

## NATURAL HISTORY OF VAGINAL PESSARY USE FOR PELVIC ORGAN PROLAPSE: A 5 YEAR PROSPECTIVE FOLLOW-UP.

### Hypothesis / aims of study

Pelvic organ prolapse affects approximately 50% of all parous women over 50 years of age, with a lifetime prevalence risk of 30-50% [1]. Although surgery is commonly performed for treatment of pelvic organ prolapse, non-surgical treatment options include pelvic floor exercises and vaginal pessaries. Supportive pessaries have long been used for the treatment of prolapse. A retrospective study evaluating long term outcome after pessary use have been published [2].

The aim of our study was to prospectively evaluate the use of vaginal pessaries for pelvic organ prolapse and to identify the reasons for non-use over five years.

### Study design, materials and methods

This is a prospective observational study. All women referred to a specialist urogynaecology clinic with pelvic organ prolapse, who agreed to pessary treatment between June 2002 and June 2005 were included in this study. Women with prolapse requesting treatment were offered a choice of vaginal pessary or surgery. The ring pessary was the pessary of choice. In some patients different sizes of pessaries were tried before comfortable retention was obtained. If the ring pessary was unsuccessful and the patient was sexually active, a cube pessary was used. Women were advised to remove the cube pessary daily and also before sexual intercourse. If the ring pessary was unsuccessful and the patient was not sexually active, a gellhorn or a doughnut pessary was inserted. The pessary was considered to be successful if it was retained without discomfort and the patient was still using a vaginal pessary 4 weeks after pessary insertion. These women were seen at six monthly intervals for change of pessary. For patients who discontinued the pessary, the reason was documented e.g. complications, temporary use of pessary. This data was collected annually from June 2002 until March 2010.

### Results

Of the 246 women who opted to use a pessary, 187 successfully retained the pessary at 4 weeks after insertion. The median age and parity of pessary users was 70 years (range 22-98) and 2 (range 0-8) respectively. 93.5% of women were Caucasian, 4.1% Asian and 1.2% Afro-Caribbean. 50.4% women had previously undergone a hysterectomy, 8% had previous prolapse and 13 % had incontinence surgery. The types of pessaries used included 191 rings (77.6%), 40 gellhorns (16.3%), 6 cubes (2.4%), 5 incontinence rings (2%) and 4 doughnuts (1.6%). Follow-up data of these pessary users over the 5 year period is given in Table 1.

Four weeks after insertion, 51 women who discontinued the pessary due to complications underwent surgery and 8 women decided not to have any further treatment. All women who were pessary failures over the years decided to have surgery except two (one at 4 years and one at 5 years) who stopped using pessary and did not want any further treatment.

Follow-up time	Continued pessary users n (%)	Failure n (%)	Temporary pessary users n (%)	Lost to follow-up n (%)	Deceased n (%)
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Table 2 shows that most complications occur in the first 6

months of insertion of the pessary. In subsequent years the failure rate was no more than 0.4% per year. Pessaries that failed during the insertion period were the ring (45/191= 23.5%), gellhorn (2/40 = 5%), cube (3/6 = 50%) and doughnut (1/4 = 25%). 92.5% of successful pessary users had no complications within 4 weeks of insertion. The complications reported in successful pessary users were pain and discomfort (2.1% within 4 weeks of insertion) which decreased to none after the first year of use. Excoriation/ bleeding and discharge were reported by 2.1% at the insertion period and 3.7% at 5 years. Other complications included dislodgement of pessary or constipation and were seen in 3.2% of women 4 weeks after pessary insertion, followed by a progressive decrease to 1.2 % at 3 years and none thereafter.

### Interpretation of results

This is the largest prospective study to date evaluating long term pessary use. In women who opted to use pessary as the first line of treatment, 28% continued at 5 years. Most complications occurred within the first 6 months and were almost negligible thereafter. Women who discontinued use of the pessary did so as it was convenient for them to have surgery during the time period and not because they had a complication due to pessary use. It has previously been shown that women who choose to use 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 QOL can be as favourable as surgery [3].

### Concluding message

Vaginal pessary use is a non-invasive treatment option for patients with POP. In our experience during this prospective study when women were given the choice of pessary and surgery, 28% continued to use pessaries at 5 years from insertion without any increase in complication rates. This prospective study therefore provides useful information for clinicians to use during counselling on the effectiveness of treatment options.

4 weeks	187	59 (24)			
6 months	152 (81.2)	12 (6.4)	18 (9.6)	5 (2.7)	0
1 year	126 (67.3)	1 (0.5)	20 (10.7)	2 (1)	3 (1.6)
2 years	101 (54)	2 (1)	9 (4.8)	3 (1.6)	11 (5.8)
3 years	81 (43.3)	2 (1)	5 (2.7)	10 (5.3)	3 (1.6)
4 years	68 (36.3)	2 (1)	1 (0.5)	6 (3.2)	4 (2.1)
5 years	53 (28.3)	2 (1)	1 (0.5)	10 (5.3)	2 (1)

Table 2: Reasons for pessary failures over time.

**References**

1. Fernando RJ, Thakar R, Sultan AH, Shah SM, Jones PW. Effect of vaginal pessaries on symptoms associated with pelvic organ prolapse. *Obstet Gynecol* 2006;108:93-9.
2. Sarma S, Ying T, Moore KH. Long-term vaginal ring pessary use: discontinuation rates and adverse events. *BJOG* 2009;117:1715-1721.
3. Abdool Z, Thakar R, Sultan AH, Oliver R. Prospective evaluation of outcome of vaginal pessaries versus surgery in women with symptomatic pelvic organ prolapse. *Int. Urogynecol. J* (2009) 20 (suppl 2):S73-S239.

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<b>Is this a clinical trial?</b>	<b>No</b>
<b>What were the subjects in the study?</b>	<b>HUMAN</b>
<b>Was this study approved by an ethics committee?</b>	<b>No</b>
<b>This study did not require ethics committee approval because</b>	<b>This is an observational study of normal clinical practice</b>
<b>Was the Declaration of Helsinki followed?</b>	<b>Yes</b>
<b>Was informed consent obtained from the patients?</b>	<b>No</b>

Follow-up time	Pessary expelled n (%)	Excoriation/ Bleeding n (%)	Pain/ discomfort n (%)	No improvement/ worse symptoms n (%)	Others disimpaction/ dislodgement n (%)	Total n
4 weeks	40 (16.3)	3 (1.2)	13 (5.3)	0	3 (1.2)	59
6 months	7 (2.8)	2 (0.8)	2 (0.8)		1 (0.4)	12
1 year	0	1 (0.4)	0	0	0	1
2 years	1 (0.4)	1 (0.4)	0	0	0	2
3 years	1 (0.4)	0	1 (0.4)	0	0	2
4 years	0	1 (0.4)	1 (0.4)	0	0	2
5 years	1 (0.4)	0	0	0	1 (0.4)	2