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MANAGEMENT OF PELVIC ORGAN PROLAPSE BY VAGINAL PESSARIES – ONE YEAR FOLLOW UP

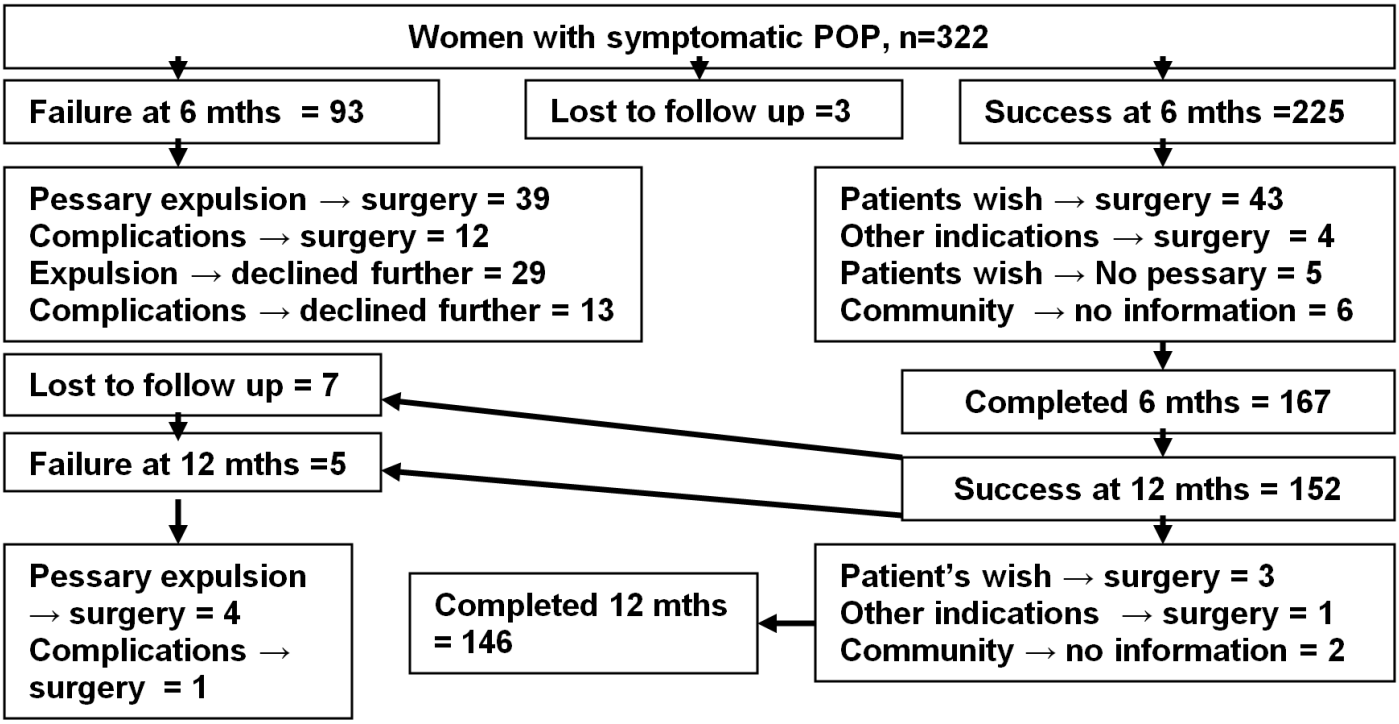
Hypothesis / aims of study

Pelvic organ prolapse (POP) has a lifetime prevalence of 30% with an 11% risk for surgery. In spite of the long history of successful use of pessary, currently there are no robust trials providing evidence for treatment with pessaries, type of device, the indications for use and follow-up. Although there is evidence that vaginal pessaries are an effective and simple method of alleviating symptoms of POP and associated pelvic floor dysfunction at 4 months, long term data is not available (1). The aim of our study was to prospectively evaluate prolapse, bladder, bowel and sexual symptoms 12 months after pessary insertion using a validated questionnaire and to assess risk factors for failure.

Study design, materials and methods

We conducted a prospective longitudinal study in a dedicated POP clinic located in a University Hospital. Women who were referred to this clinic between June 2002 and August 2007 with symptomatic POP were given the option of either having a pessary inserted or surgery. The ring pessary was tried first, failing which a variety of others including gellhorn, cube and donut pessaries were used. Pessary success was defined as adequate reduction of prolapse, without discomfort and absence of expulsion on movement, squatting and Valsalva. Failure was defined as the persistent inability to retain a pessary or need for removal due to discomfort. Women who chose the surgical option were also offered a vaginal pessary in the interim. All women who chose to have a pessary inserted completed a Sheffield prolapse symptom questionnaire (2) before insertion, at 6 months and 12 months. Data was collected regarding patient demographics, degree of prolapse and type of pessary used. Statistical analysis was performed using the SigmaStat 3.0 software programme. Friedmans analysis of variance was used to compare the symptom changes and risks factors significant for pessary failure was ascertained by logistic regression analysis.

Results Three hundred and twenty two women with POP chose to have a pessary. Mean age of the study sample was 70.6 yrs (SD=12.8) and median parity was 2 (range 0-8). There were 300 (93.2%) Caucasians, 5 (1.6%) Afro-caribbeans and 17 (5.3%) Asians. One hundred and twenty-four (38.5%) women had previous hysterectomy and 35 (10.8%) had previous pelvic floor repair. Four patients died during the period of follow up. The flow of participants through the study is shown below:



Of the 322 patients seen in the clinic, 108 completed the Sheffield Prolapse questionnaire at all three time points: baseline, 6 and 12 months.

Vaginal symptoms: There was significant symptom relief between the baseline and 6 months (p=<0.001), but no significant symptom relief between the 6 and 12 month time periods. The symptoms were awareness of a lump in the vagina, lump coming out of the vagina and dragging pain in the lower abdomen. The improvement in the degree of bothersomeness for the above symptoms also showed a similar profile. There was no significant relief from soreness in the vagina with pessary usage.

Bladder symptoms: Pessary usage significantly improved the need to push the prolapse back in order to empty the bladder (p=<0.001) between the baseline and 6 months, but no significant symptom relief between 6 and 12 months, with a similar improvement in the degree of bothersomeness. There was no significant relief of voiding difficulties, urge or stress incontinence. Urgency as well as the degree of bothersomeness, improved significantly at 12 months (p=0.002), but not at 6 months.

Bowel symptoms: There was no significant improvement in fecal urgency, fecal incontinence, digitation and obstructed defecation symptoms between baseline and 6 months and between 6 and 12 months.

Quality of life: There was a significant improvement in enjoyment of life and interference with physical activity between the baseline and 6 months, with no significant symptom relief between the 6 and 12 month time periods. There was also a significant improvement in the incidence of low back pain from baseline to 6 months (p=<0.001), but no difference between 6 and 12 months.

Alteration in sexual activity: Seventy one patients were not sexually active at baseline and this did not change with pessary usage. Eighteen patients were sexually active and continued to be sexually active with pessary usage, but 10 patients who were sexually active prior to pessary insertion stopped sexual activity after pessary usage. Nine patients who were not sexually active at baseline became sexually active after pessary insertion. There was no significant change in the frequency of intercourse with pessary usage.

Risk factors for pessary failure: The following risk factors were analysed by univariate logistic regression and were found not to be significant in predicting pessary failure; hysterectomy (p=0.141), previous repair (p=0.080), cystocele (p=0.992), rectocele(p=0.824), enterocele(p=0.714), vault/uterovaginal prolapse (p=0.922). However age (p=<0.001) and parity (p=0.036) significantly predicted failure and remained significant on multivariate analysis [age (p=0.002); parity (p=0.038)]

Interpretation of results

To date this study is the largest prospective trial to assess the effectiveness of pessary usage in the long term. Additionally we used validated questionnaires at each time point which strengthens the robustness of the results. Vaginal symptoms caused by prolapse and the need to reduce prolapse in order to empty the bladder significantly improved at six months and this was sustained at 12 months. Furthermore the risk of failure and complications did not change after 6 months. Although urgency to pass urine improved at 12 months there was no improvement or deterioration in symptoms of incontinence as the type of pessaries used were primarily specific for prolapse. We have also shown that it is possible to continue sexual activity with a pessary *in situ*. The significant improvement and reduction in bothersomeness of prolapse symptoms after one year of pessary use indicates that this is an alternative option to surgery. The majority of failures occurred in the first 6 months (94%) highlighting the fact that if the pessary was successful at 6 months it is likely to be successful at 12 months. Pessaries have been shown to be as effective as surgery and therefore should be offered as an alternative option to surgery (3).

Concluding message

This study demonstrates that vaginal pessaries are an effective and simple method of alleviating prolapse symptoms even in the longer term. The improvement in the quality of life underscores the debilitating effect of pelvic organ prolapse and the degree of relief offered by a non-invasive and cheap option of a vaginal pessary. In absence of a randomized trial, this study provides the best available evidence of the effectiveness of pessary use and should therefore be offered as an option to all women with symptomatic prolapse.

References

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Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require eithics committee approval because	**No ethics committee approval was required as it was part of clinical management of patients.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**No**