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LONG TERM OUTCOMES OF PESSARY USE IN WOMEN WITH PELVIC ORGAN PROLAPSE

Hypothesis / aims of study

The main objective of this retrospective study is to evaluate whether long-term use of vaginal pessaries is an appropriate conservative treatment for women with pelvic organ prolapses. Therefore, we aim to evaluate patients' satisfaction and length of use of the pessary depending on age, prior pelvic history, prolapse type and severity, associated symptoms (lower urinary tract symptoms, bowel dysfunction, sexual dysfunction), pessary type, intermittent use, maintenance type, and concomitant use of topical estrogen and/or mucolytic cream. Secondary objectives include the evaluation of the complications related to pessary use and the relationship with concomitant use of topical estrogen cream.

Study design, materials and methods

From January 1998 to December 2010, 429 women with pelvic organ prolapse had a pessary trial at our institution. Prior to the trial, every woman underwent a thorough history and gynecological exam. Therapeutical options were explained to the patient, and if pessary was chosen, the trial was performed on the same day. Vaginal atrophy or constipation had to be treated prior to the trial. Patients received instructional documentation about pessary maintenance and were encouraged to use topical estrogen and mucolytic cream at home. A follow-up appointment was scheduled one month later. History and gynecological exam were repeated, and a maintenance regime for the pessary was chosen (self-maintenance, maintenance by nurses in regional clinics or by nurses in our own clinic). Additional follow-up appointments were then scheduled yearly, or before as patient needs. Data gathered included descriptive information regarding each patient, specific information concerning pessary use, incidence of vaginal erosions or other associated morbidities, final choice of treatment, and patient's satisfaction rate.

Results

Average age at presentation was 71.1 $\pm$ 9.7 years old. 50% of patients had had hysterectomy and 22% had had a prior prolapse surgery. Patients with previous hysterectomy, prolapse surgery, or multiple prolapses favored surgery as the final treatment. 62% (n = 258) of women had a successful pessary trial, which was defined as a one-month use of the pessary with subjective improvement of symptoms and no significant complication. Median duration of pessary use was 35 months (1-136). 96% of women were satisfied or very satisfied with their pessaries. 66% (n = 170) of patients could handle pessary by self-maintenance, while 23% (n = 59) needed assistance from a regional nurse, and 11% (n = 28) necessitated maintenance by our clinic nurses. Among these three groups, 71%, 61%, and 43% of the patients respectively continued using the pessary. Of these women, 12% (n = 30) eventually used the pessary intermittently. Pessary self-maintenance was associated with a prolonged use of the pessary (38 months vs 30 months for the nurse group vs 27 months for the clinic group, p = 0.021). Mucolytic cream use was also associated with a prolonged use of the pessary (38 vs 26 months, p = 0.001). The overall erosion rate was 16% (n = 42) and was not associated with the degree of prolapsus. The average age at the time of erosion was 78.4 $\pm$ 6.9 years old. 60% (n = 25) of women developing an erosion had vaginal atrophy documented at the first evaluation. 43% (n = 18) had an intensive estrogen cream treatment prior to the pessary trial. 76% (n = 32) were using estrogen cream at the time of erosion. Constipation and longer duration of pessary use were associated with higher rates of erosions (23 vs 12%, p = 0.027, and 45 vs 33%, p = 0.015 respectively), while sexually active women had a significantly lower rate of erosions (7 vs 21%, p = 0.007). Finally, contrary to our expectations, use of topical estrogen cream seemed to associate with a higher rate of erosions (25 vs 5%, p < 0.001). However, older age was also associated with a higher rate of erosions (p < 0.001), and older patients were more likely to use topical estrogen cream because of vaginal atrophy (p < 0.001). Furthermore, multivariate analysis using the forward-selection technique demonstrated that erosions are associated with older age (p = 0.011), constipation (p = 0.018), and use of topical estrogen cream (p = 0.001). There was no major complication. 66% (n = 170) of women who underwent a successful pessary trial are still using a pessary.

Interpretation of results

The pessary seems to be an effective and safe alternative treatment for women with symptomatic pelvic organ prolapse. These long-term results show that patient's satisfaction is excellent and that the majority of women who underwent a successful pessary trial continue to use the pessary through time. There was no significant complication related to the treatment after a median follow up of 35 months. Pessary self-maintenance regime appears to be an important aspect of pessary management as it leads to a prolonged use of the pessary and to the choice of pessary as the final choice of treatment. Use of topical estrogen cream while wearing the pessary, and even intensive estrogen cream treatment prior to the pessary trial for patient suffering from severe vaginal atrophy did not seem to protect from complication. Indeed, use of topical estrogen cream was associated with a significantly high rate of erosions. This could be explained by older patients having more significant vaginal atrophy, or by the fact that estrogen cream did not produce the expected effect on vaginal trophicity in older women.

Concluding message

Based on our experience, vaginal pessaries appear to be an appropriate treatment option for women with troublesome pelvic organ prolapses. Careful maintenance and follow-up are essential, especially as the occurrence of vaginal erosions is difficult to predict. At the moment, erosions do not seem totally preventable with the use of topical estrogen cream. Unexpected results regarding the use of topical estrogen cream warrant the need for further studies to evaluate this component in the pessary management.

Specify source of funding or grant **Not applicable**

Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Comité d'éthique de la recherche en santé chez l'humain du Centre Hospitalier Universitaire de Sherbrooke**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**No**