



How often should ring pessaries be removed or changed in women with advanced POP? A prospective observational study

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Abstract

Introduction and hypothesis This study aimed to evaluate the efficacy and safety of ring pessaries under continuous use for > 2 years. Our starting hypothesis was that their use without periodic removal, cleaning or replacement for between 24 to 48 months after insertion is safe and effective.

Methods This was a prospective observational and descriptive study. One hundred one women who successfully completed the 24 first months of continuous use of a ring pessary were included and monitored for another 24 months. The objectives were to establish the percentage of patients maintaining its use 48 months after insertion, the reasons for discontinuation and the adverse events. Another purpose of this study was to determine the timing of replacement of the vaginal pessary in long-term users.

Results Of the women, 92.1% (93/101) had successful pessary use, and it was discontinued by three patients (2.9%, 3/101); 76.2% (77/101) of the women continued pessary use after the end of the study, and in 16 (15.8%, 16/101) patients, after pessary removal, the prolapse disappeared and did not recur. Forty-five women (48.4%, 45/93) presented some adverse events that required temporary pessary removal. The most common one was an increase in vaginal discharge (73.3%, 33/45). In four women (8.9%, 4/45), the ring pessary was detected embedded in the vaginal epithelium.

Conclusions Continuous use of a ring pessary can be recommended for 2 years in hysterectomized women and for 4 years in non-hysterectomized women if there are no complications.

Keywords Continuous use · Embedded pessary · POP · Removal · Ring pessary

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Introduction

The vaginal pessary is a commonly used non-surgical treatment for pelvic organ prolapse (POP). The ring pessary without support is the most widely used type because it is easier to insert and allows sexual activity without removal [1].

There is wide variation in the global practice of the management of pessaries for POP. There are no evidence-based guidelines to advise practice, and more studies are needed to define optimal pessary use. Self-care is usually recommended for patients to manage the pessary to prevent adverse events. To remove it each night weekly or twice weekly is commonly advised [2], but only 30% of older women are comfortable touching their genitals and handling the vaginal pessary, a finding that has significant implications for its use [3]. Not removing pessaries is controversial, although there is no evidence that changing the pessary has benefits or will prevent fistulae [4].

Several studies have evaluated the results of pessary fitting, with success rates ranging from 41% to 74% [5], complication

rates from 56% to 58% [6, 7] and a mean discontinuation rate of 49.1% [1]. In all of them, the pessary was changed regularly every 3 or 6 months. In a prospective cohort study of 24-month follow-up, with continuous use of a pessary ring without periodic removal, cleaning or replacement, the success rate was 91.8%, adverse events were described in 27% of the women, and pessary use was discontinued by 8.2% of the patients [8]. In a recent meta-analysis, the authors estimated the adverse event rate at 17.3% of the women with continuous pessary use (no interval cleaning or replacement between 6 to 24 months) [9]. These better results obtained in the last studies could be due to the absence of removal, replacement or periodic self-manipulation of the pessary. Thus, if the pessary should not be removed, protocols for management should be reviewed [4].

The COVID-19 pandemic presents a significant change for both patients and practitioners. The Centers for Disease Control and Prevention (CDC) have set forth recommendations to prevent infections in healthcare settings by decreasing or eliminating non-urgent office visits [9].

Miceli et al. [8] proposed that wearing a continuous vaginal ring pessary for 24-months reduces the follow-up schedule post-pessary insertion and the number of control visits with minimal risk of adverse events. To our knowledge, there is no evidence to report about continuous pessary use for > 2-year periods. Thus, clinical studies are necessary to provide new evidence for counseling and long-term follow-up in women who wish to try the pessary.

Our starting hypothesis was that the continuous use of a ring pessary without periodic removal, cleaning or replacement between 24 to 48 months after insertion is safe and effective in women with advanced stages of POP.

Our primary objective was to determine the percentage of patients maintaining the continuous use of a pessary 48 months after the start of pessary use. The secondary objectives were to establish the reasons for discontinuation and the adverse events. Other purposes of this study were to compare the differences in clinical characteristics of the women with successful pessary use with and without adverse events and to analyze possible predictive factors and the differences in adverse event rates between hysterectomized and non-hysterectomized women and therefore to manage these data to establish the optimal timing of replacement of the vaginal pessary in long-term users.

Materials and methods

We performed this prospective observational and descriptive study in a tertiary obstetrics and gynecology department between January 2013 and January 2020. It was approved by the institutional ethics committee of Hospital Virgen Macarena

(register no. 1168-N-17), Medical School, Seville University, Spain. All participants provided signed consent.

The detailed fitting process, efficacy and adverse events for the 24 first months of continuous use of a ring pessary without periodic removal, cleaning or replacement in 123 women with symptomatic advanced POP (stage III and IV) were previously described [8]. This study included those 101 women with successful use of a ring pessary without support (Corysan, Barcelona, Spain) after 24-month follow-up. None of these women refused to participate. All women were followed up for another 24 months (24 to 48 months after pessary insertion). If there were no complications, the participants were monitored every 6 months until the study conclusion at 48 months of pessary use. They were advised not to remove, clean or self-replace the pessary. Vaginal estrogen (10 mg/g promestriene cream, 0.5 g each time, twice a week) was prescribed to the patients.

All patients were always evaluated and treated by the same gynecologist (corresponding author). A telephone hotline number was given to all women for early consultation if needed, and the patients were counseled to call the center in case of complications.

At each visit, a vaginal examination was performed. Complications such as increased or abnormal vaginal discharge, bleeding, ulceration, discomfort or pain, extrusion of the pessary, new-onset urinary incontinence and an embedded, entrapped or epithelialized pessary were recorded. Increased vaginal discharge was previously defined [8]. If participants discontinued using the pessaries, the reasons for discontinuation were recorded, and surgery was discussed.

If abnormal vaginal discharge, bleeding or ulceration occurred, the women were advised to take a 2-week rest without a pessary. The pessary was reinserted after checking that the complication was solved in those cases in which POP persisted. When the POP disappeared and did not recur, the pessary was not reinserted, and women returned after 1 week for a follow-up examination. If there was no recurrence, the follow-up schedule was at 4 weeks and every 6 months for these patients.

Treatment of the embedded or entrapped pessary includes fragmentation of the device without anesthesia in the outpatient clinic. The visible portion of the ring pessary was grasped and divided completely using surgical scissors. The pessary was removed by sliding it through the epithelial tunnel out of the vagina. In all cases, a rectal examination was performed to confirm intact mucosa. The epithelial tunnel was always left intact. A new examination was carried out after 2 weeks. Insertion of the same size of vaginal pessary was performed when POP recurred. If the vaginal vault appeared correctly supported and the POP did not recur in this clinical control, the pessary was not reinserted. These patients returned 1 week later for a new vaginal examination, and if there were no complications or POP recurrence, they were instructed to

continue without a pessary. In this group of women, the follow-up schedule consisted of a new examination at 4 weeks and then every 6 months until the end of the study.

Descriptive statistics were used for demographic data. We calculated the mean and standard deviation for continuous variables. Two-sample t-test and chi-square tests were used to perform univariate analyses to identify potential predictors. Predictors with $p < 0.3$ in univariate analyses were included in multivariate analyses using a binary logistic regression model. $p < 0.05$ was considered statistically significant in the final model. Odds ratios (ORs) and 95% confidence intervals (CIs) are given unless otherwise stated. Statistical analyses were performed using SPSS v.24.0 for Windows (IBM España SA, Madrid, Spain).

Results

From January 2013 to January 2016, 123 women with advanced and symptomatic pelvic organ prolapse (POP) were selected to try a ring pessary. Of the 101 patients who were successful at the 24-month follow-up and were included in this study, the mean age was 66.7 ± 10.3 (range, 38–87) years, and the median gravidity and parity were 3.4 ± 1.4 (range, 0–8) and 3.1 ± 1.2 (range, 0–7), respectively. Nearly all the patients (92.1%, 93/101) were postmenopausal, and none had previously received estrogen therapy. Fifty-three (52.5%, 53/101) patients were sexually active. Sixty-seven (66.3%, 67/101) had a BMI ≥ 25 kg/m². Eleven were smokers, 58 (57.4%, 58/101) had a history of heavy work, and 48 (47.5%, 48/101) were caregivers of dependent persons.

Most of the patients (92.1%, 93/101) had concomitant medical diseases such as rheumatological diseases (60.4%, 61/101), cardiovascular diseases (59.4%, 60/101) and/or diabetes (18.8%, 19/101). Twenty-eight (27.7%, 28/101) women had a recurrence after pelvic floor reconstructive surgery. Fourteen (50%, 14/28) had mesh repair of the anterior vaginal wall, and the remaining patients (50%, 14/28) had hysterectomies. Twelve of those (85.7%, 12/14) had a transvaginal hysterectomy (all had a fourth-stage vault prolapse). The mean genital hiatus (gh) and total vaginal length (TVL) were 5.1 ± 1.1 and 8.3 ± 0.6 cm, respectively, which resulted in a gh/TVL ratio of 0.61.

Fifty-five (54.5%, 55/101) patients had stage III POP, and the remaining patients (45.5%, 46/101) had stage IV POP. The most affected prolapse compartment was the apical compartment (90.1%, 91/101).

At baseline, the three most common prolapse symptoms were bulging (100%, 101/101), pelvic pressure (90.1%, 91/101) and bleeding (57.4%, 58/101). Each woman had at least two of these symptoms. Regarding urinary symptoms at baseline, 56.4% (57/101) of the patients reported voiding

difficulty, 35.6% (36/101) reported urge urinary incontinence, and 31.7% (32/101) reported stress urinary incontinence (SUI).

Of the 101 women who were included in this study, four (3.9%, 4/101) patients died from non-pessary-related causes during follow-up [stroke ($n = 3$) and influenza complicated with pneumonia ($n = 1$)] at 26, 36, 40 and 47 months of follow-up. One (1%, 1/101) patient was a drop-out at 28 months in the follow-up due to change of residence. Pessary use was discontinued by three patients (2.9%, 3/101). The reasons for ceasing pessary use were vaginal bleeding in two patients, and one woman requested pessary removal by concomitant endometrial polyp diagnosis. After discontinuing pessary use, these patients opted for surgical treatment (Fig. 1).

Ninety-three (92.1%, 93/101) patients had successful use. If all periods of follow-up after initial recruitment (48 months) are included, the efficacy reaches 80.9% (93/115). Seventy-seven (76.2%, 77/101) women continued pessary use at the end of the study. In 16 (15.8%, 16/101) patients, after pessary removal the POP disappeared and did not recur. They were considered successful treatments. The reasons for ceasing pessary use in these 16 women were: abnormal vaginal discharge ($n = 12$), bleeding or excoriation ($n = 2$) and an embedded or entrapped pessary ($n = 2$).

Adverse events were evaluated in those 93 women with successful use at the end of the study. Forty-five patients (48.4%, 45/93) presented some adverse events that required temporary pessary removal. The most common one was an increase in vaginal discharge during a medical visit. This event was reported by 33 women (73.3%, 33/45), 20 in the 3rd year (24 to 36 months of follow-up) and 13 in the 4th year after pessary insertion. In all of these patients, the pessary was removed for 2 weeks, the culture was negative, and the vaginal discharge disappeared spontaneously. The same ring pessary was reinserted in 21 patients because the POP reappeared in the pessary-free period. In the remaining 12 women, the POP did not recur, and the pessary was not reinserted.

In four women (8.9%, 4/45), the pessary was removed because of bilateral vaginal pain, localized in the later pubic ramus. Bleeding or excoriation was observed in four patients (8.9%, 4/45). In all cases, pain and bleeding disappeared spontaneously after the pessary removal, and six patients needed reinsertion because the POP reappeared in the pessary-free period.

In four women (8.9%, 4/45), at the medical controls (3 at 30 months and 1 at 48 months of follow-up) vaginal examination showed the ring pessary embedded in the vaginal epithelium, creating a bridge over it. The pessary always was removed, and the epithelial tunnel was left intact. Three women had been previously hysterectomized (23.1%, 3/13). One was a non-hysterectomized postmenopausal patient (1.2%, 1/80). All of them had a fourth-stage prolapse. In two women (both of them

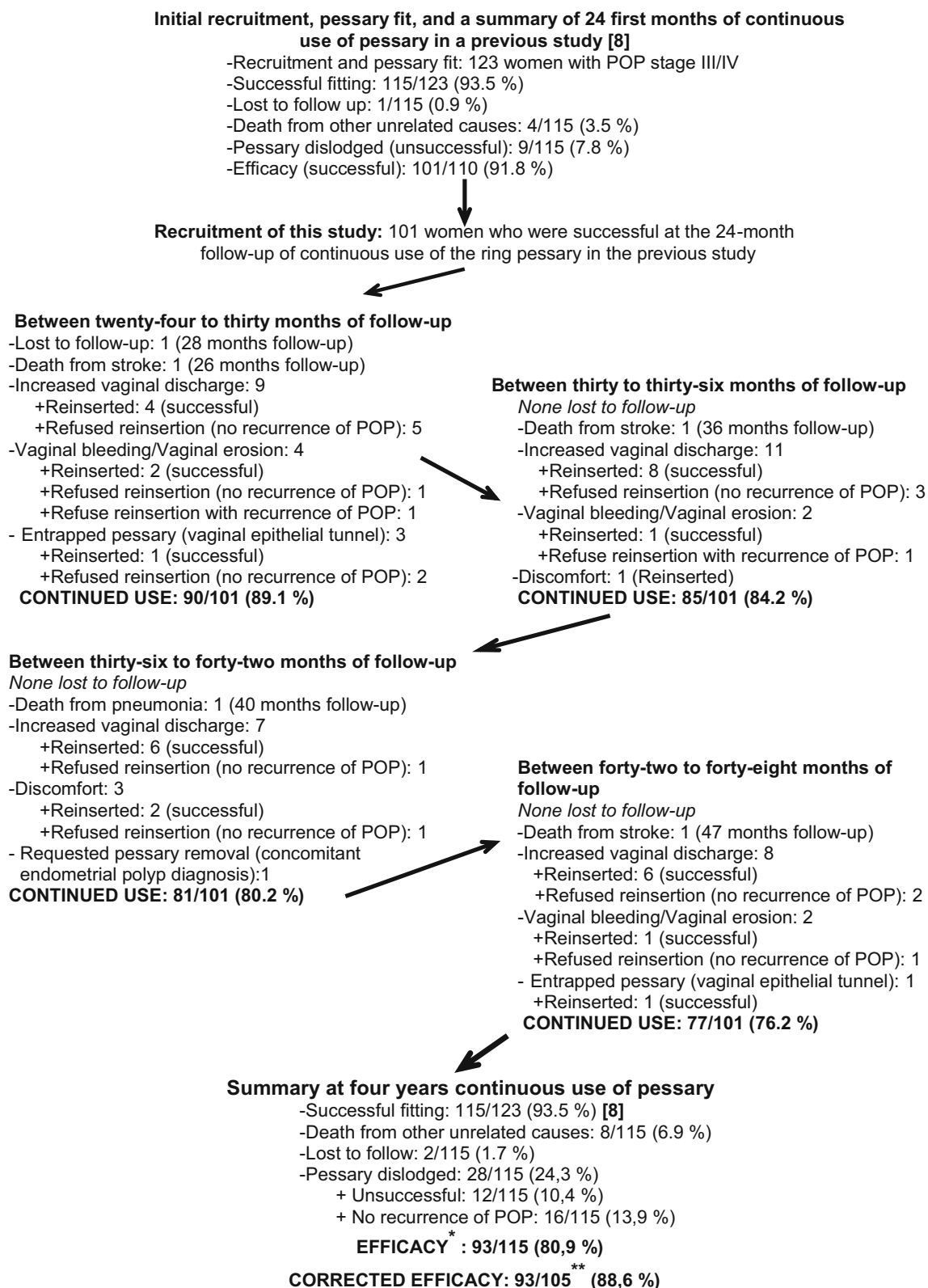


Fig. 1 Diagram showing the number of patients who continued ring pessary use, the causes of removal and the reasons for discontinuation

hysterectomized), the pessary was not reinserted because the epithelial bands in the vagina prevented further POP. At the end of the study (after 18 months without

pessary), these patients were still asymptomatic, with no evidence of POP, and did not complain of any symptoms caused by the retained epithelial tunnel.

Table 1 Demographic and clinical parameters of women with and without adverse effects that required the temporary removal of the pessary

Demographics and potential risk factors	Without adverse events <i>n</i> =48	With adverse events <i>n</i> =45	<i>p</i> value	Multivariable OR	Analysis 95% CI	<i>p</i> value
Mean age, years, \pm SD	64.0 \pm 11.1	67.9 \pm 8.3	0.17 ^c	1.01	0.93–1.06	0.97
Mean age of menopause, years, \pm SD	42.3 \pm 18	49.2 \pm 8.1	0.03 ^c	1.01	0.96–1.07	0.52
Mean gravidity \pm SD	3.2 \pm 1.4	3.7 \pm 1.4	0.13 ^c	1.13	0.55–2.33	0.73
Mean vaginal deliveries \pm SD	2.9 \pm 1.2	3.4 \pm 1.2	0.10 ^c	0.98	0.41–2.33	0.97
BMI > 25 kg/m ² <i>n</i> (%)	33 (68.8)	31 (68.8)	1 ^b			
Large baby \geq 4 kg <i>n</i> (%)	24 (50.0)	30 (66.7)	0.09 ^c	0.36	0.14–0.91	0.03
Sexually active, <i>n</i> (%)	28 (58.3)	22 (48.9)	0.41 ^b			
Medical comorbidities, <i>n</i> (%)	40 (80.3)	44 (97.8)	0.03 ^d	0.23	0.01–3.39	0.29
Diabetes, <i>n</i> (%)	8 (16.7)	9 (20.0)	0.60 ^b			
Cardiovascular diseases, <i>n</i> (%)	24 (50.0)	30 (66.7)	0.09 ^b	0.86	0.27–2.70	0.80
History of breast cancer, ovary and/or bowel cancer, <i>n</i> (%)	2 (4.2)	2 (4.4)	0.99 ^b			
Tamoxifen therapy, <i>n</i> (%)	2 (4.2)	2 (4.4)	0.99 ^b			
Rheumatological diseases, <i>n</i> (%)	27 (56.3)	29 (64.4)	0.40 ^b			
Lumbar disc herniation, <i>n</i> (%)	6 (12.5)	11 (24.4)	0.11 ^b	0.58	0.17–1.99	0.39
Anticoagulation therapy, <i>n</i> (%)	5 (10.4)	8 (17.8)	0.24 ^b	0.69	0.18–2.68	0.60
Caregiver, <i>n</i> (%)	25 (52.1)	18 (40)	0.41 ^b			
History of heavy job, <i>n</i> (%)	32 (66.7)	22 (48.9)	0.06 ^b	2.17	0.84–5.57	0.10
Smoking, <i>n</i> (%)	6 (12.5)	4 (8.9)	0.50 ^b			
Chronic cough, <i>n</i> (%)	6 (12.5)	4 (8.9)	0.50 ^b			
Chronic constipation, <i>n</i> (%)	31 (64.6)	29 (64.4)	0.99 ^b			
Previous non-genital abdominal surgery, <i>n</i> (%)	9 (18.8)	8 (18.8)	1 ^b			
Prior hysterectomy, <i>n</i> (%)	8 (16.7)	5 (11.1)	0.59 ^b			
Prior mesh repair of anterior vaginal wall, <i>n</i> (%)	8 (16.7)	9 (20.0)	0.60 ^b			
History of urinary urge incontinence, <i>n</i> (%)	17 (35.4)	16 (35.5)	0.99 ^b			
History of stress urinary incontinence (SUI), <i>n</i> (%)	13 (27.1)	17 (37.8)	0.27 ^b	0.67	0.24–1.83	0.44
Total vaginal length (TVL), cm \pm SD	8.3 \pm 0.6	8.3 \pm 0.7	0.96 ^c			
Genital hiatus (gh), cm \pm SD	5.1 \pm 1.2	5.1 \pm 1.1	0.86 ^c			
Stage of apical compartment, <i>n</i> (%)			0.80 ^b			
Stage III	33 (73.3)	34 (75.6)				
Stage IV	12 (26.7)	11 (24.4)				
Stage of anterior compartment, <i>n</i> (%)			1 ^d			
Stage III	25 (100.0)	26 (96.3)				
Stage IV	0 (0.0)	1 (3.7)				
Predominant compartment of support loss, <i>n</i> (%)			1 ^d			
Anterior wall	5 (10.4)	4 (8.3)				
Apex	43 (89.6)	44 (91.7)				
Posterior wall	0 (0.0)	0 (0.0)				

SD standard deviation, BMI body mass index

^a Two-sample t-test, ^b chi-square test, ^c Mann-Whitney *U*-test, ^d Fisher's exact test

Table 1 shows the results of the univariate and multivariate analysis of the patient's characteristics with and without adverse effects that required the temporary removal of the pessary. The clinical and epidemiological parameters were similar between the two study groups except for the mean age of menopause ($p = 0.03$) and medical comorbidities ($p = 0.03$)

with no statistical difference ($p > 0.05$). Eleven predictors in univariate analyses, with $p < 0.3$, were included in the multivariate analyses. Only previous history of deliveries with the largest size range of babies (OR 0.36 [95% CI 0.14–0.91]) was a factor associated with adverse event presence during pessary use. We did not find a reasonable clinical explanation

for this finding; therefore, these results will need to be verified in future studies.

Discussion

A problem with pessary use is the long-term continuation rate [10]. Several studies have evaluated the effectiveness of pessaries at short-term use, with success rates ranging from 41% to 74% [5]. Conversely, few studies have evaluated long-term follow-up periods. A retrospective study (over 6 to 15 years) reported that only 14% of their patients continued pessary use at the 7-year median follow-up. In this study, the average duration was 1.4 years for those patients who discontinued pessary use [6]. A 5-year prospective observational study reported 28.3% success at the end of follow-up, and the average duration of pessary use was 3.5 years [11]. In all of these studies, the pessary was cleaned or replaced regularly every 3 or 6 months.

In our previous study at the 24-month follow-up, the continuous use of a ring pessary without periodic removal or replacement was associated with a success rate of 91.8%, and pessary use was discontinued by 8.2% of the patients [8]. In this new study period (24 to 48 months of follow-up), 76.2% (77/101) of women continued pessary use at the end of the study, and it was discontinued by 2.9% (3/101) of the patients. In 15.8% (16/101) of women, after temporary pessary removal, the POP disappeared and did not recur; therefore, it was considered a successful treatment. If we included all periods of follow-up after initial recruitment, the efficacy at 48 months of follow-up was 80.9% (93/115), or 88.6% (93/105) if we exclude patients who died from non-pessary-related causes and drop-out women.

Self-care is usually recommended for patients to manage the pessary to prevent complications [2]. Removing the pessary each night weekly or twice weekly is commonly advised. Manchana recommended removing and cleaning the pessary at least once weekly and reported success of 52% of the patients at the 13-month mean follow-up [10], which is much lower than our rate of success at 48 months of follow-up with continuous use of a ring pessary.

A prospective cohort study determined the efficacy of routine follow-up visits for pessary cleaning at 3 and 9 months after insertion. They concluded that frequent pessary cleaning in asymptomatic women is not efficient, and there is no difference in the severity of the pessary-related adverse effects between a 3- and a 9-monthly follow-up interval [12].

Frequent pessary removal for cleaning or replacement can cause anxiety, which may lead to discontinuation of pessary use because only half of the patients could manage the pessary either by themselves or with their caregivers [10]. Moreover, 70% of older women feel uncomfortable with handling the vaginal pessary [3]. In these patients, pessary removals can

be traumatic and painful, a finding that has significant implications for pessary use.

Continuous use of a pessary for long periods has the benefits of convenience and comfort. These reasons may have contributed to our high success rate and elevated continuation rates. To wear a ring pessary for 2 to 4 years, without periodic removal or replacement, could be an excellent option for asymptomatic women.

Currently, there is no standard recommendation for the timing to change the vaginal pessary. Most clinicians reported replacement every 3–6 months, the rationale being to prevent infection and fistulae. A survey of 555 clinicians found that 23.3% of them changed pessaries for patients 3–6 monthly, 67.0% 6 monthly and 9.7% 6 to 12 monthly [13].

It is not clear whether the interval of replacement can affect the risk of adverse events. The complication rates did not vary between the 3-month and 6-month changing intervals and even tended to decrease with interval length up to the 12-month follow-up period [13]. A recent trial reported the outcome of two ring pessary replacement intervals, 3 and 6 monthly. Higher complication rates were observed in the 6 monthly group compared to the 3 monthly group, although it was not statistically significant. Patient satisfaction scores were similar in both groups [14]. Therefore, there is no evidence that regular changing of the pessary is preventive.

In this study period (24 to 48 months of follow-up), we reported an overall complication rate of 48.4% (45/93), which included vaginal discharge (73.3%), pain (8.9%), bleeding (8.9%) and embedded pessary (8.9%).

In the first 24 months of follow-up, vaginal discharge was observed in 5.2% of women [8], while 35.5% (33/93) of patients reported vaginal discharge 24 to 48 months after the pessary insertion, and the latter had a negative vaginal culture. In all of them, the pessary was removed for 2 weeks, and the vaginal discharge disappeared spontaneously, being, therefore considered a symptom related to the prolonged presence of the pessary. We agree with Collins [15] that this type of aseptic vaginal discharge is probably a reactive inflammatory process, and we think that vaginal discharge may be the reference symptom for removing the device in continuous pessary users in long-term programs.

The prevalences of pain and bleeding were similar to those reported in the first 24 months of follow-up. Conversely, no patient reported the extrusion of the pessary during defecation or daily activities in the follow-up period of 24 to 48 months. None of the women had pessary dislodgement after 6 months of the pessary insertion [8].

Neglected vaginal pessaries can cause major complications (hydronephrosis, fistula, fecal impaction, bowel incarceration and urosepsis). When a pessary is not removed for a very long period, it can become embedded in the vaginal wall, making it difficult to remove [16]. A search of the English literature from 1950 to 2007 identified six cases of embedded pessaries.

They were all related to neglected pessaries [17]. It is essential, therefore, to instruct the patients about the importance of regular medical controls of the pessary, especially in long-term continuous use.

In the first 24 months of follow-up, embedded pessaries were not observed. We detected the first three cases in hysterectomized women (3/13) at 30 months of pessary use. In all cases, the epithelial bridge originated on the vaginal vault. Only one woman with an intact uterus (1/80) developed an embedded pessary on the left lateral side of the vagina at 48 months of follow-up. Our results showed an elevated prevalence of embedded pessaries in hysterectomized women (23.1%, 3/13) compared to non-hysterectomized patients (1.2%, 1/80). This finding moves us to consider changing or removing the pessary 24 months after continuous use as a recommendable strategy, specifically in hysterectomized patients with POP, to prevent this complication.

It is possible to successfully remove an embedded pessary in the office and without anesthesia. In all cases, this was achieved by sectioning of the ring pessary and sliding the divided pessary through the vaginal bridge. The epithelial tunnel was left intact, and in two women (both hysterectomized) the epithelial bands in the vagina prevented further POP.

In previous studies, some cases of POP, in which the prolapse remained corrected after pessary removal, were described [18, 19]. In our study, 45 patients (48.4%, 45/93) presented some adverse events that required temporary removal, and they were evaluated 2 weeks after pessary extraction. In 16 (35.6%, 16/45) women, the POP disappeared and did not recur. The mean (range) duration of pessary insertion and for observation after removal was 45.0 (30–48) and 12.2 (1–36) months, respectively. Our results suggest that long-term continuous use of a vaginal pessary could be not only be a palliative treatment but also therapeutic for some patients with advanced POP. Nevertheless, we think that more prospective longitudinal studies should be performed to determine whether long-term continuous pessary usage can improve prolapse after discontinuation.

In our previous study, which included the first 24 months of follow-up of women wearing ring pessaries without periodic removal or replacement, we proposed reducing the follow-up schedule post-pessary insertion to three consultations: at 1 week, 6 months and 2 years, whenever there are no complications [8]. In the study period of 24 to 48 months of follow-up, the pessary discontinuation rates were low in all patients and adverse events mild in non-hysterectomized women. For this period, we propose only one control at 48 months of follow-up, if there are no complications, with two objectives: to remove the pessary and to re-evaluate the stage of POP. Conversely, in hysterectomized patients, we propose the pessary change or removal at 24 months of continuous use to prevent embedded pessary cases. The patients

should be counseled to contact the medical office in case of pessary extrusion, vaginal discharge, blood loss or pain.

The continuous use of a pessary during 24 to 48 months and the reduction of the follow-up schedule post-pessary insertion could have financial implications by reducing the economic costs associated with frequent pessary change and the health care service demand by reducing the number of medical consultations. In this time of the COVID-19 pandemic, decreased office visits have an associated benefit for both the patient and the healthcare system. Finally, we provided data that can be useful for counseling women who cannot or do not wish to carry out self-care of their pessary or to have frequent changes for whatever reason.

Limitations of the present study included the small sample size and patients assessed at only one center. We used ring pessaries without support, but no other types of pessaries, and we did not use quality of life questionnaires to assess subjective outcome. Thus, additional prospective, multicenter studies with large sample sizes are needed. Finally, a prospective randomized study is necessary to compare the efficacy and safety of continuous pessary use versus periodic removal and to determine whether long-term pessary use alters the natural history of POP.

Conclusions

In conclusion, our findings show that continuous use of a ring pessary without support can be recommended in patients with advanced stages of POP for 2 years in hysterectomized women and up to 4 years in non-hysterectomized women if there are no complications. The risk of embedded pessary is elevated in hysterectomized women with continuous pessary use > 2 years. A high success rate and mild side effects and complications are associated with continuous use of a long-term ring pessary without periodic removal, cleaning or replacement when patients are followed up properly.

Authors' contributions Alessio Miceli and Manuel Fernández-Sánchez were involved in the data collection, analysis and data interpretation, statistical analysis, and critical revision of the manuscript. José-Luis Dueñas-Diez was responsible for the study design, patient's clinical assistance, data collection and entry data analysis, and manuscript preparation.

Declarations

Conflicts of interest None.

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