Prediction of postsurgical symptomatic outcomes with preoperative pessary use

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Principal Investigator- John Occhino, MD

Co-Investigator- Brian Linder, MD

Abstract

Pelvic organ prolapse is a highly prevalent and distressing condition for patients. Despite standard office-based consultation many patients report feeling unprepared for surgery. Likewise, in cases of equivocal symptoms, it is difficult to predict the ability of surgery to improve patient's quality of life and meet expectations. Occasionally, some providers utilize a pessary to evaluate the potential role for surgical correction. However, this is an empiric practice, rather than evidence-based. In addition to the evaluation of symptomatic improvement, pessary use in this setting is an important consideration as it may provide a better functional demonstration of the expected postoperative quality of life, compared to office-based discussion. The purpose of this project is to evaluate the potential role of routine pessary placement prior to planned surgery for symptomatic prolapse in a prospective case-crossover trial where patients scheduled for operative prolapse repair will utilize a pessary preoperatively. We anticipate that this trial will define the clinical utility of routine preoperative pessary placement,and by shaping patient expectations and increasing preparedness for surgery, we anticipate improving satisfaction and quality of life.

Research Plan

I. Specific Aims:

Pelvic organ prolapse is a highly prevalent issue in adult women and can have a large impact on a woman's quality of life, leading to discomfort, decreased energy and increase social isolation. Notably, the prevalence of prolapse increases with advancing age and it is estimated that the lifetime risk of a woman undergoing surgery for bothersome prolapse is as high as 13%. Likewise, given the present age distribution in the United States, the number of women seeking treatment for this issue in the future will continue to expand. While many women will undergo surgery, preoperative counseling in preparation for surgery is variable. In fact, self-reported patient preparedness for prolapse surgery has been reported as low as 58% in a previous series from a large tertiary care center. This is an important consideration as patient preparedness for surgery is associated with patient satisfaction and symptomatic improvement.

Management options for symptomatic prolapse include pelvic floor physical therapy, vaginal pessary and a variety of reconstructive surgical techniques. Following appropriate patient counseling regarding these options, patients choose a therapy based on the known efficacies and risks for each, as well as how they perceive that the treatment will help them accomplish their individual treatment goals. For instance, while a pessary may provide symptomatic relief, it can impact sexual function and needs to be periodically removed and cleaned, which some patients may not prefer. Conversely, while surgery offers a more permanent treatment that restores the pelvic anatomy, it also carries greater risks.

Notably, both pessary use and surgery have been associated with adequate symptomatic improvement, however in disparate patient populations, which makes direct comparisons of outcomes difficult. Additionally, while some symptoms, such as a sensation of a vaginal bulge, are consistently linked to the severity of prolapse, the associations of bowel, overactive bladder or abdominal/pelvic pain symptoms and the stage of anatomic prolapse are less well defined. Uncertainty of symptomatic improvement and unrealistic patient expectations about surgery can lead to decreased patient satisfaction and poor symptomatic outcomes.

In cases of equivocal symptoms, some providers utilize a vaginal pessary preoperatively to evaluate the potential role of a surgical correction. Conceptually, symptoms that improve with the use of a pessary may indicate surgically correctable symptoms, given the similar expected anatomic changes with pessary use and surgery. However, this is an empiric practice, rather than evidence-based. Additionally, the maximal degree of anatomic improvement between pessary use and surgery has not been well studied. Likewise, there are no prior studies evaluating the degree of symptomatic change with pessary use and surgery in the same patient.

Our overall research goal is to evaluate the clinical utility of preoperative pessary placement as a part of patient counseling or preparation for surgery. In this protocol we aim to increase patient preparedness for surgery, patient satisfaction, and post-operative quality of life in adult women scheduled for surgery for symptomatic pelvic organ prolapse. To accomplish this, following counseling regarding all treatment options for prolapse, we will perform a prospective case-crossover study where 112 subjects who elected for surgical management will utilize a pessary for 1-4 weeks prior to undergoing prolapse surgery.

We propose:

Specific aim 1a: To evaluate concordance of the Patient Global Impression of Improvement Score between vaginal pessary use (assessed prior to surgery) and surgical intervention (assessed at 3 months postoperatively) for women with pelvic organ prolapse. *Hypothesis:* There is a strong correlation between the self-reported Patient Global Impression of Improvement Score following pessary use and surgery, as assessed at 3 months post-operatively.

Specific aim 1b.) To evaluate concordance in symptomatic change in pelvic and voiding symptoms (measured by validated symptom questionnaires) from baseline between pessary use (assessed prior to surgery) and surgical intervention (assessed at 3 months postoperatively). *Hypothesis:* There is a strong correlation between the changes in pelvic and voiding symptoms following pessary use and surgery, as assessed at 3 months post-operatively

Specific aim 2: To evaluate the impact of preoperative pessary use on patient preparedness for surgery (measured by validated questionnaire) as compared between the initial office consultation and following 1-4 weeks of pessary use.
Hypothesis: Preoperative pessary use will increase self-reported preoperative patient preparedness for surgery compared to office counseling alone.

II. Research Strategy

1. Significance:

A.1. Pelvic organ prolapse is a highly prevalent issue that is anticipated to become even more common as the population ages. In fact, a population-based survey found that 6% of women over 40 years old self-reported having symptomatic pelvic organ prolapse.[3] This is a pertinent consideration as the presence of prolapse symptoms is associated with lower scores on evaluations of quality of life, including decreased mobility, energy, sleep and increased social isolation.[4] Likewise, pelvic organ prolapse has a high societal cost burden, with the annual direct costs of pelvic organ prolapse surgery estimated at roughly $1 billion dollars.[5] By comparison, this total direct cost is double that of surgery for stress urinary incontinence ($500 million dollars) and is comparable to the annual total direct cost of surgery for breast cancer ($1.1 billion dollars).[5] Notably, the impact of prolapse on patients and society will likely be magnified in the future as the population ages, given that older age is a risk factor for prolapse. In fact, it was recently estimated that up to 12.6% of women will undergo a surgical repair for pelvic organ prolapse by age 80.[6]

A.2. While pessary use is a recognized treatment option for prolapse, there is no consensus on indications for use, and limited comparative evidence of outcomes versus surgery. Pessaries have long been used for symptomatic pelvic organ prolapse, with early uses described roughly three thousand years ago.[7] Currently, pessary placement is sometimes quoted as the first-line therapy for pelvic organ prolapse, given its limited risks, though there is no consensus regarding pessary use among subspecialists.[8] Offering a pessary to a woman with symptomatic prolapse was recently reported as a quality of care metric in the treatment of pelvic organ prolapse.[9] In practice, however, use of a pessary is more limited, and for some providers, pessary use is restricted to non-surgical candidates.[8] Notably, in an evaluation of a large multidisciplinary tertiary care center, discussion of pessary use was documented in 43% of office visits.[9] Similarly, only 22% of Urologists undergoing board certification or recertification who reported managing women with pelvic organ prolapse, actually logged a pessary placement procedure.[10]

Additionally, despite a long history of clinical use, there is little comparative evidence regarding pessaries versus other treatment options. In fact, a recent Cochrane analysis noted only one randomized trial, which compared two different types of pessaries, and commented that there is urgent need for comparative studies evaluating the use of pessaries in comparison to surgery. Thus, it seems that pessaries are variably used in practice, with no consensus on the indications for use, and limited comparative data. Our proposed protocol, a comparative study of symptomatic improvement between pessary use and surgery, would help in clarifying the role of pessary use in everyday clinical practice and influence patient counseling for patients presenting with symptomatic prolapse.

A.3. Current methods of patient counseling are not meeting the needs of women with pelvic organ prolapse. While some symptoms, such as sensation of a vaginal bulge have been shown to be consistently linked to the severity of prolapse, the association of other symptoms and degree of anatomic prolapse is less well defined.[13-16] For instance, at times it is difficult to predict the impact of surgical prolapse correction on lower urinary tract symptoms (e.g. overactive bladder), bowel symptoms or abdominal/pelvic pain.[13, 14 15-18] This unique feature of prolapse surgery likely contributes to the known limitations of the surgical informed consent process in general with regard to how well surgical patients understand the risks and benefits of procedures, despite standard office counseling.[19] Secondary to this, at times patients with excellent anatomic pelvic floor outcomes by objective criteria are dissatisfied with their surgical results.[20] In an effort to better align the

expectations of the patient and potential surgical outcomes, there is an increased focus on patient-centered goals for pelvic floor surgery.[21, 22]

In pelvic organ prolapse treatment, presently, the pessary test is occasionally empirically used for cases of pelvic organ prolapse with equivocal symptomatology, in order to better inform preoperative counseling and shape patient expectations for prolapse surgery. Interestingly, while this is practiced empirically, there is no evidence available evaluating a correlation between symptom improvement with pessary use and surgical intervention. Thus, if improvement of overactive bladder symptoms, pain or bowel symptoms from pessary use mirrors that of surgery, universal preoperative pessary use may be a low-cost, low-risk, and widely accessible tool for addressing patient's unmet counseling needs.

A.4. Active participation of patients by utilizing a pessary prior to surgery could increase preparedness for surgery.

Despite standard office based preoperative counseling, a previous series from a large tertiary care center reported that only 58% of patients strongly agreed that they were prepared for the surgery. This is an important consideration as patient preparedness for pelvic organ prolapse surgery has been associated with patient satisfaction and subjective symptomatic outcomes, regardless of the anatomic outcome.[2]

Notably, numerous previous methods for improving patient education for surgery such as hand out leaflets, [19] multimedia presentations,[31] printing of personalized 3-D models,[32] as well as decision aids [33] have been studied with mixed results. While these methods may potentially improve patient knowledge of the anticipated surgery, none allow for a demonstration of functional outcomes. As such, universal use of a pessary preoperatively, could uniquely improve patient preparedness for surgery by demonstrating the potential functional result of surgery.

B. Innovation

The proposed project is a new approach to addressing the gaps in patient counseling and preparedness for surgery that currently exist. The proposed protocol will clarify the utility of pessary placement given the noted heterogeneity in current clinical practices. Additionally, while pessaries are at times used clinically to help differentiate potential symptoms that may improve with surgery, this is an empirical rather than evidence-based practice. Thus, correlation of symptomatic change in bladder, bowel or pain symptoms with pessary use and surgery is important for pre-operative counseling. Additionally, with recent evidence regarding the importance of preoperative patient preparedness on surgical outcomes and patient satisfaction, evaluating the use of a pessary as part of patient education and preoperative preparation may highlight a potential innovative, low-cost, low-risk, and widely accessible tool for improving patient care and obtaining the best experience for our patients.

C. Approach- Experimental Design and Methods:

C.1. Study design and overview

Overview: This is a single center, prospective, case-cross over trial of pessary use prior to reconstructive pelvic floor surgery for pelvic organ prolapse. The goal of the study is to evaluate the comparative efficacy of pessary use on pelvic floor symptoms versus surgical correction. Additionally, we will assess the impact that preoperative pessary use has on patient self-reported preparedness for surgery.

Study procedure and design: All patients will undergo baseline symptom evaluation via validated questionnaire at the time of their initial office consultation. Following this, the patient will undergo pessary fitting at least 7 days prior to scheduled surgical prolapse repair. The pessary will be left in place and symptomatic change from baseline assessed via validated questionnaire roughly 4 weeks after use or immediately prior to surgery (i.e. with the pessary in place). The pessary will then be removed at the time of surgery, and the patient will undergo surgical correction of their pelvic organ prolapse (including all restorative surgical procedures, abdominal and transvaginal). A concomitant anti-incontinence procedure will be performed at the discretion of the treating physician in consultation with the patient. The patient's symptomatic

outcome from surgery will then be reassessed by validated questionnaire at 6 weeks and 3 months postoperatively. (See Study Design Flow Chart)

C.2. Participants

Study population: The study will be open to women (over age 18) presenting for evaluation and management of symptomatic pelvic organ prolapse at Mayo Clinic (Rochester, MN), who elect to undergo surgical management.

Inclusion criteria: Female patients: 1) older than 18 years of age; 2) with symptomatic pelvic organ prolapse; 3) electing for surgical repair of pelvic organ prolapse (transvaginal or transabdominal) at least 7 days after office consultation. A minimum of one week was chosen as the duration of pessary use, as this was found sufficient in a study evaluating diagnosing occult urinary incontinence with pessary use prior to prolapse surgery;[36] 4) who understand and have signed written informed consent for preoperative pessary placement.

Exclusion criteria: Patients that: 1) have previously been managed with a pessary for pelvic organ prolapse; 2) patients undergoing obliterative prolapse surgery (i.e. Colpocleisis), 3) are scheduled for surgery for pelvic organ prolapse less than 7 days after office consultation 4) have an isolated rectocele; 5) have allergies to both latex and silicone; 6) have an active pelvic infection.

C.3. Outcome Assessment

The primary aim (1a) will be assessed using the 7-point Likert scale of the Patient Global Impression of Improvement (PGI-I).[1, 35] Concordance will be estimated along with a 95% confidence interval. Patient's will be considered treatment success if they answer "much better" or "very much better" on the PGI-I scale.[35] The additional primary aim (1b) will be assessed using Lin's concordance correlation coefficient for responses to: Pelvic Organ Prolapse Distress Inventory-6 (POPDI-6) which measures prolapse symptom severity, Pelvic Floor Impact Questionnaire-7 (PFIQ-7) to evaluate patient bother from their bladder/vaginal/bowel symptoms, and the Overactive Bladder Symptom Score (OABSS). The secondary aim will be assessed by evaluating patient responses to a preoperative preparedness questionnaire. Patients will be considered prepared for surgery if they answer "strongly agree" on a 6-point Likert scale, with responses ranging from "strongly disagree" to "strongly agree" to the question: "Overall, I feel prepared for my upcoming surgery."[2]

C.4. Sample Size Considerations

Aim 1: Using the 7-point Likert scale of the PGI-I, we anticipate an overall concordance of at least 80% between the within patient ratings following pessary use and 6-weeks following surgery after collapsing the categories into a) much better or very much better, b) a little better, no change, or a little worse, or c) much worse or very much worse. In order the estimate the concordance with a ½ width of the 95% CI of 10% (i.e. 95% CI of 70.8-90.5%), the study will need 62 patients.

Aim 2: Based on a recent study of 79 women who underwent reconstructive pelvic surgery after standard office counseling, 58% strongly agreed that they were prepared for their upcoming surgery.[2] If we assume that following pessary use, 75% will endorse that they strongly agreed that they were prepared for their upcoming surgery, then the study will have 80% power to detect this difference with a sample size of 84 patients. This calculation was based on two-sided McNemar's test for comparing correlated proportions assuming a mild correlation (0.30) between the paired measures and a type I error of 0.05. Assuming a conservative 25% drop-out rate (failure to wear the pessary or complete follow-up questionnaires) then the study would need to consent 112 patients.

Feasibility: The Division of Urogynecology at Mayo Clinic, Rochester, MN typically performs roughly 1350 surgeries annuals (averaged from surgical volume from 1/1/2013 to 1/1/2015). Among those, the four fellowship trained Urogynecologists typically perform roughly 650 prolapse procedures per year. Thus, given the large surgical volume, recruitment for this study is feasible as a single center trial.

C.5. Data Collection

Preoperative demographic data, complete medical and surgical histories, as well as current medications and allergies will be obtained to ensure patients meet inclusion and exclusion requirements. Participants will fill out the following validated questionnaires and questions prior to any intervention and following each

treatment (pessary and surgery): Pelvic Floor Impact Questionnaires (PFIQ-7),[37] Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6),[37] and Overactive Bladder Symptom Score (OABSS).[38] Thus, questionnaire assessments will be completed at the time of initial consultation, immediately prior to surgery (after pessary use), at 6 weeks postoperatively during office consultation, and via mailed questionnaires and phone interviews at 3 months. Patient preparedness for surgery will be assessed via validated questions after completing the standard office based counseling and signing the surgical informed consent (prior to pessary use), as well as immediately prior to surgery (after pessary use), according to validated questions evaluating self-reported preparedness for pelvic surgery.[2] Furthermore, following treatment with a pessary (prior to surgery), at 6 weeks and 3 months after surgery patients will complete the Patient Global Impression of Improvement (PGI-I) question.[1, 35] All adverse events associated with pessary use or surgery will be documented and abstracted.

Baseline characteristics for the patients included in the trial will be reported as median with inter-quartile range for continuous variables and counts with percentages for categorical variables. The percent concordant will be calculated along with the corresponding 95% confidence interval. Given the paired nature of the data (post-pessary vs. post-surgery), differences between the two time points for dichotomous responses will be assessed using McNemar's test whereas differences between ordinal responses will be assessed using Bowker's test for symmetry. The correlation between the two time points for summary scores from validated questionnaires (POPDI-6, PFIQ-7, OABSS) will be assessed using Lin's concordance correlation coefficient. All calculated p-values will be two sided and will be considered significant if < 0.05.

Study Schedule	Initial visit	After pessary use, day of surgery	Surgery	6 wks after surgery (clinic visit)	3 mos after surgery (mailing)
Medical History and Physical	X				
Informed Consent	X				
Pessary Fitting	X				
Preparedness for Surgery	X	X			
PFIQ-7	X	X		X	X
POPDI-6	X	X		X	X
OABSS	X	X		X	X
PGII		X		X	X
Surgery			X		

C.6. Potential limitations of the study design and alternative strategies:

Potential Limitations:

Carry-Over Effect: This would be encountered if preoperative pessary use changed the pelvic floor in a way that influenced the outcome of surgery. As there is no "wash-out" time from pessary removal to surgery, such an effect would impact the surgical outcome. Given that the pessary is a mechanical change in anatomy of the pelvic floor, we anticipate that with pessary removal there would not be residual impact from the pessary.

Recruitment: As patients would be counseled regarding surgery and pessary use and would have elected for surgery prior to study consent, we could encounter difficulties with recruitment in that patients would need to consent to temporary pessary use. Given the volume of patients seen in our department and the sample size needed, we feel that this should not be prohibitive.

Alternative strategies:

Observational cohort: An alternative strategy would be to compare symptomatic improvements between pessary use and surgery in two separate cohorts of patients, in an observational study. As there would be

significant selection bias in patients that undergo pessary placement rather than surgical correction, this methodology was not preferred.
Randomized clinical trial: A randomized clinical trial could be performed where patients are randomized to preoperative pessary use or proceeding directly to surgery. This approach could potentially minimize the impact of confounding variables. This method was not preferred due to perceived difficulty in recruitment (as patients may have a specific time in which they prefer to have surgery) and difficulty in surgical scheduling.

C.7. Timeframe: (24 months)

For Aim 1, we estimate that it will take 8 months for recruitment of the 62 patients, assuming a recruitment rate of 15% (~54 surgeries for prolapse in our division per month, as estimated by averaging volume from 2013 and 2014). For completion of Aim 2, we estimate that it will take 14 months to recruit the 112 patients for study, assuming a recruitment rate of 15%. Given the surgical volume in our division we anticipate being able to meet the accrual requirements.

	2016							**2017**												**2018**				
Study Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Aim 1																								
Data Collection	x	x	x	x	x	x	x	x																
Data Analysis									x	x														
Manuscript										x	x	x	x											
Aim 2																								
Data Collection	x	x	x	x	x	x	x	x	x	x	x	x	x	x										
Data Analysis															x	x	x							
Manuscript																		x	x	x	x	x	x	x

D. Safety and Monitoring

Data Safety and Monitoring: A data safety and monitoring plan will be employed during the trial. The accuracy of the data will be validated during periodic audits by study coordinator. Original documentation will be maintained with the principal investigator. All patient information will be collected under the supervision of the principal investigator and kept in a locked file cabinet to protect patient confidentiality. Data will be entered into a REDCAP database by a study assistant. Data analysis will be performed as described by the collaborating statistician.
Patient Safety and Monitoring: Interim monitoring of serious complications will be performed when 50% of the planned sample size has reached the 6-week follow-up time point. The principal investigator or his designate will review each adverse event within 96 hours of its occurrence to determine if; 1. relationship to the study interventions; 2. whether the event necessitates changes to the protocol, consent form or study interventions. In addition, an internal committee comprised of the Principal Investigator and a co-investigator will review serious complications on a quarterly basis. Notably, pessary use for pelvic organ prolapse has been shown to be safe, with the most common risk to the patients being pelvic discomfort and vaginal discharge.[39] More serious adverse events (vesicovaginal and rectovaginal fistula formation), are related to neglected pessaries, whereas patients in the study will have pessaries in place for 1-4 weeks.[39, 40]
Inclusion of women, minorities and children: The risk factors, pathophysiology and management of pelvic floor disorders substantially differ between men and women. This proposal will therefore exclusively focus on pelvic floor disorders in women, including women of child-bearing potential. We intend enrolling all eligible female patients who are willing to participate in consecutive order without regard to race. Most of our patients are Caucasian, post-menopausal women, but younger women (>18 years old), will be allowed to participate depending on the study criteria. Likewise minority women meeting inclusion and exclusion criteria will be invited to participate. This study will not include the recruitment of children (age <18 years old).

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Study Design Flow Chart