specific Adverse Events			
Genitourinary	430 (229)	78 (33)	0.90
Vascular/hematologic	12 (12)	2 (2)	0.69
Wound - no surgical intervention	125 (114)	15 (14)	0.66
Gastrointestinal	14 (14)	1 (1)	1.0
Pulmonary	15 (15)	4 (4)	0.28
Neurologic	10 (10)	1 (1)	1.0
Cardiovascular ^f	2 (2)	0 (0)	1.0
Allergic - hives, itching	2 (2)	0 (0)	1.0
Constitutional ^g	3 (3)	0 (0)	1.0
Dermatologic - rashes, erythema	6 (6)	0 (0)	1.0
Total Number of Adverse Events	619	101	
Patients^e with Event (%)	320 (56%)	42 (52%)	0.55

^a Adverse event defined as a deviation from the normal intra- or post-operative course.^b Severity grade determined by a slightly modified version of the Dindo classification system, which is based on the level of therapy required to treat an event.

- I.** No pharmacologic, surgical, or radiologic intervention (allowed therapeutic regimens include antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy).
- II.** Required pharmacologic treatment with drugs other than such allowed for grade I complications (antibiotics, blood transfusions and total parenteral nutrition are included).
- III.** Required surgical, endoscopic or radiologic intervention.
- IV.** Life-threatening complication requiring intensive care management.
- V.** Death.

^c p values were calculated from Fisher's exact test except for the length of stay, which was done by t test.^d Serious Adverse Events were defined as severity grade III-V; no grade V events occurred in either group.^e Percent equals number of unique patients with any adverse event divided by the number of patients in the treatment group.^f Cardiovascular events include; bradycardia treated in recovery room (1), junctional rhythm ruled out for myocardial infarction (1).^g Constitutional events include; fever of unknown origin (2), hypokalemia (1).

Table 3
Unadjusted Mean or Frequency of Continence Outcomes by Age Group

Characteristics	Age Group		p value ¹
	<65 years N=448	≥ 65years N=72	
Satisfaction, Total	400	66	0.28
Mean ± SD ²	4.2 ± 1.0	4.1 ± 1.1	
Surgical Retreatment, Total	448	72	0.003
N (%)	19 (4.2)	10 (13.9)	
Positive Stress test Total	404	68	0.01
N (%)	63 (15.6)	20 (29.4)	
Change in Pad Weight, grams, N, mean ±SD	362 -24.9 ± 73.5	64 -40.0 ± 75.0	0.13
Change Average Accidents per day, N, Mean ±SD	382 -2.8 ± 3.2	66 -2.5 ± 3.2	0.56
Change in MESA Stress Index, N, mean ±SD	412 -59.0 ± 24.9	68 -52.6 ± 27.5	0.03
Change in MESA Urge Index, N, mean ±SD	412 -21.7 ± 23.8	68 -18.9 ± 23.4	0.39
Change in UDI, N, mean ±SD	386 -113.9 ± 60.0	60 -98.0 ± 54.7	0.05

¹ P-value for test of equality of two age groups

² SD, standard deviation

Table 4

Multivariable Analyses of 24-Month Outcomes Between Older and Younger Women

Outcome *	Adjusted Mean Difference [≥65 years group compared to <65 years group] (95% CI)	p-value
Change in MESA Stress Index	7.8 (1.5, 14.1)	0.015
Change in MESA Urge Index	6.9 (1.5, 12.2)	0.012
	Adjusted odds ratio [≥ 65 years group compared to <65 years] (95% CI)	p-value
Surgical Retreatment	3.86 (1.30, 11.48)	0.015
Positive Stress Test	3.68 (1.70, 7.97)	0.001

* Adjusted for age, treatment group, household income, number of meds prescribed, number of vaginal deliveries, any hormone replacement therapy, prolapse, baseline UDI total, baseline IIQ total, baseline MESA stress index, baseline MESA urge index