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Patient-reported outcomes after combined surgery for pelvic floor disorders in older compared to younger women

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Abstract

OBJECTIVE—To compare patient-reported outcomes after combined surgery for pelvic organ prolapse (POP) and stress urinary incontinence (SUI) between older and younger women.

STUDY DESIGN—Retrospective cohort study including 122 younger (<65 years) and 70 older women (≥ 65 years old) who underwent combined POP and SUI surgery. SUI and POP treatment failure were based on validated measures. Logistic regression was used to calculate adjusted odds ratios and 95 % CI.

RESULTS—Mean follow-up was 10 ± 1.2 months. Women in both age groups reported significant improvement in symptoms and life impact postoperatively. In multivariable analyses, older women had an increased odds of SUI treatment failure (AOR 1.10, 95% CI 1.05–2.5), but not POP treatment failure (AOR.90, 95% CI.29–2.8).

CONCLUSIONS—Women 65 years and older undergoing combined surgery for POP and SUI are at risk for recurrent SUI, but still experience significant improvements in symptoms and life impact.

Keywords

pelvic floor disorders; age; patient-reported outcomes; surgical treatment; urinary incontinence; pelvic organ prolapse

Introduction

Both stress urinary incontinence (SUI) and pelvic organ prolapse (POP) are common conditions and many women will choose to undergo surgical treatment due to patient preference or dissatisfaction with conservative therapy. Because the prevalence of both SUI and POP have been shown to increase with age[1, 2] it is expected that the number of older women undergoing

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surgical treatment for these conditions will also increase. There is a growing body of evidence showing that although older women may be at higher risk for morbidity following procedures for pelvic floor disorders, the absolute risk of death is very small.[3–4] However, data are conflicting regarding the impact of age on patient-reported outcomes after surgical treatment.[5–6] Additional information on surgical outcomes in older women could help to improve patient counseling and inform patient decision making and expectations.

The primary objective of this study was to estimate the effect of age on post-operative patient-reported outcomes in symptoms and life impact after combined surgery for pelvic organ prolapse and stress urinary incontinence.

Material and Methods

This study was approved by the Institutional Review Board at Women and Infants' Hospital (Providence, RI). We conducted a retrospective cohort study including women who underwent combined surgery for both symptomatic POP and SUI through the Division of Urogynecology at our institution from June 2006–August 2007. We chose to include only women undergoing combined surgery for POP and SUI to minimize potential confounding of combined POP repair on surgical failure after anti-incontinence surgery.[6]

All patients underwent preoperative multi-channel urodynamic testing confirming SUI and complete Pelvic Organ Prolapse Quantification (POPQ) examinations[7] preoperatively and postoperatively. Women reporting mixed incontinence symptoms were included only if they had predominant stress incontinence defined by self-report and if stress incontinence was confirmed on urodynamic testing. We classified these women as having mixed incontinence based on symptoms even if urodynamic testing did not reveal detrusor overactivity. Baseline incontinence severity was assessed using the Incontinence Severity Index.[8]

All women completed the Pelvic Floor Distress Inventory-20 (PFDI-20) to measure symptom severity of PFDs and Pelvic Floor Impact Questionnaire-7 (PFIQ-7)[9] to measure life impact of PFDs at baseline and postoperatively at 6 and 12 months. Our primary outcome was treatment failure at 12 months post-operative. We defined POP treatment failure based on patient report with an affirmative response to the question "Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?" on the PFDI-20. We defined SUI treatment failure based on patient report with an affirmative response to the question "Do you experience urine leakage related to physical activity, coughing, or sneezing?" on the PFDI-20. Data on patient demographics, clinical characteristics, intraoperative surgical details and perioperative complications were also collected. Anti-incontinence procedures included both retropubic and transobturator midurethral slings at the discretion of individual surgeons.

We categorized women into 2 age groups: younger women were defined as age younger than 65 years and older women were defined as 65 years or older. We chose to dichotomize women into these 2 age groups for multiple reasons. First, studies in the general surgery literature support that patients over age 65 are at increased risk for postoperative functional decline and mortality following elective surgical procedures,[10, 11] and this is in keeping with the urogynecologic literature.[3] Second, there is currently no consistent age cutoff in the urogynecologic literature evaluating age as a risk factor for treatment outcomes, and studies include a wide range from 60–80 years of age.[4] Finally, a recent study by Barber, et al supports that treatment failure for SUI tends to increase after the age of 60.[6] Therefore, we feel that using a cutoff of age 65 years is appropriate for our analyses. Of note, we performed sensitivity analysis using age 60 as our cutoff and this did not significantly change our findings, as there were only 11 women between the ages of 60–64.

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Within group and between group improvements in preoperative and postoperative PFDI-20 and PFIQ-7 scores were compared using paired t tests and independent t tests, respectively. Two multivariable logistic regression models were constructed to estimate the effect of age on risk of treatment failure (POP treatment failure and SUI treatment failure). Variables with P≤0.1 on bivariate analysis were assessed for potential confounding and interaction in our models. All analyses were performed using STATA SE 9.0 (Stata Corp., College Station, TX). P-values ≥.05 were considered statistically significant.

To estimate a sample size calculation, based on previous literature we assumed the proportion of subjective SUI success following midurethral slings in older women to be between 55%–77%[12, 13] and for younger women to be 92%. [13] On the basis of these estimates, we determined that a sample size of 65 women per group would have 80% power to detect a 20% difference at an alpha =.05.

Results

During the study period, 353 charts were reviewed and 192 women met study inclusion criteria. Of the eligible women, 122 (64%) were less than 65 years of age and 70 (36%) were 65 years or older and the median age was 53 years. The mean follow-up time was 10 ± 1.2 months, and was not significantly different between groups. Patient demographics and clinical characteristics are presented in Table 1. A higher proportion of older women had comorbidities including hypertension, diabetes mellitus, coronary disease and chronic lung disease. The proportion of women reporting mixed incontinence or a history of prior urogynecologic surgery was similar between the two age groups. Other than hysterectomy and vaginal vault suspension, the type of combined POP repairs was similar between groups. There was only one woman who had an abdominal hysterectomy; all others hysterectomies were performed through a vaginal approach. For type of vaginal vault suspension, 34 (18%) had uterosacral suspension, 21 (11%) had sacrospinous ligament fixation, 3 (1.5%) had abdominal sacro-colpopexy, 3 (1.5%) had laparoscopic sacro-colpopexy and 3 (1.5%) had a trans-vaginal mesh augmented apical suspension. The majority of women had retropubic midurethral slings (90%) and the proportion of retropubic versus transobturator slings was similar between age groups.

Preoperatively, older women had lower baseline PFDI-20 scores (91 ± 56 vs 107 ± 56, P=.02) and PFIQ-7 scores (37 ± 45 vs 69 ± 73, P=.003) compared to younger women. There was no difference in peri-operative complications between groups (7% in older versus 12% in younger, P=0.3). Complications included urinary tract infection and discharge home with catheter.

Post-operatively, women within both age groups had significant improvements in overall PFDI-20 and PFIQ-7 scores and for the separate prolapse, urinary and colorectal-anal subscales of the questionnaires (P<.01 for all). Between groups, older women had lower mean improvements in overall PFDI-20 scores (mean improvement 63 ± 31 versus 83 ± 63 points for older versus younger women, respectively, P=.04). There was no difference in overall improvements in PFIQ-7 scores between groups (30 ± 40 versus 50 ± 60 points for older versus younger, respectively, P=.10). For both the PFDI-20 and PFIQ-7, improvements in urinary subscales were lower in older versus younger women, whereas there were no differences in improvements in the prolapse subscales between groups.

For treatment failure, 12/110 (11%) younger women and 15/70 (21%) older women reported SUI treatment failure (P=.03) and 10/110 (9%) younger women and 9/70 (13%) older women reported POP treatment failure (P=.06). In multivariable analyses, older women were at increased odds for SUI treatment failure (AOR 1.10, 95% CI 1.05–2.5), after adjusting for parity, comorbidities, baseline overall POPQ stage, combined vaginal vault suspension, and colpocleisis (Table 3). Due to collinearity between insurance and age group, insurance was

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dropped from the model. In addition, because all women who underwent hysterectomy also underwent vaginal vault suspensions, only vaginal vault suspension was included as a covariate in the models. Older women were not at increased odds for POP treatment failure (AOR .90, 95% CI .29–2.8) after adjusting for parity, comorbidities, baseline POPQ, combined vaginal vault suspension, and colpocleisis.

Comment

The first baby boomer generation is expected to reach 65 years of age in 2011, resulting in significant growth of the older population for many subsequent years. However, the number of older women included in surgical trials for pelvic floor disorders is small and this population is often under-represented.[14, 15] This highlights the importance for studies to report morbidity outcomes as well as patient-reported and quality of life outcomes following surgical treatment in older women. In our study, we found that older women undergoing combined repairs for POP and SUI may be at increased risk for recurrent SUI. However, they still experience significant improvement in symptoms and life impact, although this may not be to the extent reported by younger women.

Although there is a growing body of literature reporting on morbidity and mortality following pelvic floor surgery in older women, [4, 16] the number of comparative studies evaluating patient-reported and quality of life outcomes in this population is small. Studies comparing "subjective" outcomes following midurethral slings for SUI have been conflicting, with some studies reporting no differences between older and younger women,[13, 17, 18] and others reporting that older women are at higher risk for recurrent SUI.[19–21] Although most of these studies included some women who underwent combined POP repairs, many did not adjust for this as a potential confounder. In addition, the definition of treatment success is not consistent between studies and many did not utilize validated patient-reported measures. Barber, et al recently reported on 162 women randomized in a tension-free vaginal tape versus transobturator tape trial and reported that age and combined POP surgery were independently associated with recurrent SUI (defined by PFDI-20 response).[6] Specifically, the authors reported that each decade increase in age was associated with a 1.7 increased odds of recurrent SUI. Our study results are in line with these findings, although the magnitude of our risk is smaller. Clinically, this growing body of literature may improve counseling of women of all ages considering surgery and can provide additional information to help patient decision-making and expectations.

Studies evaluating POP patient-reported outcomes following surgery in older women are more limited. Richter, et al reported on 322 women randomized in the multi-center Colpopexy and Urinary Reduction (CARE) study and found that women over age 70 were not at increased risk for postoperative self-reported incontinence, stress testing for incontinence or prolapse stage compared to younger women.[5] One important note about the CARE trial is that it included women with POP and minimal to no reported symptoms of SUI. This likely represents a very different patient population from our study, which includes only women with symptomatic SUI, and may explain differences in our findings. On the other hand, consistent with Richter's findings, we also found no difference between age groups for POP treatment failure or POP-specific patient-reported outcomes.

We found that although both older and younger women had significant improvements in symptom and life impact measures for both SUI and POP, older women had smaller overall improvements compared to younger women. We also found that older women had lower baseline PFDI-20 and PFIQ-7 scores. This is consistent with previous studies that suggest that younger women may report more severe scores on validated questionnaires for urinary incontinence.[18, 22] It is possible that the degree of improvement was less for older women

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compared to younger women because older women started out with lower baseline PFDI-20 and PFIQ-7 scores to begin with.

There were no serious complications in our study population and age was not associated with an increased risk of minor complications (urinary infection or need for prolonged catheterization). Only 65% of the older women had comorbidities, and this may reflect population characteristics of women who choose to undergo surgical treatment or an inherent bias of surgeons to select healthier patients. We were unable to determine specific selection criteria individual surgeons may have for older women in our study and what role this may play in patient morbidity or quality of life outcomes. This may limit the external validity of our findings.

A strength of our study was that we only included women undergoing combined POP and SUI procedures, which addresses an important confounder. We also utilized validated patient-reported measures specific for POP and urinary incontinence. One limitation is that we were unable to compare women in more extreme age groups, such as the old elderly (older than 80 years) due to the small number of women in the older age group. We chose a cutoff of age 65 to define older and younger women. There is currently no consistent age cutoff in the literature and studies have shown that patients over age 60–65 are at increased risk for recurrent SUI as well as morbidity and mortality. We performed sensitivity analyses using age 60 as a cutoff which did not change our findings. Also, we were unable to evaluate the effect of age on longer-term outcomes beyond the 12 month post-operative visit. It is possible that our study did not have enough power to detect differences between age groups for POP treatment failure, or that differences may have been seen if follow-up had been longer. Finally, our study only includes women undergoing combined surgery for POP and SUI and the findings may not apply to women undergoing surgery for POP or SUI alone.

In conclusion, older women may be at increased risk for recurrent SUI compared to younger women; however, they can still expect significant improvements in symptoms and life impact following combined surgery for POP and SUI. This information is important for clinicians caring for older women and can help to inform patient decision-making and expectations.

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Table 1

Demographic and clinical characteristics by age group

Variable	Younger than 65 years (N=122)	65 years or older (N=70)	P-value
Age (years, SD)	46.8 (7.7)	71.2 (1.1)	<.001
Parity (median, range)	2 (0–7)	3 (0–6)	<.05
Race			
African-American	4 (3)	0	
Asian	1 (1)	0	
Native American	1 (1)	0	
Caucasian	107 (88)	63 (90)	
Unknown	9 (7)	7 (10)	.50
Insurance			
Medicare	2 (2)	15 (22)	
Medicaid	4 (3)	1 (2)	
Private	97 (80)	26 (37)	
Other	17 (13)	27 (38)	
Unknown	2 (2)	1 (1)	<.05
Body mass index (mean, SD)	29.8 (6.9)	28.2 (5.1)	.15
Mixed incontinence (n, %)	33 (27)	25 (35)	.2
Prior urogynecologic surgery (n, %)	44 (36)	27 (38)	.8
Comorbidity* (n, %)	47 (39)	45 (65)	<.05
Baseline POPQ stage			
2	92 (76)	33 (47)	
3	30 (24)	35 (50)	
4	0	2 (3)	<.05
Baseline Incontinence Severity Index(mean, SD)	6.5 (.4)	7.1 (.6)	.3
Leak point pressure <60 cm H20 (n, %)	17 (14)	11 (15)	.8
Baseline PFDI-20 score (mean, SD)	106.5 (56)	90.5 (56)	.05
Baseline PFIQ-7 score (mean, SD)	69.1 (73)	37.2 (45)	.003
Retropubic sling† (n, %)	112 (92)	61 (87)	.2
Combined hysterectomy (n, %)	30 (25)	28 (40)	.03
Combined vaginal vault suspension‡ (n, %)	46 (38)	36 (51)	.04
Combined colpocleisis (n, %)	0	6 (9)	.001
Combined anterior repair (n, %)	55 (45)	35 (50)	.5
Combined posterior repair (n, %)	46 (38)	27 (38)	.9

*Includes hypertension, diabetes mellitus, coronary artery disease and chronic lung disease.

†All other patients received transobturator sling.

‡All women who underwent hysterectomy also underwent vaginal vault suspension.

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Table 2

Outcomes following concurrent surgery for pelvic organ prolapse and stress urinary incontinence between age groups

Variable	Younger than 65 years (N=122)	65 years or older (N=70)	P-value
Change in PFDI-20* component (mean, SD)			
Overall score	−83.0 (63)	−63.2 (31)	.04
Pelvic Organ Prolapse Distress Inventory	−27.5 (25.2)	−21.3 (26.8)	.13
Urinary Distress Inventory	−41.4 (29.9)	−28.5 (31)	.007
Colorectal-Anal Distress Inventory	−13.8 (22.1)	−12.2 (20.5)	.6
Change in PFIQ-7† component (mean, SD)			
Overall score	−49.8 (60.1)	−30.0 (40.2)	.10
Pelvic Organ Prolapse Impact Questionnaire	−13.8 (26.4)	−6.9 (21.3)	.08
Urinary Incontinence Questionnaire	−24.9 (31.9)	−14 (27.5)	.04
Colorectal-Anal Impact Questionnaire	−11.4 (23.7)	−2.9 (11.6)	.01
Postoperative POPQ stage (median, range)	1 (0–2)	1 (0–2)	.88

*Pelvic Floor Distress Inventory-20

†Pelvic Floor Impact Questionnaire-7

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Table 3

Multivariable logistic regression analysis for effect of age on stress urinary incontinence treatment failure

Variable	Adjusted Odds Ratio	95% CI
Age > 65 years	1.10	1.05–2.5
Parity	.65	.32–1.3
Comorbidity*	2.8	.50–15.4
Baseline POPQ†		
Stage 3	1.1	.7–1.9
Stage 4	1.3	.8–3.9
Combined vaginal vault suspension	.97	.70–4.7
Combined colpocleisis	2.14	.20–40.5

*Compared to women without comorbidities including hypertension, diabetes mellitus, coronary artery disease and chronic lung disease.

†Compared to women with POPQ Stage 2