

# Prospective Evaluation of Outcomes of Mechanical Devices in Women with Symptomatic Pelvic Organ Prolapse in Ogbomoso, South-Western Nigeria

Akintunde Olusegun Fehintola<sup>1\*</sup>, Olufemi Timothy Awotunde<sup>2</sup>, Olumuyiwa Ayotunde Ogunlaja<sup>2</sup>, Lawrence Olujire Olujide<sup>3</sup>, Samuel Eniola Akinola<sup>2</sup>, Sunday Adekunle Oladeji<sup>2</sup>, Babatola Bakare<sup>4</sup>, Olurotimi Idowu Aaron<sup>5</sup>

<sup>1</sup>Department of Obstetrics, Gynaecology, and Perinatology, Obafemi Awolowo University, Ile-Ife, Osun State, Nigeria

<sup>2</sup>Department of Obstetrics and Gynaecology, Bowen University Teaching Hospital, Ogbomoso, Oyo State, Nigeria

<sup>3</sup>Department of Obstetrics and Gynaecology, Royal Hampshire County Hospital, Winchester, UK

<sup>4</sup>Department of Obstetrics & Gynaecology, Unimed Teaching Hospital, Ondo, Ondo State, Nigeria

<sup>5</sup>Department of Anaesthesia, Obafemi Awolowo University, Ile-Ife, Osun State, Nigeria

Email: \*akintunds@yahoo.com

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## Abstract

**Background:** Symptomatic pelvic organ prolapse (POP) impacts the sufferers' quality of life negatively. There is a preference for a mechanical device in certain conditions though the definitive management of POP is surgical. **Objectives:** We conducted the study to evaluate the outcome of management of POP using mechanical devices. **Methods:** It was a prospective study. It took place in the gynecology unit of the Bowen University Teaching Hospital Ogbomoso between May 2014 and April 2019. We followed up with eligible patients who opted for pessary use for a median duration of 18 months (Range 12 - 84 months). We excluded those who refuse to participate in the study. **Results:** Of the 127 patients with symptomatic POP, seventy-five (59.1%) opted for the use of mechanical devices, and 70 successfully retained them four weeks after insertion. We lost Six (9.2%) patients to follow up. Of the 64 women included in the analysis, 16 (25%) discontinued use at some point after four weeks, whereas 36 (56.3%) used the pessary successfully throughout the follow-up period. Overall, 12.1% of the women experienced minor complications (6.9% pain or discomfort, 3.2% excoriation or bleeding, and 2.0% dis-impaction or constipation). After cessation of pessary use, 12 (25%) of the 48 women chose surgery, and 10 (20.8%) chose no further treatment. **Conclusion:** This study concluded that pessary use for pelvic organ prolapse is safe in low resource settings. Therefore, it is justifiable to offer pessaries in the

initial management of uterovaginal prolapse to all patients who opt for conservative management and those awaiting surgery.

### Keywords

Mechanical Device, Symptomatic Pelvic Organ Prolapse, Complications, Discontinuation

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## 1. Introduction

Pessaries have been in existence in one form or another since biblical times [1], and currently, many different kinds of pessaries are available to treat the various types of pelvic descent. We defined Pelvic organ prolapse (POP or U-V prolapse) as any pelvic structure that protrudes into the vagina (cystocele, rectocele, enterocele) [2]. Patients with asymptomatic prolapse who are asymptomatic do not require treatment

Though surgery is the definitive treatment for symptomatic U-V prolapse in this era of safe anesthesia, there is a preference for medical management in situations where a woman is still desirous of more children with 3<sup>rd</sup>-degree U-V prolapse. Patients who are not fit for surgery, those who refuse surgery and women with U-V prolapse in pregnancy can also use pessary. Those with U-V prolapse in pregnancy can also use a pessary. We also use a pessary to relieve acute urinary retention or pain due to incarcerated retroverted uterus in pregnancy, treatment of unsuccessful surgical repair, and neonatal pelvic organ prolapse [3]. Furthermore, the pessary helps relieve symptoms while the patient is awaiting surgery. Physicians also use it as a diagnostic tool amongst patients with stress incontinence. Pessary insertion in this condition is to confirm that surgery will be helpful to the patient [3]. Other forms of treatment modalities for U-V prolapse include general measures in the forms of estrogen use by menopausal women, physiotherapy, and electrical stimulation. These forms of treatment, however, are only used for mild conditions of U-V prolapse [3]. Pessary fitting is an art rather than a science, a trial and error process whereby the clinician's training and experience best predict success [4]. The subjective nature of pessary fitting comes from little or no formal clinical training. Furthermore, there is no consensus on clinical indications for various types of pessaries, patient characteristics for sizing, or appropriate pessary care [4] [5]. Manufacturer product information and texts give general guidelines for pessary fitting; however, the previous survey did not support this recommendation [6]. Unfortunately, the modern vaginal pessary is not readily available in the Nigerian market. This scarcity is probably due to the low prescription rate by doctors and its high cost. The result is that medical practitioners denied many patients who should benefit from vaginal pessary therapy this benefit [3]. There is a lack of data on pessary's use as a viable alternative to surgery in women with POP in Nigeria, hence the need for this study.

This present study evaluated the use of vaginal pessaries for pelvic organ prolapse (POP) and identified complications and reasons for discontinuing pessary use over the follow-up period prospectively. This present study will serve as baseline data for references and further research.

## **2. Materials and Methods**

### **2.1. Study Setting**

This study is a prospective study of patients with symptomatic POP who opted for mechanical device (vaginal pessary) insertion as a management option at the Department of Obstetrics' gynecological unit Gynaecology, Bowen University Teaching Hospital, Ogbomoso between May 2014 and April 2019.

### **2.2. Ethical Consideration**

We obtained ethical clearance to carry out this study from the ethics and research committee of the Bowen University Teaching Hospital, Ogbomoso, Oyo state. During data collection, we informed patients about the study, confidentiality, and the right not to participate or withdraw at any time without affecting their health or other services. We presented written and verbal information about Pessary insertion to the patients and obtained informed consent. We gave a printed educational leaflet on the procedure to literate patients.

### **2.3. Inclusion/Exclusion Criteria**

We excluded those who refused to participate in the study. We selected patients after clinical, laboratory, and radiological evaluation to eliminate significant co-morbidities.

### **2.4. Patients' Procedure of Mechanical Device Insertion and Follow-Up**

After the initial evaluation, eligible patients will undergo the counseling section on insertion, removal, and vaginal pessary maintenance. Postmenopausal women require three months of topical estrogen applied 2 or 3 times weekly before fitting a pessary comfortably.

Materials needed include a set of fitting rings, gloves, lubricant, and an autoclave. The moment a patient has decided to try a pessary, she will return on a separate visit for fitting. The visit includes fitting the pessary, having the patient try it temporarily, rechecking the fitting. We fit pessaries by trial and error.

We placed the patient in the lithotomy position and examined it at rest. The researchers observed as she bears down slowly with the Valsalva maneuver (not by coughing, as this is too brief). We then insert a lubricated speculum and rotate it 90°. We then gently open it so that the anterior and posterior walls are visible, both at rest and with the Valsalva maneuver. One can see prolapse in the opposite compartment. We describe three degrees of uterovaginal prolapse using the location of the lowest part of the prolapsed uterus in relation to the level of

the hymen [7]. The researchers then assess the prolapse while the patient is straining. We diagnose the First-degree prolapse when the descent is still within the vagina, second-degree when it has descended to the introitus, and third-degree when it has fallen outside the introitus [7]. If the prolapse is 1<sup>st</sup> or 2<sup>nd</sup> degree, a ring pessary is an excellent treatment, though we offered those with 3<sup>rd</sup> degree who opted for pessary the mechanical device with considerable success.

### 2.5. Fitting a Pessary

We begin by inserting the middle finger behind the cervix in the posterior fornix and the index finger against the pubic notch. We then use the distance between these two fingers as a starting point in pessary sizing. The researcher will withdraw the fingers and choose the fitting ring whose diameter best approximates this distance. We then fold the fitting ring in half, lightly lubricate the entering end, and insert it so that part of the ring is behind the cervix and the opposite side is behind the pubic notch. We are aiming for the largest size that fits comfortably. The index finger is swept around the perimeter of the ring to check for pressure points. If the ring does not fit properly, we try a smaller or larger size. The average pessary size is 4 or 5, the range being from 2 to 7 cm. The patient then spends about an hour walking around and tries to void.

When she returns, we will remove the fitting ring and insert the appropriate pessary. We treat a cystocele using a ring with support (filled-in center) while using a ring without support (hollow) for U-V prolapse. We treat stress incontinence using a ring with a knob. We use Gelhorn Pessary in advanced POP (**Figure 1** & **Figure 2**). We consider a fitting as proper and adequate when the provider could place a finger between the pessary and the vaginal walls, and after fitting, the subject could stand cough and strain with the pessary retained. Multiple pessaries could be fitted at one visit to determine the correct size for subject use. We consider a pessary fitting unsuccessful if the interventionist failed to obtain a good fit after three attempts. Also, it is unsuccessful if the participant found the pessary painful or the participant did not plan to use the pessary after fitting.



**Figure 1.** Different vaginal pessaries in our clinic (From the left to right: Portex ring pessary, Shelf pessary, Doughnut pessary, and Gelhorn pessaries).



**Figure 2.** Incontinence ring and incontinence dish (courtesy of Milex website).

## 2.6. Follow Up

The interventionist must check the patient within a week after the new pessary insertion. He then sees the patient at the clinic in 4 weeks. He will note all those who successfully retain their pessaries for four weeks. We examine all patients wearing pessaries every 3 to 6 months to check for vaginal erosions or ulcers. We removed the pessaries in those with lesions until the lesions have healed and treated affected areas with topical estrogen.

Pessaries can be removed every day, every week, or monthly, at patients' discretion. They remove the pessaries for washing with soap and water. Patients can leave ring pessaries in place or removed for intercourse. Patients can also insert their pessaries as needed (e.g., to address stress incontinence with exercise). We removed, washed, and re-inserted their pessaries every 3 to 6 months for those who could not care for the devices on their own. An acidifier or estrogen was applied vaginally 2 or 3 times weekly to reduce infections and odors. We can also use Oral or transdermal estrogen or an estradiol-17 ring (placed behind the pessary) in some patients.

## 2.7. Data Collection

We recruited every consecutive eligible patient at presentation to the facility. We used standardized proforma to collect information on the socio-demographic characteristics of the patients. These include the patients' age, parity, and occupation. We obtained the clinical presentation, predisposing factors, and POP etiologies from the patients' history. We also recorded the weight (in Kilogram) and the patients' height (in Meters). The researchers also classify the POP, the indications for pessary uses, and the type of vaginal pessary inserted. We recorded all this information in the proforma and updated these records at every clinic visit.

## 2.8. Data Analysis

We carried out data entry and analysis using Statistical Package for Social Sciences (SPSS) version 20. The researchers represented the Socio-demographic characteristics, POP's clinical presentation, and other outcome variables in frequency distribution and simple percentages. We presented appropriate variables in flow-charts and line graphs.

## 3. Results

The prevalence of POP calculated from this study was 5.4% (54 per 1000) of total gynecological conditions managed during the study. Of the 127 patients with symptomatic POP, seventy-five (59.1%) opted to use various mechanical devices (as shown in **Figure 1** and **Figure 2**). Seventy (93.3%) patients successfully retained them four weeks after insertion. We lost six (9.2%) patients to follow up, as shown in the flowchart in **Figure 3**. The mean age at presentation in this study was  $51.4 \pm 3.3$  years. The mean parity of the patients was  $4.2 \pm 1.6$ . Grand multiparity accounted for 77.4% of the cases. Approximately 90.3% were at least 40 years old, while the remaining 9.7% were younger than 40. The majority of the patient (66.7%) had 2<sup>nd</sup>-degree prolapse. A sensation of something protruding through the vagina was the most frequent presentation (80%), followed by low back pain (58.7%), while 14 patients (18.7%) had decubitus ulcers at presentation. Difficult deliveries at home or with TBAs accounted for 62.7%, while menopause and chronic cough predisposed 53.3% and 20.0% to prolapse in this study, as shown in **Table 1**.

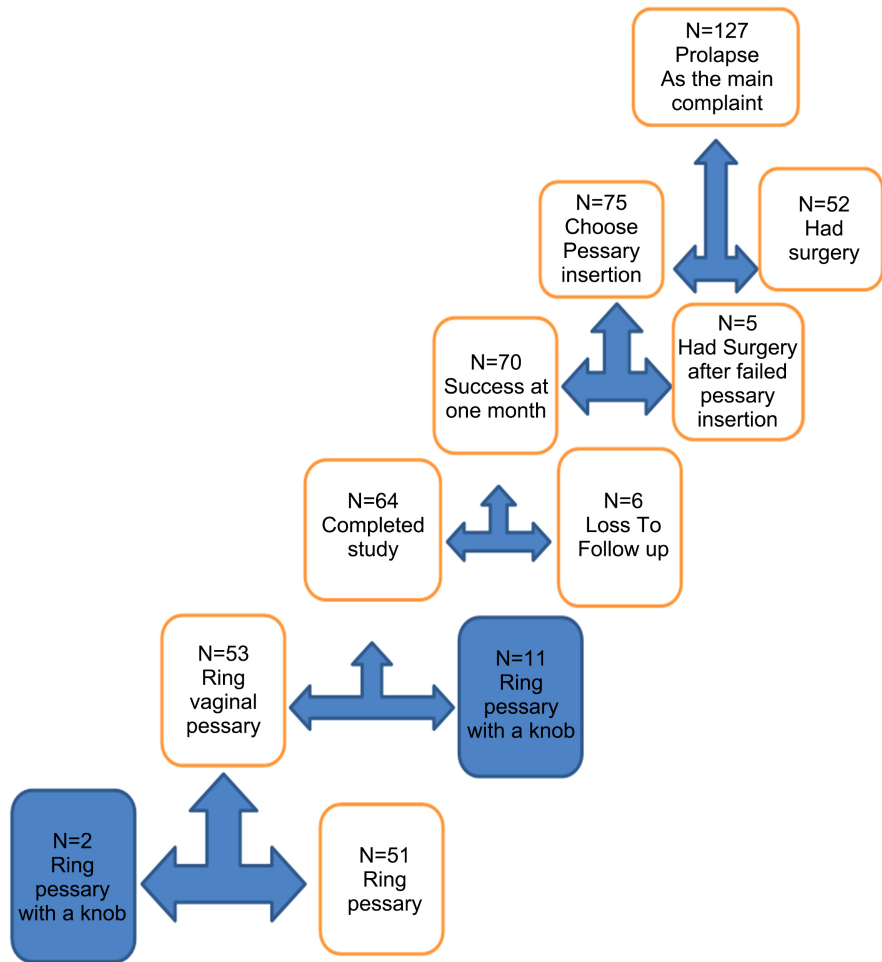
The most frequent indication for pessary use was patients' refusal of surgical treatment (40%), while fertility preservation was the reason in 21.3%. Eleven (14.7%) patients had pessary due to simultaneous stress urinary incontinence (SI), as shown in **Table 2**. Of the 127 women with prolapse, 75 (59.1%) had pessary fitted. Seventy (93.3%) out of the 75 patients that had pessary fitted returned still using it at four weeks. Because of concomitant stress incontinence, 11 women chose ring pessary with a knob for bladder neck support and two after failed portex ring fitting (see blue-shaded areas in **Figure 3**). Fifty-two patients chose surgical management from the onset while five patients later opted for surgery after a failed pessary fitting making a total of 57 (57/127, 44.9%) patients.

Thirty-six out of the 64 patients (56.3%) continued to use pessary at the study end-point. Twelve (18.8%) died with pessary in situ, while 16 (25%) discontinued pessary use. Of those who stopped, the median duration of use was 1.1 years (range 0.5 - 4 years). As shown in **Figure 4**, about 50% of the patients had discontinued pessary use by 1.6 years. Reasons for discontinuation were diverse. The majority was due to complications from pessary use (50%). Some stopped when they were ready for surgery (25%), while others discontinued due to convenience (25%). The most typical complication of pessary use among the study participants is copious vaginal discharge (35.9%), while 1.6% developed deeply impacted pessary that we removed in the theatre under anesthesia, as shown in **Table 3**.

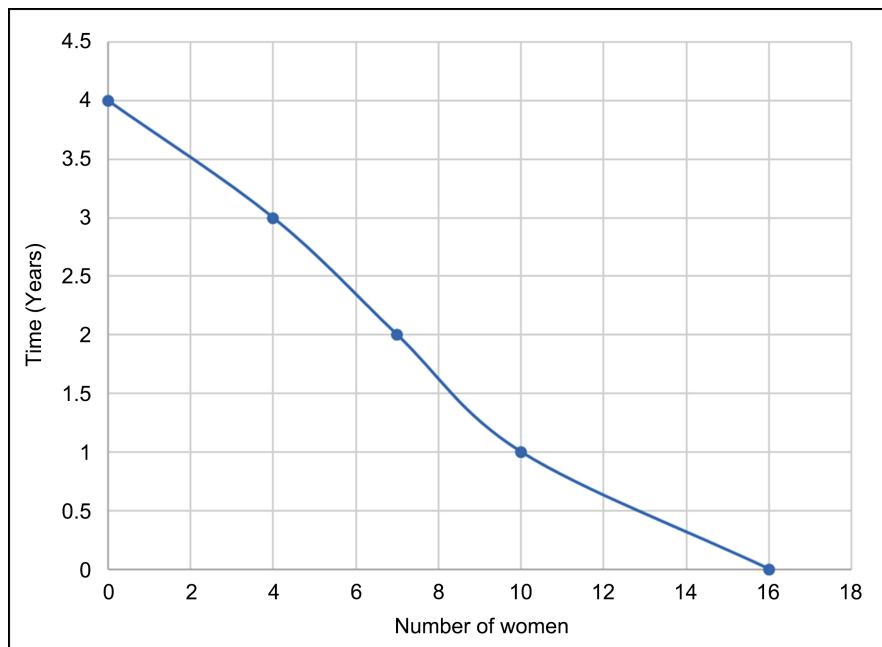
**Table 1.** Descriptive statistics of patients who had mechanical device insertion for POP.

Variables	Frequency (n = 75)	Percentage (%)
<b>Age (in years)</b>		
<40	07	9.3
≥40	68	90.7
Mean (±SD)	51.4 (± 3.3)	
<b>Parity</b>		
0	04	5.3
1 - 4	13	17.3
≥5	58	77.4
Mean (±SD)	4.2 (±1.6)	
<b>Classification of POP</b>		
1 <sup>st</sup> degree	03	4.0
2 <sup>nd</sup> degree	50	66.7
3 <sup>rd</sup> degree	22	29.3
<b>Clinical presentation of POP</b>		
Sensation of something coming down the vagina	60	80.0
Dysuria	18	24.0
Decubitus ulcer <sup>s</sup>	14	18.7
Stress incontinence	11	14.7
Urinary retention	02	2.7
Low backache	44	58.7
Others	16	21.3
<b>Etiologies of POP</b>		
Difficult labo <sup>rs</sup>	47	62.7
Postmenopausal	40	53.3
Chronic cough	15	20.0
Lifting heavy objects	30	40.0
Others <sup>x</sup>	10	13.3
<b>BMI (kg/m<sup>2</sup>)</b>		
<25.0	44	58.7
25 - 29.9	20	26.7
≥30.0	11	14.6
Mean (±SD)	23.4 (±3.6)	
<b>Types of pessary</b>		
Ring pessary	64	85.3
Ring pessary with a knob	11	14.7

<sup>x</sup>multiple responses noted.



**Figure 3.** Flow chart of women with prolapse as the primary complaint.



**Figure 4.** Graph of the duration of pessary use in those who discontinued pessary use.



**Table 2.** Indications and outcome of pessary insertion.

Variable	Frequency (n = 75)	Percentage (%)
<b>Indications for pessary use</b>		
Surgery refusal	30	40.0
Fertility preservation	16	21.3
Poor surgical risk	05	6.7
UVP in pregnancy	07	9.3
Awaiting surgery	06	8.0
Diagnostic test (SI)	11	14.7
<b>Outcome of insertion</b>		
Successful	70	93.3
Unsuccessful	05	6.7

**Table 3.** Complications of vaginal pessaries.

Variables	Frequency (n = 64)	Percentage (%)
Vaginal bleeding	19	29.7
Copious vaginal discharge	23	35.9
Pain/constipation	17	26.6
Theatre for removal	01	1.6
Urinary incontinence	02	3.2

<sup>x</sup>multiple responses.

## 4. Discussion

POP is a highly prevalent condition that is becoming more common as the population ages. It is of considerable importance to the practicing gynecologist in the tropics because of its strong association with repeated childbirth and poor labor conduct. It is one of the most frequent indications for surgery and attendance at the gynecology clinic. However, epidemiologic studies of its prevalence are rare [8] [9].

In a study of 1006 women between ages 18 and 83 presenting for routine gynecological care, only 24% had normal support, 38% had 1<sup>st</sup> degree, 35% had 2<sup>nd</sup> degree, and 2% had 3<sup>rd</sup> degree POP. Therefore, some loss of pelvic organ support is present in most adult women [10].

Currently available treatments for symptomatic POP include physiotherapy, mechanical devices, and reconstructive surgery. However, surgery has a known reoperation rate of 10% - 30% [11] [12].

Gynecologists have different opinions about offering pessaries to women. A study from the American Urogynecology Society in the year 2000 reported that 77% of the doctors provided pessaries as first-line therapy for pelvic organ prolapse, but 12% only offered pessaries to women who were not surgical candidates

[13]. The higher the prolapse severity, the more likely they were to choose surgery over expectant management or pessary.

To our knowledge, this present study is the first to report, prospectively, the outcome of pessary uses over a 3- to 6-year period in Nigeria. There is a lack of data on the use of mechanical devices in managing POP in our country. This scarcity may be because modern vaginal pessary is not commonly available in the Nigerian market. This scarcity is probably due to the low prescription rate by doctors and its high cost. The result is that medical practitioners denied many patients who should benefit from vaginal pessary therapy this benefit. Komolafe *et al.* [3] looked at an affordable alternative to the modern ring pessary in the form of the ring-shaped vulcanized rubber sold as silencer rubber or oil seal rubber in 4 patients with symptomatic POP. They recorded an improvement in symptoms over a short period of follow-up in these patients.

The prevalence of uterovaginal prolapse in this review is 54 per 1000 gynecological patients. This prevalence is similar to the report from Ibadan (45 per 1000 gynecological admissions) but higher than the finding from Lagos, which is 0.74 per 1000 gynecological patients, 7.6 per 1000 gynecological admissions from Ilorin and 21 per 1000 gynecological admissions in Nnewi and Enugu, South-East Nigeria [14] [15].

These prevalence variations might be due to the differences in the populations studied and the differences in the study periods. Previously, people with uterovaginal prolapse rarely presented to the hospital, but nowadays, patients present to the hospital because of increased awareness, hence expanding the prevalence/number of cases. Also, Ogbomoso, being a semi-urban town, has a large proportion of farmers and women who tend to deliver their babies outside hospital settings.

In this study, approximately 59% of the participants opted for pessary insertion. This finding is similar to the report from previous studies [13] [14] [15]. [16] This high pessary utilization rate may be explained by the fact that there are very few contra-indications to its use, making the physicians, especially in the developed world, offer it to almost every woman with symptomatic POP. The most common indication for pessary uses in this study was the refusal to undergo surgical management. This contrasts with the finding from previous surveys [14] [15] where most women opted for pessary for fertility preservation or poor surgical risk.

The significant aversion to surgical management, as witnessed against most surgical procedures, including Caesarean Section in the developing countries [17], may explain the high prevalence of surgery refusal among the participants in this study. Almost nine out of every ten women who had pessary insertion in this study retained it after four weeks of insertion with significant improvement in their symptoms. This finding is similar to that of Fernando *et al.*, where about 75% of the women had successful pessary insertion [17]. There is a wide variation in the success rate (65% - 97%) from previous studies [17] [18] [19]. This

variation occurs because there is no agreement on what is considered successful vaginal pessary fitting. In this study, we consider a vaginal fitting to be successful if the woman carries the pessary for at least four weeks without expulsion and there is improvement in the symptoms.

Although rare with appropriate use, complications with pessaries reported include actinomycosis and bacterial vaginosis [18] [19]. Others are bleeding, discomfort, pain, vaginal erosion, impaction, excoriation, and ulceration, especially with atrophic vaginitis [20]. Researchers reported more severe complications, such as peritonitis, fistula formation [19] [20] erosion into the bladder or bowels and dense adherence to another pelvic structures [21] hydronephrosis, and vaginal cancer [22] in neglected pessaries. Among patients who successfully retained a pessary in our study population, the most typical pessary use complication was mal-odorous vaginal discharge (35.9%). This finding is comparable to the report of Sarma *et al.* [23]. This author, in his series, reported copious vaginal discharge in 25.5% of the patients. Vaginal bleeding was the second leading complication in our study. Vaginal bleeding constituted major stressors for patients, and it is a leading cause of discontinuation of pessary use in our series. Other reasons for discontinuation of vaginal pessary in our study include varying degrees of discomfort and patient readiness for surgical management. This report is similar to those of Hanson *et al.* [24] and Wu *et al.* [21] where most of the respondents discontinued their pessaries due to complications and were ready for their surgery.

## 5. Limitation of the Study

The small sample size in this study may impair the generalizability of its findings. However, findings from this study corroborated those of the existing literature in the field of urogynecology.

## 6. Conclusion

This study concluded that pessary use for pelvic organ prolapse is safe in low resource settings and avoids surgery complications. Therefore, it is justifiable to offer pessaries in the initial management of uterovaginal prolapse to all patients who opt for conservative management and those awaiting surgery. This issue is crucial in countries like Nigeria, where there is still a great aversion to surgical management.

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## Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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### List of Abbreviations and Acronyms

**POP** = Pelvic Organ Prolapse

**U-V Prolapse** = Uterovaginal prolapse

**BMI** = Body Mass Index

**SI** = Stress Incontinence

**UVP** = Uterovaginal prolapse