Patient characteristics that are associated with continued pessary use versus surgery after 1 year

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Pessary
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Objective: The purpose of this study was to identify patient characteristics in women with symptomatic pelvic organ prolapse that is associated with continued pessary use versus surgery after 1 year.

Study design: Fifty-nine women with symptomatic pelvic organ prolapse who were satisfied with their pessary at 2 months were evaluated prospectively at 1 year. Characteristics of women who continued to use a pessary were compared with women who underwent pelvic reconstructive surgery to identify predictors for continued pessary use versus surgery.

Results: Forty-three women (73%) continued pessary use, and 16 women (27%) underwent surgery. Characteristics that were associated with continued pessary use were older age (76 vs 61 years; p < .001) and poor surgical risk (26% vs 0%; P = .03). Characteristics that were associated with surgery were sexual activity (81% vs 26%; P = .001), stress incontinence (44% vs 16%; P = .03), stage III-IV posterior vaginal wall prolapse (44% vs 16%; P = .03), and desire for surgery at the first visit (63% vs 12%; P < .001). Age ≥65 years was the best cut-off value for continued pessary use, with sensitivity of 95% (95% CI, 84%, 99%) and a positive predictive value of 87% (95% CI, 74%, 94%). Logistic regression demonstrated that age ≥65 years (P < .001), stage III-IV posterior vaginal wall prolapse (P = .007), and desire for surgery (P = .04) were independent predictors.

Conclusion: Age ≥65 years was associated highly with continued pessary use. Desire for surgery and stage III-IV posterior vaginal wall prolapse were associated with discontinued pessary use and pelvic reconstructive surgery.

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Pelvic organ prolapse is a common condition that affects 30% of women aged 20 to 59 years in Sweden.1 The 2 methods of treatment for symptomatic pelvic organ prolapse are the insertion of a vaginal pessary or pelvic reconstructive surgery. The lifetime risk of surgery for prolapse or urinary incontinence by age 80 years is reported to be 11%,2 and the risk of recurrent pelvic organ prolapse after surgery is at least 10% to 30%.2-4


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Previous studies have shown pessaries to be useful in the treatment of women with pelvic organ prolapse. Wu et al reported that 66% of women who were satisfied with a pessary after 1 month continued to use a pessary at 1 year. However, there is minimal data regarding patient characteristics that are associated with the continued use of a pessary or the decision to undergo surgery. Common reasons that are listed for discontinued pessary use after successful pessary fitting include urinary incontinence, prolapse around the pessary, pelvic pain, vaginal discharge, and vaginal erosions. In our practice, all women who discontinued the use of their pessary before 1 year were excluded if they were lost to follow-up or if they underwent pelvic reconstructive surgery. Women who changed the pessary themselves were excluded. Women who changed the pessary were divided into 2 groups: women who continued to use their pessary after 1 year and underwent pelvic reconstructive surgery. Women were also asked whether they had any pain, expulsion, bleeding, or difficulty with defecation that was associated with the pessary. The pessary was removed and cleaned, and the vagina was examined. After 2 months, 67 of 73 women (92%) with a successful pessary fitting trial were satisfied. Nearly all prolapse symptoms resolved after 2 months, and 50% of urinary symptoms improved. However, occult (de novo) stress incontinence was reported by 21% of women who did not have stress incontinence initially and was associated with patient dissatisfaction. These 67 women represent the cohort for this study. Women who changed the pessary themselves returned for follow-up examination every 6 to 12 months; otherwise, they returned for follow-up every 2 to 3 months.

The 67 women who were satisfied with their pessary after 2 months of use were evaluated at 1 year. The women were divided into 2 groups: women who continued to use a pessary after 1 year and women who discontinued the use of their pessary before 1 year and underwent pelvic reconstructive surgery. Women were excluded if they were lost to follow-up or if they discontinued the use of their pessary without undergoing pelvic reconstructive surgery. Demographic data, clinical symptoms, comorbidities, and physical examination findings were summarized with means, medians, and percentiles, which then were compared between the 2 groups. The 2-sample t test was used to compare continuous variables; the Wilcoxon rank-sum test was used to compare ordinal variables, and the chi-squared test (or Fisher’s exact test) was used to compare categorical variables between the 2 groups. Univariate analysis was performed to calculate odds ratios (ORs) for variables that were associated with continued

Methods

Between March 2001 and August 2003, a prospective, observational study that was approved by our Institutional Review Board was conducted. Initially, 100 consecutive women with symptomatic pelvic organ prolapse, stage 2 or greater, were offered a pessary; 73 women had a successful pessary fitting trial. After 2 months, 67 women were satisfied with their pessary and represent the cohort for this study.

Baseline demographic data, clinical history, comorbidities, and sexual activity were recorded. Women were considered poor surgical candidates if they had severe comorbidities (severe cardiovascular disease, severe osteoporosis with multiple compression fractures, steroid-dependent chronic obstructive pulmonary disease, or dementia). Pelvic prolapse symptoms (bulge, pressure, spincting, and vaginal discharge) and urinary symptoms (stress incontinence, urge incontinence, and voiding difficulty) were assessed at baseline and at 2 months to identify changes that were the result of pessary use. Women were asked whether they intended to undergo pelvic reconstructive surgery.

All the women were examined, and pelvic prolapse was staged with the pelvic organ prolapse quantification system. Methods, definitions, and descriptions conform to the standards that are recommended by the International Continence Society. The women were examined on a standard pelvic examination table in the dorsal lithotomy position. All examinations were performed with an empty bladder, after a catheterization for a postvoid urine residual. A split speculum examination was used to stage the prolapse.

As reported in our previous fitting trial, 100 women were fitted with either a ring (with diaphragm) or a Gellhorn pessary (Milex, Chicago, Ill) and returned back and v...
pessary use or surgery. A receiver-operator characteristic curve was calculated to identify the best cut-off value for age as a predictor for continued pessary use. Forward stepwise logistic regression was performed to identify independent predictors of continued pessary use or surgery. Spearman’s correlation coefficients were calculated to identify correlated variables. Life-table analysis was used to calculate a Kaplan-Meier curve for continued use of a pessary in this cohort. Probability values of < .05 were considered statistically significant. All statistical methods were performed with the SAS software package (SAS Institute Inc, Cary, NC).

Results

The mean age of the 67 women who were satisfied with pessary use at 2 months was 71 years (range, 40-92 years); mean parity was 3.3 (range, 0-12); 91% of the women were white; 90% of the women had experienced menopause; 33% of the women were undergoing estrogen replacement therapy; 49% of the women had had a hysterectomy; 42% of the women had had pelvic reconstructive surgery; 40% of the women were sexually active, and 25% of the women desired surgery at the initial visit when the pessary was fitted. Eleven women (16%) were considered poor surgical candidates because of ≥1 of the following severe comorbidities: severe cardiovascular disease (4 women), severe osteoporosis with multiple compression fractures (3 women), steroid-dependent chronic obstructive pulmonary disease (3 women), and dementia (4 women). On pelvic organ prolapse quantification system staging, 25% of the women had stage II prolapse; 60% of the women had stage III prolapse, and 15% of the women had stage IV prolapse. The median prolapse stages for each compartment were stage III anterior vaginal wall prolapse (range I-IV), stage II posterior vaginal wall prolapse (range I-IV), and stage II vault/uterine prolapse (range I-IV).

Fifty-nine of the 67 women were available for follow-up after 1 year. Forty-three women (73%) continued their pessary use for at least 1 year. Sixteen women (27%) discontinued pessary use before 1 year and underwent pelvic reconstructive surgery; these 16 women used their pessary for a mean of 5.9 months (range, 2.5-12 months) before surgery. Eight women were excluded because 1 woman died, 5 women were lost to follow-up (they returned to their out-of-state referral physicians), and 2 women discontinued their pessary without undergoing surgery. There were no differences in demographics between the group of women who were lost to follow-up and the group of women with 1 year of follow-up.

Demographic data for the women who continued pessary use or underwent surgery are listed in Table I. After univariate analysis, older age was associated with continued pessary use (mean, 76 years vs 61 years; OR, 1.14 per increasing year; 95% CI, 1.05, 1.22; P < .001). However, women who were sexually active (81% vs 26%; OR, 12.6; 95% CI, 3.0, 52.7; P < .001) or desired surgery at their initial visit when the pessary was fitted (63% vs 12%; OR, 12.7; 95% CI, 3.2, 50.2; P < .001) were more likely to continue their pessary (26% vs 0%; P = .03). However, the stage of prolapse of the anterior vaginal wall or vaginal apex was not associated with either group. Neither the ring nor the Gellhorn pessary was associated with continued pessary use or surgery. However, the Gellhorn pessary was associated with continued pessary use in the 14 women with stage III or IV posterior vaginal wall prolapse: 6 of the 7 women who continued the use of the pessary used a Gellhorn pessary, whereas all 7 of the women who discontinued the use of the pessary used a ring (P = .005). Therefore, space-occupying pessaries were more successful in this subgroup.

Neither urge incontinence nor voiding difficulty was associated with either group, but women with persistent or occult stress incontinence underwent surgery more

<table>
<thead>
<tr>
<th>Table I</th>
<th>Demographics of women who continued pessary use compared with women who underwent pelvic reconstructive surgery</th>
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<tbody>
<tr>
<td>Demographic</td>
<td>Continued pessary use (n = 43)</td>
</tr>
<tr>
<td>Age (y) *</td>
<td>76 (40-92)</td>
</tr>
<tr>
<td>Parity (n)</td>
<td>3.6 (0-12)</td>
</tr>
<tr>
<td>White race (n)</td>
<td>38 (88%)</td>
</tr>
<tr>
<td>Sexually active (n)</td>
<td>11 (26%)</td>
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<tr>
<td>Desired surgery at first visit (n)</td>
<td>5 (12%)</td>
</tr>
<tr>
<td>Able to change pessary (n)</td>
<td>12 (28%)</td>
</tr>
<tr>
<td>Hysterectomy (n)</td>
<td>21 (49%)</td>
</tr>
<tr>
<td>Previous prolapse surgery (n)</td>
<td>18 (35%)</td>
</tr>
</tbody>
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* Data are given as mean (range).
† Two-sample t test.
‡ Fisher’s exact test.
§ Chi-squared test.
often (44% vs 16%; OR, 4.0; 95% CI, 1.1, 14.3; \( P = .03 \)). Seventeen women had stress incontinence at baseline, before the insertion of the pessary. At 2 months, stress incontinence resolved in 8 women and persisted in 9 women. Of the 8 women whose stress incontinence resolved with pessary use, only 1 woman (13%) underwent surgery. Four of the 9 women (44%) whose stress incontinence persisted (despite the use of the pessary) and 3 of 5 women (60%) who had occult stress incontinence underwent surgery. However, the sample size was too small for meaningful analysis of the association between a change in stress incontinence symptoms and continued pessary use.

A receiver-operator characteristic curve was calculated for age (Figure 1) to identify the best cut-off value for continued pessary use. Age \( \leq 65 \) years was the best cut-off value for continued pessary use (sensitivity, 95% [95% CI, 84%, 99%]; specificity, 63% [95% CI, 39%, 82%]; positive predictive value, 87% [95% CI, 74%, 94%]; negative predictive value, 83% [95% CI, 54%, 97%]).

Forward stepwise logistic regression demonstrated that age \( < 65 \) years (\( P < .001 \)), stage III or IV posterior vaginal wall prolapse (\( P = .007 \)), and desire for surgery at the first visit (\( P = .04 \)) were independent predictors for discontinued pessary use and surgery. Sexual activity was not an independent risk factor, because it was strongly correlated negatively with age (\( r = -0.62; \ P < .001 \)) and positively correlated with desire for surgery (\( r = 0.55; \ P < .001 \)). Similarly, being a poor surgical candidate was not an independent risk factor, because it was correlated positively with age (\( r = 0.32; \ P = .01 \)) and correlated negatively with desire for surgery (\( r = -0.28; \ P = .03 \)).

Substitution of age (a continuous variable) into the aforementioned logistic regression in place of age \( \leq 65 \) years (a dichotomous variable) shows how strong a predictor of continued pessary use that age was. Among women without stage III or IV posterior vaginal wall prolapse who did not desire surgery at the first visit, only 15% at age 40 years would be predicted to continue pessary use, compared with 58% at age 50 years, 92% at age 60 years, and 99% at age \( \geq 70 \) years.

Life-table analysis of the 67 women who were satisfied with pessary use at 2 months demonstrated that the cumulative probability of continued pessary use was 0.72 (95% CI, 0.58, 0.82) at 1 year and 0.64 (95% CI, 0.45, 0.79) at 2 years. A Kaplan-Meier survival curve for continued pessary use is given in Figure 2.

Vaginal erosions developed in 2 women, which resolved with daily vaginal estrogen cream. They continued the use of the pessary. No other complications were noted.

**Comment**

Our study showed that advanced age was associated with the continued use of a pessary for 1 year, whereas
stage III or IV posterior vaginal wall prolapse and desire for surgery at the first visit were associated with discontinued pessary use and pelvic reconstructive surgery. Research that identifies the characteristics that are associated with continued pessary use in women with prolapse is needed to design clinical trials that compare the use of pessaries with surgery.

Previous studies have shown pessaries to be useful in the treatment of women with pelvic organ prolapse, but no studies have compared pessaries with pelvic reconstructive surgery for the treatment of these women (Medline search, 1965-2003). If a clinical trial is designed to compare pessaries with pelvic reconstructive surgery for the treatment of pelvic organ prolapse, it may be necessary to exclude women who express a desire for surgery at the first visit or who have stage III or IV posterior vaginal wall prolapse. Heit et al reported that, in women with pelvic organ prolapse, increasing age and decreasing prolapse severity were associated with the choice of treatment with a pessary, whereas previous prolapse surgery was associated with the choice of treatment with surgery. However, in their study, choices were made at the woman's first visit, after counseling by the physician; in our study, the women made their choice after at least 2 months of satisfactory pessary use.

Age was the strongest predictor in our study, according to the logistic regression model. Every 10 years of increase in age was associated with a 20% to 40% increase in continued pessary use, which makes age an easily assessed predictor for continued pessary use in women who are fitted successfully with a pessary for pelvic organ prolapse. In our study population, age \( \geq 65 \) years was the best cut-off value for continued pessary use (sensitivity, 95%; specificity, 63%; positive predictive value, 87%; negative predictive value, 83%). Although identified as a risk factor in the univariate analysis, being a poor surgical candidate because of severe comorbidity was not an independent risk factor, because of its correlation with age. Women who are poor surgical candidates might not have the option to undergo surgery because of their health, but we included this variable to see whether it influenced continued pessary use. Sexual activity also did not remain an independent risk factor because of its strong correlation with age.

Stage III or IV posterior vaginal wall prolapse was associated with discontinued pessary use and the choice to undergo surgery. Women with advanced posterior vaginal wall prolapse may experience less symptomatic relief with pessaries than women with advanced apical or anterior vaginal wall prolapse, because the more distal location of most rectoceles may be less well supported than the more apical location of most cystoceles and vault prolapse. Of note, the Gellhorn pessary was more successful than the ring pessary in the treatment of women with stage III or IV posterior vaginal wall prolapse.

We did not find an association of anterior or apical vaginal wall prolapse with continued pessary use. These results differ from a retrospective study by Sulak et al, who reported greater continued pessary use in women with greater pelvic support loss. Pelvic support loss was defined in their study as the sum of the prolapse grades (range 0-4) from 4 sites: cystocele, rectocele, cervix or vaginal cuff, and cul de sac. We evaluated this concept by summing the stages of prolapse (range 0-4) for the 3 vaginal wall compartments: anterior, posterior, and apical. However, we did not find an association between the sum of the stages of these 3 compartments and continued pessary use. Further research into this discrepancy is warranted.

Desire for surgery at the time the pessary was fitted was also associated with discontinued use of the pessary and the choice to undergo pelvic reconstructive surgery. However, one third of the women who initially desired surgery changed their mind and continued to use their pessary, which suggests that perhaps all women with prolapse should be offered nonsurgical treatment. Therefore, a pessary trial may be warranted, even in women who express a desire for surgery. Additionally, a pessary trial may help to unmask occult stress incontinence before a planned pelvic reconstructive surgery.

Although it was not identified as an independent risk factor for discontinued pessary use by logistic regression, our study identified a trend that more women with persistent or occult stress incontinence discontinue their pessary than do women without stress incontinence (44% vs 16%; \( P = .03 \)). Our study was limited because of the small sample size.

In this study, life-table analysis demonstrated that 72% of women who were satisfied with their pessary after 2 months continued to use their pessary for 1 year.
and that 64% of these women continued to use their pessary for 2 years. These results are very similar to those reported by Wu et al.\(^5\) In their prospective study, life-table analysis showed that 66% and 64% of women who were satisfied with their pessary after 1 month of use continued to use the pessary at 1 and two years, respectively. From our original cohort of 100 women, of which 27 women were unable to be fitted with a pessary and 73 women were fitted successfully, approximately 30% to 40% of the women had surgery; 20% of the women opted for no treatment, and 40% to 50% of the women continued pessary use.

Because our study has shown age to be an important determinant in continued pessary use, future randomized controlled trials that compare pessary use with surgery ideally would recruit older women, because they might be less likely to withdraw from the pessary arm of the study and choose to undergo surgery. However, although this would decrease bias in favor of surgery, the exclusion of younger women would narrow the external validity of such a study to older women only. The information gained from our study on characteristics that are predictive of continued pessary use can be helpful in the design of future trials to further evaluate the treatment of pelvic organ prolapse.

References