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## Impact of age on mid- to long-term outcomes of transvaginal native tissue repair for apical vaginal prolapse

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### Abstract

**Aims**—To compare surgical success rates in older versus younger women a minimum of 3 years post transvaginal native tissue repair for apical prolapse. Post-operative symptom severity and quality of life improvement, surgical complications and retreatment were also examined.

**Methods**—Women who underwent transvaginal native tissue repair for apical prolapse between 2011 and 2013 were eligible. Subjects completed the Pelvic Floor Distress Inventory (PFDI–20), Pelvic Floor Impact Questionnaire (PFIQ–7), and Patient Global Impression of Improvement (PGI–I), and were categorized as “younger” (age<70) or “older” (age ≥70). The primary outcome of surgical success was defined as the absence of bulge symptoms and no re-treatment for prolapse.

**Results**—Of 641 eligible patients, response rate was 51.0%. 62.7% of subjects had hysterectomy prior to index surgery. Surgical success was noted in 72.9% of younger and 82.2% of older subjects (Adjusted odds ratio [aOR] 1.72, 95% CI (0.93, 3.17). Older women had greater improvement from baseline in PFDI-20 score (–87.5 (IQR 74.0) vs –54.2 (IQR 80.2), p= 0.01). Retreatment rate and surgical complication rates were similar between groups (both p>0.05).

**Conclusions**—Older and younger women had similar surgical success rates a minimum of 3 years post-operative; however, older women had a greater overall symptom severity improvement. This information may be helpful in counseling older women regarding surgical expectations and decision-making.

### Keywords

aging; pelvic organ prolapse; patient reported outcome measures; geriatric; quality of life

## 1. INTRODUCTION

The prevalence rate of pelvic organ prolapse (POP) increases with age and the aging population in the US is rapidly growing.<sup>1</sup> The US Census Bureau projects that the number of people ages 65 and older will nearly double to more than 83 million by 2050.<sup>2</sup> The demand for care for pelvic floor disorders is also projected to increase by 35% between 2010 and 2030.<sup>3–4</sup> While POP rarely affects overall health status, many older women elect to undergo

surgical prolapse repair to improve quality of life. Older women undergoing pelvic reconstructive surgery experience higher complication rates (specifically shock, urinary tract infection, respiratory, and psychiatric complications<sup>7</sup>) and longer hospital stays, although complication rates are low overall.<sup>5-8</sup> Despite this, older age has been associated with lower risk of anatomic recurrence after pelvic reconstructive surgery.<sup>9-11</sup>

In addition to anatomic data, patient reported outcomes have been increasingly incorporated into the urogynecologic literature and practice. The absence of vaginal bulge symptoms postoperatively correlates significantly with the patient's assessment of overall improvement, but anatomic success alone does not.<sup>12</sup> Many studies have demonstrated that patients consider relief of symptoms and improvement in QOL the most important outcomes of prolapse surgery.<sup>12-14</sup> The ICS-IUGA 2012 joint report on terminology recommends using patient-reported outcomes, particularly the presence or absence of vaginal bulge symptoms, as well as satisfaction, quality of life (QOL) and perioperative data for reporting surgical outcomes.<sup>15</sup>

Studies investigating patient reported outcomes following transvaginal reconstructive surgery demonstrate lower recurrence risk in older women, though many of these studies do not use validated questionnaires.<sup>9-10</sup> In one study using validated measures (Pelvic Floor Distress Inventory-20; PFDI-20 and Pelvic Floor Impact Questionnaire-7; PFIQ-7)<sup>16</sup>, similar patient reported prolapse outcomes between older and younger women were found 10 months post combined prolapse and stress urinary incontinence surgery.<sup>17</sup>

There remains a paucity of longer-term data describing outcomes for older women undergoing transvaginal reconstructive surgery. The objective of this study is to compare mid-to long-term outcomes in older versus younger women undergoing primary transvaginal native tissue apical (uterine or vaginal vault) prolapse repair. We hypothesized that there would be no difference in surgical success between older and younger women.

## 2. MATERIALS AND METHODS

This is a retrospective cohort study including all women who underwent primary transvaginal native tissue apical prolapse repair between January 2011 and December 2013 at a single academic institution. Uterosacral ligament suspension (USLS) and sacrospinous ligament fixation procedures (SSLF) were identified by Current Procedural Terminology (CPT) codes. USLS and SSLF procedures were performed as described in the OPTIMAL trial<sup>18</sup>. Patients were excluded for the following reasons: non-English speaking, prior apical surgical prolapse repair, prior prolapse repair with mesh, mesh or obliterative procedures used in current prolapse repair, abdominal approach in current prolapse repair. Prior hysterectomy was allowed. Institutional Review Board approval was obtained.

Eligible subjects were mailed questionnaires including measures of symptom distress (PFDI-20), symptom specific impact on QOL (PFIQ-7) and impression of treatment success (Patient Global Impression of Improvement; PGI-I).<sup>19</sup> Questionnaires also inquired about any retreatment (pessary or further surgery for prolapse). Subjects were called as a reminder to return the survey 2 & 4 weeks after initial mailing. Baseline data was abstracted from the

electronic medical record and included demographics, preoperative Pelvic Organ Prolapse Quantification (POPQ)<sup>20</sup> measures, past medical, surgical, obstetric and gynecologic history, as well as preoperative symptom distress and impact questionnaires (PFDI-20 and PFIQ-7). Surgical and perioperative data, including reoperations were also abstracted from the electronic medical record.

Subjects were categorized into two groups: younger women, defined as less than 70 years of age on day of surgery, and older women, defined as 70 years or greater. The primary outcome of surgical success was assessed at a minimum of 3 years post-surgery and was defined as both the absence of bulge symptoms and no re-treatment for prolapse. Secondary outcomes were subjective success (defined as answer “no” to question 3 on PFDI-20: “do you usually have a bulge or something falling out that you can see or feel in your vaginal area”), post-operative symptom severity (PFDI-20 subscales and total score), symptom specific quality of life (PFIQ-7 subscales and total score), overall impression of improvement (measured by PGI-I and change in pre- versus postoperative PFDI-20 and PFIQ-7 subscales and total score), as well as surgical complications, length of stay and re-treatment.

Median values of each subscale and total scores at baseline were calculated for the PFDI-20 and PFIQ-7 total and sub-scale scores, as well as median change from baseline to a minimum of three years post-surgery. Missing values were accounted for by using the mean from answered items only. Bivariate comparisons using chi-squared test for categorical variables and Student’s t-test or Wilcoxon rank-sum test for continuous variables were performed. Binomial logistic regression was used to test the independent association between age and surgical success, adjusting for prior hysterectomy, prior posterior repair, preoperative vaginal hormone replacement therapy (HRT), comorbid hypertension, parity and body mass index (BMI). Results were considered significant when  $p < 0.05$ . All analyses were performed using SAS version 9.4 (Cary, NC).

### 3. RESULTS

During the three-year period, 641 patients meeting inclusion criteria underwent primary vaginal native tissue apical prolapse repair. Overall response rate was 51.0% with 327 of the 641 mailed questionnaires returned. Response rate was 49.0% (n=237) for younger and 56.3% (n=90) for older groups ( $p = 0.13$ ). Baseline characteristics were similar between responders and non-responders (data not shown; all  $p > 0.05$ ). Median follow-up time was 58 months (4.8 years) for each group (IQR 18 for younger and IQR 14 for older,  $p=0.87$ ). Baseline clinical and demographic characteristics are shown in Table 1. 60.8% of younger, and 66.7% of older women had undergone prior hysterectomy ( $p = 0.32$ ).

Preoperatively, PFDI-20 and PFIQ-7 scores were similar for older and younger women as shown in table 1 ( $p = 0.15$ ,  $p = 0.85$ , respectively). There was no difference in apical suspension procedure (USLS vs. SSLF) or any of the concomitant surgical procedures between groups (all  $p > 0.05$ , Table 2).

Surgical success (absence of vaginal bulge symptoms and no retreatment) did not differ between groups, and was noted in 72.9% (172/237) of younger and 82.2% (74/90) of older subjects, aOR 1.72, 95% CI (0.93, 3.17). Subjective treatment success was noted in 76.3% (180/237) of younger versus 84.4% (76/90) older women ( $p=0.11$ ).

Surgical complications ( $p=0.30$ ) and length of stay ( $p=0.94$ ) were similar between groups (Table 3). Of the 28 urinary tract injuries (11.8%) in younger subjects 18 injuries (7.6%) were trocar related cystotomies during midurethral sling placement, 3 injuries (1.3%) were other cystotomies, and 7 injuries (3.0%) were transient ureteral obstructions that resolved with suspension suture removal. Of the 7 urinary tract injuries (7.8%) in the older group, 6 injuries (6.9%) were trocar related cystotomies during midurethral sling placement, and 2 injuries (2.3%) were transient ureteral obstructions which resolved with suspension suture removal (one patient sustained both transient ureteral kinking and trocar related cystotomy during sling placement). Overall frequency of trocar related cystotomy during midurethral sling placement was 7.3%.

Women in both age groups had improvements in overall PFDI-20 and PFIQ-7 scores, as well as in prolapse, urinary and colorectal-anal subscale scores (Table 4). While both groups met the minimally important difference (MID) of  $-45$  for the PFDI-20,<sup>17</sup> older women had a greater improvement from baseline compared to younger women ( $-87.5$  (IQR 74.0) vs  $-54.2$  (IQR 80.2),  $p=0.01$ ) in the overall PFDI-20 score. Older women also had a greater improvement from baseline in the POPDI subscale ( $-41.7$  (IQR 30) vs  $-29.2$  (IQR 33.3),  $p=0.01$ ) (Table 4). While both groups demonstrated improvement in PFIQ-7 scores from baseline and nearly met the MID ( $-36$ ),<sup>17</sup> there was no significant difference in improvement from baseline between younger and older groups (younger  $-34.9$  (IQR 76.2) vs older  $-33.3$  (IQR 85.7),  $p=0.75$ ). Both younger and older groups reported a median PGI-I of 2 (IQR 2), or prolapse symptoms that were “much better” than before surgery ( $p=0.48$ ).

Retreatment specifically for prolapse occurred in 5.5% of younger women and 6.7% of older women ( $p=0.68$ ). Of the 13 younger women who had retreatment for prolapse, one elected non-surgical management with pessary and 12 underwent surgical management of prolapse recurrence. Of the six older women who were retreated, one elected non-surgical management and five underwent surgical management. Retreatment for any reason occurred in 10.5% of younger and 7.8% of older women ( $p=0.52$ ). Retreatment included use of pessary and repeat procedures related to the primary surgery, such as sling revision.

#### 4. DISCUSSION

In this mid- to long-term follow-up surgical prolapse treatment study, older women not only achieved similar surgical success compared to younger women undergoing primary transvaginal apical prolapse repair, but also showed a greater improvement in pelvic floor distress symptoms, specifically prolapse bother symptoms. Complication rates, length of stay and retreatment rates were similar between groups, and both older and younger women met the MID for improvement in the total PFDI-20.

The current results add to the literature investigating patient reported outcomes following transvaginal reconstructive surgery, which demonstrate lower recurrence risk in older women, though many of these studies do not use validated questionnaires for patient reported outcomes.<sup>9-10</sup> In one study using validated measures, similar patient reported prolapse outcomes between older and younger women were found 10 months post combined prolapse and stress urinary incontinence surgery.<sup>16</sup> As in this study, the current results also demonstrates that older women have similar subjective success rates to younger women, with a longer follow up a minimum of 3 years post-transvaginal native tissue prolapse repair. The current results also partly contrast with the findings of Sung et al, where older women had smaller improvements in symptom severity and life impact than younger women. In their study, older women had lower baseline PFDI-20 and PFIQ-7 scores, whereas in the current study baseline scores were similar between older and younger women.<sup>16</sup>

Consistent with previous studies, unexpected surgical complications for both older and younger women in this study were low. The majority of surgical complications in both groups were trocar related cystotomy during midurethral sling placement. While we did report a slightly higher rate of this complication than some previously published studies, this rate falls within range of most clinical trials. For example, in a recent Cochrane review<sup>21</sup>, nearly a third of the 40 trials reporting on bladder perforation during retropubic midurethral sling procedures described rates higher than 7%. Differing from previous studies, length of stay was not longer for older women in this study.<sup>5</sup> This is likely secondary to the minimal invasiveness of transvaginal surgery and easier recovery compared to open abdominal surgery.

While the aging population in the US continues to grow, the number of studies investigating patient-reported outcomes for older women with pelvic floor disorders remains sparse. Though older women may experience increased length of stay and morbidity, overall complication rates are low.<sup>5,-8, 22-23</sup> Older women undergoing reconstructive compared to obliterative surgery achieve similar improvement in quality of life and have similar complication rates, indicating that reconstructive surgery remains a viable option for older women with symptomatic prolapse.<sup>24</sup>

Limitations of this study include the retrospective design and associated inherent bias. Additionally, our study may be limited by non-response bias, although we assume this may affect both younger and older age groups similarly given similar baseline characteristics between groups. Objective anatomic success rates were not assessed, however validated subjective outcome measures are associated with objective outcomes, while anatomic outcome alone may not reflect subjective improvement.<sup>12</sup> We therefore feel these results are compelling. Finally, approximately 25-30% of baseline subjective data were not available for analysis, limiting the sample size characterizing change from baseline data.

Strengths of this study include the large sample size of over 320 subjects, and high response rate with over 50% of questionnaires returned. With a median follow up time of 4.8 years, the current data presents significantly longer-term results than previous studies assessing the differential impact of age on prolapse surgery outcomes. At this mid- to long-term assessment, there was a high rate of sustained surgical success for both older and younger

subjects. The use of validated measures significantly adds to the strength of this study. Finally, a higher age cutoff to define “older” women was used, distinct from previous studies.<sup>16, 24–25</sup> While there is currently no consensus regarding an age cutoff to define “older” women, 70 years was chosen due to the increasing life expectancy of US adults, and that 70–75 years is the age when many preventative screenings cease.<sup>26–27</sup> This age cutoff may better represent the proportion of older women currently undergoing urogynecologic surgery in practice.

## 5. CONCLUSIONS

This study demonstrated that older women achieve similar sustained surgical success rates compared to younger women undergoing transvaginal native tissue prolapse repair. At mid- to long-term follow-up, although both older and younger women experienced a significant improvement in pelvic floor symptoms and quality of life after surgery, the improvement in symptoms severity was greater among older women. Older women can be reassured that reconstructive native tissue repair of apical and other compartment prolapse remains a viable treatment option, with excellent durability, patient satisfaction and improvement in symptoms and quality of life, despite older age at the time of surgical repairs. This information will be useful when counseling patients regarding surgical expectations and decision-making.

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**Table 1.**

Baseline Clinical and Demographic Characteristics of Younger and Older Patients

	Younger women (<70) n=237	Older women (≥ 70) n=90	P-value
Age – median (IQR)	61 (11)	74 (5)	<0.01
Race			0.06
White	210 (88.6)	86 (95.6)	
Non-white	27 (11.4)	4 (4.4)	
Body mass index			0.56
Non-overweight	71 (30.0)	26 (28.9)	
Overweight	91 (38.4)	40 (44.4)	
Obese	75 (31.7)	24 (26.7)	
Parity – median (IQR)	2 (1)	3 (2)	<0.01
Number of vaginal deliveries			<0.01
0	8 (3.8)	4 (5.0)	
1 or 2	137 (65.2)	35 (43.8)	
3	65 (31.0)	41 (51.3)	
Post-menopausal	216 (92.0)	90 (100)	<0.01
Medical comorbidities			
Hypertension	98 (41.4)	57 (63.3)	<0.01
Diabetes Mellitus	19 (8.0)	6 (6.7)	0.68
COPD or Asthma	23 (9.7)	12 (13.3)	0.34
Ever tobacco use	60 (25.3)	25 (27.8)	0.65
Previous pelvic surgery			
Hysterectomy	144 (60.8)	60 (66.7)	0.32
Urinary incontinence procedure	39 (16.5)	22 (24.4)	0.10
Anterior repair	22 (9.3)	13 (14.4)	0.18
Posterior repair	19 (8.0)	16 (17.8)	0.01
Preoperative vaginal hormone replacement therapy	168 (70.9)	80 (88.9)	<0.01
POP-Q measurements – median (IQR)			
Ba	1 (2)	2 (3)	0.07
Bp	-1 (2)	-1 (4)	0.20
C	-3 (4)	-2 (5.5)	0.99
TVL	10 (1.5)	10 (2)	0.18
POP-Q Stage			0.09
2	134 (57.0)	39 (43.3)	
3	83 (35.3)	42 (46.7)	
4	18 (7.7)	9 (10.0)	
Baseline Quality of Life measures – median (IQR)			
PFDI-20	121.8 (104.4)	126.0 (72.9)	0.15



	Younger women (<70) n=237	Older women ( 70) n=90	P-value
POPDI	50 (36.7)	52.1 (29.2)	0.23
CRADI	21.9 (43.8)	37.5 (31.3)	0.10
UDI	41.7 (41.7)	45.8 (41.7)	0.48
PFIQ-7	66.7 (95.2)	48.8 (102.4)	0.85
POPIQ	19.0 (47.6)	21.4 (47.6)	0.92
CRAIQ	9.5 (33.3)	9.5 (33.3)	0.66
UIQ	31.0 (46.8)	28.6 (37.6)	0.77

\* Data presented as n (%) unless otherwise noted

IQR, interquartile range; COPD, chronic obstructive pulmonary disease; POP-Q, pelvic organ prolapse quantification; PFDI-20, pelvic floor distress inventory-20; POPDI, pelvic organ prolapse distress inventory; CRADI, colorectal-anal distress inventory; UDI, urogenital distress inventory; PFIQ-7, pelvic floor impact questionnaire-7; POPIQ, pelvic organ prolapse impact questionnaire; CRAIQ, colorectal-anal impact questionnaire; UIQ, urogenital impact questionnaire

**Table 2.**

## Index Surgical Procedures

	Younger women n=237	Older women n= 90	P-value
USLS or SSLF			0.25
USLS	183 (77.2)	64 (71.1)	
SSLF	54 (22.8)	26 (28.9)	
Total Vaginal Hysterectomy	93 (39.2)	29 (32.2)	0.24
Anterior repair	190 (80.2)	79 (87.8)	0.11
Posterior repair	182 (76.8)	67 (74.4)	0.66
Enterocoele repair	65 (27.4)	32 (35.6)	0.15
Retropubic midurethral sling	119 (50.2)	43 (47.8)	0.69
Transobturator midurethral sling	23 (9.7)	10 (11.1)	0.71
Perrineorrhaphy	42 (17.7)	13 (14.4)	0.48
Other concomitant procedure	32 (13.5)	8 (8.9)	0.26

\* Data presented as n (%) unless otherwise noted

USLS, uterosacral ligament suspension; SSLF, sacrospinous ligament fixation

**Table 3.**

## Perioperative characteristics

<b>Surgical complications</b>	<b>Younger women n=237</b>	<b>Older women n= 90</b>	<b>P-value</b>
Any	31 (13.1)	8 (8.9)	0.30
Urinary tract injury	28 (11.8)	7 (7.8)	0.29
Bowel injury	0 (0.0)	1 (1.1)	0.28
Hemorrhage	1 (0.42)	0 (0.0)	1.00
Intraoperative blood loss > 1 liter	3 (1.3)	0 (0.0)	0.57
Blood transfusion	2 (0.84)	0 (0.0)	1.00
Length of stay			0.94
1 day	227 (95.4)	86 (95.6)	
2 days	11 (4.6)	4 (4.4)	
Indwelling catheter or clean intermittent catheterization at 2 weeks	12 (5.2)	3 (3.4)	0.77
Retreatment	24 (10.1)	7 (7.8)	0.52
Retreatment for prolapse	13 (5.5)	6 (6.7)	0.68

Data presented as n (%) unless otherwise noted

**Table 4.**

## Patient-reported Outcomes

	<b>Younger women n=237</b>	<b>Older women n= 90</b>	<b>P-value</b>
Composite success	172 (72.9)	74 (82.2)	0.08
Subjective success	180 (76.3)	76 (84.4)	0.11
PFDI – median (IQR) <sup>*1</sup>	47.9 (82.3)	53.1 (88.5)	0.81
POPDI	12.5 (33.3)	12.5 (25)	0.64
CRADI	15.6 (28.1)	19.4 (31.3)	0.30
UDI	20.8 (37.5)	16.7 (41.7)	0.43
PFIQ – median (IQR) <sup>*1</sup>	9.5 (42.9)	9.5 (47.6)	0.49
POPIQ	0 (4.8)	0 (9.5)	0.32
CRAIQ	0 (14.3)	2.4 (27.8)	0.22
UIQ	4.8 (23.8)	4.8 (47.6)	0.71
PGL-I – median (IQR) <sup>*1</sup>	2 (2)	2 (2)	0.48
	<b>Younger women n=173</b>	<b>Older women n= 62</b>	<b>P-value</b>
PFDI – median (IQR) <sup>*2</sup>	-54.2 (80.2)	-87.5 (74.0)	0.01
POPDI	-29.2 (33.3)	-41.7 (30)	0.01
CRADI	-3.1 (31.3)	-12.5 (25)	0.13
UDI	-16.7 (37.5)	-29.2 (45.8)	0.16
PFIQ – median (IQR) <sup>*2</sup>	-34.9 (76.2)	-33.3 (85.7)	0.75
POPIQ	-14.3 (38.1)	-9.5 (33.3)	0.41
CRAIQ	0 (19.0)	-4.7(23.8)	0.88
UIQ	-14.3 (39.7)	-14.3 (33.3)	0.98

Data presented as n (%) unless otherwise noted

IQR, interquartile range; PFDI-20, pelvic floor distress inventory-20; POPDI, pelvic organ prolapse distress inventory; CRADI, colorectal-anal distress inventory; UDI, urogenital distress inventory; PFIQ-7, pelvic floor impact questionnaire-7; POPIQ, pelvic organ prolapse impact questionnaire; CRAIQ, colorectal-anal impact questionnaire; UIQ, urogenital impact questionnaire; PGI-I, patient global impression of improvement

<sup>\*1</sup> Post-surgery scores

<sup>\*2</sup> Changes in scores from baseline to post-surgery