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Does vaginal estrogen treatment with support pessaries in vaginal prolapse reduce complications?

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Abstract

Objective: Pelvic organ prolapse is often co-existant with atrophy of the genital tract in older women who tend to prefer vaginal pessaries for prolapse. Vaginal estrogen therapy is used by some along with a support pessary for prolapse with no robust evidence to back this practice. We aimed to evaluate differences in complications of support pessaries for vaginal prolapse in postmenopausal women, with and without vaginal estrogen use.

Study design: We prospectively assessed postmenopausal women attending the urogynaecology clinic for a pessary change. We asked them about the level of discomfort during pessary change (visual analogue scale for pain), discharge, bleeding and infection. Ethics approval was not required as this was a service evaluation project. Statistical analysis for relative risk was performed, including sub-group analysis for 'ring pessary' and 'non-ring group' (Shelf, Gellhorn, Shaatz).

Results: Between July 2013 and December 2014, we assessed 120 postmenopausal women using support pessaries for prolapse. The mean age was 70 years; 45% of the patients used vaginal estrogen. There were no statistically significant differences in complications with or without vaginal estrogen use, although the trend was higher amongst non-users. The 'non-ring' sub-group not using vaginal estrogen had a higher risk of vaginal ulceration, bleeding and discharge.

Conclusion: Postmenopausal women may have lesser complications when using vaginal estrogen with a support pessary for prolapse, particularly with pessaries other than the ring. An adequately powered randomised controlled trial is needed to assess conclusively whether vaginal estrogen enhances comfort and reduces complications of support pessaries for prolapse.

Keywords

Postmenopausal women, prolapse, vaginal estrogen, vaginal pessary

Introduction

Pelvic organ prolapse (POP) affects 30–50% of parous women over 50 years of age.[1] Although mostly asymptomatic,[2] prolapse may present with symptoms of a bulge, pelvic pressure and is often associated with bladder, bowel and sexual dysfunction. Conventionally, pessaries have been used as an alternative to surgery for women who are medically unfit, wish to have children, decline surgery or as a temporary method to control symptoms while awaiting/deferring surgery.[3] One study reported that almost two-thirds of these women choose a vaginal pessary over surgery as the initial treatment.[4] Success rates with short-term use of vaginal pessaries to treat POP range from 56 to 100%.[5,6] It has been shown that use of vaginal pessaries over a 5-year period was associated with minor complications in 12.1% of women[7] while major complications were only seen with neglected pessaries.[8]

Alongside the development of POP, postmenopausal vaginal atrophy, due to estrogen deficiency, is a common and a well-recognised condition.[9] Lack of estrogen can be associated with fissures, telangiectasis,

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ecchymoses and ulcerations. The mechanical weakness compounded with changes in vaginal pH leads to an increased risk for urogenital infections.[10] In a recent systematic review vaginal estrogen application has been shown to possibly play a useful role as an adjunct in the management of common pelvic floor disorders in postmenopausal women.[11] For symptoms of vaginal atrophy localised delivery of hormonal therapies provides a benefit over systemically administered hormones in that estrogen is delivered directly to the target organ; with low systemic absorption, there is proven effectiveness in the treatment of vaginal symptoms and reduced risk of systemic side-effects.[12–14] It is presently recommended to use the lowest effective dose of estrogen and to use vaginal estrogen therapy (VOT) when it is considered solely to treat symptoms of vaginal atrophy.[15,16]

There is limited evidence from randomised controlled trials regarding the use of estrogens for the prevention and management of POP.[17] Although VOT has been used anecdotally for postmenopausal patients using a vaginal pessary to support POP, to the best of our knowledge there is no published literature on its effectiveness.[18] The aim of this pilot study was to prospectively evaluate differences in the complications with vaginal pessary for POP in postmenopausal women with and without vaginal estrogen use and to provide clinicians with some evidence to advise on VOT with pessaries.

Methods

We prospectively assessed consecutive postmenopausal women attending the urogynaecology clinic for a pessary change. The urogynaecology nurse specialist or doctor reviewing them in the clinic evaluated these women for ulceration, discharge, pain, bleeding and infection and history of using VOT. This was a standalone evaluation based on symptoms and examination findings. We routinely use a visual analogue scale for pain from 0 to 10, which is a validated pain scale that is used to record all types of pain. The vaginal estrogen use was recorded for current frequency of usage, which ranged from 3 months to 1 year. The type of formulation used was as per patient choice and included either Oestriol cream 0.1%, Oestradiol 10 mcg pessaries or Oestradiol rings 1.94 mg being used between once a week to twice a week application or as required. The decision to use VOT was based on patients' symptoms and/or clinician's assessment of vaginal atrophy. We confirmed with the research and development department in the hospital that ethics approval was not required prior to commencing as this was a service evaluation project of routine clinical practice amongst pessary users

Statistical analysis for relative risk (RR) was performed, including sub-group analysis of RR for 'ring pessary' and 'non-ring group' (Shelf, Gellhorn, Shaatz).

Results

During the study period between July 2013 and December 2014, 120 postmenopausal women were assessed. The mean age was 70 years (range 51–92 years); 45% (n = 51) of the patients used vaginal estrogen and 8% had previously used systemic HRT, with no patients concurrently using systemic HRT with VOT. Mean duration of use of pessaries was 12 months; 57% patients had been fitted with a support pessary for up to 6 months, 21% had it for the last 7–12 months, 12% had been having a pessary for 13–24 months and 11% had been fitted with one for between 25 months and 15 years, with 4–6 monthly change of pessary. Ring pessary was the commonest type used followed by Shelf (13%), Gellhorn (12%) and Shaatz pessary (1%) (Figure 1). Advancing age and ring pessary use was associated with reduced pain scores during pessary change (Tables 1 and 2).

There were no statistical differences in pain, infection, ulceration, bleeding and discharge, between the pessary users with or without VOT, although the trend for complications seemed to be higher in those without VOT use (Table 3). On subgroup analysis, there were no significant differences found between those with or without VOT in ring pessary users (Table 4).

In the 'non-ring' sub-group, the pessaries used were Shelf, Gellhorn or Shaatz. There was a higher risk of vaginal ulceration, bleeding and discharge in the non-users of VOT (Table 5). Apart from the ones listed above no other significant complications were noted in the study group.

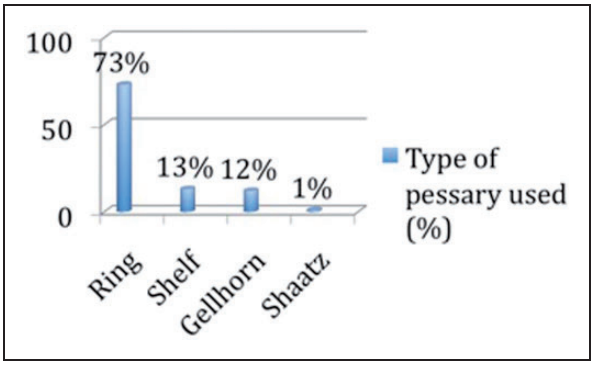

Figure 1. Type of Pessary used. This figure explains the distribution of different pessary types used by the study population.

Table 1. Vaginal pain (VAS) experienced during the pessary change in different age groups.

Age groups (years) n = 120	No pain % (Score = 0)	Mild pain % (Score 1–3)	Moderate pain % (Score 4–6)	Severe pain % (Score 7–10)
51–60 (n = 25)	52	40	0	8
61–70 (n = 32)	50	22	28	0
71–80 (n = 32)	66	28	6	0
81–90 (n = 28)	38	45	3	0
>90 (n = 3)	100	0	0	0

Table 2. Vaginal pain (VAS) according to type of pessary.

VAS	Ring pessary group % (N = 88)	Other pessaries group % (N = 32)
No pain (0)	57 (50)	50 (16)
Mild pain (1–3)	37 (33)	22 (7)
Moderate pain (4–6)	6 (5)	22 (7)
Severe pain (7–10)	0 (0)	6 (2)

Table 3. Vaginal complications – all pessary users.

Symptoms/signs in all pessary users (N = 120)	Vaginal estrogen (N = 51)	No vaginal estrogen (N = 69)	RR (95% CI)	*p* Value
Pain	22	29	0.75 (0.46–1.24)	0.272
Infection	2	5	0.40 (0.07–2.02)	0.268
Ulceration	6	12	0.50 (0.19–1 28)	0.151
Bleeding	3	8	0.37 (0.10–1 38)	0.140
Discharge	8	9	0.88 (0.35–2.22)	0.801

Table 4. Vaginal complications – ring pessary users.

Symptoms/signs in ring pessary users (N = 88)	Vaginal estrogen (N = 32)	No vaginal estrogen (N = 56)	RR (95% CI)	*p* Value
Pain	14	23	0.87 (0.53–1.42)	0.592
Infection	1	4	0.43 (0.05–3.74)	0.451
Ulceration	3	6	0.87 (0.23–3.26)	0.842
Bleeding	2	3	1.16 (0.20–6.61)	0.862
Discharge	7	5	2.45 (0.84–7.08)	0.098

Table 5. Vaginal complications- 'non-ring/other pessary users.'

Symptoms/signs in 'non ring' users (N = 32)	Vaginal estrogen (N = 19)	No vaginal estrogen (N = 13)	RR (95% CI)	*p* Value
Pain	8	6	0.91 (0.41–2.00)	0.820
Infection	1	1	0.68 (0.04–9.98)	0.781
Ulceration	1	6	0.11 (0.01–0.83)	0.033
Bleeding	1	4	0.17 (0.02–1.36)	0.095
Discharge	2	3	0.45 (0.08–2.36)	0.349

Discussion

Our results demonstrated that there was a significantly higher risk of ulceration in the 'non-ring' sub-group who did not use VOT (RR 0.11, 95% CI–0.01–0.83, *p* value 0.033). The symptoms of vaginal pain, infection, ulceration and bleeding amongst all POP pessary users were more in the 'no-estrogen' group (Table 3), although in this sample this did not reach statistical significance, we would suggest this is a size effect (as there was no power calculation) and almost certainly remains clinically significant. Additionally, pain scores appeared to be lower in the older age group and ring pessary users.

The strength of our study was that it had a pragmatic design assessing patients in real life rather than in a study environment. Despite the limitations of small numbers and non-randomised design, the data from this study adds to the evidence base of an issue that is important in routine urogynaecological practice. We did not collect data on variables such as body mass index or degree of prolapse, as we did not think this would influence the outcomes in our study population. We did not test for patient compliance and relied on patients' history for frequency of use of VOT.

Women can be successfully fitted with a pessary 71–90% of the time, with ring pessaries being the most frequently used and widely available, followed by Gellhorn and cube or donut pessaries.[6,19,20–22] In our study, the ring pessary was the commonest type of support pessary used. In a randomised cross-over trial, there was no difference in patient satisfaction or symptom relief between those using a ring pessary versus those using a Gellhorn pessary.[23]

Complication rates vary in literature, which is most likely subject to variation in reporting. In a study by

Hanson et al.,[21] 11.5% of 1216 women developed complications and the common complications included erosions (8.9%) and vaginal infections (2.5%). This is in contrast to the study by Bai et al.,[24] where 73% of women had complications, including bleeding, erosions or foul smell.[24] Erosion rates reported range from 3% to 9%[6,19] and may present as vaginal bleeding, odour or increased discharge, which can be typically brown. These are traditionally treated with local estrogen or may undergo spontaneous resolution with time. Vaginal discharge is a common symptom with pessary use, which can be caused by a physiological response to friction of the pessary against the vaginal mucosa or infection. A recent study showed that the microscopic analysis of vaginal discharge in postmenopausal women mainly showed features of vaginal inflammation or vaginitis.[25]

Pessary use is common among women with POP, but there is evidence to show that complications can limit the duration of use. Vaginal complications like bleeding may prompt further investigation in the form of ultrasound scan for assessment of endometrial pathology. These situations can be stressful for the patient and also have resource implications.

Patients using a pessary for prolapse may have a lower risk of complications like ulceration, infection and pain with the use of vaginal estrogen and this might be particularly relevant in 'non ring' pessary users. Recent evidence from a retrospective cohort study suggests a higher incidence of vaginitis among women who did not use vaginal estrogen along with a support pessary for prolapse.[26]

Use of vaginal low-dose estrogen to treat atrophy of the vagina may improve the subjective cure rates and minimise surgical site wound infections by altering the vaginal flora to premenopausal levels. We are about to start a pilot randomised controlled trial (RCT) on the effectiveness of vaginal low-dose estrogen on the outcome of POP surgery in postmenopausal women.[27] Similarly, an adequately powered and robustly designed RCT would be helpful to confirm the hypothesis that vaginal estrogen enhances effectiveness and reduces complications of support pessaries used for POP in postmenopausal women.

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Conflict of interests

S Bulchandani: Travel Bursary Astellas; P Toozs-Hobson: Received consultancy fees and travel support from Astellas and Allergan; T Verghese: None; P Latthe: Travel bursary/ Speaker fees- Astellas & Pfizer.

Ethics approval

Letter from R&D department attached; ethics approval not required as evaluation of routine practice.

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