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ORIGINAL ARTICLE

Vaginal pessaries in the management of symptomatic pelvic organ prolapse in rural Kilimanjaro, Tanzania: a pre-post interventional study

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Abstract

Introduction and hypothesis The objective of this study was to evaluate the outcomes of vaginal pessaries in managing symptomatic pelvic organ prolapse (POP) in a low-income setting.

Methods A pre-post interventional study was conducted in the Kilimanjaro region, Tanzania. Seventy-one women with symptoms and a POP stage II or more on the POP quantification test were fitted with a vaginal pessary. Pelvic examination, POP Distress Inventory (POPDI-6) and POP Impact Questionnaire (POPIQ-7) were completed at baseline, after 3 months and after 12–18 months. Changes in the POPDI-6 and POPIQ-7 scores, complications and satisfaction associated with pessary use before and after the intervention were obtained.

Results Pessary treatment was associated with a reduction in the overall POPDI score from 55.0 (50.0, 60.0) at baseline to 25.0 (25.0, 30.0) after 12–18 months' use. The overall POPIQ score was reduced from 54.2 (41.7, 66.7) at baseline to 25.0 (25.0, 29.2) after 12–18 months' use of the pessary. Vaginal discharge was reported in 72.4 and 32.4% of the women after 3 and 12–18 months' use respectively, whereas 72.4 and 25% of the women had some degree of granuloma, erosion or infection at 3 and 12–18 months respectively. Despite the reported complications, 78% of the women were satisfied with the pessary when interviewed after 12–18 months and 81% wanted to continue using it.

Conclusions Vaginal pessary improves symptoms and quality of life associated with symptomatic POP. Therefore, it may be a treatment option in managing POP in low-income countries such as Tanzania.

Keywords Vaginal pessary · Pelvic organ prolapse · POPDI · POPIQ · Tanzania

Introduction

Pelvic organ prolapse (POP) is a common female health condition in both low- and high-income countries [1, 2]. In a recent study from Tanzania, based on a random sample of 1,047 women, we have documented that 65% of the women have at least one type of POP and 7% are having a symptomatic POP requiring some form of treatment [3]. Other studies from sub-Saharan Africa have reported prevalence rates of 12– 55% [4–7]. Women living in low-income countries are thought to suffer more from POP than women living in high-income countries because of difficult access to treatment and hard physical work, with impaired ability to work or perform daily household chores [2]. Apart from bothersome symptoms that are associated with severe stages of POP, women in low-income countries are further faced with low self-esteem, non-disclosure for fear of isolation, and sexual and marital dysfunctions [2, 8].

Symptomatic POP can be managed either conservatively, using pessaries, or through surgery. Pessaries have long been employed in managing symptomatic POP [9] and in high-income countries, it has been documented that the use of pessaries improves urinary, bowel, sexual and general quality of life symptoms associated with POP [10–14]. The acceptance and effect of pessaries for POP treatment has until now just been evaluated very sporadically in low-income settings.

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Due to poverty, poor access to healthcare services and scarcity of trained surgeons, women in low-income countries are left with limited access to treatment for POP and thus may have to resort to traditional healers to alleviate the symptoms [2]. In a Ugandan study involving 56 women with POP, 20 women had not sought treatment either because they were unaware of available treatment or could not afford treatment [15]. Of the 36 women who had requested some form of help; 19 had seen a traditional healer, 7 had sought help from a healthcare facility, but were told there was no treatment available and 8 women were just given tablets in a healthcare facility, whereas 2 women were told they had cancer. A more recent qualitative study further elucidates that the sufferings and challenges in coping with POP in Ethiopian women are compounded by cultural taboos and a lack of health education [8].

Although POP is a common problem among African women, there seems to be a lack of awareness about the condition and a lack of access to treatment. In settings with limited health care resources, pessaries may be a simple, affordable and acceptable treatment option for women with symptomatic POP. To test this assumption, the present study was aimed at evaluating the outcomes and acceptance of pessary use among Tanzanian women with symptomatic POP.

Materials and methods

This study was nested within a larger project focusing on Pelvic Floor Disorders in Tanzania, which is a collaborative partnership between Kilimanjaro Christian Medical Center (KCMC), Odense University Hospital and the University of Southern Denmark. A pre-post intervention study was conducted among women with symptomatic POP from three districts in the rural Kilimanjaro region, Tanzania. The study was divided in two subgroups. Enrolment for subgroup 1 was carried out during February to May 2015 and for subgroup 2 in June to August 2015.

Sampling and inclusion

Subgroup 1 involved women who were enrolled through a multi-stage random sampling whereby female heads of 1,195 selected households were interviewed at their homes and then invited the next day to attend a selected health centre for a pelvic examination. Among 1,048 examined women, 70 were found to have clinically relevant POP (descending ≥ 1 cm beyond the hymeneal ring). These women were interviewed about POP symptoms using validated questionnaires and if they complained about symptoms they were offered pessary treatment. Overall, 32 women accepted the treatment offer (Fig. 1). Women in subgroup 2 were enrolled from the same areas following announcements about pelvic floor disorders and possible treatment. The announcements were made in churches, mosques, at the local market, reproductive and child health (RCH) clinics and outpatient clinics. In addition, public announcements using vehicles with loudspeakers were utilised to raise awareness. The announcements instructed women with POP symptoms to attend a selected health centre on specified dates for a pelvic examination and possible treatment. Among 377 women who showed up at the clinic, 39 were found to have clinically relevant POP with associated symptoms. These 39 women were offered pessary treatment, which all accepted. Thus, a total of 71 women were enrolled in the study.

Data collection

A structured questionnaire interview was performed to obtain information on socio-demographic characteristics, reproductive history and symptoms of urinary incontinence and POP. We used the Pelvic Organ Prolapse Distress Inventory (POPDI-6) and the Pelvic Organ Prolapse Impact Questionnaire (POPIQ-7) to obtain information on POP symptoms and POP related quality of life [16]. The questionnaires were translated into Kiswahili and pilot tested on six elderly nurses and 20 randomly selected women. The pilot testing resulted in omission of one question from the POPDI-6: "Ever have to push on the vagina or around the rectum to have or complete a bowel movement?", and "Feeling frustrated?" from the POPIQ-7. The questions were found to be difficult to translate into meaningful Kiswahili phrases that could be understood by the rural population. Therefore, our adapted POPDI-6 and POPIQ-7 versions had five and six questions respectively. The final questionnaire was then back-translated into English. A trained nurse administered the adapted POPDI and POPIQ questionnaires. In both questionnaires, options for responses were "not at all", "somewhat", "moderately" or "yes, very much", with scores of 1 to 4 progressively. To obtain a total score of 100, the mean score for each questionnaire was obtained and then multiplied by 25 [16]. The higher the score, the worse the symptoms or quality of life related to symptomatic POP. In the clinic, a pelvic examination was performed by a resident trained by two gynaecologists to perform the standard Pelvic Organ Prolapse Quantification Test (POP-Q) and staging [17].

Pessary fitting

Participants who responded with "somewhat," "moderately," or "yes, very much" to at least two symptoms and who had a clinically relevant POP (descending ≥1 cm below the hymeneal ring) during gynaecological examination were offered pessary treatment. Those who accepted were fitted with a Milex ring pessary with support (Milex® Pessaries, CooperSurgical, Inc). The size of the pessary was determined

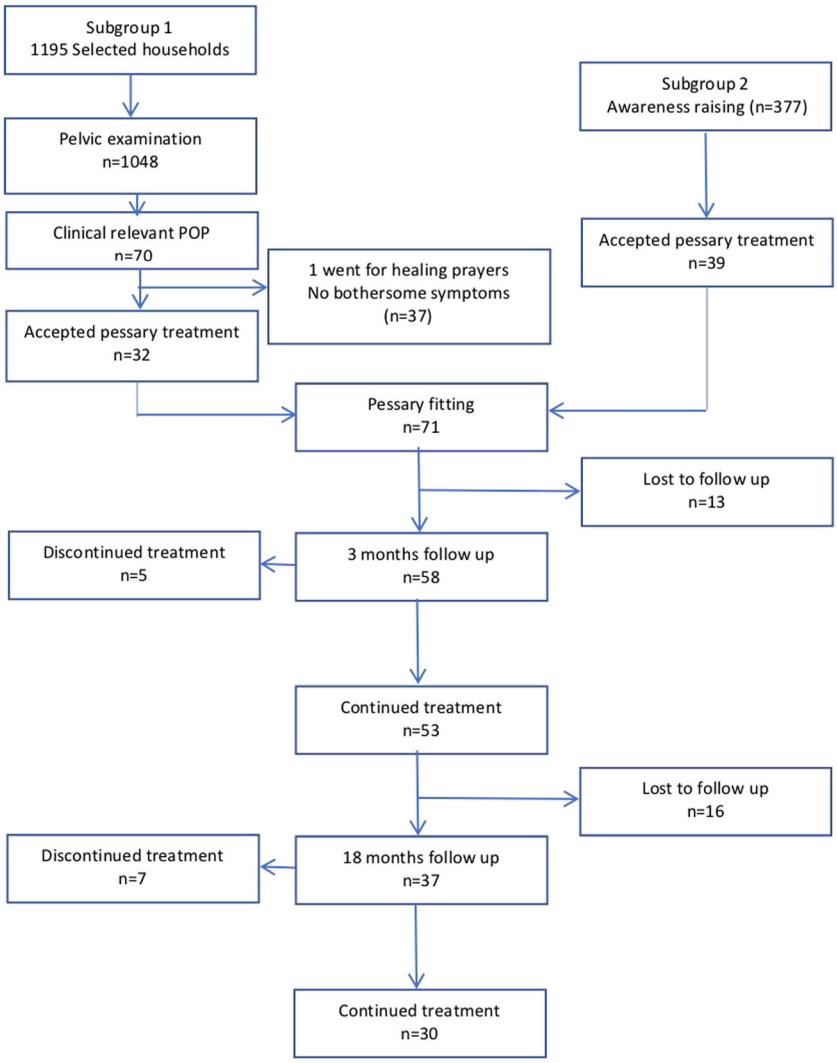

Fig. 1 Flowchart of the enrolment of participants

by its supportive effect and comfort. None of the women had vaginal ulcers before pessary fitting. The pessaries were lubricated before they were inserted and the size of the pessaries ranged from 64 to 83 mm, with those most commonly used being 70 mm and 76 mm. Following pessary fitting, the women were asked to perform some physical activities such as walking and squatting, and were asked to empty their bladder before leaving the clinic. A smaller pessary was employed if the women felt uncomfortable whereas a larger one was fitted if the woman had problems retaining the first. The women were also instructed on how to remove, clean and reinsert the pessary (at least once a month) and to return to the clinic after 3 months for a check-up. The women were initially given a 3-month follow-up and were thereafter given a 6-month appointment at KCMC. However, only a few women attended KCMC after 6 months. Therefore, a 12- to 18-month follow-up was established, where women were phoned and asked to attend for follow-up and guaranteed transport reimbursement. The women were given contact information of the clinician who had fitted the pessary in case of any problems. Two weeks before the scheduled follow-ups, text messages and phone calls were made to remind the women of their appointment.

3 and 12–18 months' follow-up

At the follow-up visits, the adapted POPDI and POPIQ questionnaires were administered again. Participants were asked whether, in the past 3 months, they had experienced abnormal vaginal discharge or bleeding (apart from menstrual bleeding) and/or vaginal pain or discomfort during the 3 and 12–18 months' follow-up period respectively. Responses were, "No, not at all", "Somewhat", "Moderately", or "Yes, very much". Those who responded with "somewhat", "moderately" or "yes, very much" were subsequently grouped as "Yes" versus "No" for those who responded "no, not at all". Visual analogue scale (VAS) scores were used to assess satisfaction with the pessary on a scale of 0–10. A pelvic examination was also performed and complications of granuloma, erosions, infections or necrosis were noted as "None", "Mild",

"Moderate" or "Severe" as deemed by the examiner. These were managed by at least a 2-week pessary holiday in addition to an antibiotic and/or antifungal depending on the diagnosis. Women who wanted to continue using the pessary were given 6-monthly check-up appointments whereas those who opted out were referred to a tertiary consultant hospital for further management. Efforts were made to make home visits among women who did not return to the hospital for their follow-up appointment to assess acceptance of the pessary treatment among those women.

Data analysis

Paired *t* test and the Wilcoxon signed rank test were used to compare scores of each item in both the modified POPDI and POPIQ questionnaires, including each scale's total score before and after pessary treatment. The VAS scores for satisfaction levels were analysed by simple frequency distribution in percentages. For comparison purposes, satisfaction levels were dichotomized into "satisfied" and "not satisfied". Statistical analyses were conducted using SPSS software (v 20.0; SPSS, Chicago, IL, USA) whereby results yielding $p < 0.05$ were considered statistically significant. In addition, odds ratios were calculated to compare satisfaction rates among specific subgroups.

Ethics clearance

Ethical clearance was obtained from the KCMUCo Clinical Research Ethics Review Committee (Reference no. 592). Women eligible for the study signed an informed consent. Women who were found to have other gynaecological problems apart from POP were offered treatment or referral to KCMC as needed. Furthermore, if the women had signs of lesions on the portio or if they complained about irregular bleeding they were referred for visual inspection with acetic acid (VIA), which is the standard screening procedure for cervical cancer in Tanzania. Transport costs to the health centres were refunded to those who turned up for clinical examination and follow-up appointments.

Results

A total of 70 women in the POP prevalence survey were found to have a clinically relevant POP descending 1 cm or more below the hymnal remnants; 32 of these women had associated POP symptoms and were offered pessary treatment. In all, 31 women accepted the treatment offer whereas one woman declined and opted for prayers instead. In addition, 39 women with clinically relevant POP following community awareness raising were offered pessary treatment; all 39 women accepted (Fig. 1).

The characteristics of the enrolled women are summarised in Table 1. The women had a mean age of 47.8 ± 11.8 years, median hours spent in heavy lifting of 3 (range 0–10) hours, a median BMI of 25.2 (17.2–39.6) kg/m^2, and a median parity of 5 (range 1–15) children. Most of them resided in Same district, had completed primary school as their highest level of education and worked as farmers, and only 2 (2.8%) had undergone a hysterectomy.

The predominant prolapse stage was stage II in 61 women (85.9%), 4 (5.6%) had stage III and 6 (8.5%) had stage IV prolapse, with the anterior compartment being the most frequently affected in 44 women (62%), the apical compartment in 2 women (2.8%), whereas in none was the posterior compartment most affected. Twelve women (16.9%) had involvement of both the anterior and posterior compartment, 12 (16.9%) had involvement of the anterior and central compartment, whereas 1 woman (1.4%) had POP in all three compartments. The women had a mean total vaginal length of 8 cm (±1.2) and genital hiatus of 4 cm (±0.9).

In all, 13 women (18%) were lost to follow-up at 3 months and 34 women (48%) were lost to follow-up at 12–18 months. Among women who were lost for 3 months' follow up, 67% lived in Same district (approximately 100 km from KCMC), whereas only 43% of the women who complied with the follow-up resided in Same. The women who were lost for 3 months' follow-up, were older, aged 55 and above (46 vs 28%), were more often employed as farmers (85 vs 72%), had more often given birth five times or more (76 vs 53%), and had a stage III–IV prolapse (25 vs 12%) more often.

Follow-up information after 3 months of pessary use was obtained among 54 women who returned to the health clinic and 4 women who were interviewed at home. Of the 58 women interviewed, 53 (91.4%) stated they wanted to continue using the pessary, whereas 5 (8.6%) women wanted to stop using it due to discomfort, interference with sexual intercourse and inability to follow-up for pessary care. Among the 53 women who wanted to continue using the pessary, 28 women (52.8%) attended the 12- to 18-month follow-up at the clinic whereas 9 (17.0%) women were interviewed at home after 12–18 months. Among these 37 women, 30 (81.1%) were still using the pessary and wanted to continue using it whereas 7 (18.9%) had decided to discontinue using the pessary (2 had undergone hysterectomy after at least 6 months of pessary use, 2 opted for surgical treatment, whereas 3 had stopped using the pessary due to vaginal discomfort). In general, the subgroup analysis of the data revealed that the women who were lost to follow-up had similar characteristics in terms of age, parity, education, occupation and prolapse stages as those who were retained, except for longer hours spent in heavy lifting and living far from the KCMC.

Discomfort related to symptoms and quality of life following 3 months' and 12–18 months' use of the pessary was improved (Table 2). The overall POPDI score was reduced

Table 1 Characteristics of the participants

Characteristic	Data	
Age groups, mean (SD)		48.3 (±11.7)
25–34	9	12.6%
35–44	20	28.2%
45–54	20	28.2%
≥ 55	22	31%
District		
Hai	25	35.2%
Same	35	49.3%
Rombo	11	15.5%
Education level		
No formal	3	4.2%
Incomplete primary	10	14.1%
Completed primary	50	70.4%
Secondary and above	8	11.3%
Occupation[a]		
Formal employment	5	7.1%
Farmer	52	74.3%
Business	13	18.6%
Heavy lifting hours, median (range)		3 (0, 10)
≤ 1	15	21.1%
2–4	36	50.7%
≥ 5	20	28.2%
Body mass index in kg/m^2[b], median (range)		25.2 (17.2, 39.2)
< 18	1	1.5%
18–24.9	32	47.1%
≥ 25	35	51.5%
Parity, median (range)		5 (1, 15)
Primipara	2	2.8%
2–4	28	39.4%
≥ 5	41	57.7%
Duration of first labour, median duration being <12 h		
< 12 h	48	67.6%
12–24 h	17	23.9%
≥ 2 days	5	7%
Do not remember	1	1.5%
Weight of the first child, g[c], median (range)		3,500 (2,300–5,100)
< 4,000	46	73%
≥ 4,000	17	27%
Previous hysterectomy		
Yes	69	97.2%
No	2	2.8%
POP-Q stage, median (range)		2 (2, 4)
Stage 2	61	85.9%
Stage 3	4	5.6%
Stage 4	6	8.5%
Predominant compartment		
Anterior	44	62%
Central	2	2.8%
Anterior and posterior	12	16.9%
Anterior and central	12	16.9%
All	1	1.4%
POP-Q grid measurements, mean value (SD)		
Aa	−0.1	±1.1
Ba	0.3	±1.4
C	−1.9	±2.5
Ap	−2.0	±0.9
Bp	−2.0	±0.9
D[d]	−5.0	±2.5
TVL	8.0	±1.2
Gh	4.0	±0.9
Pb	3.5	±0.8

[a] One missing

[b] Three missing

[c] Eight women could not recall the birthweight

[d] Two women had undergone a previous hysterectomy

to 45% of the baseline score after both 3 months and 12–18 months of pessary use and most of the individual symptom scores were reduced to 33% of the baseline scores. Similarly, the overall POPIQ scores were reduced to 44% of the baseline score at 3 months' and 12–18 months' follow-up, with individual scores for the ability to engage in physical activities and emotional health being reduced to 33% and the scores for the ability to perform household activities and to travel a distance of more than 30 min without symptoms being reduced to 50% at both 3 months' and at 12–18 months' follow-up. Regarding the ability to participate in social activities, a statistically significant change was observed at the 3-month follow-up, but not at the 12–18 months' follow-up.

Self-reported vaginal complications were assessed among 58 women who were interviewed after 3 months of pessary use and 37 women who were interviewed after 12–18 months (Table 3). Vaginal discharge was the most common complaint, followed by vaginal discomfort, pain and bleeding. The latter complaint was reported among 8.7% of the women at 3-month follow-up and was not reported by any women at 12–18 months' follow-up. Pelvic examination was performed among 54 and 28 women who had used the pessary for 3 months and 12–18 months respectively. No severe complications were observed; however, 40 of the women (74.1%) had some degree of granuloma, erosion or infection when examined after 3 months of pessary use. The corresponding figure was 7 (25%) among women who were examined after 12–18 months pessary use. Infection was the most commonly observed complication after 3 months and after 12–18 months' use of the pessary.

Table 2 Overall and individual scores of the modified POPDI and POPIQ at baseline, after 3 months' pessary use and after 12–18 months' pessary use

Item	Scores			*p* value	
	Baseline *n* = 71	3 months *n* = 58	12–18 months *n* = 37	3 months	12–18 months
Overall POPDI median score	55.0 (50.0, 60.0)	25.0 (25.0, 30.0)	25 (25.0, 35.0)	<0.001	<0.001
Pressure/bulging	3.0 (2.0, 3.0)	1.0 (1.0, 1.0)	1.0 (1.0, 2.0)	<0.001	<0.001
Heaviness or dullness	3.0 (2.0, 3.0)	1.0 (1.0, 1.25)	1.0 (1.0, 2.0)	<0.001	<0.001
Something is falling out	3.0 (2.0, 3.0)	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)	<0.001	<0.001
Difficulties emptying bladder	1.0 (1.0, 2.0)	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)	<0.001	0.005
Push bulge to empty bladder[a]	1.1 (0.3)	1.0 (0.0)	1.1 (0.5)	0.059*	0.705
Overall POPIQ median score	54.2 (41.7, 66.7)	25.0 (25.0, 29.2)	25.0 (25.0, 29.2)	<0.001	<0.001
Household activities	2.0 (2.0, 3.0)	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)	<0.001	<0.001
Physical activities	3.0 (2.0, 3.0)	1.0 (1.0, 2.0)	1.0 (1.0, 1.0)	<0.001	<0.001
Activities outside the home	1.0 (1.0, 2.0)	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)	<0.001	0.016
Ability to travel >30 min	2.0 (1.0, 2.0)	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)	<0.001	0.002
Participating in social activities	1.0 (1.0, 2.0)	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)	<0.001	0.18
Emotional health	3.0 (2.0, 4.0)	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)	<0.001	<0.001

Values are shown as median and interquartile range in parentheses

*Obtained from the *t* test

[a] Presented as mean and standard deviation in parentheses

At the 3-month follow-up, 55 of the 58 women (94.8%) were either very satisfied or satisfied with the pessary. The same applied for 29 of the 37 women (78.3%) who were interviewed after 12–18 months. When comparing the satisfaction level by age group, women who were aged 35–44 years tended to be more satisfied with the pessary treatment when assessed after 3 months and after 12–18 months, although the findings were not significant (Table 4).

Table 3 Vaginal complications following 3 months and 12–18 months pessary use

Complications	3 months' follow-up		12–18 months' follow-up	
	n/*N*	%	*n*/*N*	%
Self-reported				
Discharge	42/58	72.4	12/37	32.4
Bleeding	5/58	8.6	0	0
Pain	9/58	15.5	8/37	21.6
Discomfort	19/58	32.8	9/37	24.3
Vaginal examination[a]				
Granuloma	13/54	24.1	1/28	3.6
Necrosis	0	0	0	0
Erosion	13/54	24.1	2/28	7.1
Discharge	14/54	25.9	4/28	14.3

[a] Vaginal examination was performed in 54 women at 3 months' follow-up and 28 women at 12 months' follow-up

Discussion

To the best of our knowledge, no previous study has described the acceptance and continuation rate of pessary use for POP treatment in sub-Saharan Africa. The findings from our study are highly consistent with studies from high-income countries, showing that pessary treatment alleviates symptoms and improves quality of life among women suffering from pelvic organ prolapse [10–12, 19–25]. The satisfaction rate in our study was high, with 81% of the women wanting to continue using the pessary after 12–18 months. This high continuation rate reflects an improvement of symptoms and quality of life in a group of women who had no previous access to treatment for pelvic organ prolapse.

After 3 months and 12–18 months of pessary use, the overall POPDI and POPIQ scores were reduced to almost half of the baseline score. Similar results have been reported in a randomised crossover trial from the USA comparing two different types of pessaries and showing that both pessaries were effective and equivalent at relieving symptoms of protrusion and voiding dysfunction [20]. In another USA-based study, prolapse scores after 6 months and/or 12 months of pessary use fell to 15% of the baseline score in the continuation group compared with 77% in the discontinuation group, relating to improvements in symptoms and quality of life [12].

Vaginal discharge was the most common self-reported complication whereas infection was the most common complication upon examination. Despite the reported complications, 78% of

Table 4 Comparison of satisfaction levels by age group and POP stage among 58 women who attended the 3-month follow-up and 37 women who attended the 12- to 18-month follow-up

	3-month follow-up			12- to 18-month follow-up		
	Satisfied	Not satisfied	OR (95% CI)	Satisfied	Not satisfied	OR (95% CI)
Age[a]						
25–44	24 (92.3)	2 (7.7)	1.00	7 (63.6)	4 (36.4)	1.00
45+	31 (96.9)	1 (3.1)	2.58 (0.22–30.2)	22 (84.6)	4 (15.4)	3.14 (0.62–16.0)
POP stage						
Stage II	49 (96.1)	2 (3.9)	1.00	24 (75.0)	8 (25.0)	1.00
Stage III–IV	6 (85.7)	1 (14.3)	0.24 (0.02–3.12)	5 (100)	0 (0)	3.82 (0.19–76.5)

Where zeros cause problems with computation of the odds ratio, 0.5 is added to all cells (a, b, c, d) [18]

[a] Information about age was missing for three women

the women were satisfied with the pessary when interviewed after 12–18 months and 81% wanted to continue using it. The complication rates in our study are lower than what has been found in other studies where complication rates of 12–27% have been reported [22, 25–28]. This may be because the women in our study were relatively young and thus still had some oestrogen production. They may therefore not have encountered problems with vaginal atrophy, where the lining of the vagina becomes thin, dry and vulnerable. Another explanation may be that the women were instructed thoroughly about how to remove and insert the pessary in relation to the pessary fitting. The detailed counselling and training of the women were performed as it was foreseen that geographical and socio-economic barriers might deter regular 6-monthly follow-up. We found that the complication rate dropped between the 3-month and the 12- to 18-month follow-up. The relatively higher rates of complications at the 3-month follow-up may be attributed to initially poor pessary care at home. The importance of pessary self-care and how to do it was therefore stressed at the 3-month follow-up. This re-counselling and training may explain why the frequency of complications was lower at 12–18 months. Another explanation could be that women who had experienced problems using the pessary had stopped using it and consequently did not show up for the 12–18 months' follow-up. If the latter was the case, it may have led to a falsely low complication rate.

Patient satisfaction in our study was high, with 78% of those women who contributed with follow-up data saying that they were satisfied with the pessary treatment after 12–18 months' use and 81% stating they wanted to continue using it. In general, the follow-up in many published papers is short and the use of validated urogynaecological questionnaires such as the POPDI and POPIQ is limited. However, Lamers et al. [29] conducted a review in 2011 where they found satisfaction rates of 70–92% with medium-term pessary use. Similarly, an English study based on 151 women reported that 86% of the women had been using the pessary successfully for over 5 years [21]. In contrast, an Australian study found that only 14% of the women continued pessary use after 6–16 years' observation time [30]. The high satisfaction rate in our study is in accordance with most studies and reflects the fact that the use of pessaries in the treatment of POP is effective in alleviating POP-related symptoms.

Although the pessary appears to be an effective and acceptable treatment of POP among Tanzanian women, other treatment modalities should also be considered. Some women may experience problems with discharge and erosions and may therefore be in need of alternative treatment. In addition, a significant number of the women were relatively young where the presence of POP could interfere with the women's perceptions of their body and their sexual activity. For those reasons, the need and acceptance of alternative treatment solutions such as surgical repairs should be evaluated in future studies. However, when discussing alternative treatments, it should be respected that for a poor woman living in a rural area, surgical treatment may be an expensive option that involves a travel to a hospital where the procedure is offered by a gynaecologist at a relatively high cost. In contrast, pessary treatment can be initiated in rural settings by trained midlevel staff at a modest cost.

There are some strengths and limitations to this study. First, POP is a complex and sensitive topic to study and we consider it a strength that we translated POPDI and POPIQ into Kiswahili. This enabled us to evaluate the women's symptoms and quality of life 3 months and 12–18 months after pessary fitting, reflecting the impact of short- and long-term pessary use. The use of POPDI and POPIQ further made the study findings internationally comparable. The translation process was performed according to a standardised guideline [31]. The English version was translated by native Kiswahili-speaking nurses, pilot testing was performed and revisions were made to encompass the feedback from the pilot testing. The final questionnaire was then back-translated into English. We

believe that the thorough pilot testing of the questionnaire and the training of our research assistants enhanced the validity and the reliability of the responses. However, we did not evaluate the responsiveness of the questionnaires. Ideally, a thorough validation study, including the responsiveness of the translated POPID-6 and PFIQ-7 should have been performed before study implementation, but time and resources did not allow for this. Another potential flaw is the loss to follow-up: 18% did not show up after 3 months and 48% after 12–18 months. It cannot be ruled out whether the women who were lost to follow-up were using the pessary or not. If they were not complying with the follow-up owing to dissatisfaction with the treatment, the continuation rate found and the satisfaction rate are falsely high. However, when assessing the loss to follow-up, it was found that a large proportion of the women who did not comply with the follow-up procedure lived far from the KCMC, which may reflect that it was the geographical distance rather than dissatisfaction with the treatment that had an impact on whether the women came for follow-up.

Conclusion

Vaginal pessaries improve symptoms and quality of life in Tanzanian women with symptomatic POP. Although their use may be complicated by vaginal discharge and infections, high satisfaction rates were found. Vaginal pessaries may therefore be considered an acceptable treatment modality in managing symptomatic POP in low-income countries such as Tanzania where access to healthcare is poor and specialised care is scarce.

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Compliance with ethical standards

Conflicts of interest None.

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