



## Does monthly self-management of vaginal ring pessaries reduce the rate of adverse events? A clinical audit

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### ABSTRACT

**Objective:** To determine the rate of adverse events (AE) in women who self-manage their vaginal ring pessary on a monthly basis. We hypothesised that the AE rate would be lower compared to previously published traditional management protocols.

**Study design:** Audit study of 75 women with pelvic organ prolapse and/or stress incontinence, who were fitted with a vaginal ring pessary during a five-year period, and who have self-managed their vaginal rings for at least two years, in a tertiary referral urogynaecology clinic.

**Main outcome measures:** AEs included vaginal bleeding, malodorous vaginal discharge, extrusion of the device, pain/discomfort, and disorders of defaecation or de novo urinary incontinence. AEs that led to discontinuation of usage were termed “major”.

**Results:** Of the 75 women who were taught to self-manage their ring pessary, 68 were initially successful. At a median follow-up of 50.5 months [IQR 43–76 months; median 4.2 years], 36 women (52.9%) were still using their ring pessary. Five women (7.4%) had vaginal erosions and bleeding leading them to cease pessary use (four proceeded to surgery). Three minor AEs were identified (4.4%), resolving after discontinuation of ring use two weeks. Thus, the overall AE rate was 11.8% (8/68).

**Conclusions:** In contrast to previous published AE rates of 43–56% in women having ring changes at a clinic every 4–6 months, the AE rate was 12% in the women who performed monthly self-management of vaginal ring pessaries. Such information should be made available to patients considering a vaginal ring pessary.

### 1. Introduction

Pelvic organ prolapse is a common but often disabling condition with a lifetime prevalence of 30–50 % [1,2]. A wide choice of surgical procedures have been developed for prolapse, but some women are reluctant to embark upon general or regional anaesthesia or to be hospitalised. Vaginal ring pessaries are used to restore the prolapsed organs to their normal position and therefore relieve symptoms. They have come to occupy a recognised place in the gynaecologists' armamentarium, with renewed interest since the late twentieth century [3–5]. More recently, vaginal rings have been modified so as to correct urinary stress incontinence and these are also gaining in popularity [6].

However, data about long-term success and/or complications of vaginal ring pessary use has only emerged in the last two decades. In

2009, Sarma et al. followed 167 women over a median of 7 years [range 2–14 years] and found that complications such as vaginal bleeding, malodorous discharge, extrusion, and pain occurred in 56 % of cases. Most women in this study had their vaginal ring changed by a continence nurse or a gynaecologist every 4–5 months. [7] In 2011, Lone et al. followed 187 women who used similar vaginal rings for a median of 3.5 years [range 2.5–5 years] and had the ring changed in the clinic every six months. Their data revealed that 80 women stopped using the ring because of vaginal bleeding, extrusion, and pain (43 %). However, the incidence of malodorous vaginal discharge was not stated. [8].

Since publication of the 2009/2011 [7,8] data, which revealed a worrisome rate of complications, our department has encouraged women to self-manage their vaginal ring pessaries. We offer training in self-management to all interested women. The ring is removed by the

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woman every month, washed in hot soapy water and then reinserted, with annual medical review and speculum exam. Currently, there are no publications about the likelihood of significant long-term adverse events in women who self-manage their rings.

The aim of this audit was to evaluate all women who were taught self-removal and self-insertion of their vaginal ring pessary over a period of six years, to determine whether the adverse event (AE) rate will be lower in women who remove and wash their own ring pessary on a monthly basis, compared with previous studies of less frequent changes by health care providers in the clinic.

## 2. Methods

An audit of the self-insertion management strategy was conducted in a metropolitan tertiary referral urogynaecology unit. The notes of all patients who had been successfully taught self-management during the six year audit period (from 2011 to 2016), were reviewed. The cases were followed prospectively for at least 2 years in those patients who were first encountered in 2016. “Successful” self-management was defined as the patient who was comfortably fitted with a vaginal ring pessary that she could wear for at least two weeks and which she was able to self-remove and reinsert. Patients typically used Portex rings, Ring with Support or Shaatz if only complaining of prolapse, while those with mixed prolapse and urinary incontinence were mainly fitted with a Continenace Dish or Intral device (Fig. 1). Post-menopausal women are advised to use vaginal oestriol cream twice weekly, or vitamin E cream, to soften the vaginal tissues at the introitus. Women using cube pessaries and Contiform devices were excluded, as they are required to self-change their device daily or weekly, respectively.

After initial fitting of a prolapse or continence ring pessary, women were encouraged to learn from a specialist nurse how to self-remove and self-insert their pessary. Patients were shown how to compress the ring into an oblong shape then guide it gently into the introitus and upwards towards the cervix, then ensure that the inferior edge of the ring rested above the back of the pubic bone on the lower anterior vaginal wall (a diagram was shown to the patient first). Removal, by grasping the ring and pulling it firmly downwards, was then shown, and the patient was encouraged to perform both manoeuvres. Patients were advised to

wash the ring in hot soapy water once every month (this interval was chosen for convenience, especially in the case of menstruating women). Patients were reviewed two weeks after the training session, to check correct device size and to provide any further training needed for self-management (see Section 4). Annual speculum examination was conducted by a urogynaecology clinician, and a new vaginal ring was provided every 12 months.

Demographic data collected, in those women who were interested to learn self-management, comprised age, parity, body mass index, prolapse and urinary symptoms, menopausal status, and duration of self-management. Adverse events that were enquired about included vaginal bleeding, malodorous discoloured vaginal discharge, extrusion of the device, pain/discomfort, disorders of defaecation or de novo urinary incontinence. Malodorous discharge was defined as profuse discoloured mucopurulent discharge, which was treated by ring removal for 2–3 weeks, salt baths and metronidazole oral therapy.

A major AE was defined as a prolonged event that caused the patient to cease use of the ring entirely. An adverse event was a short term difficulty resolved by 2–3 weeks of rest and oestriol use with continued pessary use afterwards. In women with persistent red or brown vaginal bleeding (not staining), a speculum examination was performed to identify possible erosions (or granulation tissue, which was treated with silver nitrate) and the pessary was left out of the vagina for 2–3 weeks, with daily salt baths and topical oestriol cream.

Patients who discontinued are denoted separately from long term successful users, as duration of use might influence the incidence of complications.

## 3. Results

The demographic data of the 75 women who were taught to self-remove and reinsert their vaginal ring pessary are shown in Table 1. Seventy were trained during the audit period (2011–2016) and five had been trained up to six years previously. Fig. 1 shows the types of pessaries that were used and self-managed in this study.

As shown in Fig. 2, seven women did not continue self-management at the two week visit, of whom three women couldn't reach the device due to short fingers or obesity and now have their ring changed by

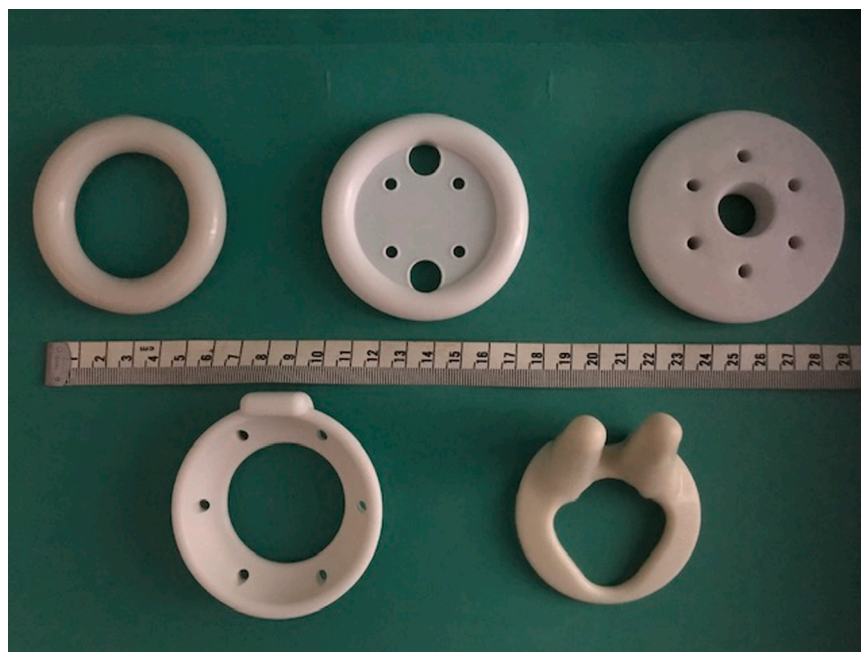


Fig. 1. Vaginal pessaries used in this study. Top row: Portex ring, Ring with Support, and Shaatz, respectively. Bottom row: Continenace dish and Intral device, respectively.

**Table 1**  
Demographic details of the 75 women taught to self-manage their vaginal ring pessary.

Age at first visit (years)	61	[52–66]
Parity	2.5	[2,3]
Body mass index (kg/m <sup>2</sup> )	27.8	[24.5–34.9]
<b>Main complaint</b>		
– Prolapse symptoms	42	57.5 %
– Urinary incontinence	20	24.7 %
– Mixed	13	17.8 %
<b>Postmenopausal</b>	63	84 %
<b>Type of pessary ring fitted</b>		
– Portex ring	29	38.7 %
– Ring with Support	5	6.7 %
– Shaatz	11	14.7 %
– Continence dish	28	37.3 %
– Intron	2	2.7 %

health care providers in the clinic. Two women wanted surgery immediately, but required rings temporarily during a weight loss programme and declined self-management. One woman decided that her prolapse symptoms were not severe enough to warrant the ring. The seventh woman had psychiatric issues that occupied her attention.

Of the 68 women who were successfully taught how to self-manage their vaginal ring pessary, 36/68 (52.9 %) continued self-management until the end of the audit period (Jan 2019). Their median length of ongoing pessary self-management was 50.5 months [IQR 43–76 months; median 4.2 years]. Their median age was 61.0, IQR 51.0–65.0.

Of the 68, there were 24 women who initially learned self-management (35%) but discontinued, at a median duration of use of 18 months [IQR 8.5–33.5]. Their median age was 63.0, IQR 53–69. Of these, fifteen women eventually preferred surgical treatment despite having no AE from their ring pessary. A further five women (7.4 %) stopped using the device because of major adverse events, of whom four had a surgical repair and one chose observation of the prolapse (Fig. 2). Eight women (12 % were either lost to follow-up or chose to have a nurse change their ring in the clinic because of advancing frailty.

Of the 36 women who continued with the device for a median 4.2 years, three women with minor AEs were noted (4.4 %). In all three cases, vaginal spotting/ bleeding and erosion resolved after three weeks of ring removal and daily use of oestriol cream. These women continued

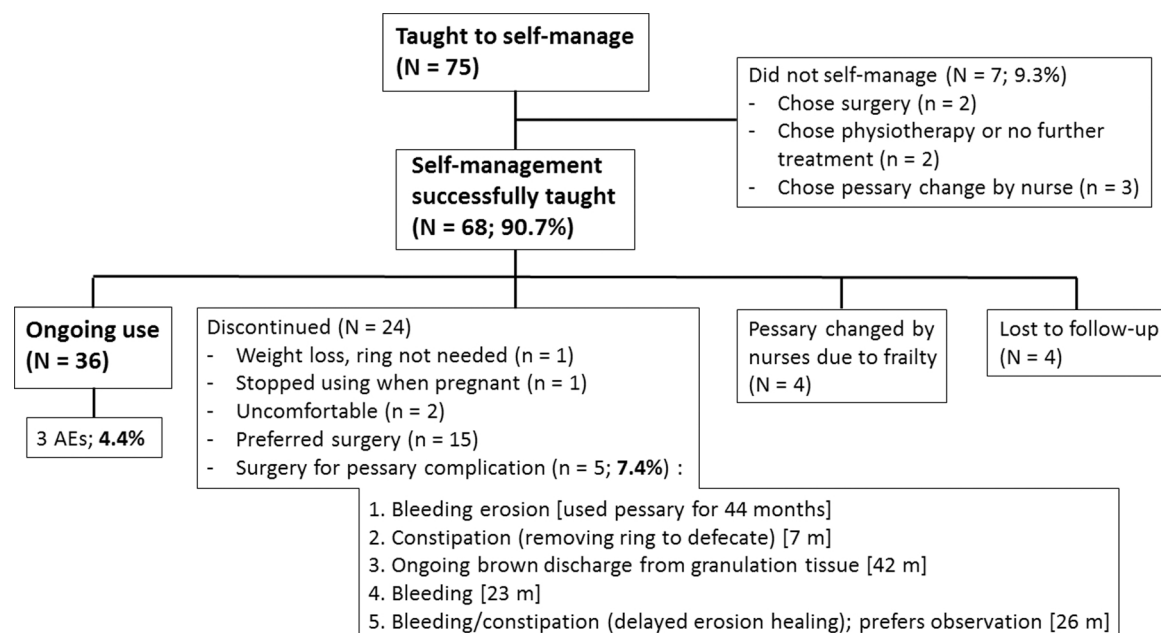
to use their pessaries for 29, 47 and 76 months, respectively, at conclusion of the audit. Thus, the overall rate of adverse events was 8/68 (11.8 %).

#### 4. Discussion

The results of our audit show that for women who self-manage their vaginal ring pessary on a monthly basis, a low complication rate (overall 11.8 %) was found at a median duration of use of 4.2 years. In contrast, studies in which rings were left in situ for 4–6 months and changed by health care providers in a clinic over 3.5 – 7 years duration, revealed complication rates of 43–56 % [7,8].

This study came about because anecdotal experience in our Unit prior to 2011 suggested that women who self-cleaned the device monthly had a low chance of adverse events. When the high rates of adverse events were published in 2009/ 2011, we decided to establish a policy of teaching women to self-manage the device and then audit the results. Our specialist gynaecology nurses became skilled over time in providing this training. For example, women often needed to try different positions for removing the device (one foot on the toilet stool, or bending over in the shower after applying soap to the introitus), and women with rather short fingers sometimes engage their partners to remove the device but find that insertion of the ring is less difficult. Also, some preliminary education was often needed about vaginal anatomy, in keeping with a previous study showing that 65 % of post-menopausal women have very limited anatomical understanding of this area [9].

As to the applicability of vaginal rings generally, and the possible significance of our findings, several surveys amongst gynaecologists regarding their day to day practice of pessary use have been published: two from the USA [3,4], Three British studies [5,10] and one from the Netherlands [11]. All five surveys indicated that gynaecologists routinely offer vaginal ring pessaries as a primary treatment option. Velzel et al. [2015] discovered that the percentages quoted by gynaecologists for the risks of vaginal discharge and bleeding varied enormously (5–40 %) [11]. As to the possibility of self-management, Bugge et al. noted that 17.7 % of the 527 British health care providers “advised women to manage their pessary themselves” [10], whereas 53 of the 91 Dutch gynaecologists answered “yes, always” when asked whether they gave “advice about self-management” [10]. This contrasts with the reports of Gorti [5] and the two American studies [3,4] which do not



**Fig. 2.** Flow chart of women who were taught how to self-manage their vaginal ring pessary during the audit period. AEs Adverse events.

comment at all about self-management of vaginal rings. Donnelly et al. [12] stated that “we taught all women who were successfully fitted learned how to insert and remove the pessary” for stress or mixed incontinence, but the percentage of women who actually performed self-management was not stated and AEs were not tabulated. Cundiff et al. [3] stated that 53 % of women were taught self-management, but the regime was not stated and AEs were not reported, similar to Kearney and Brown [13]. Hence the present Audit appears to provide the first data set regarding the rate of adverse events associated with the self-management strategy. Our department was concerned about the high risk of adverse event under the traditional “clinic change” strategy, so we changed our policy in 2011 and began to audit the results, thus “closing the feedback loop” in the audit cycle.

It was interesting to find that over 90 % of the 75 Australian women who opted for vaginal ring pessaries were willing and able to learn how to self-manage their vaginal ring pessary. This is despite a median age of 61 years, with a range of 30–88 years. The ages of women who continued long term self-management were no different to the age of those who withdrew. Overall willingness amongst patients to use a vaginal ring pessary also appears to be high, as 58% of the British women in the publication of Lone et al. chose a ring instead of surgery [8]. In the publication of Donnelly, two thirds of women offered pessaries were interested in pursuing this treatment modality [12].

## 5. Conclusion

As gynaecologists have now largely abandoned the use of vaginal mesh implants for prolapse repair, this new data regarding the safety of self-managed vaginal ring pessaries will be of considerable interest. Our findings, that the previously substantial rate of adverse events for ring pessaries (43–56 %) is reduced to 12 % when self-management is employed, should be made known to affected patients when discussing treatment options. This strategy also provides women with greater self-control over their prolapse and/or incontinence problems, and is likely to result in cost-savings for the health service [12].

## Details of Ethics Approval

This study was approved by the South Eastern Area Local Health District/Human Research Ethics Committee Central Network. It was classified as an audit study with low negligible risk (LNR) requiring verbal consent, with approval number 08/STG/4.

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## Disclosure of interests

None of the authors report a conflict of interest.

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## Contribution to authorship

KHM: study design, supervision of data collection, provision of funding, final manuscript preparation KL: data collection and entry, data analyses, preliminary manuscript preparation, WA: patient training, data collection, KP: patient training, data collection, NiTW: study design, data collection and entry, data analyses, manuscript preparation.

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