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Changes in the symptoms and quality of life of women with symptomatic pelvic organ prolapse fitted with a ring with support pessary

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ABSTRACT

Objectives: The study aim was to assess the effect of treatment with a ring with support pessary on bothersome symptoms and the quality of life of patients with symptomatic pelvic organ prolapse (POP).
Study design: In this prospective observational study, 142 patients with symptomatic POP were successfully fitted with a ring with support pessary between November 2015 and November 2016 and followed up until December 2017. Prolapse and urinary symptoms were assessed, and the Pelvic Floor Distress Inventory-20 (PFDI-20) and Pelvic Floor Impact Questionnaire-7 (PFIQ-7) were administered at baseline and at each follow-up visit. Univariate analyses, McNemar's test and paired t-tests were used for data analyses.
Main outcome measures: Changes in prolapse and urinary symptoms and quality of life after fitting with a ring with support pessary use.
Results: The median (range) duration of follow-up was 17 (13–24) months. At the study endpoint, 98 patients (74.8%) continued to use the pessaries. Wider vaginal introitus (≥5 cm) was found to be a predictor of pessary discontinuation. Although de novo stress urinary incontinence occurred in 27.1% of patients, almost all prolapse symptoms and most of the concurrent urinary symptoms were resolved, with voiding difficulty resolved most significantly. Scores on both the PFIQ-7 and PFDI-20 had significantly improved at the study endpoint, with changes in scores on the urinary and prolapse sub-scales of both questionnaires demonstrating clinical significance (effect size > 0.5).
Conclusions: A ring with support pessary is a safe and effective conservative treatment for POP; it not only relieves bothersome prolapse and urinary symptoms but also significantly decreases their impacts on health-related quality of life. However, the method has a limited effect on defecatory symptoms.

1. Introduction

Pelvic organ prolapse (POP) is a common medical condition. Although POP rarely causes severe morbidity or mortality, it can decrease the patient's quality of life due to lower genital, urinary, and gastrointestinal tract symptoms [1]. The prevalence of symptomatic POP has been reported to range from 4.3 to 8.3% [2,3] and estimated to continue increasing as the population ages. The vaginal pessary is a noninvasive treatment for POP and has been widely used. Seventy-five percent of specialist clinicians in the United States offer a pessary as the first-line treatment for symptomatic prolapse [4].

Unlike the methods used to treat life-threatening disease, the treatment of POP aims to relieve specific aspects of pelvic floor dysfunction, including urinary, prolapse, and defecatory symptoms, and to improve the quality of life of patients. Vaginal bulge, pelvic pressure, vaginal splinting, urinary incontinence, dysuresia and constipation are common symptoms related to POP, which can severely affect the quality of life of women. The Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ) are two validated complementary self-administered questionnaires, which together can be used to assess the extent to which all forms of pelvic floor disorders affect health-related quality of life (HRQOL) [5]. Pelvic Floor Distress Inventory-20 and Pelvic Floor Impact Questionnaire-7 are the short versions of the PFDI and PFIQ, respectively, are more practical and have been validated for use in women with POP [6].

The use of a pessary for 3–12 months can not only reduce bothersome symptoms but also improve the quality of life of patients with symptomatic POP [7–12]. However, the studies of longer-term pessary use are limited and have mainly focused on the continuation rate and adverse events associated with vaginal pessary use [13,14], with

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minimal data on symptom relief or quality-of-life improvement [15].

The pessary can be categorized into two types, namely, support and space-filling. The ring pessary is the most commonly used support type and is easy to insert and remove. The ring pessary can be successfully fitted at different stages of prolapse and has been proposed as the first-choice treatment for POP [1,16]. Thus, we focused on the changes in bothersome symptoms and the quality of life of patients with symptomatic POP after longer-term use of the ring with support pessary.

2. Methods

2.1. Study participants

This was a prospective observational study. Between November 2015 and November 2016, patients with symptomatic POP came to the Department of Obstetrics and Gynaecology, Peking Union Medical College Hospital (PUMCH), Beijing, for POP treatment. Three treatment options were offered to the patients, namely, pelvic muscle exercises, pessary use, and surgery. Vaginal pessaries were mainly offered to patients who were poor candidates for surgery or who were not keen on undergoing surgery and who had not yet completed their families. Patients who were successfully fitted with a ring with support pessary were included in this study. Subjects were excluded if they had current genital ulcers or unexplained genital bleeding and if they were mentally or physically incapable of completing the questionnaires or refused to participate in this study. The study was approved by the ethics committee of PUMCH.

2.2. Study design

The demographic data (age, parity, body mass index) and medical history (medical comorbidities, previous surgical history) of patients who received pessary treatment were recorded. Patients were examined by one experienced urogynecologist and staged according to the POP quantification system [17]. The vaginal introitus width was not included in the POP-Q system and was measured according to prior literature [18]. The pessary fitting process was followed as previously described [19]. The ring with support pessary (CooperSurgical, Trumbull, CT, USA) was fitted initially, followed by Gellhorn pessary if the ring pessary failed. At the first visit, the largest pessary that could be successfully retained without discomfort after the patient had ambulated for more than half an hour and after she had performed Valsalva maneuvers in the office was chosen. The patient or her caregiver was taught to manage the pessary. The pessary was recommended to be removed at least once a week for one night of pessary-free rest. We prescribed topical estrogen cream (1 mg/g estriol cream, 0.5 g each time, twice a week) regularly to postmenopausal patients if they had no contraindications. Pessary fitting was successful if patients were comfortable, retained the pessary, and planned to continue pessary use when they returned for the two-week follow-up visit after the initial successful fitting. The type and size of the vaginal pessary inserted were also recorded. Then, the patients were monitored at 3, 6, and 12 months during the first year and at 6-month intervals afterwards. A vaginal examination was performed at each visit. If vaginal ulceration occurred, 2 weeks of pessary-free rest and topical estrogen cream were advised. If patients discontinued the use of the pessaries, the reasons for discontinuation were carefully recorded, and we discussed surgical treatment further with the patients if desired.

In our study, in the continuation group, we evaluated the patients' subjective outcomes using the Patient Global Impression of Change (PGI-C) questionnaire at each follow-up visit; the PGI-C evaluates patient satisfaction using a 5-point Likert scale that ranges from 5 (very satisfied) to 1 (very dissatisfied). Patients were asked questions regarding prolapse and concurrent urinary symptoms at baseline and each visit. Prolapse symptoms included vaginal bulging and pelvic pressure, and we asked the following questions: (1) Do you see or feel a bulge in your vagina? (2) Do you feel pelvic pressure? Urinary symptoms included stress urinary incontinence (SUI), urge urinary incontinence, voiding difficulty and a need for splinting to void. The following questions were asked: (1) Do you leak urine when you cough, laugh, sneeze, or exercise? (2) Do you leak urine when you have the urge to empty your bladder? (3) Do you have to strain to empty your bladder or have difficulty emptying your bladder? (4) Do you need to insert your fingers into your vagina (splint) to void urine? Replies of "never" or "rarely" were recorded as "no", whereas replies of "sometimes," "usually," or "always" were recorded as "yes". The data at baseline and the latest visit were collected to identify the changes in prolapse and concurrent urinary symptoms. All of these questions were asked, and the data were analyzed as we previously described [20].

Patients were administered the PFDI-20 and PFIQ-7 at baseline and each follow-up visit. Both questionnaires contain subscales for urinary, prolapse, and colorectal anal symptoms. Higher scores indicate more dysfunction. In the pessary continuation group, the baseline and latest available questionnaires were used. The minimum clinically important difference (MCID) refers to the smallest change in the score associated with a clinically meaningful change in the quality of life [21]. We defined the MCID of the PFDI-20 and PFIQ-7 as an effects size of 0.5 based on previous studies [22,23].

2.3. Statistical analyses

Independent samples *t*-tests, nonparametric tests and a chi-square test were used to compare the patient characteristics at baseline in the continuation and discontinuation groups to identify the predictors of pessary discontinuation. McNemar's test was used to evaluate prolapse and concurrent urinary symptom changes, while a paired *t*-test was used to compare score changes in each subscale (urinary, prolapse, and colorectal anal) of the PFDI-20 and PFIQ-7 before and after pessary fitting in the pessary continuation group. We performed statistical analyses with SPSS v.24.0 software (IBMCorp, Armonk, NY, USA), and a P value less than 0.05 was considered statistically significant.

3. Results

Between November 2015 and November 2016, 218 patients with symptomatic POP participated in pessary fitting trials, and 186 of these patients had a successful fitting. A total of 142 patients were successfully fitted with the ring with support pessary, and the remaining 44 patients were successfully fitted with a Gellhorn pessary. All of the 142 patients who were successfully fitted with the ring with support pessary were eligible and traced until the study conclusion date of December 2017. Eleven participants were lost to follow-up, so we analyzed the remaining 131 participants. The patient characteristics at baseline both in the continuation and discontinuation groups are presented in Table 1. The mean (SD) ages of the patients in the continuation and discontinuation groups were 68.1 ± 9.5 and 66.4 ± 10.5 years, respectively. The mean (SD) body mass indexes (BMIs) were 24.4 ± 2.9 and 24.5 ± 2.3 kg/m^2 in the two groups, respectively. Nearly all of the patients were postmenopausal, and none of them received hormone therapy (HT). Of the 131 patients analyzed in this study, only 2 (1.5%) were classified as stage II, while the remaining 129 had advanced POP (with 114/131 (87%) classified as stage III and 15/131 (11.5%) classified as stage IV). We found that wider vaginal introitus (≥5 cm) was significantly associated with pessary discontinuation ($P < 0.001$). The pessary sizes that were fitted successfully ranged from size 2 to size 5. Size 3 was the most commonly used size (73/131, 55.7%), followed by size 4 (42/131, 32.1%), size 2 (15/131, 11.5%) and size 5 (1/131, 1%).

Among the 131 participants, 98 (74.8%) continued to use the pessary and 33 ceased pessary use at the study endpoint (shown in Fig. 1). The median (range) duration of follow-up for all 131 patients was 17 (13–24) months. Of the 98 patients who continued to use a pessary at the study endpoint, the median (range) duration of use was 18 (13–24)