Published in final edited form as:

Am J Obstet Gynecol. 2008 May ; 198(5): 577.e1–577.e5. doi:10.1016/j.ajog.2007.12.033.

Patient Selected Goal Attainment for Pessary Wearers: What is the Clinical Relevance?

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Abstract

Objective—To evaluate whether patient determined goal achievement is associated with pessary continuation.

Study Design—Patients identified goals they wished to achieve from pessary use. Patients were asked whether they continued pessary use and if goals were met 6–12 months later. Goals were divided into eight categories. Fisher's exact test was used to evaluate categorical variables, t-tests for continuous variables, and regression methods to calculate odds ratios (OR).

Results—Eighty women enrolled in the study. Sixty-four had follow-up data. Goals commonly listed were bladder (36%), activity (20%), general health (13%), and prolapse related (11%). Thirty-four women continued and 30 discontinued pessary use. Women who continued pessary use were more likely to meet one or two goals (OR 17.5, 21.1 and 95% CI 4.8–64.4, 5.7–78.9, respectively)

Conclusion—Patient goals are variable and subjective. However, when assessed for achievement, they're associated with pessary continuation. Women who attain self-determined goals are likely to continue pessary use.

Keywords

Pessary; outcome; goals; quality of life

Introduction

The medical community increasingly relies on evidence based medicine to evaluate both new and previously accepted therapies. Meaningful use of evidence based medicine requires the selection of appropriate treatment outcomes. Pelvic floor disorders, including prolapse and incontinence, are not life-threatening but do affect patients' quality of life. Evaluation of treatment outcomes of pelvic floor disorders has shifted from relying solely upon anatomical and functional outcomes as defined by third-party payers, administrators and physicians to patient-centered outcomes.⁽¹⁾ Accurate measurement of subjective outcomes is best accomplished with the use of validated questionnaires.

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This research was presented at the 28th Annual American Urogynecologic Society Scientific Meeting, Hollywood, Florida, Sept. 27th–29th, 2007

Reprints unavailable

Individual patient goal setting and attainment scaling offers a new method of measuring therapeutic success. The role of this method as a way to evaluate treatment outcomes is still evolving. GAS has been extensively used in mental health and rehabilitation services. GAS has been found to be a sound outcome measure in these disciplines, supporting the assertion that goals are best defined according to patients' unique problems which may be ignored by standardized instruments.^(2,3) It also offers an individualized method of measuring therapeutic success in pelvic floor support disorders. Studies with both short and longer term follow-up have investigated the use of Goal Attainment Scaling (GAS) to evaluate the success of pelvic floor support surgery from the patients' perspective.^(4,5,6,7) Based on this prior work, GAS is well suited to evaluate pessary therapy outcomes.

The objective of this study was to evaluate the achievement of patient determined goals with pessary use, establish whether goal achievement was associated with continued pessary use, and to understand what patients hoped to achieve with pessary use.

Materials & Methods

Women referred to a dedicated pessary clinic were recruited September 2004 through January 2006 to participate in a study evaluating pelvic floor symptoms and goal attainment in pessary users. We have reported the pelvic floor symptoms findings previously, and have described details of the pessary fitting, types of pessaries used, pessary maintenance and reasons for pessary discontinuation in the prior publication.⁽⁸⁾ The focus of this report is to evaluate goal attainment among pessary users.

Certified Nurse Midwives experienced in pessary use are in charge of the University of New Mexico (UNM) pessary clinic. Patients are referred to this clinic after they are evaluated in the UNM Urogynecology Clinic. Women were enrolled in this Institutional Review Board approved study at their initial pessary visit. All women gave written consent prior to participation. They identified goals they wished to achieve from pessary use at this visit. Subjects recorded one to five goals they wished to achieve from pessary use on a self-administered questionnaire form which read, "Please list up to five goals you hope to achieve by using a pessary." Goals were not changed or modified by investigators. Patient characteristics recorded included age, parity, ethnicity, menopausal status, surgical history and stage of pelvic organ prolapse as measured by the Pelvic Organ Prolapse Quantitation examination.⁽⁹⁾

At two, six and twelve months after initiation of pessary use women were contacted via phone by research nurses uninvolved in their clinical care. If patients could not be reached after three attempts by research nurses, the questionnaire forms were mailed to them. Subjects were asked at follow-up whether or not they were still using their pessaries. They were queried whether or not each of their goals were met using a five point Likert scale (ranging from "strongly disagree" to "strongly agree"). Subjects who answered "strongly agree" or "agree" to the statement, "My expectation has been met", were classified as meeting goals while subjects who answered "not sure/disagree/strongly disagree" were classified as not meeting goals. Patients also rated symptom relief using a seven point Patient Global Impression of Improvement (PGI-I) Scale. They were asked, "Compared to the time before I used the pessary I feel I am..." with answers ranging from "very much better" to "very much worse".

Goal attainment and PGI-I results in women who continued pessary use at six to twelve months were compared to the results of women who quit pessary use. The last answer given by patients to the question, "Are you still using your pessary?" determined whether they were in the continue or quit groups.

Patients were defined as continuing pessary use if they answered “yes” to the question, “Are you still using your pessary,” at their six and/or twelve month follow-up. Patients who answered “yes” to this question at two months but were missing six and twelve month follow-up were considered lost to follow-up. We did not assume pessary continuation in subjects missing information after two month follow-up.

Patients were defined as quitting pessary use if they answered “no” to the question at two, six or twelve month follow-up. We assumed patients who quit pessary use were unlikely to resume use without returning to pessary clinic for refitting. The pessary clinic providers continue to care for pessary users at UNM after their initial fittings.

In the pessary continuation group, six or twelve month goal attainment and PGI-I results were used for final follow-up. Twelve month data were used if available. If unavailable, six month data were used. In the quit group the information given at time of pessary discontinuation was used if later goal attainment and PGI-I data were unavailable. If patients quit pessary use at two months but six or twelve month data were available, the later information was used. If patients quit pessary use at two months, but later information was unavailable, then the two month data was used based on the last observation carried forward method.

Patients were considered lost to follow-up if they answered the initial questionnaire but did not answer subsequent questionnaires, or if they continued pessary use at two months but were lost thereafter

Goals were divided into eight categories; bladder, bowel, prolapse, activity-related, general health, sexual, self-image (including physical appearance and social relationships) and pain related. Two investigators categorized patients’ goals. When there was disagreement in categorization, the two investigators reached consensus. For analysis of goal attainment based on categories, if patients duplicated a category when listing goals, the category was only counted once.

Power analysis was performed prior to study initiation. We assumed goal attainment was defined by “agree/strongly agree” (4 and 5 points) on a 5 point Likert Scale and assumed 80% power, alpha equal to 0.05, and a 20% lost to follow-up rate. Based on these assumptions, sixty patients were required to find a 40% difference in the quit and continuation groups’ rates of goal attainment. Eighty subjects were required for the pelvic floor symptom questionnaire portion of the study, which has been previously reported.⁽⁶⁾ We chose to enroll 80 patients to fulfill requirements for the previously published symptom questionnaire portion of the study as it required the larger number of subjects.

For statistical analysis Fisher’s exact test was used to evaluate categorical variables, t-tests were used to evaluate continuous variables, McNemar’s test of symmetry to compare changes in goal attainment and Odds Ratios (OR) were calculated for 95% Confidence Intervals (CI) using regression methods.

Results

Eighty women were enrolled in this study and sixteen women (20%) were lost to follow-up, leaving 64 women (80%) who are the focus of the study. After our previous pelvic symptom questionnaire results were reported,⁽⁸⁾ we have had additional follow-up information. Two women who continued pessary use at six months in our previous report discontinued use by twelve month follow-up. Thus, at final follow-up in this study there are 30 women who have quit and 34 women who have continued pessary use.

Of the 30 women in the quit group, fifteen women (15/30=50%) discontinued pessary use by two month follow-up, nine women (9/30=30%) by six month follow-up, and six women (6/30=20%) by twelve month follow-up.

In the 34 women in the continue group, six month data were used for eight subjects (23%) and twelve month data for twenty-six subjects (76%). Of the 30 women in the quit group, 2 month data were used for ten subjects (33%), 6 month data for ten subjects (33%) and 12 month data for ten subjects (33%).

We tested the validity of combining six and twelve month results. Goal attainment was compared in all women who had both six and twelve month data available. McNemar's Test of Symmetry showed no significant difference in goal attainment results between the 6 and 12 month results ($P>0.05$).

Patient characteristics in the pessary continue and quit groups did not differ in age, body mass index (BMI), parity, ethnicity, menopausal status, POP-Q findings or history of hormone use and sexual activity (Table I). There was also no difference between groups' surgical histories. Only three percent of women in both quit and continue groups had a history of prior incontinence (1/30 and 1/34, $P=1.0$) and prolapse (1/30 and 1/34, $P=1.0$) operations. Approximately one-fourth of women in both quit and continue groups had prior hysterectomies (8/30=27% and 8/34=24% respectively, $P=1.0$). Similarly, no differences were noted in patient characteristics between women with follow-up and women lost to follow-up (all $P>0.05$).

The sixty-four women in this study listed one to five goals they wished to achieve with pessary use. The majority of women listed two goals; 12 women listed one goal, 28 listed two goals, 16 listed only three goals, 7 listed four goals and 1 listed five goals. A total of 149 goals were listed by the 64 women. At final follow-up 39 of the sixty-four women (60%) had met at least one goal and 30 of the sixty-four women (46%) had met at least two goals. There were differences in goal attainment at final follow-up between pessary continue and quit groups. The majority of women who continued pessary use (30/34=88%) met at least one of their goals. The minority of women who quit pessary use (9/30=30%) met at least one of their goals. The odds of continuing pessary use if at least one goal was met was 17.5 times higher than if one goal was not met ($OR=17.5$, $CI=4.8-64.4$). Similarly, there was a difference in goal attainment between the number of women in continue and quit groups who met two of their goals (26/34=77% and 4/30=13% respectively, $OR=21.1$, $CI=5.7-78.9$).

The continue and quit groups also differed in Patient Global Impression of Improvement scores at final follow-up. For each point improvement in the PGI-I scale, the odds of pessary continuation increased more than four-fold ($OR=4.6$, $CI= 2.3-9.1$).

The goals listed by women were divided into eight categories, a modification of the categories used by Hullfish.⁽⁶⁾ (Table 2). Specifically, we separated symptoms related to bladder (urinary), bowel, prolapse and sexual function symptoms into individual categories since there are female pelvic floor disorder symptom questionnaires which address these categories.^(10,11) We consolidated social relationships, self-image and physical appearance into a single category and added a separate category for pain. The most commonly listed goal category was bladder (54/149=36% of goals listed), followed by activity related goals (29/149=19%), general health (19/149=13%), prolapse (17/149=11%), self-image (14/149=9%), sexual goals (9/149=6%), pain issues (4/149=3%) and bowel (3/149=2%) categories. There were no differences between continue and quit groups in the frequency with which they listed the eight categories (all $P>0.05$).

The continue and quit groups were compared to determine if there were differences between goal attainment within categories. The pessary continuation group was more likely to attain goals compared to the quit group in the bladder (20/27=74% versus 5/27=19%, $P<0.001$), activity (11/14=79% versus 4/15=27%, $P<0.01$), general health (9/11=82% versus 1/8=13%, $P<0.01$) and sexual (4/5=80% versus 0/4=0%, $P<0.05$) categories. This difference did not reach statistical significance between continue and quit groups in the bowel (0/1=0% versus 0/2=0%), prolapse (8/10=80% versus 3/7=43%), self-image (6/8=75% versus 2/6=33%), and pain (3/3=100% versus 0/1=0%) categories (all $P>0.05$).

Comment

The major objective of this study was to find if attainment of patient determined goals was associated with continued pessary use. A secondary objective was to understand what patients expected from pessary use and to determine how often these expectations were met.

Goal attainment scaling (GAS) has been used in other disciplines to evaluate success. GAS has more recently been used to evaluate surgical effectiveness from the patients' perspective. Four articles have addressed GAS in pelvic floor surgery.^(4,5,6,7) They found that patient satisfaction was associated with goal attainment at three month^(4,6) and longer term follow-up.^(5,7) Although patient satisfaction was associated with goal attainment and subjective improvement using validated symptom questionnaires,⁽⁷⁾ patient satisfaction was not associated with objective evidence of cure of urinary incontinence.⁽⁴⁾ This highlights the discrepancy between objective measures and patients' subjective impression of success.

Pessary use, compared to surgical interventions, offers a unique opportunity to link behavior to subjective parameters such as goal attainment and impression of improvement. Surgery is irreversible. Patients cannot undo surgery; they can simply regret having surgery performed. In contrast, if patients are dissatisfied with pessary use, they can quit using them. In this study 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 one or two of their goals, the odds were approximately seventeen times greater that they would continue pessary use.

Pessary continuation was also compared to the PGI-I, a global index of improvement. A global index is a single item instrument used to rate severity or improvement in a condition.⁽¹²⁾ The PGI-I has been validated for use in urinary incontinence.⁽¹³⁾ It is the best measure of the perception of change or improvement for an individual.⁽¹⁴⁾ In this study, each one point improvement in the PGI-I scale was associated with a 4.6 fold increase in likelihood of pessary continuation. Thus, both goal attainment and patients' perception of global improvement were associated with continued pessary use.

We categorized patients' goals. A limitation of the study is that categorization can be arbitrary. For example, the stated goal... "Feel comfortable that I won't leak with sex" could be either a sexual or bladder/urinary goal. Acknowledging this limitation, we found the most commonly stated goal addressed bladder or urinary problems. Activity related goals were the second most commonly named, followed by general health and prolapse issues. Self-image, pain, sexual and bowel problems represented the minority of goals. There were differences in goal attainment between continue and quit groups in bladder, activity, general health and sexual categories and not in the other categories. The continue pessary group trended toward greater goal attainment in three other categories (prolapse, self-image and pain) though this did not reach statistical significance. Bowel goals were named only three times, and were not attained. In this population, numbers were inadequate to distinguish goal attainment for all categories comparing continue and quit groups. Power analysis for the study was based on overall goal attainment and not for each individual category. Goal

attainment in the quit and continue groups may have differed in other individual categories if there had been more subjects.

There were several other limitations to our study. Although we believe that our findings can be generalized to most gynecologic populations, our patients were referred to the pessary clinic following an evaluation in a subspecialty clinic. Thus, patients were counseled about pessary use before coming to the pessary clinic. This could have affected the goal expectations. Nonetheless, most patients in general gynecology clinics also receive counseling regarding benefits of pessary use and we believe their expectations would be similar to those stated by our patients. Secondly, there was a potential for selection bias. Approximately one third of women evaluated in the pessary clinic participated in this study and they may have differed from those who didn't participate. We do not have information regarding women who declined participation.

The strengths of this study include its design and novel approach to goal attainment. Clinicians from the pessary clinic were not involved in obtaining patient follow-up information. Patients may have more accurately reported goal attainment to investigators uninvolved in their care. A unique feature of this study was that we compared patients who quit pessary use to those that continued use. We found that goal attainment is an effective measure of pessaries' success. This is highlighted by comparing these two groups' GAS results. Although only half of patients attained their stated goals, goal attainment was associated with greatly increased odds of pessary continuation.

Patient goals are highly variable and subjective parameters. However, when assessed for achievement, they are associated with pessary continuation. We found that women who attain self-determined goals for pessary use and who have global improvement in symptoms are likely to continue pessary use at 6–12 month follow-up.

For purposes of this study we did not negotiate or alter patient goals. In clinical practice, discussion of goals could be used to initiate dialogue between patients and clinicians regarding likelihood of goal attainment. Conversations regarding goals and probabilities of goal attainment would clarify patient expectations.

Our findings underscore the importance of including patients' objectives in defining therapeutic success. Previous work has shown discrepancy between patients' subjective impressions of success and objective findings.⁽⁴⁾ As the medical field is increasingly outcomes driven,, patient determined outcomes are central to defining success.

Acknowledgments

This study was supported by The Dept of Health and Human Services/National Institutes of Health/Graduate Clinical Research Center University of New Mexico Grant #5M01 RR00997.

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Table I

Patient Characteristics

	Quit Use N=30	Continued Use N=34	P
Age $\pm$ SD (yrs)	50.5 $\pm$ 10.9	53.5 $\pm$ 12.1	0.30 [*]
Mean BMI $\pm$ SD (kg/cm ²)	30.3 $\pm$ 6.8	27.3 $\pm$ 5.3	0.07 [*]
Parity (mean) [rank score]	Mean=2.8 [score=34.6]	Mean=2.4 [score=30.7]	0.39 [†]
Ethnicity (%):			0.56 [‡]
Caucasian	18 (60)	24 (72)	
Hispanic	9 (30)	7 (21)	
Other	3 (10)	2 (6)	
Postmenopausal (%)	15 (50)	16 (47)	1.0 [‡]
Hormone treatment	5 (16)	3 (8)	0.46 [‡]
Sexually Active (%)	17 (57)	21 (62)	0.6 [‡]
POP-Q Stage by compartment Mean stage [rank score]			
Anterior	Mean=1.8 [score=28.7]	Mean=2.1 [score=34.7]	0.17 [†]
Apex	Mean=1.2 [score=29.6]	Mean=1.2 [score=31.4]	.64 [†]
Posterior	Mean=1.1 [score=27.5]	Mean=1.5 [score=34.2]	0.12 [†]
Overall POP-Q	Mean=1.9 [score=28.9]	Mean= 2.1 [score=34.6]	0.18 [†]

^{*} 2 sample T-test (Satterthwaite unpaired t-test)

[†] Wilcoxon Rank Sum Test

[‡] Fishers exact test

Table II

Examples of Goals

Category	Example
Bladder/Urinary	"Have control over bladder leaking"
	"Correct urinary incontinence"
	"Not to leak while running"
	"To be able to cough and sneeze without leaking"
Bowel	"Correct flatulence"
	"Increased ease with defecation"
	"To be more comfortable with BMs"
Prolapse	"Keep that thing up; bladder or whatever it is"
	"Not feeling a bulging feeling"
Activity	"Able to work comfortably"
	"To take long walks"
	"To go back to work"
	"To be able to travel by plane or car for a long distance"
General Health	"Avoid surgery if possible"
	"Feel better"
	"Restore my muscles"
	"Aid physical comfort"
Social Relationships (includes self-image and physical appearance)	"To have confidence"
	"Drastically improve self-esteem"
	"Increased confidence"
	"To stop feeling subconscious of my problem"
Pain	"Sit without pain in bladder area"
	"Help with pain in pelvic area"
	"Dramatically improve outcome in prevention of pelvic pain"
Sexual	"Feel comfortable in a sexual situation"
	"To help my intercourse feel more comfortable"
	"Improve sexual feelings"
	"Feel comfortable that I won't leak with sex"