

One-year prospective comparison of vaginal pessaries and surgery for pelvic organ prolapse using the validated ICIQ-VS and ICIQ-UI (SF) questionnaires

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Abstract

Introduction and hypothesis Vaginal pessaries, pelvic floor exercises and surgery are treatment options for women with symptomatic pelvic organ prolapse (POP). The aim of this study was to compare the outcomes of pessaries and surgery in women with symptomatic POP using the validated International Consultation on Incontinence Questionnaire-Vaginal Symptoms (ICIQ-VS) and Urinary Incontinence (ICIQ-UI) Short Form (SF).

Methods Women attending the Urogynecology clinics with symptomatic POP were recruited. All women were treated using either a vaginal pessary or surgery. Outcomes were evaluated and then compared at 1 year using the validated ICIQ-VS and ICIQ-UI (SF) questionnaires.

Results A total of 287 women with symptomatic prolapse were recruited. 269 women completed the questionnaires at baseline and 183 at 1 year. At 1 year, improvement was noted in quality of life (QOL), frequency of urinary leak and vaginal symptoms in both groups except for the symptom of vaginal soreness in the pessary group and the symptom of a tight vagina in the surgery group. However, both these symptoms were not bothersome. Women who underwent surgery demonstrated an improvement in faecal evacuation and sex life. There was an overall statistically significant improvement in vaginal, sex, QOL and urinary symptom scores in both groups. No statistically significant difference was noted between the surgery and the pessary groups.

Conclusions Using validated questionnaires 1 year after treatment, women with symptomatic POP report improvement in vaginal, bowel, urinary and quality of life scores when treated with either pessary use or surgery. No statistically significant difference was noted in the two groups.

Keywords ICIQ-VS · ICIQ-UI · Pelvic organ prolapse · Pessary · Pelvic floor repair · Validated questionnaire

Introduction

Pelvic organ prolapse is a common medical condition in parous women that becomes particularly significant with advancing age [1, 2]. As life expectancy increases, this condition is acquiring greater significance: Although surgery is frequently performed for POP, nearly two-thirds of women with symptomatic POP choose a vaginal pessary as the initial treatment. POP has been shown to have an adverse impact on a woman's quality of life [3]. There is a dearth of knowledge on the outcomes of treatment of symptoms relating to bladder, bowel and sexual function, which often occur in association with POP. Treatment options for POP include pelvic floor exercises [4, 5], vaginal support pessaries [1, 5–7] and surgery [8].

Vaginal pessaries have been mainly offered to women who are medically unfit for surgery, those who have not yet completed their families, as a temporary measure while awaiting surgery and those who were not keen to have surgery for POP [9]. However, Kapoor et al. [10] have shown that when women with symptomatic POP were offered pessaries, nearly two thirds opted for pessaries as the initial treatment. Pessaries have been shown to be effective in improving POP symptoms [11–14]. The long-term use of vaginal pessaries has been evaluated using lengthy questionnaires, most of which are not validated. Komesu et al. [13] found an improvement in

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prolapse, urinary and bowel symptoms in women who continued pessary use. Clemons et al. [14] demonstrated that nearly all prolapse symptoms and 50 % of urinary symptoms had improved by 2 months of pessary use. However, in this study [14], there was no control group, highlighting the need for further well-designed comparative studies addressing the treatment options. We have previously published short-term [12] and long-term [15] results, but used the Sheffield POP questionnaire [16], which has not had vigorous validation and hence changed to the International Consultation on Incontinence Questionnaire-Vaginal Symptoms (ICIQ-VS) [17] and UI (SF) [18] questionnaires after they became available.

The aim of this study was to compare the outcomes of pessaries and surgery in women with symptomatic POP using the validated ICIQ-VS and the International Consultation on Incontinence Questionnaire-Urinary incontinence (ICIQ-UI) Short Form (SF) 1 year after treatment was instituted.

Materials and methods

Between August 2009 and December 2010 all women with symptomatic POP referred to a specialist urogynaecology clinic at Croydon University Hospital, were offered a choice of pessary or surgery as the first-line treatment.

A detailed history was taken by a senior registrar, subspecialty trainee in urogynaecology or consultant urogynaecologist. Demographic data were collected including age, parity, body mass index, prolapse symptoms, urinary symptoms, sexual status, previous surgery, medical co-morbidities, hormone replacement therapy, constipation, chronic cough and smoking status. The patients completed the validated ICIQ-VS [17] and ICIQ-UI (SF) [18] questionnaires to assess vaginal, sexual, urinary and quality of life symptoms prior to treatment. All women gave written consent to use the data from questionnaires for scientific publications. This observational questionnaire study did not need Ethical/Institutional Review Board approval.

All women were examined and the degree of prolapse was determined using the International Continence Society (ICS) pelvic organ prolapse quantification system (POP-Q) [19]. All women with POP were given information (verbal and written) about the benefits and risks of pelvic floor exercises, pessary use and surgical treatment. Women who needed more time to decide were allowed so and invited to return in few weeks with a decision on the type of treatment. Women included in the pessary group were those who chose pessaries rather than surgery as a treatment option. For women who opted to use the pessary, details of size and type of pessary inserted were recorded. When women chose to use a pessary, the ring pessary was the pessary of choice, and in some patients different sizes and types of pessaries were tried before comfortable pessary retention was obtained. Pessary treatment was

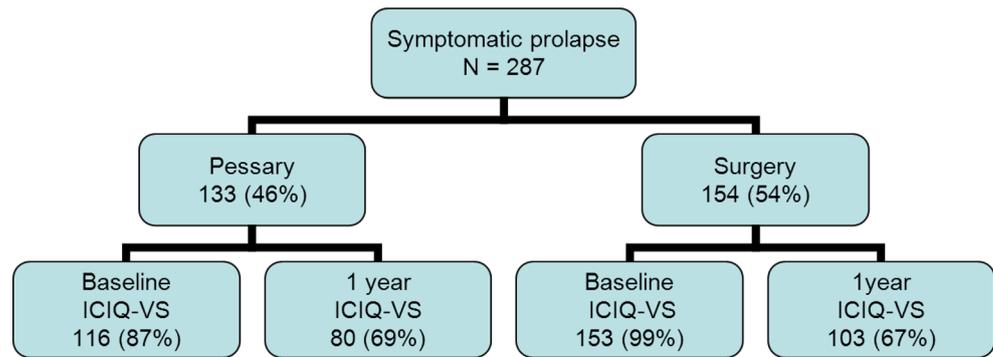
considered to be successful if the prolapse was reduced above the hymen and the woman felt comfortable following pessary insertion and managed to retain it during a Valsalva manoeuvre [15, 20]. If the ring pessary was unsuccessful and the patient was sexually active, a cube pessary was fitted. Women were shown how to use the cube pessary and were instructed to remove the device and replace it on a daily basis. If the ring pessary was unsuccessful and the patient was not sexually active, a Gellhorn or a doughnut pessary was offered. Vaginal oestrogens were only prescribed if there was evidence of vaginal atrophy. Women who opted for the surgical correction of prolapse were given verbal and written information on the benefits and risks of the procedure and signed a consent form for the procedure. We excluded women who were fitted with pessaries solely for urinary incontinence or those who underwent concomitant urinary incontinence surgery. Moreover, women who started in the pessary group, but subsequently opted for surgery were excluded from the analysis.

Women who opted for pessary treatment were seen at 6-monthly intervals for a change of pessary and these women completed the ICIQ-VS and ICIQ-UI (SF) questionnaires at their 1-year visit. In our unit, the routine practice is to send postal questionnaires to all surgical patients 1 year after surgery in a stamped, self addressed envelope and results were then compared with pre-treatment questionnaires (pessary/surgery). A second questionnaire is sent 2 to 3 months later to those who fail to respond.

The software program SPSS 15 was used for statistical analysis. The Wilcoxon signed rank test was used to assess change in symptoms and bother scores from baseline to 1 year within each of the two groups. The Mann–Whitney *U* test was used to compare the change in symptoms between the two groups. *P* value < 0.05 was considered to be statistically significant for analysis.

Results

A total of 287 women were referred with POP symptoms during the study period. One hundred and thirty-three (46.3 %) women with symptomatic prolapse opted for pessary use and 154 (53.7 %) opted for surgery (Fig. 1). Compared with the mean (\pm SD) age of women at the time of surgery, those at the time of pessary insertion were older (67 ± 14.1 vs 59 ± 11.9) years) respectively. The median (range) parity was 2 (0–8) in the pessary group and 2 (0–6) in the surgery group. There was no statistically significant difference with regard to previous prolapse repairs or hysterectomy between the groups. Further details of demographic data and previous gynaecological surgery are given in Table 1. Seventeen women in the pessary group and one woman who opted for surgery did not complete the ICIQ-VS questionnaire at baseline.

Fig. 1 Flow diagram of study participants

Reasons for not completing the questionnaire are shown in Fig. 2

In the pessary group, 2 (1.5 %) had stage 1, 111 (83 %) stage 2 and 21 (15.8 %) had stage 3 POP. In women who opted for surgery, 87 (56.5 %) had stage 2, 60 (39 %) stage 3 and 7 (4.8 %) stage 4 POP.

One hundred and one (76 %) were fitted with a ring pessary, 28 (21 %) a Gellhorn pessary, 2 (1.5 %) a cube and 2 (1.5 %) with a doughnut pessary. Twelve women (9 %) discontinued the use of the pessary within 6 months of insertion. Reasons for discontinuation included, difficulty in retaining the pessary (7), vaginal discomfort (2) and vaginal discharge (3). Although 8 women (6 %) did not experience any untoward symptoms, they changed their decision and opted for surgery and therefore were excluded from the analysis. At 1 year, the ICIQ VS questionnaire was completed by 80 women (60 %) in the pessary group and 103 (67 %) in the surgery group. Reasons for not completing the ICIQ VS questionnaire at 1 year are outlined in Fig. 2.

Table 1 Baseline characteristics of the study population ($n=158$)

Patient characteristics	Pessary group $n=191$	Surgery group $n=266$	Mann–Whitney U test
Age (years) ^a	67±14.1	59±11.9	0.03*
BMI (kg/m ²) ^a	30.5±7.2	26.5±6.5	0.514
Parity ^b	2 (0; 8)	2 (0; 6)	0.712
Types of previous gynaecological surgery ^c			
Hysterectomy	45 (23.5)	66 (24.8)	0.616
POP surgery	12 (6.28)	38 (14.2)	0.557
Ethnicity ^c			
Caucasian	161 (84)	212 (79.6)	0.553
Asian	16 (8.3)	29 (11)	0.601
Afro-Caribbean	14 (7.3)	25 (9.3)	0.567

BMI body mass index, POP pelvic organ prolapse

* p value<0.05=statistically significant

^aData presented as mean±SD

^bMedian (range)

^cNumber of patients (percentage)

In the surgery group, 49 (32 %) had anterior colporrhaphy, 18 (12 %) posterior colporrhaphy, 8 (5 %) anterior and posterior colporrhaphy, 42 (27 %) vaginal hysterectomy and anterior colporrhaphy, 18 (12 %) vaginal hysterectomy, 9 (6 %) sacrocolpopexy and 8 (5 %) sacrospinous fixation. Two of the recurrent vaginal prolapse surgeries (1 %) were mesh-augmented (biological). The mean time interval for the questionnaires between baseline and the 1-year responses for the pessary and surgery groups were 12 (SD 3.2) and 14 (SD 5.9) months respectively.

Twenty-seven women in the pessary group were sexually active compared with 48 women in the surgery group (Table 2). In women who successfully used the pessary, at 1 year, there was a statistically significant improvement in all vaginal symptoms except vaginal soreness. Improvement was also noted in the frequency of urinary leak and quality of life (QOL) symptoms. The bothersomeness of all vaginal and QOL symptoms (interference with daily life) showed a significant improvement. Although improvement was noted in bowel symptoms this was not significant. However, this symptom was not bothersome. There was no improvement noted in any of the sex symptoms in the pessary group. Women who had surgery demonstrated a statistically significant improvement in bowel, sex, urinary frequency leaks and vaginal symptoms, except for the symptom of “tight vagina” (not bothersome). This is also reflected in the improvement in bothersomeness of all vaginal, bowel and sex symptoms, and improvement in all vaginal, sex, urinary and quality of life scores in the surgery group. There was no statistically significant difference noted in symptoms noted in women who were treated by surgery or a pessary (Table 2).

We found that prior to intervention, 33 % of women complained of symptoms of stress urinary incontinence, 21 % urgency and 46 % had mixed urinary incontinence. Statistically significant improvement was noted in the frequency of leak episodes in both treatment groups ($p<0.05$). Significant improvement was noted in the overall ICIQ-UI score ($p<0.05$) in both groups and the difference between the two groups was not statistically significant ($p=0.138$; Table 3).

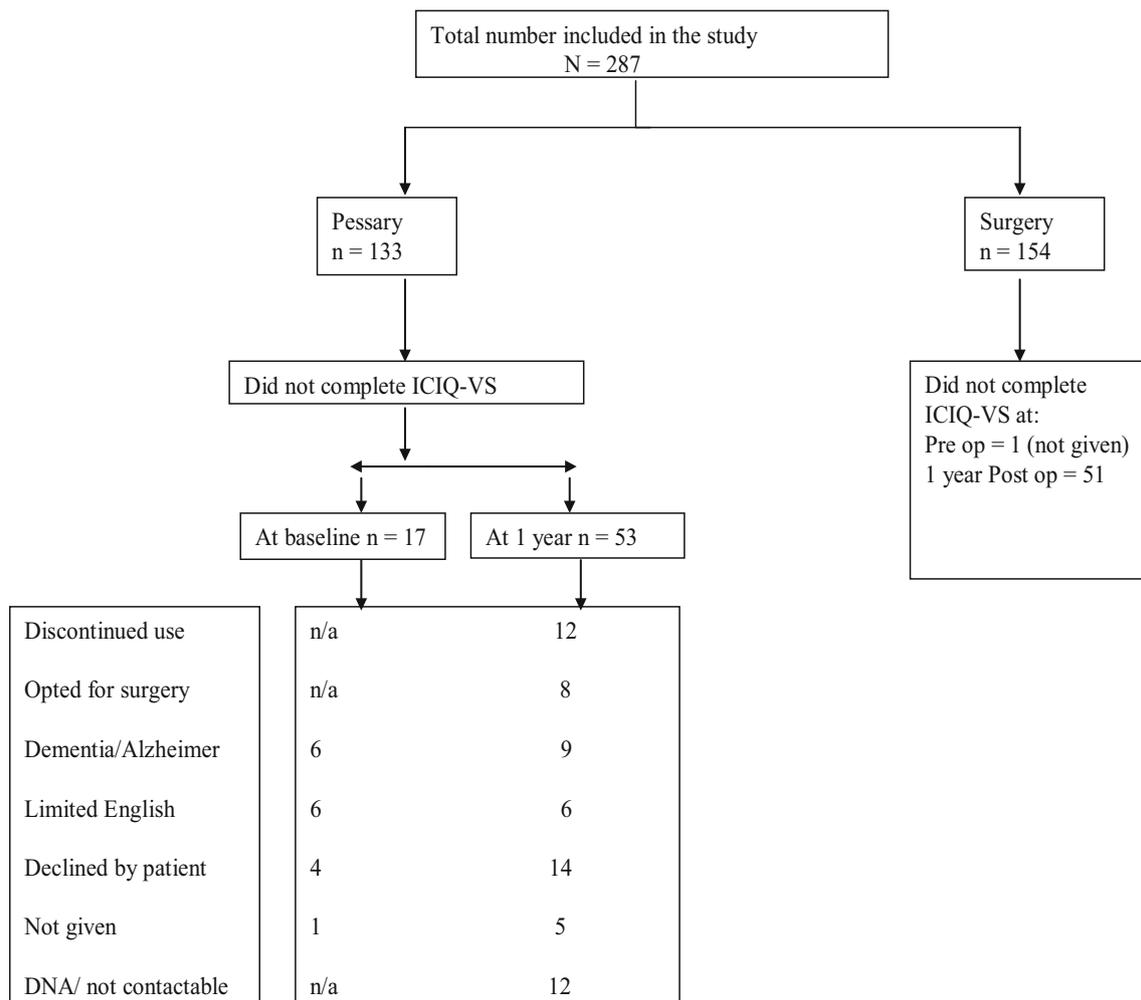


Fig. 2 Flow diagram of study participants

Discussion

In this prospective study, at 1 year, we found improvement in vaginal and urinary symptoms in addition to their bothersomeness, irrespective of whether women with pelvic organ prolapse were treated with a pessary or surgery. Although there was an improvement in the symptoms of vaginal soreness, faecal evacuation and sexual symptoms in the women who had surgery at 1 year, this was not demonstrated in the pessary group. However, these symptoms were not bothersome. Reflecting the improvement in symptoms, improvement in quality of life was noted.

In concordance with recommendations based on the expert opinion, all women presenting with symptomatic POP were offered treatment with a vaginal pessary or surgery [21]. We included a cohort of participants making up two distinct treatment groups to allow for comparative data analysis. The improvement in symptoms is consistent with the findings reported by previous studies evaluating pessary [5–15, 22, 23] and surgical correction [7–10, 15, 23, 24]. The ICIQ-VS [17] is a

comprehensive, fully validated questionnaire comprising 14 items. It is a robust and simple tool that provides a measure to assess the impact of vaginal symptoms and associated sexual matters on quality of life and outcome of treatment. Its brevity also makes the ICIQ-VS an ideal research tool. The ICIQ-VS [17] explores the vaginal symptoms (awareness of dragging pain in the lower abdomen, vaginal soreness, reduced vaginal sensation, vaginal laxity, a lump/bulge coming down the vagina, a vaginal lump that can be felt or seen, vaginal dryness, vaginal digitations to evacuate bowels, tight vagina, interference of vaginal symptoms with sexual life and relationship with the partner) in addition to bother and interference with everyday life. We also included the ICIQ-UI (SF) questionnaire, which provides a short and robust measure to assess the impact of symptoms of incontinence on quality of life and outcome of treatment [18]. The final shortened version of the questionnaire used has been shown to have high levels of validity, reliability and sensitivity. This tool assesses the presence/absence of urinary leakage, the amount of leakage and its interference with everyday life. Moreover, it also

Table 2 Change of symptoms from baseline to 1 year after pessary and surgery use using the International Consultation on Incontinence Questionnaire-Vaginal Symptoms (ICIQ-VS)

Symptoms	Pessary <i>n</i> =80		Surgery <i>n</i> =103		Mann–Whitney <i>U</i> <i>p</i> value**
	Change in score (<i>p</i> value)*	Bothersome, <i>p</i> value*	Change in score (<i>p</i> value)*	Bothersome, <i>p</i> value*	
Dragging	−2.08 (0.008)	<0.001	−6 (<0.001)	<0.001	0.769
Soreness	−0.4 (0.918)	0.003	−5.1 (<0.001)	<0.001	0.997
Sensation	−1.2 (0.021)	<0.001	−2.4 (0.015)	0.002	0.785
Loose vagina	−1.9 (0.006)	<0.001	−5.2 (<0.001)	<0.001	0.113
Lump felt	−6.9 (<0.001)	<0.001	−8 (<0.001)	<0.001	0.156
Lump seen	−5.2 (<0.001)	<0.001	−7.2 (<0.001)	<0.001	0.493
Dry vagina	−1.4 (0.013)	<0.001	−4.4 (<0.001)	<0.001	0.122
Tight vagina	−3.7 (<0.001)	0.008	−1.2 (0.198)	0.004	0.382
Faecal evacuation	−4.6 (0.051)	0.081	−6.1 (<0.001)	0.021	0.441
Interfered with sex life ^a	−1.4 (0.141)	0.142	−2.89 (0.004)	0.004	0.930
Affected relationship ^a	−1.2 (0.120)	0.123	−2.45 (0.014)	0.014	0.345
Sex life spoilt ^a	−1.3 (0.129)	0.127	−2.6 (0.003)	0.008	0.342
Interfered with daily life	−5.5 (<0.001)	<0.001	−6.8 (<0.001)	<0.001	0.629
Vaginal score	−7 (<0.001)	–	−3.6 (<0.001)	–	0.118
Sex score	−1 (0.309)	–	−8 (<0.001)	–	0.245
QOL score	−5.5 (<0.001)	–	−12.7 (<0.001)	–	0.362

*Wilcoxon signed rank test

**Mann–Whitney *U* test^aData for sexually active patients

enquires about when the woman leaks and helps in assessing the type of urinary incontinence.

Vaginal symptoms

We found a significant improvement in all vaginal symptoms in the pessary group at 1 year, except with regard to the symptom of vaginal soreness, which can be explained by the presence of the pessary as a foreign body in contact with the vaginal walls. In women who opted for surgery, improvement was noted in all vaginal symptoms except for “tight vagina” which could have been an expectation of the women in this group. However, these symptoms that did not show an improvement were not bothersome for the patients and there was not a statistically significant difference between the two groups. Our findings of improvement in both groups concur with those of other studies [12, 15, 23].

Bowel and sexual symptoms

We found improvement in bowel symptoms when women with POP were treated with surgery compared with pessary use. However, the difference between the two groups was not statistically significant. Kuhn et al. [11] reported statistically

significant improvement in stool outlet problems. Our previous finding of improved bowel evacuation at 4 months post-pessary use showed that improvement in faecal evacuation was only marginally improved ($p=0.045$), suggesting that surgery might be more effective in addressing bowel-emptying symptoms.

We found a significant improvement in the sexual function after surgery, but no improvement in any of the sex symptoms in the pessary group over time. This non-improvement in the pessary group may be explained by the awareness of the presence of a vaginal pessary. We have previously shown that patients who prefer surgical treatment are younger (58 vs 66 years), and are more likely to describe more severe and bothersome symptoms of sexual function, bowel-emptying and quality of life [9]. This suggests that the improvement could be due to the pre-operative status of the patient. In a study with this methodology where the patient can self select, treatment bias cannot be excluded. However, despite the difference within the two groups at 1 year, we found no statistically significant difference between the two treatment groups. The effect of pessaries on sexual function was also evaluated by Kuhn et al. [11] in 31 sexually active women with stage 2 or greater POP. The Female Sexual Function Index (FSFI) questionnaire was used in that study to evaluate sexual

Table 3 Change of symptoms from baseline to 1 year after pessary use and surgery using the International Consultation on Incontinence Questionnaire-Urinary Incontinence (ICIQ-UI)

Symptoms	Pessary		Surgery		Mann–Whitney U
	<i>n</i> =80		<i>n</i> =103		
	Change in score (<i>p</i> value)*	Bothersome, <i>p</i> value*	Change in score (<i>p</i> value)*	Bothersome, <i>p</i> value*	
Frequency of urine leak	-2.68 (0.04)	-	-6 (0.02)	-	0.423
Amount of urine leak	0.5 (0.518)	-	-1.5 (0.121)	-	0.997
Leaking interfering with everyday life	-1.4 (0.061)	0.07	-3.6 (0.075)	0.08	0.535
Sum score	-1.4 (0.006)	-	-4.8 (<0.001)	-	0.138

*Wilcoxon signed rank test

**Mann–Whitney *U* test

function, which demonstrated a significant improvement in sexual desire, lubrication and satisfaction at 3 months. Moreover, they demonstrated an improvement in general health and prolapse symptoms as determined by the King's Health Questionnaire [25] and the Sheffield POP Questionnaire [16]. This difference in results may be explained by the small number of sexually active women in our pessary group. This study differs from ours in that women in our study had sexual intercourse with the ring pessary in situ while in their study the cube pessary was removed before sexual intercourse. We used a ring pessary in women who were sexually active, as many women in our study preferred not to handle the pessary themselves. In our study group, the two sexually active women fitted with a cube pessary were provided with instructions on removal and re-insertion techniques. This is particularly important when choosing the type of pessary for women who are sexually active. Women who had a Gellhorn pessary in situ were not sexually active in our study.

Urinary symptoms

We noted an improvement in urinary symptom scores in both groups, which most likely reflects the reduction in frequency of urinary leaks, as there was no significant difference in the amount of urine leakage and leakage interfering with everyday life. Again, there was no difference between the two groups. The improvement in the frequency of urinary leakage after both pessary use and surgery could possibly be the result of an improvement in obstructive symptoms after these treatment options. Other studies [23, 26] have also reported urinary symptom improvement. Barber et al. [23] assessed two independent populations: 42 women with stage 2 or greater prolapse in the pessary group and 64 women with stage 3 or greater prolapse in the pelvic floor surgery group. They reported that in the pessary group there was a significant improvement in the prolapse and urinary scales of the Pelvic Floor Distress Inventory (PFDI) and no significant change in the colorectal scale. In the surgery group, there was a significant improvement in the prolapse, urinary and colorectal scales of both the PFDI and the Pelvic Floor Impact Questionnaire (PFIQ).

Strengths and weaknesses

We are not aware of another prospective study that has evaluated the comparative outcomes of vaginal pessaries and surgery using the validated ICIQ-VS and ICIQ-UI (SF) questionnaires at 1 year. One of the recommendations of the International Consultation on Incontinence [27] is that there is a need for studies comparing the effectiveness of pessaries with that of surgery for the treatment of POP. However, it was acknowledged that randomisation may not be appropriate. Our study

therefore provides the best available evidence to date using patient-related outcomes with validated questionnaires.

A possible limitation of our study is the selection bias regarding treatment options, as the clinician may have been more positive about surgery when counselling younger subjects. Although the questionnaire response at 1 year was sub-optimal (67 % in the surgery group and 69 % in the pessary), it is better than that of a previous study [10]. In addition, there were a smaller number of sexually active women in the pessary group. We did not further subdivide the compartment of the prolapse (anterior, middle or posterior compartment), as this would make the analysis too complicated. This may be a topic for future evaluation.

Conclusion

This prospective study highlights that both pessary and surgery are effective treatment options for the management of women with POP. Women can be reassured that by choosing a pessary as their first option for treatment of POP, the outcome at 1 year in terms of prolapse symptoms, urinary and bowel function, and quality of life can be as effective as that of surgery. As surgery has increased morbidity and mortality [28], pessary use should be discussed as a treatment option in all women with POP.

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Authors' contributions F. Lone: project development, data collection, data analysis, manuscript writing; R. Thakar: project development, manuscript editing; A.H. Sultan: project development, manuscript editing.

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