Changes of Pelvic Organ Prolapse Symptoms and Quality of Life One Year After Pessary Fitting

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Abstract- Pelvic organ prolapse (POP) is the descend of pelvic organs, including the uterus, bladder, and rectum, to the vaginal wall. Patients with POP may present with symptoms such as vaginal bulging with other symptoms like urinary, defecatory, or sexual dysfunction. This study was conducted to evaluate the changes of POP symptoms one year after pessary fitting. Patients with symptomatic pelvic organ prolapse who presented to the pelvic floor clinic of an academic hospital between August 2016 and April 2019 were considered. Pelvic organ prolapse symptoms, including urinary, defecatory, sexual, and bulging symptoms, were recorded before and one year after pessary fitting. Pelvic floor distress inventory (PFDI)-20 and pelvic floor impact questionnaire-7 (PFIQ-7) were evaluated before and after treatment for all subjects. We analyzed the characteristics of 110 patients who used the pessary for 12 months. At the baseline, the most common prolapse symptoms were vaginal bulging and pelvic pressure. All urinary, defecatory, and sexual symptoms significantly improved one year after regular pessary use (P<0.001). Changes in PFDI-20 and PFIQ-7 before and after pessary use showed a significant improvement in both frequency and satisfaction of sexual function (P<0.001). The study showed significant improvement in bulging, urinary, and defecatory symptoms. Although the majority of patients were not sexually active, a significant proportion of sexually active patients reported an increase in sexual satisfaction.

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Keywords: Pelvic organ prolapse; Pessary; Urinary symptoms; Quality of life

Introduction

Pelvic organ prolapse is the descent of one or more of the anterior vaginal wall, posterior vaginal wall, the uterus (cervix), or the apex of the vagina (vaginal vault or cuff scar after Hysterectomy), The prevalence of POP is about 3-50% depending on the definition used (1). Patients with POP may present with symptoms related specifically to the prolapsed structures, such as vaginal bulging or vaginal pressure, or with other symptoms like urinary, defecatory, or sexual dysfunction, which can negatively impact the quality of life through the mentioned symptoms (2). Treatment is indicated for women with symptoms of prolapse or associated conditions (urinary, defecatory, or sexual dysfunction). Symptomatic patients can be managed expectantly or treated with conservative or surgical therapy. The choice of treatment depends on the patients' preference and ability to comply with conservative therapy or tolerate surgery. The mainstay of non-surgical treatment is the vaginal pessary and should be considered and offered routinely (2). They are silicon devices of different sizes and shapes which support the pelvic organs. Non-surgical management is very useful, especially in

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patients with severe medical conditions that make them a poor surgical candidates. Patient's acceptance of pessary varies from 42 to 100%, which is related to appropriate counseling and encouragement from the provider (3). In fact, there are recent studies that predicted continued pessary use (4,5).

But pessary outcomes to improve POP symptoms are controversial according to the duration of follow-up (6). Moreover, this conservative treatment could have some serious complications without regular follow-up (7).

To the best of our knowledge, there is no similar study in this field in the Iranian population; since there is a growing number of older women with POP symptoms in our country, this study was conducted to evaluate the changes in POP symptoms one year after pessary fitting.

Materials and Methods

Patients with symptomatic vaginal bulging due to pelvic organ prolapse who presented to the pelvic floor clinic of an academic hospital, Tehran University of Medical Sciences, Tehran, Iran, between August 2016 and April 2019 were considered regarding treatment plans. Inclusion criteria were patients who complained of vaginal bulging and pelvic organ prolapse confirmed by physical examination, agreement for using pessary and regular follow-up visits, no vaginal infection or abnormal uterine bleeding, normal pap test, and successful pessary fitting in the first visit.

The study was approved by the Ethics Committee of Tehran University of Medical Sciences (code No IRTUMS.IKHC.REC.1396.2274).

Successful pessary fitting and regular follow-up were accomplished for 137 patients with symptomatic pelvic organ prolapse during the study period. A total number of 7 patients discontinued pessary use which the reasons were pessary extrusion (n=3) and desire for surgical treatment (n=4). Twenty patients were lost to follow-up. So, we analyzed the characteristics of 110 patients who used the pessary for 12 months (Figure 1).

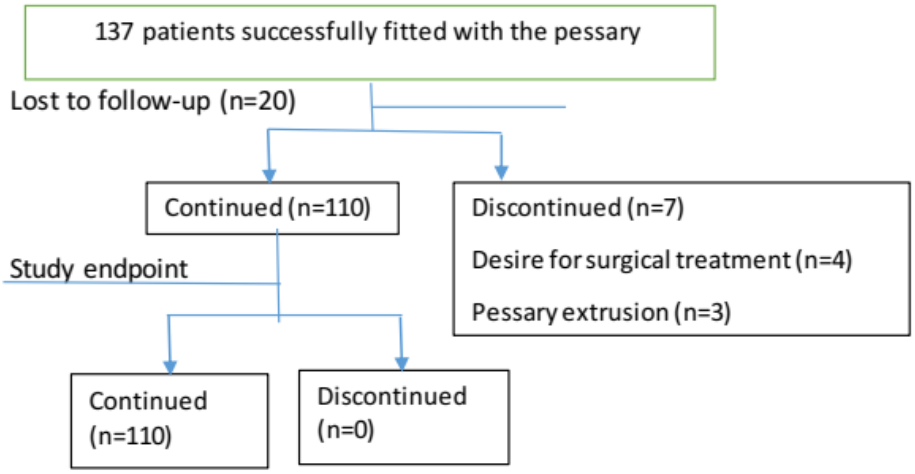

Figure 1. Study fellow chart

Basic characteristics consisted of age, BMI, sexual activity, menopausal status, past surgical history, medical history, and pelvic examination were recorded. The pessary type and size are also mentioned. The stage of prolapse was determined by a pelvic floor specialist according to the POP quantification system (8) at the first visit and one year after regular successful pessary usage. The mean duration of pessary using and follow-up was 24 months (range of 12-36 months).

Pelvic organ prolapse symptoms included urinary, defecatory, sexual, and bulging symptoms were recorded before and one year after pessary fitting. These symptoms consisted of stress and urgency urinary incontinence, incomplete bladder emptying, hesitancy, intermittent voiding, constipation, splinting, incomplete defecation, sexual dissatisfaction due to vaginal pressure or bulging, and finally, vaginal mass protrusion symptoms.

Regular follow-up visits are scheduled after successful pessary fitting. The first visit was two weeks after successful fitting. The second visit was one month later and then every three months. Any complications

like abnormal vaginal discharge, vaginal erosions, vaginal bleeding were recorded. In the case of vaginal erosion or bleeding, the pessary was extracted, and proper evaluation and treatment were performed (vaginal estrogen for vaginal ulceration and erosion, endometrial evaluation for abnormal uterine bleeding). Thereafter, the pessary was inserted if the problem was resolved. The number and the reason for pessary discontinuation also were recorded.

At the first-year visit, the patient was evaluated about urinary, defecatory, sexual, and bulging symptoms. Although pelvic floor distress inventory (PFDI)-20 and pelvic floor impact questionnaire-7 (PFIQ-7) were evaluated before and 12 months after treatment for all subjects by another researcher who was responsible for this part of the research. Both questionnaires contain subscales for urinary, defecatory, and prolapse symptoms. Higher scores indicate more dysfunction. 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 (9). We defined the MCID of the PFDI-20 and PFIQ-7 as an effects size of 0.5 based on previous studies (10,11).

Mean, and standard deviation was used for continuous variables. The change of the status for paired data was assessed by the McNemar test. Paired t-test used for comparison between continuous data before and after treatment. $P \leq 0.05$ is considered statistically significant. SPSS version 23 was used for data analysis.

Results

The patients' basic characteristics are shown in Table 1.

Table 1. Demographic characteristics

Demographic characteristics		Subjects included (n=110)
Age, year (Mean±SD)		69.96±12.8
BMI (kg/m^2) (Mean±SD)		27.8±5.2
Parity, median (range)		5 (5-12)
Prior prolapse surgery, n (%)		18 (16.36)
Menopause, n (%)		107 (97.27)
Medical comorbidities, n (%)	**Hypertension**	45 (40.90)
	Diabetes	11 (10)
	Ischemic heart disease	21 (19.9)
Level of literacy	**Illiterate**	20
	Elementary school	55
	High school	25
	University	10

In terms of anterior compartment prolapse, five patients (4.5%) had stage I, 19 (17.1%) stage II, 72 (64.9%) stage III and 14 (12.6%) stage IV. About posterior compartment prolapse, 24 patients (21.6%) had stage I, 56 (50.5%) stage II, 27 (24.3%) stage III, 3 (2.7%) stage IV. Considering apical compartment prolapse, 9 patients (8.1%) had stage I, 24 (21.6%) stage II, 56 (50.5%) stage III and 20 (18%) stage IV.

The most common pessary type used was a ring with support (n=80), and other types were Gelhorn (n=22) and donut (n=8); in fact, 80 cases (72.72%) used supportive pessary, and 30 patients (27.28%) used space-occupying pessary.

According to the pessary size; size number 3 (n=10), number 4 (n=45), number 5 (n=30), and number 6 (n=25) were used. Most of the patients couldn't manage pessary by themselves (n=107).

The mean duration of pessary using and follow-up was 24 months (range of 12-36 months).

At the baseline, the most common prolapse symptoms were vaginal bulging and pelvic pressure. Other urinary and defecatory symptoms and sexual satisfaction before and after pessary insertion are shown in Table 2.

Changes in PFDI-20 and PFIQ-7 before and after pessary use are shown in Table 3.

Table 2. Changes in prolapse and urinary symptoms from baseline to the study endpoint in women who continued to use the pessaries (n=110)

Symptom	Baseline	Study endpoint (n)		95% Confidence Interval	*P**
		No	Yes		
Vaginal Bulging	No 10	10	0	1.14-2.2	<0.001
	Yes 100	95	5		
Vaginal Pressure	No 25	25	0	1.71-2.6	<0.001
	Yes 85	65	20		
SUI	No 78	78	0	2.6-2.9	<0.001
	Yes 32	12	22		
UUI	No 53	53	0	1.9-2.3	<0.001
	Yes 57	30	27		
Voiding difficulty	No 54	54	0	1.8-2.1	<0.001
	Yes 56	20	36		
Splinting	No 90	90	0	1.67-3.20	<0.001
	Yes 20	15	5		
Rectal digitation	No 80	80	0	1.20-2.00	<0.001
	Yes 30	18	12		
Incomplete defecation	No 84	84	0	1.36-2.00	<0.001
	Yes 26	14	12		
Sexual dissatisfaction	No 20	20	0	1.16-2.1	<0.001
	Yes 12	11	1		

SUI: stress urinary incontinence; UUI: urge urinary incontinence
*McNemar test

Table 3. Changes in the PFDI-20 and PFIQ-7 before and after pessary use in women who continued pessary use

Measure/scale	Mean change in score (SD)[a]	95% Confidence Interval	P[b]
PFIQ-7	-38.5 (58.4)	2.40-3.10	<0.001
UIQ-7	-15.6 (21.7)	1.64-2.15	<0.001
CARIQ-7	-4.7 (18.3)	1.92-2.9	0.004
POPIQ-7	-18.8 (24.0)	2.60-2.90	<0.001
PFDI-20	-48.4 (52.0)	2.84-3.11	<0.001
POPDI-6	-26.2 (24.8)	1.46-1.89	<0.001
CRADI-8	-6.7 (16.5)	2.68-2.98	<0.001
UDI-6	-11.5 (17.3)	3.54-3.98	<0.001

SD: standard deviation
aA negative change in the score indicates improvement
b paired t-test

Discussion

The results of the current study showed a statistically significant improvement in mass protrusion symptoms and urinary and defecatory symptoms. Although the majority of patients were not sexually active, a significant proportion of sexually active patients reported an increase in both frequency and sexual satisfaction.

These optimizing results are inconsistent with some previous studies (6,12). Moreover, the current study also evaluated sexual function before and after successful pessary use with a higher sample size which didn't mention in those studies. This shortage of previous studies may be due to the short follow-up duration (3 and 12 months, respectively).

In this study, all types of urinary incontinence symptoms improved. However, SUI can be masked in severe cytstocele due to urethral kinking, and so de novo SUI symptoms may occur after pessary use, but it didn't happen in the current study. This finding is in contrast with some previous studies (6,12). In fact, there are some previous studies that reported 27-28% de novo SUI after using ring and ring with support pessaries, although this symptom was mild and there was no need for pessary discontinuation due to this symptom (6,12). This difference in the current study and the noted previous studies may be due to lower POP stages and using different pessary types in our study compared to other studies.

The symptoms of bladder overactivity (urinary urgency with or without frequency, nocturia, or urgency

incontinence) also improved, which may emphasize the effect of pop on the development of overactive bladder syndrome. Pelvic organ prolapse is known to be associated with anatomical distortion of the urethra and may cause voiding dysfunction. Moreover, it could increase the maximum urethral closure pressure and progressive decline in flow rates with increasing the pelvic organ prolapse stages, so the improvement in voiding symptoms with pessary use may be explained by restoration of the bladder and urethral anatomy (13).

Incomplete defecation and splinting as the symptoms of defecatory dysfunction were associated with pessary discontinuation, especially in younger women (14).

In the current study, improvement of these defecatory symptoms may be due to lower stage of posterior compartment prolapse and improvement of the quality of life after pessary use which let the patients return to normal physical activity. Defecatory dysfunction symptom has many different causes, which may compromise the resolution of the symptoms by just restoring the prolapse (6). As chronic neglected POP can lead to Neurological Defectory dysfunction, it would be difficult to specify that defecatory problem is due to fecal entrapment or neurological disruption, which was one of the limitations in the current study.

Although in the current study, a small number of participants were sexually active (n=32), but the results showed significant improvement in sexual satisfaction (Table 2).

The bothersome symptoms of POP can adversely impact patients' daily activities and quality of life. Thus, when evaluating the changes in patients' symptoms after using a pessary, it might be prudent to measure the changes in quality of life. The PFDI-20 and PFIQ-7 assess the severity and the impact of POP symptoms on daily activities, social, emotional, and physical aspects.

In the current study, the PFDI-20 and PFIQ-7 scores improved significantly after pessary use. This result is consistent with some previous studies (6,15,16). These findings confirmed the positive effects of pessary not only on physical distress but also could improve the quality of life.

One of the strengths of the current study was a long-term follow-up that, to the best of our knowledge, is the one with the longest follow-up duration in the Iranian population in this field. Another strength is collecting the standard questionnaires both at baseline and after pessary use. Performing the precise analysis of changes in all urinary, defecatory symptoms, and sexual satisfaction is the other strength of the current study. One of the limitations of the current study was the lack of neurological assessment in the patients that could reveal the more accurate or other causes of the pop symptoms. Another limitation was the lack of sexual function assessment by a standard questionnaire like the Female Sexual Function Index questionnaire (FSFI), which was previously used for the assessment of sexual function in female patients (17).

The results of this study showed a significant improvement in bulging, urinary, and defecatory symptoms. Although the majority of patients were not sexually active, a significant proportion of sexually active patients reported an increase in sexual satisfaction.

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