Title of study:

Effect of materials of vaginal ring pessary for pelvic organ prolapse on the effects of complications and patients' satisfaction: A Randomized Control Trial

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Introduction

Pelvic organ prolapse (POP) is a common gynaecological condition which attains prevalence of 15% women. It causes negative impact on physical, emotional and psychosexual aspects, thus significantly impairs patients' activities of daily living and quality of life. Treatment modalities include conservative, pessary and surgical management. Vaginal pessary is inexpensive, non-invasive and an attractive treatment option for women who possess high anaesthetic and surgical risks. Pessary-related complications include vaginal ulcer, vaginitis which would require temporary discontinuation of pessary use in order to prevent serious complications such as incarceration and fistula formation. If complications can be minimised, it is more likely that patients' satisfaction can further improve.

Vaginal pessaries are primarily made of polyvinyl chloride (PVC) or silicone. PVC has been the material of choice for local practice based on its long history in clinical use and cheaper cost. A new PVC pessary is inserted at each consultation if vaginal condition is satisfactory (1). In view of the increasing number of POP patients who opt for long term pessary use, silicone has emerged as alternative material of choice in recent years. Despite being more expensive, silicone pessaries can be washed and re-inserted for 20 washes/10 years if remained intact and not visibly damaged. As silicone pessary is more pliable, it can facilitate the process of pessary insertion and removal by squeezing of the pessary to pass through narrow introitus. (2) On the other hand, it may be more easily compressed by abdominal pressure and dislodged when straining. The UK clinical guideline for best practice in the use of vaginal pessaries for POP in 2021 suggested there is no clear preference of offering one type of pessary over another, further supported by the latest publication of a multi-centre pessary study in the UK in 2023. (3)

Study Objective

The primary objective is to determine the effect of vaginal ring pessary material on pessary complications and patients' satisfaction. The secondary objectives are to explore the effect of pessary material on procedural pain during pessary exchange as well as prolapse-related symptoms. It is hypothesised that silicone pessaries, compared to PVC pessaries, can reduce the rate of pessary-related complications from 30% to 10% and also result in higher patients' satisfaction.

Material and methods

This is a single-blinded, randomised placebo-controlled trial conducted in the pessary clinic in Princess Margaret Hospital (PMH). The procedures are in accordance with ethical standards of research and the Declaration of Helsinki. Ethical approval was sought from the Hospital Authority Central Institutional Review Board (Central IRB). Written informed consent is obtained from all participants before study group allocation.

Inclusion criteria

Eligible participants are women >=18 years old who understand written traditional Chinese, diagnosed with stage 1-4 POP according to the standard of Pelvic organ prolapse Quantification (POP-Q), using PVC pessary as long term management for POP, and are willing to participate and provide a written informed consent.

Exclusion criteria

Participants are excluded from the study if

1. Do not understand or comprehend written traditional Chinese
2. Cannot provide written consent
3. Vaginal complication requiring discontinuation of pessary use
4. Unable to follow up clinic 6 months later
5. Pregnant or lactating
6. Recruited in other research studies

Randomization

Participants are assessed for eligibility when they present to pessary clinic for routine pessary care.

Participants are recruited and assigned randomly in 1:1 ratio to receive either

- Treatment arm: replacement of a new silicone pessary
- Control arm: replacement of a new PVC pessary

Participants are randomly assigned to one of the two groups in 1:1 ratio. Randomization is carried out by an independent statistician according to computer-generated random numbers in random blocks of two, four and six, allocated by sequentially numbered, sealed opaque envelopes. When participants are prepared for pessary care inside the examination room, the new pessary will be prepared by research assistant outside the examination room according to the allocation result. The attending staff will conduct routine pessary care including pessary removal, vaginal examination and pessary replacement. Participants are not informed of the material of the new pessary. Standard patient information leaflet regarding pessary care with hotlines is provided. A 6-month follow up appointment will be arranged.

Participants will subsequently attend follow up 6 months later. A questionnaire will be given by the research assistant before the consultation to enquire for any pessary-related symptoms, and their satisfaction on the current pessary. During the consultation, the attending staff will remove the study pessary and assess the vaginal condition. The study is concluded by a short questionnaire and routine pessary care follows subsequently.

Data Collection

Patient age, parity, menopausal status, stage of prolapse on presentation, previous duration of pessary use, history of pessary complications are obtained from hospital record as demographic data.

Symptoms of pessary-related complications and patients' satisfaction are collected by self-administered questionnaires. Signs of pessary-related complications are assessed and documented by the attending staff.

Statistical Analysis

Baseline characteristics and outcomes of PVC pessary group and silicone pessary group are compared using independent t-test, Mann-Whitney U test, Pearson's chi-square test or Fisher's exact test, where appropriate.

Odds ratio for complications with 95% confidence interval was calculated.

The within-group changes of patient satisfaction and severity of prolapse with POP-Q were assessed using Wilcoxon signed-rank test.

Sample size calculation

Previous pessary study in our unit has shown the rate of pessary-related complications with follow-up interval of 6-month was 30% (only PVC pessary was available) (4). Assuming the complication rate of silicone pessary use with 6-month follow-up interval is 10%, configuring 80% power of detection, 5% of beta error and 20% of dropout rate, 140 participants are needed for recruitment.

Handling, Accessibility and Storage of Personal Data and Study Data

Records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential.

All participants will be replaced by a designated research code. Master list will be stored separately and protected with password. The electronic database and folders will be encrypted. Hard copies of the questionnaire will be stored in a lockable file cabinet.

Only principal investigator, research team member and Central IRB will be granted direct access to the subject's original research records for verification or clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally authorised representative is authorising such access.

After 3 years of study completion, hard copies will be discarded as confidential waste while soft copies will be deleted and unrecoverable.

Conflicts of interest

The author has disclosed no conflicts of interest.

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Ethical Concern

Any participation in a research study is completely voluntary. Any person is free to decline to participate for any reason. A participant can leave the research study at any time. When withdrawing from the study, the participant should let the research team know that he/she/they wishes to withdraw. A participant may provide the research team with the reasons for leaving the study, but is not required to provide their reason.

Literature Reference

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4. Tam M.S., Lee V.Y.T., Yu E.L.M. et al. The effect of time interval of vaginal ring pessary replacement for pelvic organ prolapse on complications and patient satisfaction: a randomised controlled trial. Maturitas. 2019; 128: 29-35