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ORIGINAL ARTICLE

The impact on complication rates of delayed routine pessary reviews during the COVID-19 pandemic

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Abstract

Introduction and hypothesis During the COVID-19 pandemic, guidance was issued in the United Kingdom advising a delay in routine pessary reviews. The impact of this has not been fully explored. The null hypothesis for this study is that delayed routine pessary reviews during the COVID-19 pandemic did not result in a statistically significant increase in complication rate.

Methods A retrospective comparative cohort study was conducted in NHS Tayside, Scotland, involving 150 patients pre-pandemic and 150 patients during the COVID-19 pandemic (before exclusions). Their notes were reviewed identifying age, care provider, pessary type, length of pessary usage, review date, time elapsed since the previous review, bleeding/infection/ulceration, removal issues, pessary replacement and outcome. Patients excluded were those with no pessary in situ at review, reviews at ≤4 months and >8 months (pre-pandemic) and reviews at ≤8 months (COVID-19 pandemic).

Results The pre-pandemic group (n=106) had average review times of 10.1,6.2 and 6.2 months for cubes, rings and all others. Overall rates of bleeding/infection/ulceration; reported removal issues; and pessary subsequently not replaced were 9.4%, 11.3% and 5.7% respectively. The COVID-19 pandemic group (n=125) had average review times of 14.7, 10.8 and 11.4 months for cubes, rings and all others. Overall rates of bleeding/infection/ulceration; reported removal issues; and pessary subsequently not replaced were 21.6%, 16.0%, and 12.0% respectively.

Conclusions Overall, there was a significant increase in rates of bleeding/ulceration/infection (p=0.01). When individual pessaries were considered, this only remained true for rings (p=0.02). Our data would suggest that routine ring pessary reviews should not be extended beyond 6 months or risk bleeding/ulceration/infection.

Keywords Pessaries · COVID-19 pandemic · Delayed reviews

Introduction

Vaginal pessaries have long been used for the symptomatic treatment of pelvic organ prolapse (POP) and/or urinary incontinence in women [1], and they remain the mainstay of non-surgical management [2, 3]. Their benefits have been widely reported, with figures suggesting that 71–90% of women might be successfully fitted with a pessary and symptomatic relief is achieved in 70–90% [4].

Commonly reported complications of pessaries include vaginal erosions/ulcerations, vaginal bleeding and vaginal infections [5, 6]. The reported prevalence of these complications can vary dramatically across the literature; however, a systematic review of 61 articles (including 1,190 subjects) suggests figures of 5.8%, 2.4% and 1.5% respectively. [7]. Fistula formation, hydronephrosis, urosepsis, incarceration and carcinoma are also reported and are more serious adverse effects [6], which can occur in incidents of longstanding neglect.

To avoid complications, it has been well established that women who use vaginal pessaries require regular routine clinic review. The American College of Obstetricians and Gynecologists has previously advocated for pessary replacement every 3–4 months [7], but published a further study in 2020 suggesting that 6-monthly reviews are non-inferior [9]. The 2021 "UK Clinical Guideline for best practice in the use of vaginal pessaries for pelvic organ prolapse" [10] advises 3- to 6-monthly reviews for most pessary types.

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During the unprecedented time of the COVID-19 pandemic, benign services were restructured to best optimise and utilise resources. The gynaecology pessary service was one of these services, with decisions made around delaying routine review times.

In January 2021, the Royal College of Obstetrics and Gynaecology (RCOG) and the British Society of Urogynaecology (BSUG) made the decision to advise a delay in routine pessary reviews [11]. Guidance was issued that stated that routine ring pessary changes were to be delayed up to 3 months and to a maximum of 6 months from when the last change was due. Shaatz, Gellhorn, shelf and double pessaries were to be delayed up to 3 months.

Given previous concerns regarding complications and the optimal time interval between routine pessary reviews, we hypothesised that a delay in review time would lead to an increase in complications. The primary aim of this paper is to explore what happened to pessary complication rates when an increase in routine review interval time was imposed owing to the COVID-19 pandemic.

Materials and methods

Approval

Caldicott approval from NHS Tayside was obtained for research; this grants ethical approval for the accessing of patient data.

Study design

The study design was as a retrospective comparative cohort study in a tertiary teaching hospital.

Setting

Prior to the COVID-19 pandemic, NHS Tayside, Scotland, performed routine pessary reviews at 6-monthly intervals, in accordance with national guidance. Yearly routine reviews were utilised for the women who self-managed cubes well.

Routine review involves the removal of the pessary, inspection of the vaginal tissue and replacement of the pessary if appropriate. In line with the guidance issued by the RCOG and BSUG, these were delayed during the COVID-19 pandemic. Letters were issued cancelling women's appointments, explaining the delay, and that should they encounter any concerns such as pain or bleeding to make contact.

To investigate the impact on complications rates of delayed pessary reviews within our own trust, data were collected retrospectively from routine reviews during the pandemic (cohort study group) and routine reviews pre-pandemic (comparison group).

Information, Analyst, Health & Business Intelligence (who collate and code patient data for NHS Tayside) provided us with the patient data of pessary reviews in the Trust from 2019 to 2021. Filters were set to include the care provider as consultant or nurse and to filter out urgent appointments and DNAs. Pessary reviews for the study group were filtered for August 2020 to July 2021, in which routine pessary reviews were extended to 9–12 months and for April to September 2019 in which routine pessary reviews were happening at 6-monthly intervals.

Participants

After the filters were set as above, inclusion/exclusion criteria were applied.

To be eligible for inclusion, the patient had to be a user of the NHS Tayside routine pessary service, have attended a face-to-face appointment between the dates as detailed above, and have a pessary in situ at review (i.e. could not have fallen out or been removed prior).

Exclusions

For the pre-pandemic group (comparison group): only pessary reviews with >4-month and ≤8-month time-interval were included (review times outside of this were excluded). This timeframe was set based on the knowledge that routine pessary reviews do not always happen at exact 6-monthly intervals and to ensure that the breadth of routine reviews was being captured.

For the COVID-19 pandemic group (study group): only pessary reviews with >8-month time interval since last review were included, to represent a 'delay' in review time—as per the guidance (pessaries with a review time ≤8 months were excluded).

Cubes were excluded from the upper timeframe limit as NHS Tayside reviews some of these routinely at 12-monthly intervals.

Variables

Data were collected from multiple electronic databases and patients were tracked using a unique patient identifier. Information gathered included age, care provider, pessary type, length of pessary usage, date of pessary review, date of previous pessary review, bleeding/ulceration/infection (classed as infection if being investigated as such), any other reported complication, removal issues (difficulty with the physical removal of the pessary during the check—primarily because of fibrous tissue overgrowth and/or adhesions), further pessary inserted and outcome.

The decision to specifically look at bleeding, ulceration and infection was based on their reporting as the most frequent pessary-associated complications [5, 6]. As

ulceration often leads to bleeding and infection, they have been grouped together (to limit overestimation in those who have co-existing conditions).

Study size

When filters were set for the pre-pandemic group, there were 1,263 routine reviews for August 2020 to July 2021. For the purposes of time and resources a randomised sample of 150 patients was chosen, representing over 10% of the population of reviews.

When filters were set for the COVID-19 pandemic, there were 1,428 routine reviews for April to September 2019. A randomised sample of 150 patients was also used.

Randomisation was achieved using an online random number generator. [12]

Statistical methods

Medians were used for age, length of pessary usage and timeframe between two reviews as the data were non-parametric.

The two groups were compared using Chi-squared and Mann–Whitney *U* tests. Two-tailed *p* values were generated and a value of less than 0.05 was considered to be the threshold for statistical significance. Relative risks were also used with 95% confidence intervals.

Results

Participants

After exclusions (pessary not in situ, pessary interval review time: ≤4 months and >8 months pre-pandemic, ≤8 months during the COVID-19 pandemic) 106 and 125 patients were included in the pre-pandemic and COVID-19 pandemic groups (Fig. 1).

Pre-pandemic group

Median age of 76 years (range, 47–96) with a median pessary length use of 4.5 years (range, 0.5–18.6)

The average median time between current review and last review was 12.1 months, 6.3 months and 6.4 months for cubes, rings, and all others respectively.

COVID-19 pandemic group

Median age of 80 years (range, 65–94) with a median pessary use of 7.6 years (range, 0.8–14.1). The average median time between current review and last review was 13.9 months, 10.6 months and 10.6 months for cubes, rings and all others respectively (Fig. 2).

Pessaries in situ (by type) at review are demonstrated in Table 1. *p* Values have been calculated to identify any statistically significant difference in the sizes of the groups.

Outcome data

Pre-pandemic group

Of 106 patients, 10 reported bleeding/ulceration/infection (9.4%), 12 had another pessary complication (11.3%), 6 had removal issues (5.7%) and 9 pessaries were not replaced because of complications (8.5%).

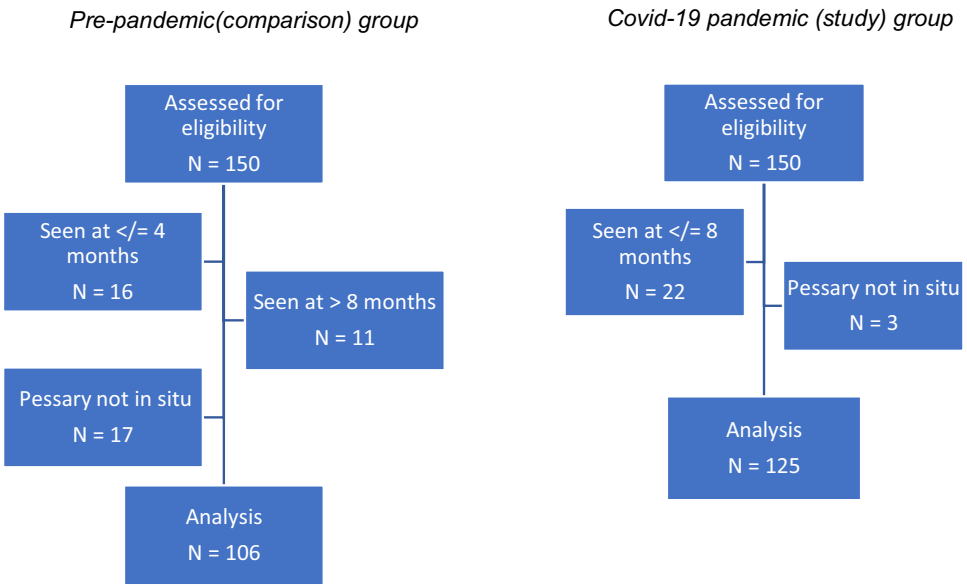

Fig. 1 Eligibility criteria for pre-pandemic and COVID-19 pandemic groups

Fig. 2 Image of different pessary types discussed in this paper

COVID-19 pandemic group

Of 125 patients, 27 reported bleeding/ulceration/infection (21.6%), 20 had another pessary complication (16%), 15 had removal issues (12%) and 18 pessaries were not replaced because of complications (14.4%).

"Other pessary complications" were not defined prior to data collection. "Other complications" reported and recorded included: fibrous tissue overgrowth, infection (without associated bleeding), discharge (not investigated as infection), pain/discomfort, atrophic vaginitis/erythema and prolapse not controlled/incontinence.

The frequency of complications was broken down by individual pessary type (Tables 2, 3).

Complications were also subdivided as demonstrated in Table 4. "Mild to moderate bleeding/ulceration" was classed if stated as such or reported as spot bleeding or bleeding with pessary replacement the same day. "Moderate to severe bleeding/ulceration" was classed as such if stated. If there was no recording of "level" of bleeding/ulceration, mild to moderate bleeding was presumed to be such if the pessary was replaced, and moderate to severe if the bleeding/ulceration was such that it required a pessary break. Infection was classed if stated as such or if swabs were taken of suspicious discharge.

Two women in the pre-pandemic group chose not to have a pessary re-inserted at review—they both reported no symptomatic benefit and wished to be referred for surgery. In the COVID-19 pandemic group, there was a discontinuation of 3 women; 2 stated no symptomatic benefit and the other woman found the removal process difficult and did not wish to have a further pessary.

Table 1 Pessaries by type in the pre-pandemic and COVID-19 pandemic groups

Pessary	Pre-pandemic (106)	COVID-19 pandemic (125)	*p* value
Cube	13	5	0.02
Gellhorn	23	26	0.87
Shelf	1	12	0.005
Ring	62	71	0.89
Incontinence dish	3	4	0.87
Shaatz	1	4	0.24
Donut	0	4	0.06

Main results

As demonstrated by their *p* values (in Table 1)—Gellhorn, ring, Shaatz and donut pessaries had comparable group sizes.

There was a statistically significant increase in overall bleeding/ulceration/infection rates in the study COVID-19 pandemic group compared with the pre-pandemic group (RR 2.3; $p = 0.01$). There was no significant increase in other pessary complications, removal issues or pessary not being replaced ($p = 0.3, 0.09, 0.25$).

When sub-divided into pessary types; the ring pessary was the only type to have a significantly increased

Table 2 Complication rates in the pre-pandemic group

Pre-pandemic	Cube (13)	Ring (62)	Gellhorn (23)	Shelf (4)	Incontinence dish (3)	Shaatz (1)	All types (106)
Bleeding/ulceration/infection	0 (0%)	2 (3.2%)	7 (30.4%)	0 (0%)	0 (0%)	1 (100%)	10 (9.4%)
Other complications	1 (7.7%)	9 (14.5%)	1 (4.3%)	0 (0%)	1 (33.3%)	0 (0%)	12 (11.3)
Removal issues	0 (0%)	1 (1.6%)	4 (17.4%)	0 (0%)	0 (0%)	1 (100%)	6 (5.7%)
Pessary not replaced as a result	0 (0%)	1 (1.6%)	8 (34.8%)	0 (0%)	0 (0%)	0 (0%)	9 (8.5%)

Table 3 Complication rates in the COVID-19 pandemic group

COVID-19 pandemic	Cube (5)	Ring (71)	Gellhorn (26)	Shelf (12)	Incontinence dish (4)	Shaatz (4)	Donut (3)	All types (125)
Bleeding/ulceration/infection	0 (0%)	11 (15.5%)	8 (30.8%)	5 (41.7%)	1 (25%)	2 (50%)	0 (0%)	27 (21.6%)
Other complications[a]	0 (0%)	13 (18.3%)	3 (11.5%)	2 (16.7%)	1 (25%)	1 (25%)	0 (0%)	20 (16%)
Removal issues[b]	0 (0%)	3 (4.2%)	8 (30.8%)	4 (33.3%)	0 (0%)	0 (0%)	0 (0%)	15 (12%)
Pessary not replaced as result	0 (0%)	7 (9.9%)	4 (15.4%)	4 (33.3%)	1 (25%)	2 (50%)	0 (0%)	18 (14.4%)

[a]Other complications reported and recorded included: fibrous tissue overgrowth, infection (without associated bleeding), discharge (not investigated as infection), pain/ discomfort, atrophic vaginitis/ erythema and prolapse not controlled/incontinence were not significantly increased.

[b]Removal issues: difficulty with the physical removal of the pessary during the check – primarily due to fibrous tissue overgrowth and/or adhesions

Table 4 Complication rates by sub-type in the pre-pandemic and COVID-19 pandemic groups

Complications	Pre-pandemic (106)	COVID-19 pandemic (125)	Relative risk (95% CI)	*p* value
Bleeding/ulceration (moderate to severe)	9 (8.5%)	19 (15.2%)	1.8 (0.9–3.9)	0.11
Bleeding/ulceration (mild to moderate)	1 (0.9%)	8 (6.4%)	6.8 (0.9–53.3)	0.03
Fibrous tissue overgrowth	1 (0.9%)	2 (1.6%)	1.8 (0.2–18.4)	0.66
Infection (without associated bleeding)	1 (0.9%)	1 (0.8%)	0.8 (0.1–13.4)	0.91
Discharge	2 (1.9%)	5 (4%)	2.1 (0.4–10.7)	0.35
Pain/discomfort	1 (0.9%)	3 (2.4%)	2.5 (0.3–24.1)	0.40
Atrophic vaginitis/ erythema	7 (6.6%)	10 (12.5%)	1.2 (0.5–3.1)	0.69
Prolapse not controlled/incontinent	4 (3.8%)	5 (4%)	1.1 (0.3–3.8)	0.93

complication rate, with both a significant increase in bleeding/ulceration/infection ($p = 0.02$) and in subsequently not being replaced ($p = 0.046$).

On looking at subdivisions of overall complications only mild to moderate bleeding/ulceration significantly increased.

There were no reported severe complications such as fistula formation or hydronephrosis.

Discussion

Main findings

Overall complication rates of bleeding/ulceration/infection at routine review increased significantly in the COVID-19 pandemic group compared with the pre-pandemic group. This is an important consideration when determining the optimal time interval between routine pessary reviews.

As stated previously—the UK's most recent guidelines advise 3- to 6-monthly reviews for most pessaries (including cubes) [8]. During the COVID-19 pandemic, an increase from 6-monthly routine reviews to those laid out by the RCOG and BSUG [9] was adhered to by NHS Tayside. Despite asking women to telephone should they experience concerns such as pain or bleeding, a significantly increased number of women in the study group had complications of bleeding, ulceration or infection when seen at their delayed routine review.

When sub-divided, bleeding/ulceration, classed as mild to moderate, demonstrated a significant increase; however, bleeding/ulceration classed as moderate/severe did not show the same statistical significance. Mild to moderate is perhaps

of less import, as by their definition they did not require removal. However, had reviews been delayed further, it is likely that some of these milder cases would have become more serious.

Eighteen of the 27 women with bleeding/ulceration did not have their pessary re-inserted and were given low-dose vaginal oestrogen cream and pessary breaks, with a re-review in 2–4 weeks. Arguably, a pessary break is a benign complication or "nuisance"; however, it results in a non-supported prolapse, which for some women may impact on quality of life (not investigated in this study).

A recent paper published in the *International Urogynecology Journal* detailed the seriousness of delayed clinical follow-up in 3 elderly women with Gellhorn pessaries who developed rectovaginal fistulas during the COVID-19 pandemic [7]. Thankfully, none of the women in our study were found to have more serious complications such as a fistula, although it may be that if our study size or study period increased, we may come across such complications.

On considering why symptomatic women did not seek urgent reviews—we suggest that during the COVID-19 pandemic, there may have been a reluctance to phone, given the known NHS pressures. It has also been suggested that there might have been fears associated with attending a hospital in a pandemic [13]. However, symptomatic women did not present pre-pandemic either. It must be noted that this cohort consisted of largely elderly patients who may have had other co-morbidities that limit their access to hospital—perhaps home appointments or hubs in GPs may be considered in the future to reduce the need for hospital visits.

Sub-division by pessary type

Rings

Our data demonstrate that for ring pessaries (the most common pessary in both groups) a delay in average review time from 6.2 to 10.8 months results in a significant increase in complications of bleeding, ulceration or infection and a significant number of pessaries not replaced. Those not replaced were prescribed oestrogen cream and had a follow-up in 2–4 weeks. As such we would suggest that routine ring pessary reviews should not be extended beyond 6 months or risk bleeding/ulceration/infection.

This differs from the prospective observational study undertaken in 2013–2016 of 123 women, which suggested that rings might be safely used continuously, without review, for 24 months [14]. Of interest is that the study reported a rate of adverse events of 27%, which correlates with our figures; however, our data suggest that this might represent a significant increase compared with reviews undertaken at around the 6-month mark.

A further prospective study has been published investigating whether rings could be left in situ for 24–48 months without removal, cleaning, or replacement. These data reported that 45 out of 93 (48.4%) had an adverse event requiring a temporary pessary break, demonstrating a further rise in "complications" with an increase in time interval [15].

Cubes

Of 18 cubes (across both groups), there was only one reported complication, which was that of ongoing incontinence issues. Cubes require removal and cleaning daily [16] and are not in situ continually. The short self-imposed pessary breaks may make them less likely to cause ulceration, bleeding and infection and as the women also self-manage, complications may be more self-evident and result in urgent reviews (which were not considered in this study).

The current recommended UK joint guidance is for cubes to be reviewed at 3–6 months [10]. Although our numbers are small, and the group sizes significantly different—it would follow logic that in women who have demonstrated independence, there is some argument to extend routine reviews to 6–12 months. Further research would be required to evaluate this finding.

Donut, Gellhorn, shelf, Shaatz and incontinence dish

Other pessaries included in the study were Gellhorn, shelf, Shaatz, incontinence dish and donut (note: there were no donut pessaries in the comparison group).

Gellhorns (the second most common pessary in both studies) are stemmed pessaries and are known to result in removal difficulties, causing pain and bleeding [6]. Our figures show that they had the highest rates of complications in both the pre-pandemic and the COVID-19 pandemic groups. Interestingly, despite the extension of time, the percentage complication rate remained similar. One explanation we offer is that women who go on to develop bleeding, ulceration or infection may have already done so by the 6-month mark and Gellhorns should be checked at 3-monthly reviews, as suggested by a recent publication in the *International Urogynecology Journal* [12].

Shelves are similarly stemmed pessaries, and there were increased complication rates with delayed reviews; however, the numbers in the groups are small. Other pessary types for which data were collected also had small numbers and we have chosen not to comment further as they are not statistically significant.

Limitations of data

This is a retrospective study with data dependent on documentation in clinic letters. We are dependent on complications having

been correctly identified and documented and recognise that there may be some clinician variability. The cohort study and the comparison group were not matched as the data provided did not have filters for pessary type and length of pessary usage and this could only be found on reviewing patients' letters. The sample sizes of most pessary types are also small, and the conclusions drawn on individual types are limited.

These data are limited to routine reviews and cannot comment on the number of complications being seen at urgent reviews. Last, there may have been additional reasons why women did not telephone and seek out urgent reviews during the COVID-19 pandemic, such as fear of coming to a hospital and concern about putting pressure on the NHS.

Conclusion

During the COVID-19 pandemic, routine pessary reviews were delayed by 3–6 months to optimise resources at a time of national medical emergency. Overall complication rates of bleeding, ulceration or infection, at the new review date, increased significantly as a result. When individual pessary types were considered—this only remained true for rings (the largest pessary type in the study). As such, we would suggest that routine ring pessary reviews should not be extended beyond 6 months or risk bleeding/ulceration/infection and subsequent need for a pessary break.

Gellhorns have the highest complication rates at routine review, regardless of extension, and may warrant the patient being seen more regularly than every 6 months.

More research is required to confirm our findings.

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Authors' contributions E.R. McNeill: project development, data collection, manuscript writing; J. Lucocq: statistics, manuscript writing; K. Brown: project development, reviewer; V. Kay: project development, reviewer.

Declarations

Conflicts of interest None.

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