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ORIGINAL ARTICLE

# Prospective evaluation of outcome of vaginal pessaries versus surgery in women with symptomatic pelvic organ prolapse

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**Abstract**
*Introduction and hypothesis* The aim of this study is to evaluate and compare the effectiveness of pessaries and surgery in women with symptomatic pelvic organ prolapse.
*Methods* A total of 554 women with symptomatic pelvic organ prolapse (POP) were recruited and treated with either a vaginal pessary ($n$=359) or surgery ($n$=195). Using the validated Sheffield POP questionnaire, outcomes were evaluated and then compared at 1 year.
*Results* At 1 year, the only significant difference between the two groups was increased frequency of intercourse in the surgery group (54% vs 46%; $p$=0.028), which was not significant when controlled for age. There was a statistically significant improvement in prolapse, urinary, bowel, and sexual function in both pessary users and those treated surgically.
*Conclusions* One year after treatment, women with POP report similar improvement in urinary, bowel, sexual function, and quality of life parameters when treated with pessary or surgical correction.

**Keywords** Prolapse · Pessaries · Surgery · Quality of life

## Introduction

Pelvic organ prolapse (POP) has a lifetime prevalence of 30–50% [1]. Symptomatic urogenital prolapse has been shown to have a negative impact on various quality of life domains [2]. Currently, non-surgical treatment modalities include pelvic floor exercises, physiotherapy and the use of support devices eg. vaginal pessaries. Previous studies have shown pessaries to be effective in improving pelvic floor dysfunction [3–6]. Using the Pelvic Floor Disorders Impact Questionnaire (PFDI-20), Komesu et al. [5] reported an improvement in prolapse, urinary (both irritative and stress incontinence symptoms) and bowel symptom scores in subjects who continued pessary use. Although the use of pessaries improved the scores in both the continued and discontinued pessary groups, the impact on bowel symptoms was not significant. A prospective study by Clemons et al. [3] demonstrated that at 2 months after pessary insertion, nearly all prolapse symptoms resolved and 50% of urinary symptoms improved from baseline. Using the cube pessary, Kuhn et al. [6] reported significant improvement in sexual desire, lubrication, and sexual satisfaction. However, both these studies [3, 6] lacked a control group, highlighting the need for additional well designed comparative studies specifically addressing current treatment strategies for POP [7].

Although the primary aims of surgery are to restore anatomy and improve quality of life, there is a paucity of data on the outcomes relating to bladder, bowel and sexual function [8]. Furthermore, there are significant cost implications for prolapse surgery, particularly when the index surgery has a quoted failure rate of up to 30% [9].

A vaginal pessary is a non-invasive treatment for POP, the use of which dates back to at least 1550 BC. Currently clinicians mainly opt for vaginal pessaries as a treatment option for those with co-morbid medical conditions, those who still desire to bear children, as interim relief prior to surgery and those who prefer non-surgical treatment [10]. However, a recent study by Kapoor et al. [11] has shown that when pessaries were offered to patients with symptomatic POP, nearly two thirds of women opted for pessaries rather than surgery as initial management.

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The aim of this study was to evaluate and compare the effectiveness of pessaries and surgery in women with symptomatic POP after 1 year using the Sheffield validated Pelvic Organ Prolapse quality of life questionnaire (SPS-Q) [12].

## Methods

Women referred to a specialist urogynaecology unit with symptomatic POP between June 2002 and May 2007 were included in this study. Written consent to use the data from the questionnaire was obtained from all patients and this was sanctioned by the Croydon Local Research and Development Committee. All patients with POP were counseled about the risks and benefits of pelvic floor strengthening, pessary use and surgical correction. Subjects included in our pessary dataset were those who chose pessaries rather than surgery as a treatment option. At the initial visit, a clinical history and demographic data were recorded. The SPS-Q [12] was completed to assess general symptoms, bladder, bowel, and sexual function. The same questionnaire was completed at 1 year following treatment. The SPS-Q is a 13-item quality of life assessment tool that addresses the impact of prolapse on bladder, bowel, and sexual function on a four-point ordinal response scale (never, occasionally, most of the time, all of the time). The content validity, criterion validity, reliability, and responsiveness of the questionnaire have demonstrated that it is a reliable and valid instrument for the assessment of symptoms related to POP. Furthermore, it has also been proven to be sensitive to change of symptoms. After completion of the questionnaire in the outpatient clinic, women were examined and the degree of prolapse was graded using the Baden–Walker halfway vaginal profile [13]. When women opted for a pessary, the ring was the first choice. Subjects who are sexually active are advised to continue normal sexual activity with a ring in-situ. If the ring pessary was not retained, a gellhorn or donut pessary was fitted if the subject was not sexually active and a cube pessary if the subject was sexually active. Subjects were shown how to use the cube pessary and were instructed to remove the device before sexual intercourse and replace it afterwards. Concomitant vaginal estrogen was only prescribed if there was evidence of vaginal atrophy.

We considered the pessary fitting successful if the pessary was retained during the Valsalva maneuver, the subject felt comfortable with the device in-situ, and the prolapse was reduced above the hymen. Subjects fitted with pessaries for urinary incontinence and those who had concomitant urinary incontinence surgery (e.g. TVT) were excluded from analysis in both the surgery and pessary groups. In addition, subjects who started in the pessary group but subsequently requested surgery were excluded from analysis in both the surgery and pessary group. Some of the women in this study have participated in previous studies [4, 11].

SPSS 15 (SPSS Inc, Chicago, IL) was used for statistical analysis. The t-test was used to compare age between the two groups and the Chi-squared test was used to compare previous repairs between the two groups. The Wilcoxon signed rank test was used to assess change in SPS-Q 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. To control for age as a potential confounder, ordinal regression was performed with age and the variables included in the SPS-Q in each of the two groups.

## Results

Of the 554 subjects with POP, 359 opted for treatment with pessaries and 195 chose surgery. Two hundred and ninety six (83%) were fitted with a ring pessary, 50 (14%), a gellhorn pessary, 8 (0.03%) a cube, and 5 (0.02%) with a donut pessary. Two hundred and forty three (68%) continued pessary use at 1 year (Fig. 1). This was confirmed by reviewing patient letters. Where this information was missing, we contacted the patient telephonically.

At 1 year the Sheffield questionnaire was completed by 68% ($n$=164) of eligible women in the pessary group and 55% ($n$=107) in the surgery group. In our unit the routine practice is to send postal questionnaires to all patients 1 year after surgery. If they do not respond, a second questionnaire is sent two to 3 months later. If they do not reply we do not contact the patient again. Of those who had a pessary inserted 195 did not complete the Sheffield questionnaire at 1 year for the reasons outlined in Fig. 1: Used pessary as an interim measure prior to surgery ($n$=58), opted for surgery because of pessary-related complications ($n$=31), requested no further treatment because of pessary-related problem ($n$=15), declined to fill in questionnaire ($n$=6), unable to contact ($n$=17), died ($n$=13), dementia ($n$=3), and long-term users who declined to fill in questionnaire ($n$=52) (Fig. 1).

### Patient demographics

The mean age was significantly higher in the pessary group compared to the surgery group (68.4 +/− 13.08 vs 60.4 +/− 12.25 years, respectively). There were no statistically significant differences with regard to vaginal parity, previous prolapse repairs or hysterectomy between pessary and surgery groups. In the surgery group 30 (15%) had posterior colporrhaphy, 44 (23%) anterior colporrhaphy, 15 (7%)

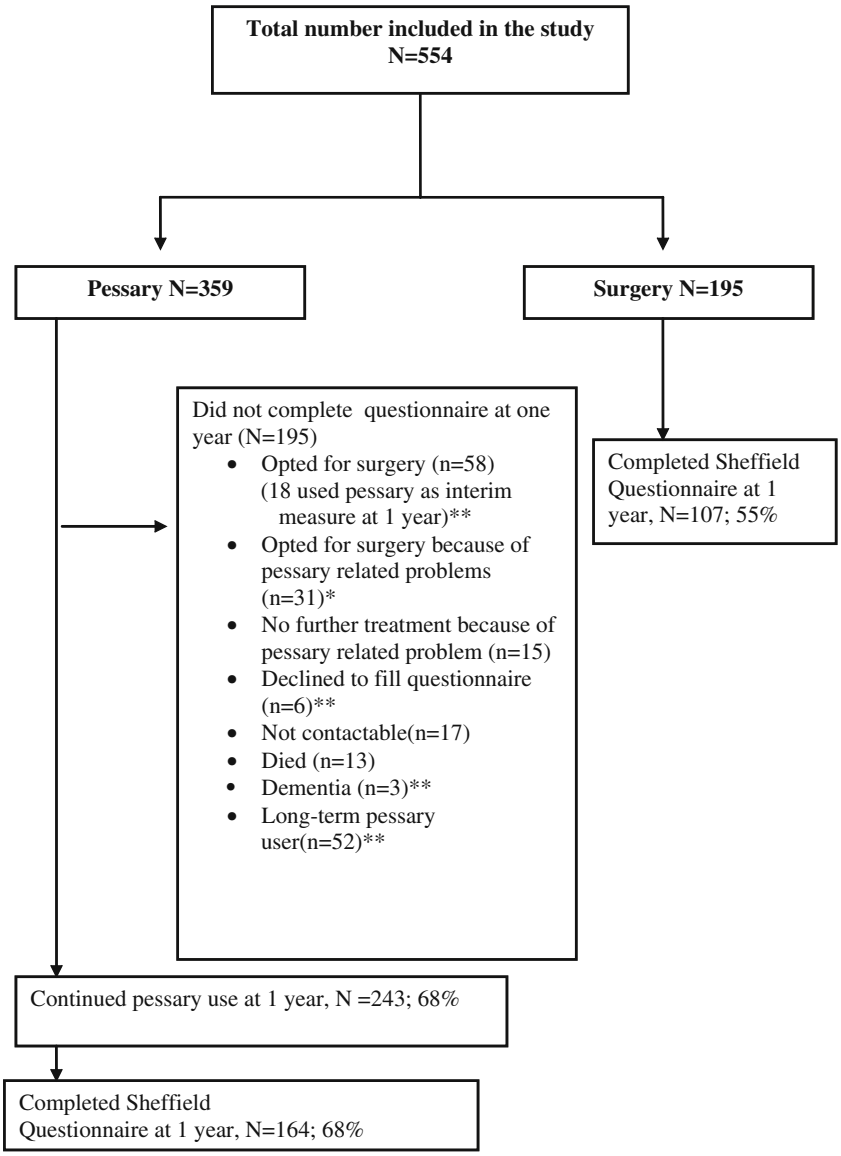


**Fig. 1** Flow diagram of study participants. *Single asterisks* pessary-related problems: pessary fell out ($n$=20), pain and discharge ($n$=5), discomfort and voiding problem ($n$=5), impacted pessary ($n$=1). *Double asterisks* continued pessary use at 1 year (164+52+3+6+18=243)

anterior and posterior colporrhaphy, 59 (30%) vaginal hysterectomy and anterior colporrhaphy, 27 (14%) vaginal hysterectomy, Mc Calls's culdoplasty and posterior colporrhaphy, 10 (5%) sacrocolpopexy, 6 (3%) vaginal hysterectomy and Mc Call's culdoplasty , 4(2%) sacrospinous fixation. None of the vaginal prolapse surgeries were mesh-augmented. The mean time interval for the questionnaires between baseline and the 1 year responses for the surgery and pessary groups were 14 months (SD 6.14) and 12 months (SD 3.1), respectively.

At 1 year there was a statistically significant improvement in prolapse, urinary, bowel and sexual function symptoms in both pessary users and those treated surgically (Table 1). Regarding bowel symptoms, fecal urgency improved in both pessary users and the surgery group, but incomplete bowel emptying only improved in the surgery group ($p$=0.011). Comparison of the two groups at 1 year demonstrated no significant differences in prolapse, bladder, bowel and sexual function symptoms, apart from frequency of intercourse which was better in the surgery group (54% vs 46% ; $p$=0.028). However, when controlling for age as a potential confounder, there was no significant difference between the two groups with regard to all of the outcome variables in the SPS-Q.

## Discussion

In this prospective study, we identified a significant improvement in prolapse, urinary and bowel symptoms as well as sexual function and quality of life 1 year after treatment of symptomatic POP with either pessary use or

**Table 1** Change of symptoms from baseline to 1 year after pessary and surgery use

| Symptom | Pessary ($n$=164) | | | | Surgery ($n$=107) | | | | Mann–Whitney U |
|---|---|---|---|---|---|---|---|---|---|
| | Better[a] | Worse[a] | No change[a] | $P$[a] | Better[a] | Worse[a] | No change[a] | $P$[a] | $P$[b] |
| General symptoms | | | | | | | | | |
| Awareness of a lump | 85 (65.3) | 7 (5.3) | 38 (29.2) | 0.000 | 74 (69.8) | 6 (5.6) | 26 (24.5) | 0.000 | 0.970 |
| Prolapse coming out of vagina | 75 (59.5) | 7 (5.6) | 44 (35) | 0.000 | 57 (54.8) | 10 (9.6) | 37 (35.6) | 0.000 | 0.908 |
| Vaginal soreness | 32 (23.7) | 14 (10.4) | 89 (66) | 0.011 | 36 (34) | 12 (11.3) | 58 (54.7) | 0.006 | 0.577 |
| Dragging pain in lower abdomen | 52 (38.5) | 14 (10.4) | 69 (51.1) | 0.000 | 52 (50) | 7 (6.7) | 45 (43.3) | 0.000 | 0.393 |
| Low back pain | 50 (36.8) | 20 (14.7) | 66 (48.5) | 0.000 | 40 (37.7) | 15 (14.2) | 51 (48.1) | 0.000 | 0.366 |
| Urinary symptoms | | | | | | | | | |
| Difficulty in emptying bladder | 37 (27.6) | 20 (15) | 77 (57.5) | 0.004 | 50 (46.7) | 15 (14) | 43 (39.3) | 0.000 | 0.858 |
| Push prolapse to void | 36 (27.5) | 10 (7.6) | 85 (64.9) | 0.000 | 25 (23.6) | 7 (6.6) | 74 (69.8) | 0.001 | 0.178 |
| Urinary urgency | 46 (34.3) | 17 (12.7) | 71 (53) | 0.000 | 36 (33.6) | 17 (15.9) | 54 (50.5) | 0.005 | 0.669 |
| Urge urinary incontinence | 28 (21) | 24 (18) | 82 (61.2) | 0.053 | 27 (25.2) | 14 (13.1) | 66 (61.7) | 0.042 | 0.131 |
| Stress incontinence | 28 (21) | 22 (16) | 85 (63) | 0.240 | 22 (21) | 16 (15) | 67 (64) | 0.412 | 0.656 |
| Defecatory symptoms | | | | | | | | | |
| Incomplete emptying of the bowel | 32 (24.4) | 23 (17.6) | 76 (58) | 0.197 | 38 (35.5) | 18 (16.8) | 51 (47.7) | 0.011 | 0.818 |
| Fecal urgency | 25 (18.4) | 12 (8.8) | 99 (72.8) | 0.022 | 23 (22) | 12 (11.4) | 70 (66.6) | 0.027 | 0.401 |
| Sexual activity[c] | | | | | | | | | |
| Satisfaction | 15 (47) | 4 (12) | 13 (41) | 0.034 | 39 (67) | 5 (9) | 14 (24) | 0.000 | 0.880 |
| Frequency | 15 (45) | 5 (15) | 13 (40) | 0.059 | 14 (25) | 15 (26) | 28 (49) | 0.637 | 0.028 |
| Interference with physical activity | 51 (39.2) | 10 (7.7) | 69 (53.1) | 0.000 | 57 (55.3) | 11 (10.7) | 35 (34) | 0.000 | 0.806 |
| Interference with enjoyment of life | 62 (47.3) | 12 (9.2) | 57 (43.5) | 0.000 | 64 (62) | 11 (10.7) | 28 (27.3) | 0.000 | 0.533 |

Data are expressed as $n$ (%)

[a] Wilcoxon signed rank test

[b] Mann–Whitney

[c] Data for sexually active patients

surgical correction. The improvement in the various domains are consistent with findings reported by previous studies evaluating pelvic floor symptom changes in pessary users [3, 5, 6, 14] and after surgical correction [15, 16].

The significant improvement in prolapse, urinary and bowel symptoms highlights the fact that both forms of treatment are effective. The SPS-Q explores the impact of prolapse (e.g., awareness of lump in the vagina, lump coming out of the vagina, vaginal soreness, dragging pain in the lower abdomen), urinary ( incomplete bladder emptying, need for digitation, urinary urgency, and stress urinary incontinence), bowel (fecal incontinence, incomplete bowel emptying, need for digitation and fecal urgency), sexual (sexual satisfaction and frequency of intercourse), and general quality of life symptoms (interference with physical activity and enjoyment of life), as well as the bother. Symptoms pertaining to prolapse of the anterior vaginal wall namely voiding difficulty, and need to push the prolapse to void, improved after both pessary use and surgery. The improvement in urgency after both forms of treatment could possibly be a result of improvement in obstructive symptoms [17]. Our study showed that fecal urgency improved in both pessary users and the surgery group, but incomplete bowel emptying only improved in the surgery group ($p$=0.011). Our previous finding of improved bowel evacuation at 4 months post pessary use was only marginally significant ($p$=0.045) [4], suggesting that surgery may be more effective in addressing bowel emptying complaints. This study is unique in that we have a large cohort of study participants making up two distinct treatment groups to allow for comparative data analysis. In addition, we excluded all subjects who required incontinence surgery as well as those fitted with pessaries solely for urinary incontinence.

The 2008 report by the International Consultation on Incontinence [18] identifies the need for studies to compare the effectiveness of pessaries versus surgery. They also acknowledge that randomization may not be appropriate in such studies and therefore this study provides the best available evidence to support this research priority. We have recently shown that patients who prefer surgical treatment are younger (58 versus 66 years), and are more

likely to describe more severe and bothersome symptoms of bowel emptying, sexual function and quality of life [11]. In a prospective observational study by Kuhn et al. [6], the effect of cube pessaries on sexual, bladder, and bowel function was evaluated by telephone survey of 71 women with stage 2 or greater POP. In Kuhn's study, sexual function was evaluated using the Female Sexual Function Index (FSFI) questionnaire which demonstrated a significant improvement in sexual desire, lubrication and satisfaction 3 months after collection of baseline data. In addition the study demonstrated improvement in general health and prolapse symptoms as determined by the King's Health Questionnaire and the Sheffield POP Questionnaire. 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 prior to intercourse. As many women in our study preferred not to handle the pessary themselves we inserted a ring pessary in women who were sexually active. In our study group, only subjects fitted with a cube pessary were instructed on removal and reinsertion. This is important information when choosing the type of pessary for women who are sexually active. One limitation of our study is the selection bias regarding treatment options as the clinician may have been more positive about surgery when counseling younger subjects. In addition we acknowledge the suboptimal response of 55% in the surgery group and 68% in the pessary group at 1 year which could affect the results of our study.

Currently there are a variety of surgical procedures employed for the treatment of POP, based in part on a lack of consensus and clinical data on the 'best procedure' for prolapse. Women face both a 11.1% lifetime risk of undergoing surgery for POP [1] as well as a 13% risk of re-operation [19–22], especially in academic referral populations (re-operation rates as high as 43–56%) [23, 24]. In most cases the repeat procedure is not performed by the original surgeon, potentially underestimating the percentage of recurrence.

Based on this study, women who choose pessaries as their first option for POP can be reassured that the outcome at 1 year in terms of prolapse symptoms, urinary, bowel, sexual function as well as quality of life can be as favorable as surgery. As surgery does have a failure rate and is associated with increased morbidity and mortality [25–27], conservative treatment options should always be discussed with all patients with POP. This prospective study therefore provides useful information for clinicians to use during counseling on the effectiveness of treatment options.

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**Conflicts of interest** None.

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