

## COMPARISON OF VAGINAL ULCER OCCURRENCE WITH PESSARY USE FOR PELVIC ORGAN PROLAPSE

### Hypothesis / aims of study

The goal of the study was to compare the occurrence of vaginal ulcer formation in women using a supported ring pessary versus a Gellhorn pessary for management of pelvic organ prolapse. We hypothesized there was no relationship between type of pessary used and occurrence of vaginal ulcers.

The pelvic organs are supported by a complex set of pelvic muscles, ligaments, fascia, and bone, which together form a hammock structure in the base of the pelvis. Pregnancy, family history of pelvic organ prolapse, obesity, advancing age, prior hysterectomy, chronic constipation, and habitual coughing put some women at risk for pelvic organ prolapse. The Women's Health Initiative in the United States reported 34% of women had vaginal wall prolapse, 19% had posterior vaginal wall prolapse, and 14% had uterine prolapse on physical examination [1].

Mild pelvic organ prolapse that is asymptomatic does not require treatment. However, when the degree of prolapse affects quality of life, a pessary is a non-surgical option for relief of such symptoms as vaginal pressure, low backache and urinary obstruction. The most common complication associated with use of a pessary is the development of a vaginal ulcer [2].

### Study design, materials and methods

This is a retrospective, longitudinal, comparative study using a convenience sample of 90 pessary users, some of whom developed a vaginal ulcer within the period of study, from 2008 to 2010. Subjects were from a nurse practitioner's (NP) urogynecology practice located in north-eastern United States. Inclusion criteria were limited and only included pessary use for at least 6 months at the time of the study. Subjects were divided into those who received nurse practitioner pessary care and those who practiced self-care with follow-up nurse practitioner visits. The NP cohort was scheduled for an office visit every three months during which the pessary was removed, cleaned, and, if there were no ulcers of the vaginal canal or cervix, re-inserted. The self-managed cohort was seen in the office for a vaginal exam every six months. Self-care was defined as patient's taking the pessary out once a week, leaving it out overnight and then re-inserting it in the morning. Both cohorts were instructed to use 1 gram of estrogen cream vaginally twice a week. Study subjects varied in age from 42 to 96 years, with a mean age of 75.6 years, with varying levels of health. Co-morbidities were not considered in either the inclusion or exclusion criteria.

A retrospective yearly view of the data was compared. Occurrence of a vaginal ulcer determined how the data was viewed: occurrence of a vaginal ulcer in the 2010 data prompted a review of the data from 2009 and 2008. This method allows a consistent retrospective analysis, although it does not include those who had an ulcer in 2009 or 2008, but not in 2010.

### Results

	Supported ring pessary	Short stem Gellhorn	Long stem Gellhorn	Total incidence
No vaginal ulcer	n=38 (95.0%)	n=14 (63.6%)	n=16 (57.1%)	n=68 (75.6%)
Vaginal ulcer ever	n=2 (5.0%)	n=8 (36.4%)	n=12 (42.9%)	n=22 (24.4%)
Total number of patients in study groups	n=40 patients	n=22 patients	n=28 patients	n=90 patients total

### Interpretation of results

A crosstabulation method was used for statistical analysis. We found that of the 40 patients who used a supported ring pessary, 95% had no vaginal ulcers. Of the 22 patients who used a Gellhorn pessary with a short stem, 64% had no vaginal ulcers, and of the 28 patients using a Gellhorn with a long stem, 57% had no vaginal ulcers. A Phi coefficient was calculated at 0.40, indicating these results are significant ( $p \sim 0.001$ ).

### Concluding message

This study has been useful to gain a greater understanding of the population of pessary users and the rate of vaginal ulceration. The mean age of the women in this sample is 75.6 years, and the literature shows that women over the age of 72

are more likely than younger women to use a pessary for extended periods of time [3]. Extended use tends to lead to more vaginal ulcers. There is good reason to follow women carefully to reduce the incidence of vaginal ulcers, particularly for women who are using the pessary for many years. The data from this study argues for the continued use of the supported ring pessary whenever feasible

References

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<b><i>Specify source of funding or grant</i></b>	<b>No funding for this project.</b>
<b><i>Is this a clinical trial?</i></b>	<b>No</b>
<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>No</b>
<b><i>This study did not require ethics committee approval because</i></b>	<b>it received IRB exemption status from the Maine Medical Center IRB due to the retrospective nature of the study.</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>No</b>