Journal of Obstetrics and Gynaecology, February 2009; 29(2): 129–131

informa
healthcare

GYNAECOLOGY

Evaluation of vaginal pessary management: A UK-based survey

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Summary
The use of intravaginal pessaries has been proven integral in the conservative treatment of pelvic organ prolapse (POP) and urinary incontinence (UI). Although there is no shortage of studies supporting the efficacy of intravaginal devices for conservative management of POP and UI and a large variety of pessaries are widely used in the UK, data on the clinical practice and recommended changing intervals are lacking. To evaluate the current clinical practice and management of patients with vaginal pessaries, self-administered questionnaires were mailed to all UK-based consultant obstetricians and gynaecologists. A total of 640 out of 1,173 (54.6%) clinicians approached returned the questionnaire, out of which 555 (86.7%) used vaginal pessaries. A total of 129 out of 555 (23.3%) clinicians claimed to change their patients pessaries every 3–6 months; 372 (67.0%) every 6 months and 54 (9.7%) reported a frequency of 6–12 months before changing the device. Complication rates of 40.3%, 35.2% and 18.5% were observed by clinicians performing 3–6 monthly, 6-monthly and up to 12-monthly changing intervals. Discontinuation of pessary use was related to recurrent involuntary expulsion in 54.0% (268/496), discomfort (27.4%, 136/49), vaginal bleeding and infection (7.8%, 39/496 clinicians) and dislike of the changing procedure (10.7%, 53/496). Changing intervals greatly vary between clinicians all over the country. The lack of differences in proportions of complications observed in 3-monthly and even up to 12-monthly observation periods suggest that 6-monthly and probably up to 12-monthly intervals represent a safe and cost-effective regimen to follow-up patients with vaginal pessaries.

Keywords
Pelvic organ prolapse, vaginal pessary, management

Introduction

Pelvic organ prolapse (POP) and urinary incontinence (UI) are disorders that particularly effect the elderly population and significantly contribute to a reduction of social and sexual activities and therefore quality of life (Junemann et al. 2001). The overall prevalence of urinary incontinence is thought to be as high as 37% in elderly females with stress urinary incontinence present in 27%, urge urinary incontinence in 9% and mixed urinary incontinence in 56% of the cases (Thomas et al. 1980). Currently available approaches to treat POP and UI include various surgical procedures as well as conservative treatment strategies including the use of intravaginal passive devices aimed to restore the correct anatomical position of pelvic organs and therefore reduction of symptoms associated with UI and POP (Junemann et al. 2001). At present, pessary use is predominantly favoured in elderly patients who opt against surgical therapy or present with several morbidities which render them unsuitable for surgery. To date, a great variety of such devices has been introduced to incontinence clinics including ring-shaped, cubic and Gellhorn pessaries. Independent of the shape of the device, rates of significant improvement of symptoms have been reported to be as high as 83% for patients with POP, 58% for urge incontinence but only reach 23% for genuine stress incontinence (Fernando et al. 2006). Although various studies have evaluated the effectiveness of continence pessaries, data on the clinical practice and management, i.e. recommended follow-up intervals of patients with fitted pessaries is still sparse. Therefore, the aim of the present survey was to evaluate recommended observation intervals and current clinical practice of consultant obstetricians and gynaecologists treating POP and UI conservatively with vaginal pessaries in the UK.

Materials and methods

A self-administered questionnaire was developed by the authors focusing on the clinical practice and management of patients with vaginal pessaries (regardless of type and size) fitted for pelvic organ prolapse and/or urinary incontinence. In order to optimise the response rate, the question form was designed to be short and simple in structure with an addressed and stamped envelope included. The form was mailed to all registered consultant obstetricians and gynaecologists in the UK. Mailing lists were obtained from the service database of the Royal College of Obstetricians and Gynaecologists (RCOG).

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ISSN 0144-3615 print/ISSN 1364-6893 online
DOI: 10.1080/01443610902719813

Clinicians were asked questions regarding the use of vaginal pessaries for pelvic organ prolapse (yes/no), frequency of change (less than 6 months, 6 months, more than 6 months) and finally occurrence of complications associated with pessary use. Complications were regarded as follows: severe discomfort, inappropriate size, vaginal bleeding or infection, significant ulceration or fistula following successful fitting of a pessary. Within this, the number of complications observed individually by responders practicing different follow-up intervals (less than 6 months, 6 months, more than 6 months) was established. In addition, clinicians were asked about the nature and cause of the complication which led to discontinuation of pessary use. No further questionnaires were sent to non-responders and no further interaction was permitted by the audit committee. Data from the completed questionnaires were entered into a Microsoft Excel file and percentages of pessary users/non-users, frequencies of change and complications within observation periods were calculated.

Results

Of the total of 1,173 clinicians who were initially sent questionnaires, 533 were excluded. In most of the cases, this was due to a lack of response or insufficient completion of the question form. The response rate was 54.6% (640/1,173 questionnaires). Of all responders, 86.7% (555/640 clinicians) used vaginal pessaries for conservative management of pelvic organ prolapse in their clinical practice, whereas 13.4% (85/640) opted against the use of vaginal pessaries. When asked about the frequency of change, i.e. routine follow-up after a pessary had been successfully fitted, 23.3% (129/555) of the clinicians claimed to change their patients pessaries every 3–6 months. A total of 67% (372/555 clinicians) of responders reported to change vaginal pessaries every 6 months. However, only 9.7% (54/555) of the consultants reported a frequency of >6 up to a maximum of 12 months before changing the device (either washing and reinsertion or fitting the patient with a new pessary).

As depicted in Table I, out of 129 responders who reported to change their patients pessaries every 3–6 months, 40.3% (52/129 clinicians) observed complications with the pessary, whereas 59.7% (77/129 clinicians) did not report any abnormalities. Similarly, 35.2% (131/372 clinicians) who opted for a 6-monthly follow-up and change of pessary reported complications, whereas 64.8% (241/372 clinicians) found no negative impact of the pessary fitted. Of the 54 responders who claimed to follow-up their patients longer than 6 up to a maximum of 12 months, only 18.5% (10/54 clinicians) reported on complications mentioned above. A total of 81.5% (44/54 clinicians) however, did not observe any problems arising with long-term use of vaginal pessaries. When asked about the primary cause for discontinuation of pessary use, 54.0% (268/496 clinicians) reported difficulties in fitting the appropriate size and recurrent involuntary expulsion of the device, followed by discomfort (27.4%, 136/496 clinicians), vaginal bleeding and infection (7.8%, 39/496 clinicians) and dislike of the changing procedure and opting for surgery (10.7%, 53/496) as the primary cause for discontinuation of pessary use. Fifty-nine out of 555 responders (10.6%) did not provide a response to the question.

Table I. Observation intervals and complication rates of patients with vaginal pessaries for conservative treatment of POP.

	3–6 months		6 months		6–12 months	
	n	(%)	*n*	(%)	*n*	(%)
Number of clinicians ($n=555$)	129	23.3	372	67.0	54	9.7
Number of complications	52/129	40.3	131/372	35.2	10/54	18.5

Discussion

Vaginal pessaries have proven to be an effective conservative treatment option for patients with POP, stress and/or urge incontinence (Roehl et al. 2006). However, there is neither a consensus on which type of pessary to use nor on the frequency of its change. Manufacturers generally recommend an observation interval of 6 months. However, this advice is not based on data obtained from clinical trials since studies on the optimal changing interval regarding cost efficacy and patient safety and satisfaction are lacking. The present survey primarily aimed to investigate the current clinical practice of pessary use and follow-up intervals in the UK. As demonstrated, there is a wide variation in practice between different consultants and different hospitals in the country. Although the majority of responders claimed to change pessaries on a 6-monthly (372/555, 67.0%) basis, 3-monthly and even up to 12-monthly intervals were observed in 23% (129 /555) and 9.7% (54/555) of clinicians, thereby underlining the variation and differences in everyday clinical practice. Recurrent involuntary expulsion of the pessary associated with patient dissatisfaction followed by discomfort and to a lesser extent vaginal bleeding and/or infection were reported to be the leading causes for discontinuation of use. Although these data are not based on clear numbers but solely on subjective estimations by the clinicians questioned, they are well in concordance with reports from Powers and colleagues (2006) and Clemons et al. (2004) who observed a short vaginal length and a wide vaginal introitus leading to the inability to retain the device to be the primary cause for unsuccessful and therefore discontinued pessary fitting. Interestingly, rates of complications such as involuntary loss, discomfort, bleeding and infection did not greatly vary between 3-monthly (52/129, 40.3%) and 6-monthly (131/372, 35.2%) changing intervals and even tended to be decreased in up to 12 monthly (10/54, 18.5%) follow-up periods. On one hand, these observations suggest the safety of changing intervals of up to 12 months. On the other hand, a number of case reports have been published reporting severe complications of neglected pessaries including the formation of massive vesico- and recto-vaginal fistulas (Popli et al. 2007; Powers et al. 2008), or the incarceration of appendices epiploicae through a vaginal wall dehiscence caused by a ring pessary (Mohammed et al. 2008). Nevertheless, vaginal pessaries do represent an effective, non-invasive treatment option for pelvic organ prolapsed which has also been demonstrated to improve sexual function and therefore overall patient satisfaction (Kuhn et al. 2008).

This survey, however, has several weaknesses, since it is purely retrospective and observation-based. In addition, the individual numbers of patients seen by clinicians might also vary and therefore contribute to a bias in reported complication rates. The primary aim, however, was to evaluate the current clinical practice in the UK. Although a

similar study has been carried out by Pott-Grienstein and colleagues (Pott-Grienstein et al. 2001), this survey has, to our best knowledge, never been carried out in the UK before. Based on our observations, the majority of UK clinicians favour 6-monthly follow-up intervals. However, no apparent differences in proportions of reported complications could be observed in 3-monthly and even up to 12-monthly observation periods. Prospective studies are needed in order to advocate longer follow-up intervals up to 12-months, which would represent a cost-effective and patient-convenient regimen to follow-up women with vaginal pessaries.

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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