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

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BACKGROUND: Pelvic organ prolapse can have a negative impact on a woman's overall functioning. When choosing between surgery or pessary, many women have information needs about long-term expectations. Whereas 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 2 treatments.

OBJECTIVE: Our primary objective was to compare patient-reported goal attainment and comprehensive physical, social, and emotional functioning outcomes after surgery vs 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 (before treatment) and up to 12 months after treatment including the following: (1) pretreatment goals and actual posttreatment goals achieved; (2) 5 functioning outcomes encompassing physical, social, and emotional function using the Patient-Reported Outcomes Measurement Information System surveys; and (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 a χ^2 test. Multiple logistic regression was used to identify variables associated with not achieving all pretreatment goals. Mean improvements in functioning scores were compared within groups and between groups using paired and independent Student *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 of 0.05. We recruited 80 women per group to account for dropout.

RESULTS: A total of 160 women were enrolled and 72 surgical (90%) (mean follow-up 12 months) and 64 pessary patients (80%) (mean follow up 8 months) had posttreatment data. Fourteen 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 with women who chose pessary ($P < .05$). Women who continued pessary use had comparable goal attainment with 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 with 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 (odds ratio, 2.70, 95% confidence interval, 1.1—6.6, $P = .03$). Regarding functioning outcomes, within groups, there were statistically significant improvements between pre- and posttreatment Patient-Reported Outcomes Measurement Information System functioning scores in all 5 domains for the surgery group and 4 of 5 domains in the pessary group ($P < .05$). When comparing between groups, women who had surgery reported significantly greater improvements in the physical function, social roles, and depression domains compared with the pessary group ($P < .05$).

CONCLUSION: 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.

Key words: goal, patient-reported outcomes, pelvic floor disorders, pelvic prolapse, pessary, surgical treatment

Pelvic organ prolapse is common, with prevalence rates reported to be as high as 41% in postmenopausal US women.[1] It is projected that the number of US women with pelvic organ prolapse will increase 46% between 2010 and 2050 from 3.3 million to 4.9 million.[2] Both conservative and surgical options are available for pelvic organ prolapse. Because treatments for pelvic organ prolapse 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 pelvic organ prolapse as a disease[3] 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 because women can be affected differently.[6] Although studies have shown that both surgery and pessary can improve pelvic organ prolapse symptoms, in general, there is less information regarding comprehensive functioning outcomes and longer-term goal attainment between the 2 treatment options.

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

Material and Methods

This study was approved by the Institutional Review Board at Women and Infants Hospital of Rhode Island

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(Providence, RI). We conducted a prospective, observational, cohort study including women choosing either surgery or pessary treatment for symptomatic, stage 2 or greater pelvic organ prolapse at the Division of Urogynecology.

Participants were recruited between September 2012 and October 2014 and followed up for up to 12 months. Adult women over the age of 18 years choosing any type of pelvic organ prolapse surgery or anticipating long-term pessary use were included.

All patients underwent preoperative pelvic organ prolapse quantification examinations[7] confirming stage 2 or greater pelvic organ prolapse. Symptomatic pelvic organ prolapse was defined as reporting a bothersome vaginal bulge. Patients could also have other pelvic floor disorder symptoms. We excluded women without symptomatic or documented pelvic organ prolapse, women unable to complete questionnaires because of cognitive or language barriers, and women who planned on using a pessary only short term. All participants signed an informed consent prior to participating in this study.

All women completed baseline questionnaires and posttreatment questionnaires (see Table 1). Women undergoing surgery completed posttreatment questionnaires at 6 and 12 months. Women who elected pessary completed posttreatment 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 posttreatment questionnaires at the time of pessary discontinuation and prior to the initiation of any additional treatment. Women who crossed over from pessary to surgery also completed questionnaires at 6 and 12 months after surgery.

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

Comprehensive functioning outcomes were measured using the Patient-Reported Outcomes Measurement Information System (PROMIS)[8] questionnaires. This system includes standardized tools to measure comprehensive patient-reported well-being in physical, mental, and social domains that have been validated across multiple medical conditions.

The use of the Patient-Reported Outcomes Measurement Information System 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 pelvic organ prolapse and surgical interventions has been limited.

In this study we used the Patient-Reported Outcomes Measurement Information System short form surveys for the following: (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 domain assesses satisfaction with performing one's usual social roles and activities, whereas satisfaction with participation in discretionary social activities domain 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.

The Patient-Reported Outcomes Measurement Information System instruments use a T-score, which have a method of interpretation built into the scoring algorithms. With a T-score, a

TABLE 1
Summary of patient-reported measures completed by participants

Goals, collected at baseline and after treatment	Baseline pretreatment goals (maximum 10, ranked in order of importance by patient) Posttreatment goals achieved (pretreatment goals relisted and patient asked to mark those achieved and not achieved)
Functioning outcome, collected at baseline and after treatment	Patient-Reported Outcomes Measurement Information System (PROMIS) surveys: 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 after treatment	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

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score of 50 is the average score of the general population, and 10 is equal to one SD. 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 to measure pelvic floor disorder symptoms and the Pelvic Floor Impact Questionnaire-7[9] to measure pelvic floor disorder impact, the Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire,[10] the Body Image Scale,[11] and the Patient Global Impression of Improvement[12] (after 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 examination 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 pretreatment goals at 12 months. Based on Elkadry et al,[13] Mahajan et al,[16] and Hullfish et al,[14] 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 an alpha of 0.05 and 80% power. We planned to recruit 80 women per group to account for dropout.

TABLE 2
Demographic and clinical characteristics of study population

Characteristics	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[a]	4 (2.5)	3 (3.8)	1 (1.3)	0.6
Race				
White	149 (93.1)	77 (96.3)	72 (90.0)	0.1
Black	1 (0.6)	1 (1.3)	0 (0.0)	
All other	10 (6.3)	2 (2.5)	8 (10.0)	
Education[a]				
High school or less	46 (29.1)	24 (30.0)	22 (28.2)	0.9
College or PG degree	112 (70.9)	56 (70.0)	56 (71.8)	
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

PFD, pelvic floor disorder; *PFDI*, Pelvic Floor Distress Inventory; *PG*, postgraduate; *PISQ*, Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire; *POPQ*, pelvic organ prolapse quantification.

[a] Numbers may not add to 100% because of missing responses.

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Goals achieved and not achieved and the proportion of patients achieving goals were compared using a χ^2 test. Multiple logistic regression was used to identify variables associated with not achieving 1 or more pretreatment goals (<100% goal achievement). Variables with a value of $P \leq .1$ on bivariate analysis were assessed for potential confounding and interaction in our models.

For the Patient-Reported Outcomes Measurement Information System functioning scores, we compared mean changes in raw scores for each Patient-Reported Outcomes Measurement Information System domain using paired Student *t* tests to assess within-group changes and independent Student *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). Values of $P \leq .05$ were considered statistically significant.

Results

A total of 160 women were enrolled into the study. In the surgery arm, 72 of 80 (90%) had follow-up, and in the pessary arm, 64 of 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).

TABLE 3
Top goal ranked by patient at baseline, by treatment group[a,b]

Goals	Total number	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		.70	.10	.02	.50	.30	1.0	.70	1.0	.70	1.0	.09

[a] Symptom goals include prolapse, urinary, bowel, or pain/discomfort symptoms. Function goals include physical, social, emotional, and sexual function goals; [b] Two women in the pessary group did not report any baseline goals.

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Clinical and demographic characteristics are presented in Table 2. Women choosing pessary were older compared with those choosing surgery and had lower baseline Pelvic Floor Distress Inventory-20 and body image scores. The 2 groups were otherwise similar in race, pelvic organ prolapse quantification 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 antiincontinence procedure. During the study period, 31 total pessary patients discontinued pessary use or crossed over to the surgery group. Of these, follow-up data were available for 14 women who discontinued pessary use and 8 who crossed over to the surgery arm. Ninety-seven percent of the women in the surgery arm reported being much better or very much better on the Patient Global Impression of Improvement compared with 70% in the pessary arm at follow-up ($P < .0001$).

Regarding baseline goals, women were asked to list and then rank their goals. Table 3 presents the distribution of the top number 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 number 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 with 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 with 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 with 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 with both the surgery and pessary continuation groups.

A higher proportion of women in the surgery group achieved 100% of their pretreatment goals compared with pessary (56% surgery group, 39% pessary continuation group, 5% pessary discontinuation group, $P < .0001$). Of note, achievement of urinary goals was not different between women who underwent a concomitant antiincontinence procedure in the surgery group compared with the pessary group (60% surgery vs 64% pessary group, $P = .8$). 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 with women who achieved all of their goals (odds ratio, 2.72, 95% confidence interval, 1.12−6.60, $P = .03$). Type of treatment, race, and the presence of other pelvic floor disorders were not associated with 100% goal achievement.

Functioning outcomes between the surgery and pessary arms are presented in Table 5. Within groups, statistically significant improvements in scores were seen between pre- and posttreatment Patient-Reported Outcomes Measurement Information System 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 with the pessary group ($P < .05$). When comparing only women who continued pessary use vs 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, $P = .04$) and depression scores (mean change 4.0 vs 0.5, $P = .03$). Women who discontinued the pessary or crossed over to surgery had no

TABLE 4
Posttreatment goal attainment by treatment group and goal category[a]

Goals achieved												
Goal category	Total number	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[b]		.0007	.006	.04	1.0	.0003	< .0001	< .0001	.20	.08	.03	.02

[a] Data represent women who reported having baseline goals in each category that were subsequently achieved after treatment; [b] *P* value compares surgery, pessary continued, and pessary crossover/discontinued groups.

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significant improvements in any of the Patient-Reported Outcomes Measurement Information System functioning questionnaires ($P > .05$ for all within-group comparisons).

For women who discontinued pessary use, reasons for dissatisfaction included the following: 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 pelvic organ prolapse achieved individual goals and experienced improvements in physical, social, and emotional functioning, although surgery is associated with greater improvements compared with pessary. Women who chose to continue with pessary have more comparable improvements in functioning and goal attainment with the surgery group. Women who discontinued the pessary or crossed over to surgery had the lowest goal attainment and had no improvements in the functioning scores.

Goals of pelvic organ prolapse treatment can be highly individual and variable. In our study, 30% of women ranked resolution of urinary symptoms as their top goal for pelvic organ prolapse 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[17] of 226 women presenting for pelvic floor disorder care, resolution of urinary symptoms was the most commonly stated goal, regardless of prolapse stage.

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 with women who continued with pessary. It is possible that pessary for pelvic organ prolapse did not satisfactorily achieve their urinary symptom goals. Komesu et al[18] reported that attainment of self-stated goals is associated with greatly increased odds of pessary continuation.

TABLE 5
Functioning outcomes by treatment group

Outcome	Baseline mean score (SD)	Posttreatment mean score (SD)	Change mean score (SD)	Within-group *P* value	Between-group *P* value
PROMIS physical function[a]					
Surgery	45.0 (7.5)	53.7 (9.3)	8.7 (8.8)	< .0001	
Pessary	48.1 (7.6)	51.6 (9.2)	3.5 (6.9)	.0003	.0004
PROMIS social roles					
Surgery	50.8 (10.6)	57.1 (9.6)	6.3 (10.5)	< .0001	
Pessary	54.2 (10.1)	57.0 (9.9)	2.8 (9.3)	.02	.049
PROMIS social discretionary					
Surgery	52.0 (9.8)	57.1 (9.8)	5.1 (8.9)	< .0001	
Pessary	54.0 (10.0)	56.4 (10.1)	2.4 (7.7)	.02	.07
PROMIS anxiety[a]					
Surgery	54.0 (10.5)	49.1 (10.1)	−5.0 (10.3)	.0001	
Pessary	49.9 (9.4)	46.7 (9.9)	−3.2 (9.1)	.008	.30
PROMIS depression[a]					
Surgery	51.1 (9.4)	47.0 (9.9)	−4.0 (9.4)	.0006	
Pessary	45.7 (8.2)	45.0 (9.2)	−0.6 (7.1)	.50	.02

PROMIS, Patient-Reported Outcomes Measurement Information System.

[a] $P < .05$ for baseline PROMIS scores between surgery vs the pessary group for physical function, anxiety, and depression domains.

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Although there can be many practical reasons that a patient may be dissatisfied with a pessary, in our study, pessary discontinuation was associated with a lack of goal attainment and a lack of improvement in functioning outcomes as well. In contrast to our findings, Shveiky et al[19] 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, whereas 23% reported improving urinary symptoms as a primary goal of prolapse treatment. 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 Patient-Reported Outcomes Measurement Information System 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 Patient-Reported Outcomes Measurement Information System functioning outcomes in pelvic floor disorders as relevant patient-reported outcome measures.

Limitations of our study include the fact that there may be selection bias between women who choose surgery vs pessary. For example, there may be different goals and functioning expectations at baseline, or because surgery confers an 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 because of the 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 with prior to the visit; however, we do not believe this would bias our study because

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 2 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. ■

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