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ELECT SURGICAL VS. PESSARY
TREATMENT FOR SYMPTOMATIC PELVIC
ORGAN PROLAPSE

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**TREATMENT GOALS FOR PATIENTS WHO ELECT SURGICAL VS.
PESSARY TREATMENT FOR SYMPTOMATIC PELVIC ORGAN
PROLAPSE**

by

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THESIS

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This work is dedicated to my mother Dr Radha M Kulkarni and my mentor Dr Rebecca G Rogers.

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Treatment Goals for Patients Who Elect Surgical vs. Pessary Treatment for
Symptomatic Pelvic Organ Prolapse

by

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Abstract

Objective: The objective of this study is to assess differences in self-described goals for treating symptomatic pelvic organ prolapse for women that choose surgery compared to women who choose pessary.

Methods: Women who had symptomatic stage 2 prolapse or greater presenting for care of pelvic organ prolapse to the Urogynecology Clinic at the University of New Mexico were recruited. These patients listed up to three goals they had of their treatment and rated the goals from 0 to 10, with 10 being the most important. In addition, patients completed the short forms of the established Pelvic Floor Distress Inventory (PFDI-20), short form of the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) and the Body Image Scale (BIS). The goals by the patients were then categorized into three categories. Each of the listed goals was categorized based on a consensus of 6 providers.

Results: There were no significant differences between the two groups' baseline characteristics. Patients' goals were categorized into three categories by a consensus of the providers. There was a significant difference in pessary and surgery patient ratings of goals only for one of the goal categories ($p < 0.05$).

Conclusion: Patient goals for treatment do not appear to differ.

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Preface

We do what we do for the patients and hope to achieve our goals as a physician not only as medically indicated but more importantly patient goals. This study underlines the importance of understanding and thereby meeting patient goals .

Introduction

Herniation of the pelvic organs to or through the vaginal opening is found in up to 41% of women on exam.¹⁻³ Younger women have lower prevalence. Data from the National Health and Nutrition Examination Survey²² showed that patients from ages 20-39 had a prevalence of 1.6%, from 40-59 years 3.8%, from 60-79 years 3% and greater than 80 years had a prevalence of 4.1%. Although the number of women who are symptomatic from their prolapse is lower,^{4,5} prolapse is associated with significant deterioration of quality of life, including bowel, bladder and vaginal complaints. Pelvic organ prolapse is not life threatening, but can be life limiting. Women with prolapse are less likely to have fulfilling sexual lives⁶ and are more likely to have urinary incontinence and bowel complaints in addition to the anatomical distortion associated with pelvic organs protruding from the vagina.⁷⁻⁸

Treatment options for pelvic organ prolapse are limited to surgery, the use of a pessary, or pelvic floor exercises. A pessary is a small plastic or silicone medical device which is inserted into the vagina or rectum and held in place by the pelvic floor musculature. Pelvic floor exercises are unlikely to correct advanced prolapse and is not generally offered as curative treatment.⁹ The only other non-surgical management of prolapse are pessaries. Pessaries can be offered as a first-line therapy for the management of pelvic organ prolapse symptoms regardless of a patient's age or prolapse severity.^{10,11} Evidence on the use of pessaries for prolapse treatment is limited; not all women can be successfully fitted with a pessary and not all women continue to use their pessary in the long

term.¹² Likewise, surgical interventions vary in invasiveness and effectiveness. Reoperation following surgery for incontinence or prolapse was 29% in one epidemiologic study.⁵ Most women with prolapse are eligible for either pessary or surgical management, yet little is known about why patients choose one therapy over the other. Individual treatment goals of patients may play a role in why women choose surgical versus pessary treatment for their prolapse. While a randomized trial comparing pessary to surgery for treatment of prolapse would be an ideal method to compare the effectiveness of the two treatments, more data are needed to investigate why women choose one treatment over another. Previous direct comparisons of surgical and pessary management of pelvic organ prolapse are sparse. In a cohort study¹³, surgically treated patients had higher one year goal attainment and satisfaction scores compared to patients treated with a pessary for treatment of a variety of pelvic floor dysfunctions. Although overall goal attainment between pessary and surgery groups was not different, surgically-managed patients had higher rates of satisfaction at one year compared with non-surgically managed patients (76% versus 37 %). Prior studies have not published baseline goal rating differences between women treated with surgery versus those treated with pessary.

Other studies which evaluated treatment goal attainment have focused either on women who choose surgery or who choose to use a pessary and do not compare women who choose pessary versus surgery to treat their prolapse. In these studies, the majority of women met their goals for treatment, regardless of whether or not they choose surgical or pessary management.^{6,7}

The primary objective of this study was to assess differences in goal setting of women who choose surgery versus pessary management for treatment of symptomatic prolapse among women eligible for both. We hypothesized that women who choose pessary for treatment for symptomatic pelvic organ prolapse have different self-selected goals for their treatment than women who choose surgery for treatment of their pelvic organ prolapse. Better insight into personal treatment goals may lead to improved patient counseling and decision making.

Methods

Study Participants

We recruited women presenting for care of pelvic organ prolapse to the Urogynecology Clinic at the University of New Mexico. Women with prolapse complaints complete the Pelvic Floor Distress Inventory¹⁴, an established measure of distress for pelvic floor problems, including pelvic organ prolapse. Women also underwent a pelvic exam to evaluate their prolapse using the Pelvic Organ Prolapse Quantification exam (POPQ)¹⁵. We recruited women who had symptomatic stage 2 prolapse or greater based on the POPQ exam, and were eligible for either surgical or pessary management (Table 1). All women gave written documentation of their informed consent, and the study was approved by the institutional review board of the University of New Mexico Health Sciences Center. We chose a conservative difference of 0.4 points on a visual analog scale in goal rating as the lowest difference that could potentially be clinically significant. Based on this difference between groups, a sample size of 50 women per group was needed to provide 80% power at alpha =0.05 to detect

Table 1 Study Inclusion Criteria

1. Symptomatic Stage 2 prolapse or greater and desire treatment
2. Attending surgeon assessment that patient able to undergo either surgical or conservative management
3. Over the age of 18
4. Able to read and write English
5. Not pregnant

large effect size differences between groups. All data were analyzed in STATA 11.0.

Study Measures

In addition, patients completed the short form of the Pelvic Floor Distress Inventory (PFDI-20)¹⁴ (condition-specific, quality of life instrument developed for women with all forms of pelvic floor disorders) the short form of the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12)¹⁶ (the sexual function questionnaire) and the Body Image Scale (BIS).¹⁷ (body image assessment questionnaire). All the questionnaires except the last one are completed by all clinic patients.

Patients listed up to three treatment goals and rated the importance of each of these goals on a scale of 0 to 10. Counseling surgeons listed three treatment goals that they thought the patients had for their treatment and rated the importance of each goal on a scale of 0 to 10, without discussing or viewing the goals written by the patient.

Patient goals were reviewed by six OB/GYN surgeons in both surgical and pessary treatment and grouped into categories by type of goal. The expert group initially utilized five treatment goal categories defined by prior authors including symptom relief, quality of life, body image, emotional outcomes and others; goal categories were modified as the analyses progressed by categorizing symptoms into one group, quality of life related goals such as improved activity, continuing with activities of daily living and combining the last three body image, emotional

outcomes and other to form an 'other' category.¹⁸ Final categories of treatment goals used in the present study were symptom relief, quality of life improvement and other goals. The "symptom" category included patient goals related to symptom abatement or management. Examples of goals in this category include reduction in symptoms associated with prolapse, bowel or bladder complaints. The "quality of life" category included goals for enhanced or improved sexual health, social interaction and changes in the patient's ability to participate in social activities. The "other" category included more general statements regarding overall happiness and well-being, emotional well-being, avoidance of alternative therapy and body image changes.

Data Analysis

We used factorial ANOVA and TukeyHSD to compare mean rating scores for each goals category between treatment groups. (Tables 5) The design of the analysis was that of Treatment Group (Pessary vs. Surgery) (between groups) X Goals (Symptom improvement vs. QOL improvement vs. Other goals) (within subjects) to analyze the rated importance of each of these 3 categories of goals by each patient. [N=50 per treatment group].

Results

Treatment Groups did not differ significantly in age, race/ethnicity, parity, body mass index (BMI) and severity of disease. (Table 2) This sample of 100 women was middle-aged and the majority were White. Responses to the PFDI-20 14, BIS 16, and PISQ-12 15 were likewise not significantly different between treatment groups. (Table 3)

Table 2 Study Participant Characteristics

Characteristic	Pessary (n=50)	Surgery (n=50)	p
Age + SD (years)	62.3+ 10	61.2+ 8.7	0.86
Race (%)			0.85
White, Non-	58	60	
Hispanic	4	2	
African American	10	6	
Native American	0	0	
Asian American	28	32	
Other			
BMI + SD	27.3 + 5.5	26.3 + 5	0.18
College graduate or higher (%)	36	16	0.08
Prolapse stage (%)			0.72
Stage 1	2	0	
Stage II	36	34	
Stage III	58	60	
Stage IV	4	6	

Table 3 Questionnaire responses to QOL questionnaires

	Pessary (n=50)	Surgery (n=50)	p
PFDI-20 ¹ (SD)	117+ 60	117+ 69	0.86
PISQ-12 ² (SD)	21.1+ 10.1	17.6+ 7.4	0.15
BIS ³ (SD)	7.7 + 5.7	7.2 + 6.7	0.60

1. PFDI-20 : Pelvic Floor Distress Inventory -20

2. PISQ-12 : Pelvic Organ Prolapse / Urinary Incontinence Sexual
Questionnaire (PISQ-12)

3. BIS : Body Image Scale

Initial review of patient goals were grouped into the five previous categories defined during study design with significant overlap observed between treatment goal groups. We then further combined treatment goal groups so that goals were ultimately categorized into "symptoms", "quality of life" and "other" as described earlier.

Patients' mean ratings of goal importance did not differ significantly between surgery and pessary groups for the symptoms and quality of life categories (Table 4). However, groups did vary in the ratings of the "other" category with the surgery group rating this "other goals" higher than did the pessary group. A 2 way 2 * 3 mixed model repeated ANOVA was performed for Treatment group (independent variable) and goal ratings (dependent variable) for the three categories. 50 patients chose pessary and 50 patients chose surgery. Patients then rated the importance of Goal 1 (Symptoms), Goal 2 (Quality of life) and Goal 3 (Other) which constituted the repeated measures on the ANOVA. We wanted to assess the effect of group i.e. pessary Vs surgery on goal ratings, assessed if there was an interaction between goal categories and treatment groups and also the effect of goals and treatment groups separately. This analysis shows a main effect for goal importance: patients rate "other goals" as significant less important than either goals of "symptom" reduction" or the presence of a main effect for goal type i.e.1, 2 or 3 (the repeated factor). The interaction between the goals and treatment groups was not significant ($p = 0.49$). In order to analyze this further, the means are plotted and show that while there is an

Table 4 Mean goal ratings of surgery and pessary patients

Category of goal	Pessary group	Surgery group	Cohen's d
Symptoms (SD)	8.76 (0.21)	8.68 (0.21)	0.18
Quality of life (SD)	8.64 (0.13)	8.95 (0.13)	0.31
Other (SD)	7.59 (0.22)	7.74 (0.22)	0.02

interaction between Goal 1 and Goal 2, there is no interaction of Goal 3 with either indicating that perhaps there is a significant difference in Goal 3 within the subjects. (Figure1). Groups 1 and 2 show a similar pattern but group 3 shows a different pattern indicating that pessary patients perhaps valued the other category far less than the surgery patients. Between subject effects showed no significant effect for the group i.e. pessary or surgery patient group ($p = 0.508$) and therefore the choice of pessary or surgery per se did not influence goal ratings (Table 5).

Discussion

Among women with symptomatic prolapse, goal rating of the importance of symptom reduction and quality of life improvement did not differ between those who chose surgery and those who chose pessary. However, women who chose surgery were more likely to rate “other” goals more highly than women who chose pessary. This finding supports the overall conclusion that women who choose a pessary for treatment of prolapse have similar symptom relief and quality of life goals to women who choose surgery. The difference in goal setting between groups was on specifics regarding changes in body image, avoiding alternative therapies or expectations from treatment.

Patient goals may provide insight into what motivates patients to choose one treatment over another and may prove a method by which to directly compare surgical to non-surgical interventions. Achieving patient goals improves patient satisfaction with treatment. 13 While goal attainment following treatment is important, goal setting prior to treatment is may provide better insight into why

Figure 1 Mean ratings of treatment goal importance of pessary vs. surgery patients

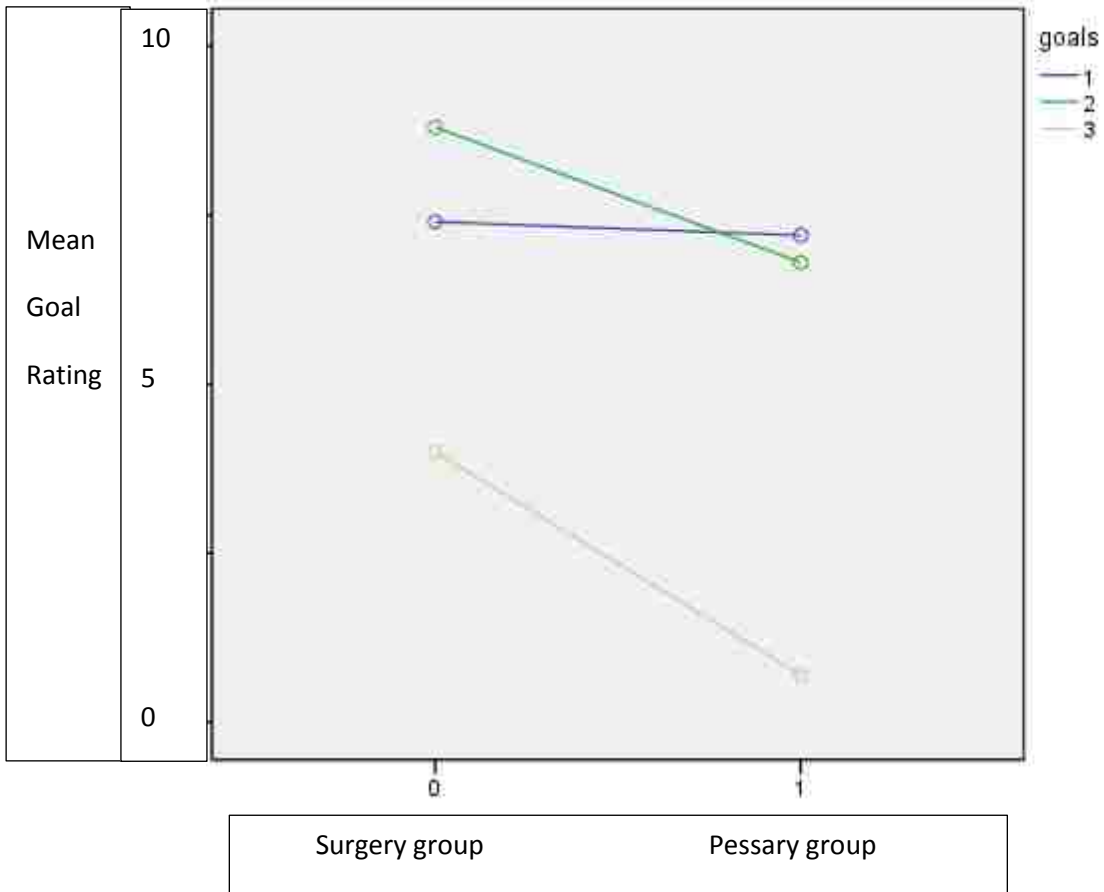


Table 5 ANOVA Summary Table of Goals and Pessary vs Surgery Patients
 Between and Within Subject Effects

Source	df	SS	MS	F	P
Pessary vs. surgery	1	2.407	2.407	0.440	0.508
Error	98	535.433	5.464		
Total	99				
Goals (within)	1.943	159.703	82.196	29.823	0.000
Goals * pessVssurg	1.887	3.843	1.978	0.718	0.485
Error	190.411	524.787	2.756		
Total	194.241				

women choose one therapy over another.

Previous direct comparisons of surgical and pessary management of pelvic organ prolapse are sparse. No data compare goal setting between women who choose conservative management with pessary versus those who choose surgical management for symptomatic pelvic organ prolapse, although a prior single study compared goal attainment following treatment between groups.

Srikrishna et al validated the PGI-I 20 questionnaire for pelvic organ prolapse and studied patient goal achievement 2 years after surgery for prolapse and urinary incontinence. 21 Patients were asked if they met their goals adequately. The mean patient goal achievement at 2 years was 85.1%.

Elkadry et al⁵ undertook a study to assess goals of patients undergoing pelvic reconstructive surgery. Established measures of patient global impression of severity (PGI-S) 5 and patient global impression of improvement (PGI-I) 20 were used to assess baseline symptom severity and improvement after surgery.

Seventy-five percent of women reported that they met all or most of their goals, 4% met half, 12% met less than half and 9% met none of their goals. Komesu et al⁷ studied women who were using a pessary to treat either prolapse or incontinence and found that women who continued using their pessary were more likely to attain goals compared to those who quit using their pessary. In that study, each 1-point improvement in the PGI-I scale was associated with a 4.6 fold increase in likelihood of pessary continuation. These studies look at

surgery or pessary separately and also have assessed goal achievement rather than goal setting.

Weaknesses of the study were that the patients listed only three of their goals independently. It may have been possible that the patients may have had more goals and therefore more differences between the two groups which has not been assessed. The categorization of goals was made by the 'expert' surgeons and not the patients and is therefore subject to possible bias (i.e. it is the surgeon perception of patient goals which may not have been completely accurate). The counseling for the choice of pessary vs. surgery was not standardized and may have been subject to individual provider bias. Further categorization of goals to elicit the precise differences between the groups could have been helpful. In addition, having patients rate the importance of a comprehensive list of all potential patient goals may add insight into patient goal setting and achievement. And, the design did not assess goals prior to consultation when providers may have influenced patients goal ratings, nor did it assess patient goals after treatment to detect possible changes in goals as a function of treatment outcomes.

The strengths of the study are that this is novel to assess the differences between the two groups of pessary and surgery patients for treatment of prolapse. We recruited patients that chose their treatment so we could assess normal goal setting independently what goals might be if patients were randomized to treatment. Had the patients been randomized the reasons for their choice of pessary or surgery would not be apparent. The patients in the different

treatment groups in the present study have similar baseline characteristics and are thus comparable.

Future directions for further studies should also include which “other” categories lead to the differences between the pessary and surgery groups. Treatment choices may be correlated with treatment goals and this needs to be studied further.

Conclusion

Patients that choose surgery compared to those that choose pessary differ in the goal categories consisting of overall happiness and well-being, avoidance of alternative therapy and body image changes. The choice of pessary or surgery itself does not appear to be related to symptoms, severity of disease or goals related to quality of life.

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