

Use of Silicon Vaginal Pessary for Treatment of Pelvic Organ Prolapse

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Abstract

Background : Use of vaginal pessary as a conservative therapy for pelvic organ prolapse is very common and upto 77% of clinicians uses ring pessary for 1st line management of prolapse. Aim to treat prolapse by conservative approach is to alleviate the symptoms of prolapse and avert or delay the need for surgery. Aim of this study was to find out improvements of symptoms related to pelvic organ prolapse and satisfaction rate after 3 months of using vaginal pessary.

Materials and methods : A prospective observational study was conducted from January 2019 –to June 2019 in the Department of Gynaecology and Obstetrics of Bangabandhu Memorial Hospital, Chattogram. Total 31 patients were included with symptomatic Pelvic Organ Prolapse (POP) willing to use pessary . Primary outcome were improvement of symptoms and their satisfaction from baseline to 3 months.

Results : Age of the respondents were between 25-80 years with a mean of 50(+-12) years, maximum respondents were postmenopausal 54.8% .Out of 31 respondents 27(87.1%) continue pessary use upto 3 months and their after, 2(6.5%) cases spontaneous expulsion took place, 2(6.5%) discontinue the use. Compare with base line findings significant improvement in patients symptoms were observed at 3 months. Nearly all symptoms related to pelvic organ prolapse resolved from baseline to to 3 months: buldge (92.3% to 7.7% , p < 0.001), dragging pain in lower abdomen (100% to 14.8% , p<0.001). Urinary symptoms voiding difficulty improved in 88% (p<0.001), urinary urgency improved in 81.8% (p<0.001), urge and stress incontinence improved in 100% (p<0.001). Incomplete emptying of bowel improved in 100%(p<0.001). During follow up 4(12.9%) women complain of vaginal discharge. At 3months 88.9% women were satisfied with pessary and 3(11.1%) were dissatisfied.

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Conclusion : This study showed that treatment with use of ring pessary in women with pelvic organ prolapse had significant improvements in the symptoms with high satisfaction rate.

Key words: Conservative treatment; Pelvic organ prolapse; Vaginal ring pessary.

Introduction

Pelvic organ prolapse refers to loss of support for the pelvic organ like bladder ,uterus, bowel and their descent into or through the introitus. International Urogynaecological Association (IUGA) and International Continence Society (ICS) jointly report on the terminology as Pelvic Floor Dysfunction.¹ Incidence of prolapse varies, 26-40% in community based population study.² Etiology is multifactorial. Vaginal birth, life style, socioeconomic factors which expose women to raised intra abdominal pressure such as chronic cough, constipation, obesity, lifting heavy weight, prolonged standing and increasing age.³ Common treatment option for pelvic organ prolapse are surgery, vaginal pessary and pelvic muscle exercise.⁴ A pessary is a device inserted into the vagina to support the walls and related pelvic organ.⁵ Initialpessary were rubber or plastic madebut modern pessary are silicon made, which has long half life, and resistant to autoclaving and repeated cleaning. Silicon also has nonabsorbent properties, in relation to secretions and orders, it is inert and hypoallergenic.⁶ Pessary are considered to be a relatively safe method of managing pelvic organ prolapse with out serious side effects.⁷ In areas of high parity and little and or no access to health care, countless women, suffer from problems associated with pelvic organ prolapse with no real possibility of resolution.⁸ Vaginal pessary provide a simple, inexpensive, and noninvasive treatment option for these patients. 85% Gynaecologist and 98% Urogynaecologist prescribe pessaries for these women.⁹ To find out outcome of using vaginal pessary in pelvic organ prolapse, causes of prolapse, improvement and patients satisfaction after using pessaries in pelvic organ prolapse.

Materials and methods:

A prospective observational study was carried out at the Department of Gynaecology and Obstetrics, Bangabandhu Memorial Hospital IAHS, Chattogram during the period of January 2019 to June 2019, at Outpatient Department presented with symptomatic pelvic organ prolapse, and who are willing to use pessary for treatment of prolapse, after fulfilling the inclusion and exclusion criteria. A total 31 patients were selected for treatment of prolapse by pessaries.

Inclusion criteria

- Symptomatic pelvic organ prolapse willing to use pessaries, provided informed written consent
- Pregnancy with prolapse.
- Pelvic organ prolapse during puerperium.
- Patients unfit for surgical treatment.

Exclusion criteria

- Presence of vaginal infection / ulcer.
- Pelvic inflammatory disease.
- History of previous surgery for prolapse.
- Previous use of pessaries, allergy to the element of pessary.

The study was performed after taking approval from the Ethical Committee, all the patients were assessed by demographic data, symptoms of pelvic organ prolapse, medical and other gynaecological history were recorded. All patients were examined after empty the bladder, in dorsal position, with straining during valsalvmanoeuvre. The vaginal pessary option were discussed with all participants. Patients who intend to use the pessaries, appropriate sized vaginal ring pessaries were fitted at vault of vagina. Patient were asked to come for followup after 3 months. During follow up patient were asked about symptoms related to prolapse, satisfaction. Side effects from use of pessaries including pain, slipping of pessaries, vaginal bleeding, discharge, foul odour, pruritis, difficulties during voiding and defecation. The pessary was removed, the cleaned and vagina was examined for erosion. A total 31 patients were included in this study. Vaginal pessary is a soft, removable device that when inserted into vagina will support areas that are affected by pelvic organ prolapse. Among different type of pessaries like Ring, Gellhorn, Cube, ring pessaries made of silicon are harmless,

soft and nonabsorbent material.¹⁰ Successful fitting was defined as a comfortable fitting at the initial visit, which continue upto 3 months followup visit. Persistent inability to retain a pessaries, or need for removal due to pain, discomfort or bleeding within 12 weeks was considered as unsuccessful fitting.

Results

Age of the respondents were between 25-80 years with a mean of 50 (+12) years, maximum of the respondents were post – menopausal (54.8%). Only 19.4% were below 40 years of age. About 93.5% women were housewife, 61.4% from lower middle class, 16.1% from upper middle class, 6.4% from rich family. About 45.2% had school education, 41.9% had no formal education, 12.9% had college education. 83.9% participant came from rural area, 16.1% from urban residence (Table I).

Table I Distribution of patient according to age, occupation, educational level, economic status and area of residence

Age	No	Percentage
< 40 year	06	19.4%
41-50 years	08	25.8%
≥ 50 years	17	54.8 %
Occupation	No	Percentage
Housewife	29	93.5%
Others	02	6.5 %
Socio economic status	No	Percentage
Poor	05	16.1%
Lower middle class	19	61.4%
Upper middle class	05	16.1%
Rich	02	6.4%
Educational level	No	Percentage
No formal education	13	41.9%
School education	14	45.2%
College education	04	12.9%
Place of residence	No	Percentage
Rural	26	83.9%
Urban	05	16.1%

Clinical presentations of the respondents revealed median parity of the women were 4, median number of vaginal delivery were 3. Only 9.7% of the women had history of caesarean section. But 29% had history of obstructed labour and difficult labour. BMI was within normal range in majority of the patients. 9.7% patients had H/O asthma (Table II).

Table II Clinical characteristics of the respondents

Variables (Units)	Frequency (%) / Median(IQR)
Para	4(2-6)
No of vaginal deliveries	3(1-4)
H/O cesarean section	03(9.7%)
H/O of obstructed labour /difficult labour	9(29%)
Diabetesmellitus	05(16.1%)
Hypertension	07(22.6%)
Asthma/COPD	03(9.7%)
Body mass index (kg/m ²)	22 (19.5-24)

Represent different types prolapse .Majority of about 24(77.4%) women had 2nd degree POP, 5(16.1%) women had 3rd degree prolapse, only 6.5%(02) had 1st degree POP (Figure 1).

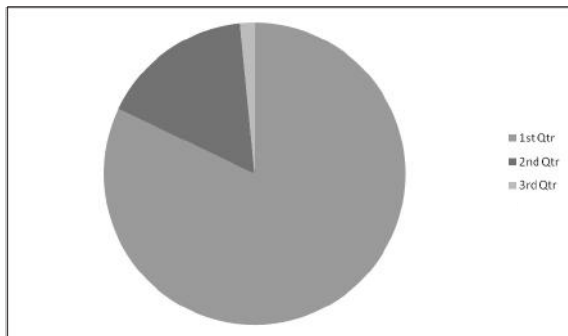


Figure 1 Showing type of POP among women included in this study

Outcome of treatment of prolapse by using pessary after 3 months, majority 27(87.1%) retained pessary. Discontinuation of pessary in 4 cases (12.9%) was due to vaginal discharge, pain and discomfort. Among complications of using pessary vaginal discharge was about 12.9% (Table III).

Table III Outcome of pessary use after 3 months in Pelvic organ prolapse

Out come	Frequency (%)
Successful fitting	27(87.1%)
Discontinue use	4(12.9%)
Spontaneous expulsion	00%
Complications	04(12.9%)
Complications	
Vaginal discharge	02 (50.0%)
Pain / Discomfort	02 (50.0%)
Urinary retention	00
Vaginal bleeding	00
Surgery needed	00

Outcome of treatment by assessing improvement of symptoms. Most of the patients presented with significant improvement of prolapse symptoms among the women with successful fitting of pessary in about 100% (27) cases. Only vaginal

discharge increased from baseline to 3 months after pessary use, but it was not statically significant. Regarding urinary symptoms like voiding difficulty, urgency, urge incontinence, stress incontinence were significantly reduced by using pessary. Among studied women defaecatory symptoms were like incomplete emptying of bowel and push prolapse to defecate improved in all reported cases after 3 months of the pessary use (Table IV).

Table IV Shows outcome of prolapse symptoms after treatment by using pessary after 3 months

Prolapse symptoms	Number (%) Base line	Number (%) At 3 months	p value
Awareness of lump	27(100%)	06(37.0%)	<0.001
Vaginal discharge	5(18.5%)	02(7.4%)	0.087
Mass coming out of vagina	26(92.3%)	00	<0.001
Dragging pain in lower abdomen	27(100%)	04(14.8%)	<0.001
Low back pain	8(29.6%)	2(7.4%)	<0.001
Urinary symptoms	Improved	Persist	
Voiding difficulty (n=25)	22(88.0%)	3(12.0%)	<0.001
Urinary urgency (n=11)	9(81.8%)	02(18.2%)	<0.001
Urge incontinence (n=5)	5(100%)	0	<0.001
Stress incontinence (n=4)	4(100%)	0	<0.001
Push prolapse to void (n=18)	15(83.3%)	03(16.7%)	<0.001
Defecation symptoms			
Incomplete emptying of bowel (n=5)	05(100%)	0	
Push prolapse to defecate (n=5)	05(100%)	0	

Satisfaction of patients after use of vaginal pessary, among 27 women, who were fitted successfully with a pessary. After 3 months, majority 24(88.9%) of the women were satisfied with successful fitting of pessary. Only 3(11.1%) of them were not satisfied for persistence of symptoms (Fig 2).

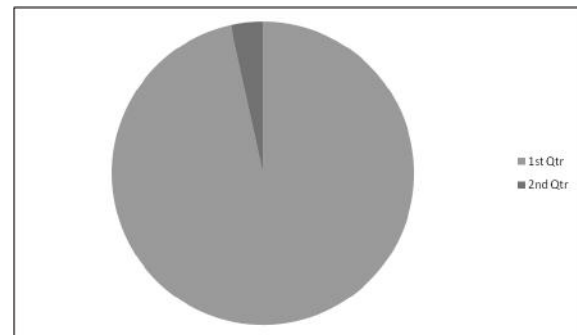


Figure 2 Satisfaction of the patients after using vaginal pessary.

Discussion

Out of 31 respondents 27(87.1%) had successful pessary fitting for symptomatic pelvic organ prolapse, 88.9% (24 out of 27) were satisfied at 3

months followup. Spontaneous expulsion occurs in 2(6.5%) respondents, 2(6.5%) discontinued due to abnormal vaginal discharge. Symptoms related to prolapse were significantly improved from base line to 3 months like vaginal buldge, dragging pain in lower abdomen, urinary symptoms bowel symptoms. During followup 4(12.9%) women complains of abnormal vaginal discharge.

Few study available focusing on the aetiology of pelvic organ prolapse, and was found that women were within 50-60 years of age.¹¹ In our study mean age of the respondents were 50(+12) years. RR Asresie A et al. studied relationship between age and stage of pelvic organ prolapse concluded that women in 6th and 7th decade of life experienced advanced stage of prolapse.¹² In present study most of the women given birth of 3 or more children. Islam RM, Bell RJ, Billah B, Hossain MB, Davis SR. conducted a study on on Bangladeshi women also revealed women having 3 or more children was positively linked with having at least one symptoms of pelvic floor disorder, which was consistent with our study.¹³ Very few patients had cesarean delivery (3/31). Other studies shows similar result.¹⁴ Vaginal delivery was primary risk factors for pelvic floor dysfunction. Howard et al in their study focused on vaginal birth as a primary risk factors for the development of pelvic floor disorders.¹⁵ Majority of our studied women had normal BMI, but study of Gurjar et al which reported that majority of women with POP had BMI of >25 Kg/m².¹⁶

In a prospective study 100 women were treated with a pessary for a period of 2 months, found 92% women were satisfied with use of pessary.¹⁷ In another study among 56 women with symptomatic prolapse, were treated by pessary, 64% were satisfied with improvement of symptoms at 3 months.¹⁸ In our selected patients of pelvic organ prolapse satisfaction rate was high about 88.9% like other studies.¹⁹ In our study concurrent stress incontinence were reported at base line in 4 patients and all of these women significant improvement of symptoms at 3 months. Clemons et al reported 20 women with stress incontinence, 11(55%) continue to use their pessary and had improvement of their symptoms.²⁰ Concurrent voiding difficulty and prolapse were evaluated in another study 94% women had improvement of urinary symptoms after using pessary.²¹ Women with symptomatic pelvic organ 87.1% continue pessary use for 3 months.

Complications after using pessary were observed that vaginal discharge were most common complications, in our study 12.9% (4) had abnormal vaginal discharge, 3(11.1%) were not satisfied to use pessary. Study by Sharma et al evaluated in 273 women over a period of 6 years, found 56% women experienced complications like vaginal discharge, pain and constipation.²² Another study by Cheung et al reported that 37% experienced vaginal discharge.²³ In present study the observed complications also were vaginal discharge, pain and discomfort. Two of the women discontinue the use of pessary. De novo vaginal discharge were short lasting and treated symptomatically. Several study on use of pessary revealed patient satisfaction about 70-93%.²⁴ With the use of pessaries for the management of pelvic organ prolapse our respondents were satisfied at the end of three months regarding improvements of prolapse related symptoms, and wants to continue the use of ring pessary. A recently published study also revealed use of pessary can produce a positive effects on womens quality of life.²⁵ Treatment of pelvic organ prolapse with use of vaginal pessaries is simple, inexpensive, non invasive, well excepted, cost effective and patients friendly. Strength of this study is that a pessary was offered to women with symptomatic pelvic organ prolapse, not just to women who were surgically unfit, or decline surgery, there by giving more a more accurate estimate of effects of the pessary on pelvic organ prolapse and its symptoms.²⁶ We will continue to followup our patients to determine whether improve symptoms correales with continued pessary use for 1 year.

Limitation

The sample size were also relatively small and from a singlecentre, which may not represent the exact scenario of the country. Outcome were assessed only at 3 months, but we will continue follow up 27 women who were still using the pessary to better determine long term use, satisfaction and safety.

Conclusion

Vaginal pessary is an acceptable treatment option for pelvic organ prolapse and also effective in improving prolapse associated symptoms. It was acceptable to most of our patients. During follow up complications were relatively minor, and easily correctable. The frequency of pessary removal were also low.

Recommendation

The vaginal pessary is a simple and effective method of treatment for pelvic organ prolapse in women who are fitted successfully with a pessary. Patient satisfaction is relatively high. In future large prospective studies with long term follow up are necessary to assess the effectiveness of pessary on pelvic organ prolapse.

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Contribution of authors

AAM-conception, design, data collection, drafting and final approval.

SAB-Interpretation of data, data analysis, critical revision and final approval.

NY-Data collection, data analysis, critical revision and final approval.

Disclosure

The author declared no competing interest.

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