Published in final edited form as:

Am J Obstet Gynecol. 2016 November ; 215(5): 659.e1–659.e7. doi:10.1016/j.ajog.2016.06.013.

Patient-reported goal attainment and comprehensive functioning outcomes after surgery compared to pessary for pelvic organ prolapse

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Abstract

Background—Pelvic organ prolapse can negatively impact a woman's overall functioning. When choosing between surgery or pessary, many women have information needs about long-term expectations. While it has been shown that both surgery and pessary can improve prolapse symptoms, there is less information comparing comprehensive functioning outcomes and goal attainment between the two treatments.

Objectives—Our primary objective was to compare patient-reported goal attainment and comprehensive physical, social, and emotional functioning outcomes after surgery versus pessary for symptomatic prolapse.

Study Design—We conducted a prospective observational cohort study including women choosing surgery or pessary for symptomatic stage 2 or greater prolapse. Women undergoing any modality of prolapse surgery or those anticipating using a pessary long-term to avoid surgery were eligible. Women completed questionnaires at baseline (pre-treatment) and up to 12 months post-treatment including: 2) Pre-treatment goals and actual post-treatment goals achieved; 2) five functioning outcomes encompassing physical, social and emotional function using the Patient-Reported Outcomes Measurement Information System surveys; 3) validated symptom and quality of life questionnaires. Treatment goals were categorized into "Symptom Goals" (prolapse, urinary, bowel, pain) and "Function Goals" (physical, social, emotional, sexual). Goals achieved were compared using chi-square. Multiple logistic regression was used to identify variables associated

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Conflicts of Interest/Disclosure Statement: The authors report no conflicts of interest. Presented at the 42nd Annual Scientific Meeting of the Society of Gynecologic Surgeons, April 10-13, 2016.

Condensation: Women treated with surgery or pessary for prolapse experience improvements in functioning and goal attainment, although improvements are greater after surgery.

with not achieving all pretreatment goals. Mean improvements in functioning scores were compared within groups and between groups using paired and independent t-tests. Assuming 80% of women would achieve complete goal attainment in the surgery group 64 women per group would be needed to detect a 20% difference at an $\alpha = 0.05$. We recruited 80 women per group to account for drop out.

Results—A total of 160 women were enrolled and 72 (90%) surgical (mean follow-up 12 months) and 64 (80%) pessary patients (mean follow up 8 months) had post-treatment data. 14 discontinued pessary use and 8 ultimately crossed-over to surgery. At follow-up, a higher proportion of women in the surgery arm reported successfully achieving symptom goals and function goals compared to women who chose pessary ($P < 0.05$). Women who continued pessary use had comparable goal attainment to women in the surgery group for almost all goal categories, whereas women who discontinued the pessary or crossed-over to surgery had significantly lower goal attainment compared to both the surgery and pessary continuation groups. On multiple logistic regression, only college education or higher was associated with an increased odds of not achieving all pretreatment goals (OR 2.70, 95% CI 1.1-6.6, $P = 0.03$).

Regarding functioning outcomes, within groups, there were statistically significant improvements between pre- and post-treatment Patient Reported Outcomes Measurement System functioning scores in all 5 domains for the surgery group and 4 of 5 domains in the pessary group ($P < 0.05$). When comparing between groups, women who had surgery reported significantly greater improvements in the physical function, social roles, and depression domains compared to the pessary group ($P < 0.05$).

Conclusions—Women undergoing either surgery or pessary for symptomatic prolapse experience goal attainment and improvements in physical, social and emotional functioning, although surgery is associated with greater improvements.

Keywords

pelvic floor disorders; pelvic prolapse; goal; patient-reported outcomes; surgical treatment; pessary

Introduction

Pelvic organ prolapse (POP) is common, with prevalence rates reported to be as high as 41% in postmenopausal U.S. women.¹ It is projected that the number of U.S. women with POP will increase 46% between 2010 and 2050 from 3.3 to 4.9 million.² Both conservative and surgical options are available for POP. Because treatments for POP are primarily aimed at improving a woman's symptoms, functioning and quality of life, information about treatment outcomes between options is important for patient decision making.

There is some debate about how to best define POP as a disease³ as well as how to best define success and failure outcomes after treatment in a standardized fashion.^{4,5} From a patient point of view, treatment goals and decisions can be highly individualized since women can be affected differently.⁶ Although studies have shown that both surgery and pessary can improve POP symptoms, in general there is less information regarding comprehensive functioning outcomes and longer-term goal attainment between the two

treatment options. The primary objective of this study was to compare goal attainment and comprehensive physical, social, and emotional functioning outcomes after surgery versus pessary for symptomatic POP. We hypothesized that surgery would be associated with higher goal achievement and improved functioning outcomes compared to pessary.

Material and Methods

This study was approved by the Institutional Review Board at Women & Infants Hospital of Rhode Island (Providence, RI). We conducted a prospective, observational cohort study including women choosing either surgery or pessary treatment for symptomatic, Stage 2 or greater POP at the Division of Urogynecology. Participants were recruited between September 2012 and October 2014 and followed for up to 12 months. Adult women over the age of 18 choosing any type of POP surgery or anticipating long-term pessary use were included. All patients underwent preoperative Pelvic Organ Prolapse Quantification (POPQ) examinations⁷ confirming Stage 2 or greater POP. Symptomatic POP was defined as reporting a bothersome vaginal bulge. Patients could also have other pelvic floor disorder (PFD) symptoms. We excluded women without symptomatic or documented POP, women unable to complete questionnaires due to cognitive or language barriers, and women who only planned on using a pessary short term. All participants signed an informed consent prior to participating in this study.

All women completed baseline questionnaires and post-treatment questionnaires (See Table 1). Women undergoing surgery completed post-treatment questionnaires at 6 and 12 months. Women who elected pessary completed post-treatment questionnaires at 3, 6, and 12 months. We included the 3 month visit for pessary participants to capture potential early pessary failures and also because the effect of pessary is more immediate. Pessary patients who discontinued the pessary and/or crossed-over to the surgery arm were asked to complete post-treatment questionnaires at the time of pessary discontinuation and prior to initiation of any additional treatment. Women who crossed-over from pessary to surgery also completed questionnaires at 6 and 12 months post-surgery.

Questionnaires were self-administered and were completed after initial counseling with the provider to determine treatment plan, but prior to any treatment initiation (surgery or pessary placement). For goals, patients were asked to list up to 10 goals of POP treatment and to rank them in order of importance. This original list was provided to patients at their post-treatment visits and they were asked to respond whether each pre-treatment goal had been achieved. Clinical and research staff did not provide assistance in determining goals.

Comprehensive functioning outcomes were measured using the Patient-Reported Outcomes Measurement Information System (PROMIS®)⁸ questionnaires. PROMIS® includes standardized tools to measure comprehensive patient-reported well-being in physical, mental, and social domains which have been validated across multiple medical conditions. The use of PROMIS® outcomes can provide a global assessment of patient well-being that is efficient, precise, and valid, and allows for comparison across disciplines. Each domain measure has undergone rigorous psychometric evaluation and refinement and has been tested across a wide variety of chronic diseases and conditions and in the general population.

Although these measures are comprehensive, their use in POP and surgical interventions has been limited.

In this study we used PROMIS® short form surveys for: 1) Physical function; 2) Satisfaction with Social Roles; 3) Satisfaction with Participation in Discretionary Social Activities; 4) Anxiety; and 5) Depression. These were also self-administered. The Physical Function domain assesses one's capability to perform a variety of physical activities. The Satisfaction with Social Roles assess satisfaction with performing one's usual social roles and activities whereas Satisfaction with Participation in Discretionary Social Activities assesses contentment with leisure interests and relationships with friends. The Anxiety domain assesses fear, anxious misery, hyperarousal, and somatic symptoms. The Depression domain assesses negative mood, negative views of self, negative social cognition, and decreased positive affect.

PROMIS® instruments use a T-score which have a method of interpretation built into the scoring algorithms. With a T-score, a score of 50 is the average score of the general population and 10 is equal to one standard deviation. A higher score means more of that domain. For example, higher scores on physical function indicate better health whereas higher scores on anxiety indicate poorer health. Patients in this study also completed the Pelvic Floor Distress Inventory-20 (PFDI-20) to measure PFD symptoms and Pelvic Floor Impact Questionnaire-7 (PFIQ-7)⁹ to measure PFD impact, Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ-12)¹⁰, Body Image Scale (BIS)¹¹, and Patient Global Impression of Improvement (PGI-I)¹² (post-treatment only).

Treatment goals listed by patients were categorized into "Symptom Goals" (prolapse symptoms, urinary symptoms, bowel symptoms, pain/discomfort symptoms) and "Function Goals" (physical, social, emotional, sexual). These goal categories were chosen based on previous work done in this field.¹³⁻¹⁵ Goals that did not fit into these categories were classified as "Other" and were excluded from this analysis. We did not exclude women based on the types of goals they listed. Two research staff members independently categorized goals at the end of the study. Any discrepancies were reviewed by a third research staff member or investigator and adjudicated by consensus. Demographic and clinical characteristics and physical exam findings were abstracted from chart review. Patients in both groups were provided \$10 for each completed questionnaire and \$15 for the final questionnaire for compensation of their time.

Our primary outcome was achievement of pre-treatment goals at 12 months. Based on Elkadry¹³, Mahajan¹⁶, and Hullfish¹⁴, overall goal attainment after surgery for pelvic floor disorders is approximately 80% short term (3 months). Assuming there is a 20% difference between surgery and pessary treatments for goal attainment, 64 women per group would be needed at a $\alpha=0.05$ and power 80%. We planned to recruit 80 women per group to account for drop out.

Goals achieved and not achieved and the proportion of patients achieving goals were compared using Chi-square. Multiple logistic regression was used to identify variables associated with not achieving 1 or more pretreatment goals (<100% goal achievement).

Variables with $P \leq 0.1$ on bivariate analysis were assessed for potential confounding and interaction in our models. For PROMIS functioning scores, we compared mean changes in raw scores for each PROMIS domain using paired t-tests to assess within group changes and independent t-tests to compare differences in scores between surgery and pessary groups. All analyses were performed using STATA/SE 12.0 (Stata Corp., College Station, TX). P-values ≤ 0.05 were considered statistically significant.

Results

A total of 160 women were enrolled into the study. In the surgery arm 72/80 (90%) had follow up and in the pessary arm 64/80 (80%) had follow up. Median follow up for the surgery group was 383 days (range 171-534) and for all pessary users was 223 days (range 11-446). The median follow up for women who continued pessary was 313 days (range 42-446). Clinical and demographic characteristics are presented in Table 2. Women choosing pessary were older compared to those choosing surgery and had lower baseline PFDI-20 and body image scores. The two groups were otherwise similar in race, POPQ stage, prior prolapse treatment, comorbidities and education level. In the surgery group, 35 (44%) underwent hysterectomy, 74% underwent some sort of apical suspension, 37% had an anterior vaginal repair, 52% had a posterior vaginal repair, and 52% underwent a concomitant anti-incontinence procedure. During the study period, 31 total pessary patients discontinued pessary use or crossed-over to the surgery group. Of these, follow-up data was available for 14 women who discontinued pessary use and 8 who crossed-over to the surgery arm. 97% of women in the surgery arm reported being “much better” or “very much better” on the PGI-I compared to 70% in the pessary arm at follow up ($P < 0.0001$).

Regarding baseline goals, women were asked to list and then rank their goals. Table 3 presents the distribution of the top #1 goal ranked by patients. There was no difference between the surgery and pessary groups in the proportion of women reporting types of symptom or function goals as their top #1 goal, except a higher proportion of women in the surgery arm and those who ended up discontinuing the pessary reported having urinary symptom goals as their top goal compared to those who continued pessary use.

At follow-up, a higher proportion of women in the surgery arm reported successfully achieving prolapse, urinary, pain/discomfort symptom goals and physical, emotional and sexual function goals compared to women who chose pessary (See Table 4). We then compared goal attainment based on pessary continuation and discontinuation. Women who continued pessary use had comparable goal attainment to women in the surgery group for almost all goal categories, whereas women who discontinued the pessary or crossed-over to surgery had significantly lower goal attainment compared to both the surgery and pessary continuation groups.

A higher proportion of women in the surgery group achieved 100% of their pretreatment goals compared to pessary (56% surgery group, 39% pessary continuation group, 5% pessary discontinuation group, $P < 0.0001$). Of note, achievement of urinary goals was not different between women who underwent a concomitant anti-incontinence procedure in the surgery group compared to the pessary group (60% surgery versus 64% pessary group,

P=0.8). A total of 49 women (36%) reported <100% goal attainment after treatment. On multiple logistic regression, only college education or higher was associated with an increased odds of not achieving 100% of pretreatment goals compared to women who achieved all of their goals (OR 2.72, 95% CI 1.12- 6.60, P=0.03). Type of treatment, race and the presence of other pelvic floor disorders were not associated with 100% goal achievement.

Functioning outcomes between surgery and pessary arms are presented in Table 5. Within groups, statistically significant improvements in scores were seen between pre- and post-treatment PROMIS functioning scores in all 5 domains for the surgery group and 4 of 5 domains in the pessary group (the Depression domain did not improve with pessary use). When comparing between groups, women who had surgery reported significantly greater improvements in the Physical Function, Social Roles, and Depression domains compared to the pessary group (P<0.05). When comparing only women who continued pessary use versus women in the surgery arm, those who underwent surgery still had significantly greater improvements in Physical Function (mean change 8.7 vs. 5.2 points, P=0.04) and Depression scores (mean change 4.0 vs. 0.5, P=0.03). Women who discontinued the pessary or crossed over to surgery had no significant improvements in any of the PROMIS functioning questionnaires (P>0.05 for all within group comparisons).

For women who discontinued pessary use, reasons for dissatisfaction included: discomfort with pessary (47%), still had bulge symptoms (42%), urinary symptoms (32%), bowel symptoms (21%), inconvenient (16%), and vaginal discharge (5%). These reasons were not mutually exclusive.

Comment

In this study, women undergoing either surgery or pessary for symptomatic POP achieve individual goals and experience improvements in physical, social and emotional functioning although surgery is associated with greater improvements compared to pessary. Women who choose to continue with pessary have more comparable improvements in functioning and goal attainment to the surgery group. Women who discontinued the pessary or crossed over to surgery had the lowest goal attainment and no improvements in functioning scores.

Goals of POP treatment can be highly individual and variable. In our study, 30% of women ranked resolution of urinary symptoms as their top goal for POP treatment whereas 18% ranked resolution of prolapse symptoms (bulge) as the top goal. This is consistent with some previous studies. In a study by Adams, et al of 226 women presenting for PFD care, resolution of urinary symptoms was the most commonly stated goal regardless of prolapse stage.¹⁷ In addition, in our study a higher proportion of women who ended up discontinuing pessary use or crossing over to surgery reported a top goal of urinary symptom resolution compared to women who continued with pessary. It is possible that pessary for POP did not satisfactorily achieve their urinary symptom goals. Komesu et al reported that attainment of self-stated goals is associated with greatly increased odds of pessary continuation.¹⁸ Although there can be many practical reasons why a patient may be dissatisfied with a pessary, in our study, pessary discontinuation was associated with lack of goal attainment

and lack of improvement in functioning outcomes as well. In contrast to our findings, Shveiky et al found that in a trial of 65 women undergoing treatment of vaginal prolapse with and without mesh, 57% reported a primary goal of improving prolapse symptoms while 23% reported improving urinary symptoms as a primary goal of prolapse treatment.¹⁹ The reasons for these differences are unclear and it is possible that our patient population may have had a higher proportion of concomitant lower urinary tract symptoms.

A strength of this study is that we used the PROMIS questionnaires to assess comprehensive functioning outcomes. There has been significant work done in other fields with these measures but their use in pelvic floor disorders and surgical interventions has been limited. In this study, we demonstrated that both surgery and pessary use are associated with improvements in a wide range of functioning ranging from physical to social to emotional function. Providing information to patients about functioning outcomes regarding both treatments can be helpful for patient decision-making. This can also help patients refine their individual treatment goals and expectations. Future research should continue to explore and assess the use of PROMIS® functioning outcomes in pelvic floor disorders as relevant patient-reported outcome measures.

Limitations of our study include that there may be selection bias between women who choose surgery versus pessary. For example, there may be different goals and functioning expectations at baseline, or since surgery confers overall greater risk, it is possible that a positive outcome would be associated with higher goal attainment. Although our study showed that women with a college education or higher were more likely to not achieve all pretreatment goals, the basis for this association is not clear. It is possible that they had higher and possibly less realistic expectations, but this remains unclear. Women in this study were recruited from a tertiary care center; therefore, it is possible that desired and achieved goals may differ in other populations or in a population with different demographics. Our goal was to determine long-term goal achievement and functioning and although a large proportion of women did meet the 12 month follow-up period, the mean follow up time in the pessary group was shorter due to loss to follow up and overall pessary discontinuation. Women were asked to list their goals after the initial counseling process with their physician which may have altered goals and expectations compared to prior to the visit; however, we do not believe this would bias our study since goals were collected using the same method in both groups. Finally, we did not exclude women who may have been poor surgical candidates who were treated with pessary and it is possible that their goals may be different; however, the median number of comorbidities between the two groups was not different.

In conclusion, our findings highlight that both surgery and pessary treatments lead to improvements in patient functioning and goal attainment. Although surgery is associated with greater improvements, not all women desire surgical treatment and those women who continue pessary use have comparable functioning and goal attainment outcomes.

Acknowledgments

Funding support: Supported by grant K23HD050108 from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

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Table 1

Summary of patient-reported measures completed by participants

Goals - collected at baseline and post-treatment	Baseline pretreatment goals (Maximum 10, ranked in order of importance by patient) Post-treatment goals achieved (pretreatment goals re-listed and patient asked to mark those achieved and not achieved)
Functioning outcomes – collected at baseline and post-treatment	Patient-Reported Outcomes Measurement Information System (PROMIS®) surveys: <ol style="list-style-type: none"> 1 Physical Function 2 Satisfaction with Social Roles 3 Satisfaction with Participation in Discretionary Social Activities 4 Anxiety 5 Depression
Other pelvic floor disorder questionnaires - collected at baseline and post-treatment	<ol style="list-style-type: none"> 1 Pelvic Floor Distress Inventory-Short Form 2 Pelvic Floor Impact Questionnaire – Short Form 3 Patient Global Impression of Improvement 4 Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire -12 5 Body Image Scale

Table 2

Demographic and clinical characteristics of study population

	Total (n=160)	Surgery (n=80)	Pessary (n=80)	P-value
Age Mean (SD)	61.6 (11.8)	59.0 (10.0)	64.2 (13.0)	0.005
Comorbidities Median (Range)	1 (0 - 4)	1 (0 - 3)	1 (0 - 4)	0.4
POPQ Stage (median, range)	3 (1-4)	2 (1-4)	3 (1-4)	0.04
Presence of Other PFDs (any)	99 (61.9)	52 (65.0)	47 (58.8)	0.5
Hispanic*	4 (2.5)	3 (3.8)	1 (1.3)	0.6
Race White Black All Other	149 (93.1) 1 (0.6) 10 (6.3)	77 (96.3) 1 (1.3) 2 (2.5)	72 (90.0) 0 (0.0) 8 (10.0)	0.1
Education* High school or less College or PG degree	46 (29.1) 112 (70.9)	24 (30.0) 56 (70.0)	22 (28.2) 56 (71.8)	0.9
PFDI score Mean (SD)	115.4 (58.8)	126.4 (58.3)	104.0 (57.5)	0.02
PISQ score Mean (SD)	35.8 (6.7)	34.9 (7.6)	37.0 (5.1)	0.2
Body image score Mean (SD)	27.0 (25.6)	31.7 (27.8)	22.2 (22.3)	0.02

* Numbers may not add to 100% due to missing responses

Table 3

Top goal ranked by patient at baseline, by treatment group^{*,†}

	Total N	Any symptom goal	Prolapse symptom (bulge) goals	Urinary symptom goals	Bowel symptom goals	Pain / discomfort	Any function goal	Physical function goals	Social function goals	Emotional function goals	Sexual function goals	Other
Surgery	80	58 (72.5)	11 (13.8)	31 (38.8)	6 (7.5)	10 (12.5)	21 (26.3)	15 (18.8)	1 (1.3)	2 (2.5)	3 (3.8)	1 (1.3)
Pessary-continued	47	32 (68.1)	13 (27.7)	7 (14.9)	1 (2.1)	11 (23.4)	13 (27.7)	12 (25.5)	0	0	1 (2.1)	2 (4.3)
Pessary –crossover or discontinued	31	20 (64.5)	4 (12.9)	10 (32.3)	2 (6.5)	4 (12.9)	8 (25.8)	7 (22.6)	0	0	1 (3.2)	3 (9.7)
P-value		0.7	0.1	0.02	0.5	0.3	1.0	0.7	1.0	0.7	1.0	0.09

* Symptom goals include prolapse, urinary, bowel, or pain/discomfort symptoms. Function goals include physical, social, emotional, and sexual function goals

† 2 women in pessary group did not report any baseline goals

Table 4

Post-treatment goal attainment by treatment group and goal category^{*}

Goals achieved												
	Total N	All symptom goals	Prolapse goals	Urinary goals	Bowel goals	Pain/discomfort	All function goals	Physical function goals	Social function goals	Emotional function goals	Sexual function goals	Other goals
Surgery	72	43/59 (72.9)	24/25 (96.0)	27/39 (69.2)	5/8 (62.5)	23/25 (92.0)	31/43 (72.1)	26/31 (83.9)	4/6 (66.7)	4/5 (80.0)	10/16 (62.5)	5/5 (100)
All pessary users	63	42/60 (70.0)	23/29 (79.3)	23/36 (63.9)	5/7 (71.4)	20/25 (80)	27/44 (61.4)	22/35 (62.9)	4/5 (80.0)	6/7 (85.7)	3/9 (33.0)	3/8 (37.5)
Pessary-continued	42	35/41 (85.4)	19/21 (90.5)	17/21 (81.0)	4/5 (80.0)	17/17 (100)	26/28 (92.9)	21/22 (95.5)	4/4 (100)	6/6 (100)	3/4 (75.0)	3/5 (60.0)
Pessary –crossover or discontinued	21	7/19 (36.8)	4/8 (50.0)	6/15 (40.0)	1/2 (50.0)	3/8 (37.5)	1/16 (6.3)	1/13 (7.7)	0/1 (0)	0/1 (0)	0/5 (0)	0/3 (0)
P-value [‡]		0.0007	0.006	0.04	1.0	0.0003	<0.0001	<0.0001	0.2	0.08	0.03	0.02

^{*} Data represent women who reported having baseline goals in each category that were subsequently achieved after treatment

[‡] P-value compares surgery, pessary-continued, and pessary-crossover/discontinued groups.

Table 5

Functioning outcomes by treatment group

	Baseline mean score (SD)	Post-treatment mean score (SD)	Change mean score (SD)	Within group P- value	Between group P- value
PROMIS Physical Function*					
Surgery	45.0 (7.5)	53.7 (9.3)	8.7 (8.8)	<0.0001	0.0004
Pessary	48.1 (7.6)	51.6 (9.2)	3.5 (6.9)	0.0003	
PROMIS Social Roles					
Surgery	50.8 (10.6)	57.1 (9.6)	6.3 (10.5)	<0.0001	0.049
Pessary	54.2 (10.1)	57.0 (9.9)	2.8 (9.3)	0.02	
PROMIS Social Discretionary					
Surgery	52.0 (9.8)	57.1 (9.8)	5.1 (8.9)	<0.0001	0.07
Pessary	54.0 (10.0)	56.4 (10.1)	2.4 (7.7)	0.02	
PROMIS Anxiety*					
Surgery	54.0 (10.5)	49.1 (10.1)	−5.0 (10.3)	0.0001	0.3
Pessary	49.9 (9.4)	46.7 (9.9)	−3.2 (9.1)	0.008	
PROMIS Depression*					
Surgery	51.1 (9.4)	47.0 (9.9)	−4.0 (9.4)	0.0006	0.02
Pessary	45.7 (8.2)	45.0 (9.2)	−0.6 (7.1)	0.5	

* P<0.05 for baseline PROMIS scores between Surgery vs. Pessary group for Physical Function, Anxiety, and Depression domains.