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Comparison of outcomes between pessary use and surgery for symptomatic pelvic organ prolapse: A prospective self-controlled study

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Purpose: We compared the degree of pelvic floor symptom improvement between pessary use and prolapse surgery.

Materials and Methods: Pessary-naïve women who elected prolapse surgery were enrolled and used a pessary preoperatively (for ≥7 days and ≤30 days). Pelvic floor symptoms were assessed at baseline, after pessary use, and at 3 months postoperatively. The primary outcome was concordance in the degree of symptoms improvement between pessary use and surgery, as assessed by Patient Global Impression of Improvement (PGI-I). Secondary outcomes were related to prolapse specific symptoms on validated questionnaires (POPDI-6, PFIQ-7). The McNemar test was used for comparisons of discordant pairs for comparisons of the PGI-I ratings after pessary use and surgery.

Results: Sixty-one participants were enrolled (March 2016 through April 2019) and 58 patients used a pessary. Mean±standard deviation age was 60.7±10.7 years; 24.1% had prior hysterectomy, and 13.8% had prior prolapse surgery. While both treatments demonstrated symptomatic improvement, concordance in the degree of overall improvement on the PGI-I score was poor (n=40); responses significantly favored more improvement postoperatively (p<0.001). Pessary use and surgery were associated with significant improvements in prolapse symptoms from baseline on POPDI-6 (both p<0.001) and POPIQ-7 (pessary, p=0.002; surgery, p<0.001). The degree of improvement was larger postoperatively compared to post-pessary use on POPDI-6 (p<0.001) and PFIQ-7 (p=0.004).

Conclusions: Both pessary use and surgery significantly improved pelvic floor symptoms from baseline. However, concordance in degrees of improvement between these treatments was poor, with more favorable outcomes after surgery for prolapse symptoms.

Keywords: Pelvic floor; Urinary bladder, overactive; Urinary incontinence; Urologic surgical procedures

INTRODUCTION

Pelvic organ prolapse is a highly prevalent condition among women that impacts their quality of life. Indeed, the presence of prolapse symptoms has been associated with decreased quality of life scores related to mobility, pain, emotional reaction, social isolation, energy, and sleep [1]. In the USA, the estimated risk of a woman undergoing surgery for

prolapse by age 80 years is as high as 13% [2,3]. With age as a risk factor for prolapse and given the age distribution in the USA, the number of women seeking prolapse treatment in the future will most likely increase [2,3].

Management options for symptomatic prolapse include pelvic floor physical therapy, vaginal pessary use, and several types of surgery. Both pessary use and surgery are associated with symptomatic improvement, however, in disparate patient populations, so direct comparisons of outcomes are difficult [4-8]. In fact, a Cochrane analysis noted only one randomized trial on this topic, which compared two types of pessaries, and commented that an urgent need exists for studies that compare outcomes with pessary use and outcomes with surgery [9]. Such data would be useful for clarifying the role of pessary use in everyday clinical practice and counseling patients.

Additionally, while some symptoms, such as a vaginal bulge, are consistently linked to the severity of prolapse, the associations of other symptoms are less well defined. For patients who have equivocal prolapse symptoms or are undergoing testing for occult stress urinary incontinence, some providers use a vaginal pessary preoperatively to evaluate the potential role for surgical correction [10,11]. Conceptually, the response of symptoms with the use of a pessary may predict surgical outcomes, given the expected anatomical changes with pessary use and surgery. However, for prolapse symptoms, this practice is empirical rather than evidence-based.

Therefore, we conducted a prospective cohort study to compare the degree of improvement in pelvic floor symptoms between pessary use and surgery, with each pessary-naïve patient using a pessary before surgical intervention.

MATERIALS AND METHODS

This prospective cohort study was approved by the Institutional Review Board of the Mayo Clinic, Rochester, MN, USA (approval number: 15-006186) and was registered at NIH ClinicalTrials.gov (https://www.clinicaltrials.gov/). Women were recruited for this study if they were 18 years or older, presented for evaluation and management of symptomatic pelvic organ prolapse, and elected to undergo surgical management at Mayo Clinic. Additional eligibility criteria included the scheduling of surgery at least 7 days after the office consultation to allow for an adequate period to evaluate changes in symptoms with pessary use [12]. The duration of pessary use was determined with reference to a previous study of ambulatory trial of pessary use for at least 1 week to predict occult stress urinary incontinence [12]. Women

were excluded from the study for any of the following: previous lack of success with pessary use, the expected need for an obliterative prolapse surgery (e.g., colpocleisis), the presence of an isolated rectocele, allergies to both latex and silicone, or an active pelvic infection. The baseline degree of prolapse was evaluated according to the simplified Pelvic Organ Prolapse Quantification System (POP-Q), which is a validated modification of the original POP-Q [13,14].

The primary outcome of the study was concordance in the degree of symptoms improvement between pessary use and surgery, as assessed by Patient Global Impression of Improvement (PGI-I). This was assessed after at least 7 days (and ≤30 days) of pessary use and at 3 months after surgery [15-17]. Participants also completed validated questionnaires preoperatively, after pessary use (for 7–30 days and preoperatively), and at 3 months postoperatively. Secondary endpoints related to subjective prolapse symptoms were evaluated with the Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6) (range, 0–100) [17] and the Pelvic Organ Prolapse Impact Questionnaire (POPIQ), which is part of the Pelvic Floor Impact Questionnaire-Short Form 7 (PFIQ-7) (range, 0–100) [17]. For these indexes, a higher score indicates worse health status or poorer quality of life.

At our institution, pessary fitting is typically performed by the surgeon or by a qualified advanced practice provider, who starts with a ring pessary appropriately sized according to the physical examination findings. If the ring pessary does not provide adequate support, is expelled, obstructs voiding, or is uncomfortable, additional shapes and sizes are used. If patients have occult or overt stress urinary incontinence, a ring pessary with an anti-incontinence knob is used. At our institution, anterior and posterior colpoperineorrhaphies are performed with native tissue repair, and apical suspension is performed with uterosacral ligament plication with Mayo-McCall culdoplasty [18]. Abdominal sacrocolpopexy is performed as described by Maher et al. [19], with a similar approach adapted for robotic-assisted surgical procedures [20]. A concomitant anti-incontinence procedure was performed at the discretion of the treating physician, in consultation with the patient, when patients had preoperative stress urinary incontinence.

The study was designed with the assumption that we would observe at least 80% concordance between patient ratings after pessary use and at 3 months after surgery, and the ratings from the 7 PGI-I categories were collapsed into the following 3 categories: 1) very much better or much better; 2) a little better, no change, or a little worse; or 3) much worse or very much worse. With a sample size of 62, the half width of the 95% confidence interval (CI) for this estimate

would be 10% (e.g., 95% CI, 70.8%–90.5%). With an assumed 25% dropout rate, the plan was to recruit 83 women, but owing to slow accrual, recruitment was stopped with 61 participants.

Baseline characteristics for patients in the study are reported with descriptive statistical measures, with mean±standard deviation for continuous variables and number (percentage of sample) for categorical variables. The McNemar test was used for comparisons of discordant pairs (e.g., treatment A vs. treatment B) for comparisons of the PGI-I ratings after pessary use and at 3 months after surgery. The Wilcoxon signed rank test was used to compare validated symptom questionnaire scores at any 2 time points (e.g., baseline vs. 3 months after surgery). All p-values were 2-sided and were considered significant when p-value was less than 0.05.

RESULTS

Overall, 61 women presented for evaluation of symptomatic pelvic organ prolapse from March 2016 through April 2019 and were enrolled in the study. Of the 61 participants, 58 used the pessary and were included in the analysis. Baseline clinical and demographic features of the 58 participants are shown in Table 1. The characteristics with the largest percentages of participants were White race, postmenopausal, multiparous, and never smoker. All participants had stage 2 prolapse or greater in at least 1 compartment (i.e., anterior, apical, or posterior). The median duration of prolapse symptoms was 1 year (interquartile range [IQR], 0.4–3.0 y). The median duration of pessary use when the questionnaire was completed was 29 days (IQR, 27–35 days). After pessary use, 11 women (18.9%) preferred to continue with the pessary and did not proceed with the previously planned surgery. Of the 47 patients who proceeded with surgery, 22 underwent abdominal or robotic sacrocolpopexy and 25 underwent vaginal prolapse repair. Concomitant midurethral sling placement was performed in 7 participants.

Among the 47 participants who had surgery, 40 completed the PGI-I form after pessary use and at 3 months after surgery. The differences in the degree of overall improvement when assessed at these 2 time points were significant (p<0.001) (Table 2). Five patients reported the same rating with both treatments, 33 reported more improvement after surgery, and 2 reported more improvement with pessary use (discordant pairs: 33 with more improvement after surgery vs. 2 with more improvement with pessary use). The results were similar when the 7-level PGI-I scale was collapsed to a 3-level scale (i.e., better, no change, and worse), and the responses favored greater improvement after surgery (p<0.001). Given the sparse nature of the data in the 7×7 contingency table (Table 2) and in the 3-level comparison, any chance-corrected measure of concordance would be poor. Among the 18 participants excluded from the above comparison (7 who had surgery but did not complete the 3-month assessment, and 11 who did not proceed with surgery), 9 reported on the PGI-I that their symptoms after pessary use were very

Table 1. Clinical and demographic features of study participants

Characteristic	Value (n=58)
White race	56 (96.6)
Age at consent (y)	60.7±10.7
Postmenopausal	47 (81.0)
Tobacco use	
Never	46 (79.3)
Former (quit >6 mo ago)	6 (10.3)
Current	6 (10.3)
Parity, number of births	
1	1 (1.7)
2	23 (39.7)
3	20 (34.5)
4	9 (15.5)
5	5 (8.6)
Delivery type	
Vaginal only	55 (94.8)
Vaginal and cesarean	3 (5.2)
Prior hysterectomy	14 (24.1)
Prior prolapse surgery	8 (13.8)
Diagnosed prolapse	
Anterior prolapse stage	
0	2 (3.4)
1	2 (3.4)
2	40 (69.0)
3	13 (22.4)
Not documented	1 (1.7)
Apical or uterine prolapse stage	
0	3 (5.2)
1	12 (20.7)
2	29 (50.0)
3	13 (22.4)
4	1 (1.7)
Posterior prolapse stage	
0	4 (6.9)
1	18 (31.0)
2	30 (51.7)
3	4 (6.9)
Not documented	2 (3.4)
Duration of current prolapse symptoms (y)	1 (0.4–3.0)

Values are presented as number (%), mean±standard deviation, or median (interquartile range).

Table 2. Comparison of global symptomatic improvement according to PGI-I scores for pessary use and surgery[a,b]

PGI-I score after pessary use	PGI-I score 3 mo postoperatively							Total
	Very much better	Much better	A little better	No change	A little worse	Much worse	Very much worse	
Very much better	1	1	0	0	0	0	0	2
Much better	8	4	0	1	0	0	0	13
A little better	6	5	0	0	0	0	0	11
No change	6	6	0	0	0	0	0	12
A little worse	2	0	0	0	0	0	0	2
Much worse	0	0	0	0	0	0	0	0
Very much worse	0	0	0	0	0	0	0	0
Total	23	16	0	1	0	0	0	40

PGI-I, Patient Global Impression of Improvement.
[a]:Among the 47 patients who had surgery, 40 completed the PGI-I form after pessary use and at 3 months postoperatively.
[b]:Data cells indicate number of patients.

Table 3. Symptomatic outcomes according to validated questionnaire scores at baseline and at follow-up after pessary use or at 3 months postoperatively

Symptom measure	No. of patients with scores	Baseline score		Follow-up score		p-value[a]
		Mean±standard deviation	Median	Mean±standard deviation	Median	
PFIQ-7						
Pessary	55	68.7±64.4	47.6	38.7±50.3	19.0	<0.001
Surgery	40	72.1±69.2	54.8	18.8±49.3	2.4	<0.001
POPIQ-7						
Pessary	55	25.5±27.9	14.3	14.2±22.0	4.8	0.002
Surgery	40	28.3±29.0	16.7	4.2±16.7	0.0	<0.001
POPDI-6						
Pessary	50	45.0±23.8	46.4	21.6±17.7	21.4	<0.001
Surgery	36	48.6±24.7	50.0	7.3±14.2	0.0	<0.001

PFIQ-7, Pelvic Floor Impact Questionnaire-Short Form 7; POPIQ-7, Pelvic Organ Prolapse Impact Questionnaire-7; POPDI-6, Pelvic Organ Prolapse Distress Inventory 6.
[a]:Wilcoxon signed rank test for comparison of scores at baseline with scores at follow-up after pessary use or at 3 months postoperatively.

much better or much better.

Both pessary use and surgery were associated with significant improvement from baseline for prolapse symptoms on the POPDI-6 (both p<0.001) and the POPIQ-7 (pessary, p=0.002; surgery, p<0.001) (Table 3). Median scores on the validated instruments were less (indicating better results) at 3 months after surgery compared with after pessary use for the POPDI-6 (p<0.001) and POPIQ-7 (p<0.001) (Table 4).

DISCUSSION

In this prospective study of women undergoing prolapse management with a trial of pessary use and subsequent surgery, we found that concordance in the degree of global symptom improvement between the treatments was poor. Although symptoms of pelvic organ prolapse improved significantly from baseline with both treatments, the degree of

improvement was significantly greater after surgery.

The present study and previous reports have identified significant improvements in prolapse symptoms from baseline with prolapse surgery and pessary use. In studies indirectly comparing these treatments, conflicting data exist regarding the degree of improvement that patients may expect with each modality [4-6,21,22]. A limitation of these indirect comparisons is an inherent selection bias. Patients are treated with either pessary use or surgery, but the cohorts may differ in age, comorbidities, and history of prolapse surgery. The present study augments the existing literature because it is novel in its assessment of pelvic floor outcomes prospectively with validated instruments among women who underwent both treatments.

Our findings are similar to those reported by a prospective observational study that evaluated functional outcomes and patient-reported goal attainment among women who

Table 4. Symptomatic outcomes according to validated questionnaire scores at follow-up after pessary use and at 3 months postoperatively

Symptom measure	No. of patients[a]	Score after pessary use		Score at 3 mo postoperatively		p-value[b]
		Mean±standard deviation	Median	Mean±standard deviation	Median	
PFIQ-7	39	40.0±51.6	19.0	18.7±50.0	0.0	0.004
POPIQ-7	39	14.0±20.1	4.8	4.3±16.9	0.0	<0.001
POPDI-6	40	23.1±17.3	21.4	7.1±13.5	0.0	<0.001

PFIQ-7, Pelvic Floor Impact Questionnaire-Short Form 7; POPIQ-7, Pelvic Organ Prolapse Impact Questionnaire-7; POPDI-6, Pelvic Organ Prolapse Distress Inventory 6.
[a]:Number of patients with scores at both time points after pessary use and at 3 months postoperatively.
[b]:Wilcoxon signed rank test for comparison of scores after pessary use and at 3 months postoperatively.

chose either long-term pessary use or surgery [5]. Notably, the study groups were somewhat disparate because the women who elected pessary use were older, had higher POP-Q stages, lower Pelvic Floor Distress Inventory-20 and body image scores. Those authors found that while both treatments significantly improved functional end points and allowed for goal attainment, the improvement was greater among those opting for surgery [5]. For instance, a larger proportion of women were "much better" or "very much better" according to their PGI-I scores after surgery compared with women who used a pessary (97% vs. 70%; p<0.001) [5]. The surgery group also had significantly greater improvements in the physical function, social roles, and depression domains compared with the pessary group [5]. Our study is unique in that each participant underwent both pessary use and surgery, allowing for direct comparisons between the treatments.

Disparate findings were identified in 2 prospective observational studies that evaluated pessary use and surgery [4,21]. In those studies, prolapse and urinary symptoms improved significantly in women treated with either a pessary or surgery, but the degree of improvement was not significantly different between the 2 treatments [4,21]. Both studies reported outcomes at 1 year after treatment, and follow-up was available for 55% to 69% of the cohorts, but the comparisons may have been affected by the exclusion of patients who discontinued pessary use [4,21]. When using this methodology, comparing those who continued pessary use and those who had surgery, Sung et al. [5] found similar results with comparable goal attainment, but patients undergoing surgery still had significantly greater improvement in physical function and depression scores. Given our study design, similar adjustments in our analyses are not possible. Our findings may differ from these studies because of differences in study methodology, patient populations, outcome measures (1 study used the Sheffield Pelvic Organ Prolapse questionnaire; the other, the ICIQ Vaginal Symptoms questionnaire), and statistical methodology.

One application of the findings from our study is the use of a pessary as a prognostic tool (i.e., a "pessary trial"). Our data support the use of a pessary if it helps the patient with decision making. For instance, those that had global symptomatic improvement with the pessary typically had at least the same degree of improvement with surgery. However, all 12 patients who reported no change in symptoms with pessary use reported improvement (i.e., "very much better" or "much better") after surgery. Thus, failure to improve with pessary use does not necessarily preclude improvement with surgical intervention, and clinical judgment along with individualized decision making is needed.

Strengths of our study include its prospective nature, the use of validated instruments, and the requirement that each participant undergo both treatments. This novel study design adds to the literature by allowing for direct comparisons between pessary use and surgery. Limitations of the study should also be noted. One significant limitation is that given slow accrual the study was closed before enrollment was completed according to the original sample size calculations. This limits our ability to detect significant differences between groups. Additionally, selection bias may be present, because the study enrolled women who opted for surgical intervention. However, it has previously been reported that randomization between pessary and surgery is not technically feasible because many patients have a strong treatment preference [22]. Furthermore, the study assessed short-term outcomes, after at least 1 week of pessary use and at 3 months postoperatively. Thus symptom improvement with longer pessary use or beyond 3 months after surgery may have impacted outcomes. Likewise, additional potential dissatisfiers that would impact ongoing pessary use (e.g., discharge, vaginal ulceration, ongoing follow-up maintenance, expulsion) may not have been experienced with short-term pessary use. Requiring a longer duration of pessary use would have added further challenges to study recruitment as patients entering the study were pursuing surgical intervention and may not have wanted to delay this further.

CONCLUSIONS

Both pessary use and surgery significantly improved patients' overall condition and pelvic organ prolapse symptoms from baseline. However, concordance in the degrees of overall improvement between these treatments was poor, with more favorable outcomes postoperatively for prolapse symptoms.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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AUTHORS' CONTRIBUTIONS

Research conception and design: all authors. Data acquisition: Amy L. Weaver. Statistical analysis: Amy L. Weaver. Data analysis and interpretation: Amy L. Weaver. Drafting of the manuscript: Brian J. Linder. Critical revision of the manuscript: all authors. Obtaining funding: Brian J. Linder and John A. Occhino. Administrative, technical, or material support: Brian J. Linder, John B. Gebhart, Felecia R. Fick, Randina R. Harvey-Springer, Emanuel C. Trabuco, Christopher J. Klingele, and John A. Occhino. Supervision: Brian J. Linder, John B. Gebhart, Christopher J. Klingele, and John A. Occhino. Approval of the final manuscript: all authors.

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