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Goal attainment after treatment in patients with symptomatic pelvic organ prolapse

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Abstract

OBJECTIVE—The objectives of this study were to: (1) assess differences in goal attainment of self-described goals after treatment of symptomatic pelvic organ prolapse (POP) for women who chose surgery compared to women who chose pessary; and (2) compare patient global improvement between groups.

STUDY DESIGN—Women who had symptomatic stage II prolapse presenting for care of POP to the urogynecology clinic at the University of New Mexico were recruited. Patients listed up to 3 goals they had for their treatment. In addition, they completed the short forms of the Pelvic Floor Distress Inventory (PFDI-20), the POP/Urinary Incontinence Sexual Questionnaire, and the Body Image Scale. Goals listed by patients were then categorized into 10 categories. Each of the listed goals was categorized based on a consensus of 5 providers. At 3 months' follow-up patients listed if they had met their self-described goals on a scale of 0–10 and also answered the Patient Global Improvement Index (PGI-I).

RESULTS—There were no significant differences between the 2 groups' baseline characteristics. Surgery patients ranked their goal attainment higher than pessary patients for all the 3 goals listed. Similarly, PGI-I scores were also higher in the surgical (2.4 ± 1.1) than the pessary (1.93 ± 0.8) treatment groups ($P < .04$). Patients in the surgery group also had better symptom improvement as measured by the PFDI-20 ($P < .02$).

CONCLUSION—Patients who chose surgery had better global improvement and met their goals better compared to patients who chose pessary.

Keywords

pessary; surgery; goal; attainment

Goal attainment scaling¹ is a technique for measuring goal achievement after therapy that is commonly used to assess patient-centered goals and outcomes. Identification of self-selected

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This study assesses goal attainment in patients that choose pessary versus surgery for the treatment of symptomatic pelvic organ prolapse

goals may help to tailor individual patients' needs to specific therapeutic interventions. This is particularly important in fields where functional outcomes are the primary objective. Understanding patient goal attainment may be especially important for diseases such as pelvic organ prolapse (POP) when treatment is typically recommended to improve quality of life rather than treat or prevent a life-threatening disease.

Among women with pelvic floor dysfunction, others have shown that patient goals and expectations vary and are linked to treatment satisfaction.²⁻⁴ Conversely, unmet goals are closely associated with patient dissatisfaction after treatment.²⁻⁴ These prior studies included only a small proportion of women seeking treatment for POP and did not compare goal attainment between those who chose pessary vs surgery treatment. For these reasons, goal attainment scaling may prove a valid outcome measure to directly compare outcomes between surgery and pessary use for treatment of symptomatic POP. In addition, goal setting may help women and their providers to better choose treatment plans when women are eligible for both surgery or pessary treatment of symptomatic prolapse.

The objectives of this study were to prospectively compare the attainment of self-selected goals in women who choose a pessary vs those who choose surgery for treatment of symptomatic stage II POP. We also aimed to assess if women who choose pessary for treatment of symptomatic stage II POP report the same global improvement in their condition as women who choose surgery for treatment of their POP.

MATERIALS AND METHODS

This study is a follow-up of our initial study comparing baseline goal differences between patients who choose surgery vs pessary for treatment of symptomatic stage II POP. Women presenting for care of symptomatic POP to the urogynecology clinic at the University of New Mexico were recruited for participation.

Women with symptomatic stage II prolapse as measured on POP quantification examination,⁵ and who were deemed eligible for either surgical or pessary treatment by the attending physician were eligible for participation. All subjects were age >18 years, able to read and write in English, and gave written informed consent. The study was approved by the institutional review board of the University of New Mexico Health Sciences Center (HHRC#10-370).

In addition to standardized pelvic examinations, patient characteristics and medical and surgical history data were collected. After clinical assessment, but prior to discussion of therapeutic interventions, women were asked to list up to 3 treatment goals. They ranked these goals from 1–3, with 1 being the most important goal. In addition patients completed the short form of the validated Pelvic Floor Distress Inventory (PFDI-20),⁶ short form of the POP/Urinary Incontinence Sexual Questionnaire (PISQ-12),⁷ and the Body Image Scale (BIS).⁸ At 3-month follow-up, women were asked if they met the goals listed at the initial visit and were asked to score how well they met their goals on a scale of 0–10; 0 represented not meeting the goal at all and 10 represented meeting the goal completely. Goals listed by the patients were categorized through an iterative process by a consensus of 5 providers

expert in the treatment of pelvic floor dysfunction. The 5 providers individually categorized each listed goal and met to compare categorizations. When assigned categories for goals varied between experts, discussion was conducted until consensus was reached. Three months after treatment, women completed the validated Patient Global Improvement Index (PGI-I),⁹ as well as repeated the PFDI-20, PISQ-12, and BIS.

Although a power analysis conducted for the parent study determined the need to recruit 50 patients for each of the surgery and pessary arms, we based our power analysis for this study to ensure our aims were met appropriately, on a report by Srikrishna et al,⁹ who found a mean goal achievement score of 9.0 ± 1.55 (SD) on a scale of 0–10 after treatment for prolapse in the validation study of the PGI-I. Assuming 80% power and alpha of .05, a sample size of 29 women per arm was adequate to detect a 1.2-point difference between the 2 study arms on a 10-point Visual Analog Goal Attainment Scale. For the parent study, we had determined that we would need 100 women (50 in each group) to have adequate power to compare initial goal rankings. Assuming that 10 women per arm would not follow up and that 10 women per arm would not adhere to their original treatment plan, we anticipated that we would have approximately 30 women in each arm to evaluate for this aim. Based on this, of the initial 100 women recruited for the parent study, we determined that a subset of 60 women would be required to have the 3-month follow-up for the current study. Descriptive statistics were reported as mean $\pm$ SD or percentage as appropriate. Comparisons between the 2 treatment groups were done by *t* tests and verified by Wilcoxon rank sum test. Categorical outcomes were compared by Fisher exact test. $P < .05$ was considered statistically significant.

RESULTS

We recruited 100 women, 50 who chose surgery and 50 who chose pessary for the initial study. In the initial study, there were no differences in goal setting between patients who chose surgery compared to those who chose pessary. In all, 65 women received treatment and gave follow-up data; 30 in the pessary group and 35 in the surgery group (the Figure outlines patient flow through the study). Pessary and surgery groups did not differ in age, ethnicity, body mass index, and history of treatment for POP at baseline (Table 1). The list of surgeries includes 15 laparoscopic sacral colpopexies, 15 vaginal hysterectomies with uterosacral ligament suspensions and 5 colpocleisis procedures.

As determined qualitatively by expert review, goals were assigned into 10 categories including symptom goals (4 categories: prolapse, urinary, bowel, pain); quality-of-life goals (3 categories: physical activity, emotional, sex); avoidance goals (1 category); body image goals (1 category); and other (1 category). Examples of goals and their categorizations are shown in Table 2. The majority of patients in both groups sought to have prolapse symptoms addressed as their first goal (60 vs 49%, surgery vs pessary $P =$ not significant). Initial ranking varied between groups for the second and third goals. Treatment of urinary symptoms was the second most common goal in the surgery group (37% of the surgery group listed this second) and quality of life-activity was the second commonest goal in the pessary group (17% pessary). Avoidance was the third most common goal in both groups (20 vs 23%, surgery vs pessary, $P =$ not significant).

At 3 months following treatment, both groups improved significantly from baseline in PFDI-20, BIS, and PISQ-12 scores after their respective treatments (Table 3). Between-group improvements were not different except for PFDI-20 total scores; the surgery group showed greater improvement from baseline (Table 3). Average goal attainment for both groups for each goal category is shown in Table 4. Surgery patients ranked their goal attainment higher than pessary patients for all goals listed. Similarly, PGI-I scores were also higher in the surgical than the pessary treatment groups (Table 5). Since the only difference was sexual activity and only a subset of women were sexually active, despite controlling for the significantly different baseline PISQ-12 scores in sexually active women, there remained significant differences in both goal attainment and PGI-I scores between the surgery and pessary groups. Not all women in each of the surgery and pessary groups were sexually active and PISQ-12 results only relate to patients who are sexually active. Therefore this may have contributed to the statistically significant differences between the 2 groups as far as goal attainment and PGI-I. To remove this confounder, an analysis was performed to control for this and there remained statistically significant differences between the 2 groups.

COMMENT

We compared goal attainment and global impression of improvement between women who chose surgery vs those who chose pessary for treatment of symptomatic prolapse. We found that women who underwent surgery for symptomatic prolapse reported higher goal attainment and greater global impression of improvement than women who chose pessary. Importantly we found that initial goal setting did not vary between groups, and although both groups reported significant improvement in prolapse symptoms, they continued to have differences in attainment of self-selected goals. We investigated potential differences in treatment goals chosen by surgical and pessary patients. We found that both surgery and pessary patients with pelvic floor dysfunction stated that their most important treatment goal was to address prolapse symptoms. Similar to our findings, another study¹⁰ that examined the qualitative aspect of patient goals and expectations found that nearly half of all women with pelvic floor dysfunction had concerns relating to symptoms caused by or exacerbated by their prolapse. A different study that evaluated goals and severity of prolapse¹¹ noted that relief of urinary symptoms was the most commonly stated goal regardless of prolapse stage. Lifestyle, daily activity, and sexual function goals were the second, third, and fourth most common goals in all stages, respectively, in this study. In our study, the second most commonly stated goals varied between women in the pessary and surgical groups; the former ranked the activity-related quality-of-life goal second, whereas the latter ranked urinary symptoms as their second goal.

Previous direct comparisons of surgical and pessary management of POP are sparse. A number of investigators have evaluated goal setting and goal attainment in women treated surgically for a variety of pelvic floor dysfunctions. One study that assessed goals of patients undergoing pelvic reconstructive surgery showed that 75% met all or most of their goals, 4% met half, 12% met less than half, and 9% met none of their goals. Srikrishna et al^{9, 12} validated the PGI-I questionnaire for POP and subsequently studied patient goal achievement 2 years following surgery for prolapse and/or urinary incontinence. The mean patient goal achievement at 2 years was 85.1%. Investigators have also evaluated goal

attainment and goal setting in women conservatively treated with pessaries for pelvic floor dysfunction. Komesu et al⁴ showed that at final follow-up, 53% of patients continued pessary use and 47% quit pessary use. Pessary continuation was closely associated with goal attainment. If women met at least 1 or 2 of their goals, the odds were approximately 17 times greater that they would continue pessary use. With the 40% drop-out in the pessary group vs 30% drop-out in the surgery group in our study, the pessary ratings may be slightly inflated because the extra 10% including these patients who do not follow-up at 3 months may reflect an even lower goal attainment and PGI-I score overall for the pessary group compared to the surgery group.

Other than our current study, there has been only one other investigation that compared goal attainment in women treated for pelvic floor dysfunction with pessary compared to surgery. In that cohort study, surgically treated patients had higher 1-year goal attainment and satisfaction scores compared to patients treated with a pessary for treatment of a variety of pelvic floor dysfunctions, including POP.¹³ And although there was a nonsignificant difference in overall goal attainment between pessary and surgery groups for POP, surgically managed patients overall had higher rates of satisfaction at 1 year compared with nonsurgically managed patients ($P = .0109$).¹⁰ The surgical cohort was followed long-term and patients showed 68% goal attainment at 1.8 years.³ In our current study, although both pessary and surgery groups demonstrated significant improvements in symptom distress, sexual function, and body image, we too found that among women treated for symptomatic prolapse, surgery patients reported higher goal attainment compared to the pessary group. Their symptom resolution was also better from baseline based on the response to PFDI-20 questionnaire after treatment. It is possible that patients do not only seek symptom improvement when they seek treatment for their prolapse. The various range of goals that patients stated in the parent paper attests to this. The wide ranging list of patient goals is not fully assessed in currently used validated questionnaires. Therefore the correlation between the validated questionnaires and goal attainment may be low. Prior to our current report, no studies have compared patient impression of improvement or goal attainment between women who choose conservative management with pessary vs those who choose surgical management for symptomatic POP.

Strengths of our current study include its prospective design. In addition, we used a panel of experts to categorize goals with discussion until consensus was reached regarding goal classification. Weaknesses include the inherent biases present when patients chose their interventions and are not randomized. Therefore the follow-up goal attainment is a reflection of the initial goals set forth independently by the patients. To minimize these biases we did find that our groups were comparable in baseline characteristics as well as questionnaire responses as measured by the PFDI-20, PISQ-12, and BIS. Although goal categorization was performed by 5 providers, there was no patient input into the categorization and this categorization is subject to provider bias. Non-standardized counseling and consultation was provided for treatment choices by different providers and may have influenced subsequent goals, choices, and goal attainment. However, non-standardized counseling is more generalizable and reflects real-life clinical counseling. We did not assess goals prior to consultation. Others have shown that patients changed their goals after an initial urogynecologic visit; patients were less likely to report symptom and information-seeking

goals initially and more likely to report treatment goals after consultation.¹⁴ Nonetheless, our cohort of women chose treatment of prolapse symptoms as their primary goal, and information seeking was not identified as a goal category in this cohort. The study also has a relatively short-term follow-up of 3 months. Goal attainment and PGI-I need to be followed longer term for better assessment and counseling.

In conclusion, patients who choose surgery have better global improvement and meet their goals better compared to patients who choose pessary. Patients who had surgery had higher goal attainment scores on the visual analog scale compared to the patients who had pessary and this was also statistically significant. Whether this is clinically meaningful is to be determined with further studies that correlate subjective and objective outcomes with goal attainment to determine the minimal clinically important differences on visual analog scores. In addition to symptoms, physical findings and quality-of-life assessment, self-expressed urogynecologic goal attainment may be integrated as the fourth dimension.¹⁵ Composite end points¹⁶ that include POP quantification, subjective measurements such as PGI-I, and minimally important clinical differences on questionnaires may not be enough to capture assessment of goals. Goal attainment is an important part of success and defining goal attainment for various modalities of treatment, ie, pessary vs surgery, for symptomatic POP may be an important tool to determine success.

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This study was conducted at the University of New Mexico, Albuquerque

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Figure 1.
Flow chart of patients included in the study

Table 1

Demographics

	Pessary N=50	Surgery N=50	p-value
Age (mean $\pm$ SD)	62.3 $\pm$ 10	61.2 $\pm$ 8.7	NS
Caucasian Race (%)	57%	59%	NS
Hispanic	46%	48%	NS
Parity (SD)	3 (1)	3 (1)	NS
Body mass index (SD)	34.5 (5.8)	33.1 (5.2)	NS
Prior treatment (%)	36	42	NS
Sexually active	10	14	NS

Table 2

Examples of goals listed by patients in different categories

Goal category	Examples
Symptoms - prolapse	"Want the bulge to go away" "Don't want to sit on a lump"
Symptoms - urinary	"Have no leakage" "Not have to wear wet pads"
Symptoms - bowel	"Have normal bowel movements" "Have no leakage of feces"
Symptoms - pain	"Get rid of the pain and pressure in vaginal area"
QOL activity	"Be able to play with grandchildren" "To exercise normally"
QOL emotional	"Not have to worry about this problem"
QOL sex	"Have lot of sex"
Avoidance	"Make sure problem does not get worse" "Avoid surgery" "Not have to do something later when older"
Body image	"Be more confident about my body"
Other	"Live a happy life"

Questionnaire changes from baseline and between group changes in patients that chose pessary vs. surgery

Table 3

	Surgery group (N=35) (Mean change (SD))	Change from baseline P value	Pessary group (N=30) (Mean change (SD))	Change from baseline P value	Differences between groups P value
PFDI-20	-89.0(68.6)	<0.0001	-43.2 (79.8)	0.005	0.02
• POPDI-6	-38.8 (25.4)	<0.0001	-12.5 (34.8)	0.055	0.09
• CRADI-8	-24.9 (25.1)	<0.0012	-10.5 (24.5)	0.023	0.40
• UDI-6	-34.4 (27.3)	<0.0001	-31.3 (30.3)	0.0009	0.055
BIS	-6.2 (7.0)	<0.0001	-6.4 (7.6)	0.0001	0.91
PISQ-12	7.5 (3.1)	<0.0001	9.1 (3.1)	<0.0001	0.22

Table 4

Goal attainment in patients that chose pessary Vs. surgery

Met goal	Pessary N=30 (Mean score (SD))	Surgery N=35 (Mean score (SD))	P value
Goal 1	6.4 (3.0)	8.6 (1.6)	0.0005
Goal 2	6.3 (2.6)	8.6 (1.8)	0.0010
Goal 3	6.3 (3.3)	8.2 (2.2)	0.03

Table 5

Patient Global Improvement Index in patients that chose pessary Vs. surgery

	Surgery group N=35 (Mean score (SD))	Pessary group N=30 (Mean score (SD))	P value
PGI-I	1.93 (0.8)	2.4 (1.1)	0.04