Predicting Treatment Choice for Patients With Pelvic Organ Prolapse

Michael Heit, MD, MSPH, Chris Rosenquist, MD, Patrick Culligan, MD, Carol Graham, MD, Miles Murphy, MD, and Susan Shott, PhD

OBJECTIVE: To evaluate which clinical factors were predictive of treatment choice for patients with pelvic organ prolapse.

METHODS: One hundred fifty-two patients were enrolled in this cross-sectional study to collect clinical data on potential predictors of treatment choice. Continuous parametric, continuous nonparametric (ordinal), and categoric data were compared with chosen management plan (expectant, pessary, surgery) using analysis of variance, the Kruskal-Wallis test, and the χ^2 test for association, respectively. All significant predictors (P < .05) of treatment choice for pelvic organ prolapse identified during univariate analysis were entered into a backward elimination polytomous logistic regression analysis for predicting surgery versus pessary versus expectant management, with surgery as the reference group.

RESULTS: The probability of choosing expectant management rather than surgery 1) increases as the preoperative pelvic pain score increases (odds ratio [OR] 1.6; 95% confidence interval [CI] 1.07, 2.40; P = .024) and 2) decreases as the prolapse severity increases (OR 0.46; 95% CI 0.29, 0.72; P = .001). The probability of choosing pessary rather than surgery 1) increases as age increases (OR 1.1; 95% CI 1.05, 1.16; P < .001), 2) decreases as the prolapse severity increases is the prolapse severity increases (OR 0.77; 95% CI 0.60, 0.99; P = .042), and 3) is less if the participant had prior prolapse surgery (OR 0.23; 95% CI 0.07, 0.76; P = .017).

CONCLUSION: Age, prior prolapse surgery, preoperative pelvic pain scores, and pelvic organ prolapse severity were independently associated with treatment choices in a predictable way and provide physicians with medical evidence necessary to support a patient's decision. (Obstet Gynecol 2003;101:1279-84. © 2003 by The American College of Obstetricians and Gynecologists.)

The incidence of significant pelvic organ prolapse ranges between 2% and 2.6%, depending on the definition of disease and the population sampled.¹ Gynecologists can expect this incidence to increase as the pool of individu-

From the University of Louisville HSC; and Rush-Presbyterian St. Luke's Medical Center, Louisville, Kentucky.

als at risk enlarges. By the year 2030, there will be a 22% expansion of the United States population, due primarily to a 72% increase in Americans over the age of 50. This will result in a 45% expansion in the number of consultations for urinary incontinence or pelvic organ prolapse because of the disproportionate need for medical care in the elderly population.²

Treatment options for patients with pelvic organ prolapse include expectant management, pessary placement, or surgical repair. Clinicians know that 50% of patients with pelvic organ prolapse will continue to use pessaries as an alternative to surgery. Approximately 25% will ultimately choose surgery after initial pessary use. Another 20% will ultimately choose expectant management after pessary use.³ However, gynecologists do not know why patients initially choose pessary over surgical or expectant management. If gynecologists understood predictors of treatment choice for pelvic organ prolapse, they could provide better counseling for future patients. Therefore we designed a cross-sectional study to identify predictors of treatment choice for patients with pelvic organ prolapse.

MATERIALS AND METHODS

Patients who reported "noticing a vaginal bulge" were enrolled in this cross-sectional study and offered expectant management, pessary, or surgery as treatment choices after a complete urogynecologic evaluation confirmed a diagnosis of pelvic organ prolapse. This single inclusion criterion was established to homogenize our study population into a group that could easily relate these treatment choices to "their bulge." Patients who presented with pelvic pressure, urinary incontinence, or dyspareunia secondary to pelvic organ prolapse were excluded. All patients were shown pictures of pelvic organ prolapse⁴ and educated about each treatment choice by the first author, who was not blinded to patient symptoms, in a consultation room after their urogynecologic evaluation. A script was not prepared for this cross-sectional study because we wanted to reproduce a

typical patient-physician interaction in as many cases as possible. Patients in whom a pessary had previously failed were offered surgery. For the purpose of this study, expectant management was defined as any choice other than pessary or surgery, including pelvic muscle exercises. The patient's treatment choice at the initial visit was considered the dependent variable for the purpose of this study.

The independent variables for the study were ascertained from the complete urogynecologic evaluation, which included an incontinence and prolapse specific history and physical examination. The specifics of the complete urogynecologic evaluation are beyond the scope of this study and published elsewhere.⁵ All patients were asked to complete two visual faces scales to quantitate the degree of pelvic and lower back pain present. The visual faces scale is scored by the patient, who circles the number or face that best reflects the degree of pain present: 0 (no pain), 1 (mild pain), 2 (moderate pain), 3 (severe pain), 4 (very severe pain), or 5 (worst pain). Faces scales provide a more direct representation of the feelings involved in quality of life than does a verbal translation of the response to a conventional question. They may also be useful in patient populations who may have difficulty completing a questionnaire. The median validity and test-retest reliability coefficients of the faces scale are 0.82 and 0.70, respectively.⁶

Pelvic organ prolapse severity was graded by two techniques. Each patient's prolapse was staged in the dorsal lithotomy position with strain using the pelvic organ prolapse quantification system endorsed by the International Continence Society.⁷ The reliability of this tool was established by repeated pelvic examinations performed on 48 subjects from two centers in the United States. The interobserver and intraobserver (test-retest) reliability coefficients of the prolapse staging system were 0.702 and 0.712, respectively.⁸

The leading edge of the prolapse, defined as the point along the vaginal wall with the greatest descent beyond the hymenal ring with strain in the supine position, was measured in centimeters. This tool was used to obtain an accurate measurement of prolapse severity in pelvic organ prolapse quantification stage III patients, whose prolapse can descend from greater than 1 cm beyond the introitus to 2 cm short of total vaginal length.

For both measurements, each patient was examined in the standing position with strain to make sure that maximum descent of their prolapse was visualized during the supine examination.

Patients were excluded from analysis if their chart was lost or no pelvic organ prolapse quantification was performed. To evaluate for selection bias, clinical and demographic comparisons between excluded and included patients were made with the Student *t* test for continuous variables, χ^2 tests for association, and Fisher exact tests for categoric variables.

Age; weight; vaginal parity; history of incontinence and prolapse surgery; pelvic and lower back pain scores; pelvic organ prolapse severity; pain medication usage; prior hysterectomy; presence of cystocele, rectocele, enterocele, or uterovaginal-vaginal vault prolapse on examination; and presence of ovaries were considered as potential predictors of treatment choice for pelvic organ prolapse. Associations between our independent and dependent variables were assessed using analysis of variance for noncategoric variables with statistically normal distributions, the Kruskal-Wallis test for noncategoric variables with nonnormal distributions, and the χ^2 test and Fisher exact test for categoric variables. The Tukey method for multiple comparisons was used to compare groups two at time when analysis of variance was statistically significant. Bonferroni-adjusted Mann-Whitney tests were done to compare groups two at a time when the Kruskal-Wallis test was statistically significant. All statistically significant predictors (P < .05) of treatment choice for pelvic organ prolapse identified during univariate analysis were entered into a multivariable analysis to control for confounding. The following potential independent variables were entered into a backward elimination polytomous logistic regression analysis⁹ for predicting surgery versus pessary versus expectant management, with surgery as the reference group: preoperative pelvic pain score, preoperative lower back pain score, age, leading edge of prolapse, presence of enterocele (yes, no), prior incontinence surgery (yes, no), prior prolapse surgery (yes, no), weight, vaginal parity, prolapse stage, prior hysterectomy (yes, no), and presence of ovaries (yes, no). P values less than .05 were considered significant. All statistical analyses were performed with SPSS for Windows 11.0 (SPSS Inc., Chicago, IL). The Human Studies Committee at our institution approved this study.

RESULTS

From August 1996 through January 1998, 152 consecutive patients who reported "noticing a vaginal bulge" were enrolled in this cross-sectional study. Six patients were excluded because no pelvic organ prolapse quantification was performed on five patients and the chart was lost for one patient. These six excluded patients did not clinically differ from the 146 study participants with respect to weight, height, vaginal parity, preoperative pelvic or lower back pain score, prescribed pain medica-

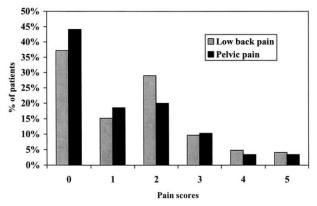


Figure 1. Distribution of pelvic and lower back pain scores. *Heit. Predicting Treatment Choice. Obstet Gynecol 2003.*

tion, prior hysterectomy, prior prolapse surgery, prior continence surgery, or presence of ovaries. Excluded patients were younger than study participants (44 \pm 12.55 versus 62.32 \pm 12.65, P = .002).

The mean age, body mass index, and vaginal parity of the study participants were 62 ± 12.7 years (range 21-88), 26.5 ± 4.8 kg/m² (range 18-44.6), and $3.23 \pm$ 2.1 (range 0-10), respectively. Sixty-eight and a half percent of participants had a prior hysterectomy, 32.9%had prior prolapse surgery, 43.2% had prior incontinence surgery, and 71% had ovaries present. Based on a physical examination, cystoceles, rectoceles, enteroceles, or uterovaginal-vaginal vault prolapse were identified in 65%, 41%, 55%, and 88% of the participants. The leading edge of prolapse descended an average of 2.2 ± 2.5 cm beyond the introitus (range -2 to 15), as defined in our study. Of the participants, 4.8% had stage I, 39.7%had stage II, 53.4% had stage III, and 2.1% had stage IV prolapse based on the pelvic organ prolapse quantification system. The distribution of pelvic and lower back pain scores as defined in our study is illustrated in Figure 1.

Of the participants, 11.1% chose expectant management, 19.4% chose pessary placement, and 69.4% chose surgery as treatment for their pelvic organ prolapse. Table 1 illustrates only those clinical and demographic variables that were predictive of treatment choice for pelvic organ prolapse. Patients who chose pessary were older than patients who chose surgery (P = .001) or expectant management (P = .001) for treatment of their pelvic organ prolapse. Patients with lower back pain were more likely to choose expectant management than a pessary (P = .035). Patients with pelvic pain were more likely to choose expectant management than pessary (P = .015) or surgery (P = .045). Patients with greater descent of the leading edge of prolapse were more likely to choose pessary (P = .029) or surgery (P = 0.001) than expectant management. Patients with higher pelvic organ prolapse quantification staging were more likely to choose pessary (P < .001) or surgery (P < .001) than expectant management.

If we consider all treatment choices, the probability of choosing expectant management rather than surgery 1) increases as the preoperative pelvic pain score increases (odds ratio [OR] 1.6; 95% confidence interval [CI] 1.07, 2.40; P = .024) and 2) decreases as the leading edge of prolapse increases (OR 0.46; 95% CI 0.29, 0.72; P = .001). The probability of choosing pessary rather than surgery 1) increases as age increases (OR 1.1; 95% CI 1.05, 1.16; P < .001), 2) decreases as the leading edge of prolapse increases (OR 0.77; 95% CI 0.60, 0.99; P =

Predictor	Expectant management	Pessary	Surgery	Р	Post hoc analysis
Age	56.69 ± 12.74	70.18 ± 12.51	60.78 ± 11.7	<.001	Older patients more likely to choose pessary than surgery ($P = .001$) or expectant management ($P = .001$)
Enterocele	4 (26.7%)	11 (39.3%)	64 (64%)	.004	
Lower back pain	2.06 ± 1.65 Median 2	1.00 ± 1.39 Median 0	1.46 ± 1.34 Median 2	.040	Patients with lower back pain more likely to choose expectant management than a pessary $(P = .035)$
Pelvic pain	2.19 ± 1.91 Median 2	0.82 ± 1.31 Median 0	1.12 ± 1.23 Median 1	.022	Patients with pelvic pain more likely to choose expectant management than pessary ($P = .015$) or surgery ($P = .045$)
Descent of leading edge of prolapse	0.19 ± 1.83	2.11 ± 1.87	2.55 ± 2.6	.002	Patients with greater descent of leading edge of prolapse more likely to choose pessary ($P = .029$) or surgery ($P = .001$) than expectant
POP-Q stage	1.87 ± 0.50 Median 2	2.57 ± 0.50 Median 3	2.61 ± 0.62 Median 3	<.001	management Patients with higher POP-Q staging more likely to choose pessary ($P < .001$) or surgery ($P < .001$) than expectant management

Table 1. Predictors of Treatment Choice for Patients With Pelvic Organ Prolapse During Univariate Analysis

POP-Q = pelvic organ prolapse quantification.

.042), and 3) is less if the participant had prior prolapse surgery (OR 0.23; 95% CI 0.07, 0.76; P = .017). Of participants choosing surgery, 91.8% were correctly classified using our regression model (expectant management versus surgery: y = 0.47 [preoperative pelvic pain score] - 0.78 [descent of the leading edge of prolapse] -2.04; pessary versus surgery: y = 0.096 [age] - 0.26 [descent of the leading edge of prolapse] - 1.48 [prior prolapse surgery] - 6.381). Only 32.1% of participants choosing pessary were correctly classified.

DISCUSSION

Age, prior prolapse surgery, preoperative pelvic pain scores, and the degree of pelvic organ prolapse as measured by descent of leading edge of prolapse were independently associated with treatment choices in a predictable way. Older patients were 10% more likely to choose pessary over surgery when all treatment choices were considered. In the consultation room, patients are often quoted as saying "I would rather have surgery now than waiting until I get older." This may reflect the patient's understanding that the risks of surgery increase with advancing age. In a review of 17,638 consecutive ambulatory surgical cases,¹⁰ elderly patients had higher incidences of any intraoperative event (OR 1.4; 99.7% CI 1.0, 2.0) and of intraoperative cardiovascular events (OR 2.0; 99.7% CI 1.3, 3.0) than their younger counterparts.

Prior prolapse surgery was the strongest predictor of a surgical choice for treatment of pelvic organ prolapse. Patients who had undergone prior prolapse surgery were 77% more likely to choose surgery over pessary when all treatment choices were considered. Prior prolapse surgery may reduce patient anxiety towards additional surgery, making it a viable option for treatment of recurrent pelvic organ prolapse. In our study, another physician performed their original prolapse surgery in 100% of cases. It is possible that these patients maintain their confidence in this treatment option because they are counseled about a second surgery by a different surgeon. Alternatively, these patients may simply be risk takers. It is important to remember that neither patient anxiety, confidence, nor risk taking were measured in this study, which limits our ability to test these hypotheses. Nonetheless, it is important to counsel patients about the 30% failure rate¹¹ of reconstructive pelvic procedures if patient confidence is maintained in risk takers, because a different surgeon is seen, or anxiety is reduced after a prior prolapse surgery.

Patients with increasing pelvic pain scores were 60% more likely to choose expectant management over surgery when all treatment choices were considered. This

may reflect the patient's perception that surgery would increase the amount of pain postoperatively or that reconstructive pelvic surgery would not reduce the amount of preoperative pain present. We recently published data showing that pelvic organ prolapse was not a cause of pelvic or lower back pain.⁵ We were unable to find any data on reconstructive pelvic surgery's ability to reduce preoperative pain regardless of whether it was associated with pelvic organ prolapse or not. Patients who recognize pain as their chief complaint and are informed of these facts may decide against surgery because of their reduced expectations for cure.

The degree of pelvic organ prolapse as measured by the descent of the leading edge was predictive of a surgical choice over both pessary and expectant management when all treatment choices were considered. Predictably, patients with greater degrees of pelvic organ prolapse were 54% more likely to chose surgery over expectant management and 23% more likely to choose surgery over pessary. This finding may reflect the added confidence patients have with pessaries over expectant management for dealing with greater degrees of pelvic organ prolapse. Notably, the degree of pelvic organ prolapse as measured by pelvic organ prolapse quantification staging was not predictive of treatment choice for pelvic organ prolapse. This may be due to the fact the pelvic organ prolapse quantification staging system poorly differentiates prolapse severity beyond stage II disease. Patients with stage III disease have descent of their leading edge of prolapse ranging from 1 cm beyond the introitus to 2 cm short of total vaginal length. In our study, descent of the leading edge of prolapse was measured to differentiate prolapse severity beyond stage II disease. If preoperative symptoms and postoperative outcomes differ for patients within stage III disease we may need to further subdivide this group because pelvic organ prolapse quantification staging was not predictive of surgical choice for treatment of pelvic organ prolapse.

There are several limitations of this study that should be considered before its conclusions can be accepted. First, we were unable to control for observer bias because the first author took the patient's medical history, performed the physical examination, and counseled the patient on treatment options. The findings in this study may simply reflect the first author's bias towards certain treatment options given the findings on initial evaluation. Patient age and degree of prolapse as measured by descent of the leading edge of prolapse would be the predictors most affected by observer bias. Prior prolapse surgery would be less affected by observer bias based on the direction of its effect on surgical choice. Physicians may be less likely to direct patients toward surgical repairs after an initial failed attempt. Preoperative pelvic pain was not affected by observer bias because the first author was unaware of pain scores during the consultative portion of the visit.

There are certainly unmeasured predictor variables such as urinary incontinence severity, impact of pelvic organ prolapse on activities of daily living, and patient attitudes (beliefs and values) toward each treatment choice, which may explain additional variance in our dependent variable. However, the validated measure of urinary incontinence severity we presently use (the Sandvik Incontinence Severity Index¹²) did not exist at the time of this study. To date, a validated measure of the impact of pelvic organ prolapse on activities of daily living has yet to be published. It is our hope that future investigators will determine if both urinary incontinence severity and impact of pelvic organ prolapse on activities of daily living will predict treatment choice. The Health Belief Model,¹³ The Theory of Reasoned Action,¹⁴ and the Theory of Planned Behavior¹⁵ all include patient attitudes (beliefs and values) as an explanatory variable for health behaviors such as treatment choice for pelvic organ prolapse. We did not measure patient attitudes toward the potential for "success" with each treatment choice and therefore were unable to determine if this psychosocial variable could explain additional variance in our dependent variable.

We were unable to compare predictors of pessary and expectant management because of sample size considerations given that only 30% of the total sample selected these treatment choices. The findings in this study reflect the initial rather than the ultimate treatment choice of study participants. For the purpose of this study, ultimate treatment choice could have been defined as the treatment chosen 1 year after a study participant's initial visit. It is possible that predictors of treatment choice for pelvic organ prolapse may have changed if we had established ultimate treatment choice as our end point of interest. Study participants were older than excluded patients, which can introduce selection bias. Because increasing age predicted pessary choice over surgery for treatment of pelvic organ prolapse, we would expect a weaker association if all patients were included.

Enteroceles are difficult to diagnose by physical examination. Fifty percent of enteroceles detected by dynamic cystoproctography are missed during a pelvic examination.¹⁶ Therefore, we may have underestimated the effect that an enterocele has on treatment choice when diagnosis is solely based on physical examination. Finally, the external validity of this study may be limited to subspecialty practices, which see a large volume of patients with pelvic organ prolapse.

Age, prior prolapse surgery, preoperative pelvic pain scores, and pelvic organ prolapse severity as measured by the descent of leading edge of prolapse were independently associated with treatment choices in a predictable way. A surgical choice can be accurately predicted in 92% of cases when each of these variables is included in a regression model and all treatment options are considered. This study provides physicians with the medical evidence necessary to support a patient's treatment choice based on a logical assessment of these variables.

REFERENCES

- Swift S, Pound T, Dias J. Case-control study of etiologic factors in the development of severe pelvic organ prolapse. Int Urogynecol J 2001;12:187–92.
- Luber K, Boero S, Choe J. The demographics of pelvic floor disorders: Current observations and future projections. Am J Obstet Gynecol 2001;184:1496–503.
- Sulak PJ, Kuehl TJ, Shull BL. Vaginal pessaries and their use in pelvic relaxation. J Reprod Med 1993;38:919–23.
- 4. Richardson AC. The anatomic defects in rectocele and enterocele. J Pelvic Surg 1998;1:214.
- Heit M, Culligan P, Rosenquist C, Shott S. Is pelvic organ prolapse a cause of pelvic or low back pain? Obstet Gynecol 2002;99:23–8.
- McDowell I, Newell C. Measuring health. 2nd ed. New York: Oxford University Press Inc., 1996.
- Bump RC, Mattiasson A, Bo K, Brubaker LT, DeLancey JOL, Klarksor P, et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Am J Obstet Gynecol 1996;175:10–7.
- Hall A, Theofrastous J, Cundiff G, Harris R, Hamilton L, Swift S, et al. Interobserver and intraobserver reliability of the proposed International Continence Society, Society of Gynecologic Surgeons, and American Urogynecologic Society pelvic organ prolapse classification system. Am J Obstet Gynecol 1996;175:1467–71.
- 9. Hosmer DW, Lemeshow S. Applied logistic regression. 2nd ed. New York: John Wiley & Sons, 2000.
- Chung F, Mezei G, Tong D. Adverse events in ambulatory surgery. A comparison between elderly and younger patients. Can J Anaesth 1999;46:305–8.
- Olsen A, Smith V, Bergstrom J, Colling J, Clark AL. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. Obstet Gynecol 1997;89:501–6.
- Sandvik H, Seim A, Vanvik A, Hunskaar S. A severity index for epidemiological surveys of female urinary incontinence: Comparison with 48-hour pad-weighing tests. Neurourol Urodyn 2000;19:137–45.
- Rosenstock IM. Historical origins of the Health Belief Model. Health Educ Monogr 1974;2:328–35.

- Ajzen I, Fishbein M. Understanding attitudes and predicting social behavior. Englewood Cliffs, New Jersey: Prentice Hall, 1980.
- 15. Ajzen I. The Theory of Planned Behavior. Organized Behav Hum Decision Processes 1991;50:179–211.
- Kelvin FM, Maglinte DT, Hornback JA, Benson JT. Pelvic prolapse: Assessment with evacuation proctography (defecography). Radiology 1992;184:547.

Address reprint requests to: Michael Heit, University of Louisville HSC, M-18, 315 East Broadway, Suite 4002, Louisville, KY 40202; E-mail: mheit@louisville.edu.

Received September 10, 2002. Received in revised form January 7, 2003. Accepted January 23, 2003.