



Predictors for dislodgment of vaginal pessary within one year in women with pelvic organ prolapse



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ARTICLE INFO

Keywords:

Vaginal pessary
Pelvic organ prolapse
Predictors

ABSTRACT

Objectives: To identify clinical risk factors for dislodgment of vaginal pessary within one year in women with symptomatic pelvic organ prolapse.

Study design: This was a prospective observational study which recruited consecutive women with symptomatic pelvic organ prolapse in a tertiary urogynecology center. Basic demographics, clinical symptoms and staging of pelvic organ prolapse were assessed. A vaginal pessary was offered where appropriate.

Main outcome measures: Demographics and clinical parameters were compared between women who were able to use a vaginal pessary for one year and those whose pessaries were dislodged within one year.

Results: A total of 779 women were recruited and had a vaginal pessary inserted. Of them, 528 women, with a mean age of 64.7 (SD 10.1) years, returned for one-year follow-up; 177 (33.5%) had their pessary dislodged within one year and 351 (66.5%) had been able to retain the pessary. Stage III or IV prolapse (OR 1.76), prolapse predominant at the apical compartment (OR 2.14) and larger genital hiatus (OR 1.63) were factors associated with dislodgment of the vaginal pessary. Age, body mass index, previous hysterectomy and short vagina were not associated with dislodgment. Nevertheless, 47.6% of women with stage III/IV prolapse could still keep the pessary for one year.

Conclusion: Higher staging of prolapse, larger genital hiatus and apical compartment prolapse are clinical predictors for dislodgment of a vaginal pessary. Despite this, nearly half of women with stage III/IV prolapse were able to use a vaginal pessary for one year. Therefore, a vaginal pessary should be offered despite their staging of prolapse.

1. Introduction

Pelvic organ prolapse (POP) is a common problem for women and causes significant impairment in their quality of life [1]. Vaginal pessary has been used in treating pelvic organ prolapse (POP) for decades. Although there have been significant advances in prolapse surgery, vaginal pessary has remained an effective treatment and improve women's quality of life [2]. The efficacy of vaginal pessary has been demonstrated in a recent randomized controlled trial [3], although it has predictable complications which may affect women's treatment decisions in the management of their POP [4]. Besides the side effects of excessive vaginal discharge or bleeding and de novo urinary symptoms, dislodgement of the pessary is a major hurdle for women to use pessary in the long term [5]. The reported dislodgement rate was 25–59% in 1–3 weeks after pessary fitting [6–11]. However, there has been limited and inconsistent information about the risk factors for pessary dislodgment. The aim of this study is to determine clinical predictors for dislodgement of pessary within one year. This will improve counselling

for women who wish to use pessary as long term treatment.

2. Methods

This is a prospective observational study conducted in a tertiary urogynaecology center from January 2010 to June 2015. Consecutive women presented with symptomatic POP, with no prior treatment for the condition before the consultation were recruited. They were seen by a gynaecologist. Demographic data, history of POP, associated urinary or bowel symptoms or any complications were obtained using standardized history sheet. This was followed by physical examination to confirm the type and stage of POP according to the POP-Q system [12]. After counselling, if women opted to have vaginal pessary, the largest ring pessary that was comfortable for the women was used. If the vaginal pessary slipped out, re-insertion of same or next size of vaginal pessary was performed up to 3 times. Double ring pessaries [13] may be used according to the clinical assessment. A follow-up visit was arranged 4–6 months later. Women were given a telephone hotline and

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advised to call back if the pessary slipped out before the second visit for reassessment and reinsertion of pessary. During the second consultation, their symptoms were reviewed and any dislodgment or side effects of the vaginal pessary were noted. The pessary was replaced for women who chose to continue its use.

Women who had pessaries fitted in our center and with follow up information available after one year were included for analysis. Women who requested to have their pessaries removed or who had prolapse surgery performed during the first year were excluded. Clinical parameters of women who had their pessaries dislodged within one year were compared to those who were able to retain the pessary. The study was approved by the Joint Chinese University of Hong Kong-New Territories East Cluster Clinical Research Ethics Committee (CRE-2009.584).

Sample size was calculated assuming 10 potential predictors and with 40% drop off rate of pessary after 1 year [3]. The minimal number of cases needed was 250 [14]. Statistical analysis was performed using SPSS 20 for Windows. All continuous variables were normally distributed. Two sample T test and Chi square tests were used to perform univariate analyses which identify potential predictors. Predictors with p value < 0.1 in univariate analysis were included in a multivariate analysis using binary logistic regression model with stepwise backward entry. A p value < 0.05 was considered as statistically significant in the final model. Multicollinearity was checked and split sample internal validation was performed in the final model.

3. Results

From January 2010 to June 2015, 1002 women were referred to our tertiary urogynaecology clinic for symptomatic pelvic organ prolapse with no prior treatment. Among them, 779 women had vaginal pessary inserted in their first consultation.

A total of 528 women were included for the analysis after one year. Of the original cohort, 52 women requested to have pessary removed due to vaginal bleeding, discharge or urinary symptoms; 120 women had prolapse surgery performed within one year and 79 women were lost to follow up. One hundred and seventy-seven (33.5%) women had their vaginal pessary dislodged within one year while 351 (66.5%) women were able to use pessary over one year. Table 1 reports the clinical characteristics of these two groups of women. Staging of prolapse, predominant compartment of prolapse and genital hiatus measurement were significantly different between two groups.

Table 1
Demographic and clinical parameters of women with pessary retained or dislodged within one year.

Demographics	Total	Women with pessary retained	Women with pessary dislodged
Age in years	64.7 (10.1) ^a	65.2 (10.5) ^a	63.7 (9.3) ^a
Body Mass Index (in kg/m ²)	25.2 (3.5)	25.0 (3.5)	25.7 (3.5)
Menopausal, Number (%)	418 (82%)	290 (84.3%)	128 (77.1%)
Sexually active, Number (%)	158 (31.4%)	101 (30.0%)	57 (34.3%)
Parity, median (range)	3 (2–4)	3 (2–4)	3 (2–4)
Number of vaginal delivery median (range)	3 (2–4)	3 (2–4)	3 (2–4)
Birth weight of biggest baby (kg) ^b	3.3 (3.2)	3.3 (3.2)	3.4 (3.2)
POPQ stage I/II, Number (%)	383 (72.5%)	282 (80.3%)	101 (57.1%) ^c
POPQ stage III/IV, Number (%)	145 (27.5%)	69 (19.7%)	76 (42.9%) ^c
Previous hysterectomy Number (%)	27 (5.1%)	16 (4.6%)	11 (6.2%)
Most severe prolapse- Anterior compartment, Number (%)	310 (58.7%)	231 (65.8%)	79 (44.6%)
Apical compartment, Number (%)	143 (27.1%)	69 (19.7%)	74 (41.8%) ^c
Posterior compartment, Number (%)	19 (3.6%)	13 (3.7%)	6 (3.4%) ^c
Anterior and Apical compartment, Number (%)	52 (9.8%)	34 (9.7%)	18 (10.2%)
Apical and Posterior compartment, Number (%)	4 (0.8%)	3 (0.9%)	1 (0.6%)
Genital hiatus (cm)	3.42 (0.76)	3.29 (0.69)	3.67 (0.83) ^c
Total vaginal length (cm)	6.98 (1.13)	7.07 (1.21)	6.94 (1.09)
Perineal body (cm)	2.01 (0.37)	2.02 (0.41)	2.0 (0.28)

^a Data are presented in Mean (Standard deviation) unless otherwise specified.

^b Birth weight of biggest baby can only recalled by 412 of women with 269 of women with pessary retained and 143 of women with pessary dislodged.

^c indicates statistical significant difference between two groups.

Total of 52 (9.8%) women had missing data for either sexual status ($n = 18$, 3.4%), BMI ($n = 25$, 4.7%) or number of vaginal delivery ($n = 34$, 6.4%). However, 48 (9.1%) women could not recall the birth weight of their biggest babies. In order to avoid bias, complete-case analysis was not adopted for the missing cases. Women with missing BMI, number of vaginal delivery and birth weight of biggest babies were allocated the median value of the women according to their outcome of pessary dislodgement or not. Cases with missing sexual status were initially accommodated by including a ‘missing’ factor and then subsequently assumed to be ‘sexually inactive’ after a preliminary multivariate logistic regression indicated that sexual status ‘missing’ was not statistically significant.

Upon multivariate analysis, stage III or stage IV prolapse (OR: 1.76, $p = 0.02$), prolapse predominant at apical compartment (OR: 2.14, $p < 0.01$) and larger genital hiatus (OR: 1.63, $p < 0.01$) were factors associated with dislodgment of vaginal pessary (Table 2). One hundred and one (26.4%) women with stage I or II POP had their pessary dislodged while 76 (52.4%) women with stage III or stage IV prolapse had pessary dislodged. For the predominant prolapse compartment, majority of women had the most severe prolapse at the anterior compartment, but only 25.4% of them had pessary dislodged while 51.7% of women with predominant prolapse at apical compartment had the pessary dislodged.

The final set of variables including stage III/IV prolapse, most severe prolapse at apical compartment and the length of genital hiatus provide a Cox & Snell R square of 0.1 and Nagelkerke R square of 0.14. The Omnibus Test of Model coefficients with Chi-square (5, $N = 528$) = 54.6, $p < 0.01$, indicating the significant relationship between the predictors and the response variable. The final model derived was:

$$Y = -2.845 \text{ (SE } 0.470) + 0.600 \text{ (SE } 0.233) \text{ if stage III/IV prolapse} \\ + 0.695 \text{ (SE } 0.228) \text{ if apical prolapse dominant} \\ + 0.512 \text{ (SE } 0.134) \times \text{ genital hiatus (cm)}$$

A Receiver operating characteristic (ROC) curve was obtained from the logistic regression. The area under the ROC curve (AUC) was 0.67 (SE = 0.025, $p < 0.01$; 95% CI: 0.596–0.742), and the p value for the Hosmer-Lemeshow (HL) goodness-of-fit test was 0.85 with Chi-square 3.32. The 95% specificity corresponds to 21% sensitivity and 90% specificity corresponds to 31% sensitivity.

In the 177 women whose pessary was dislodged, the majority dislodged the pessary within first 2 weeks after insertion; 9 (5%) had their pessary dislodged after 2 weeks, 2 (1%) failed to retain the pessary after

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