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REMOVAL TECHNIQUE OF RING PESSARY IN PELVIC ORGAN PROLAPSE: A RANDOMIZED CONTROLLED TRIAL

BY

DR. FAHAZRINIZAM BIN MAT DESA

SUPERVISOR

PROF. DR. TAN PENG CHIONG

RESEARCH PROPOSAL FOR MASTER OF MEDICINE

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DEPARTMENT OF OBSTETRICS & GYNAECOLOGY

UNIVERSITY OF MALAYA

CONTENTS

1.0 INTRODUCTION

Pelvic organ prolapse (POP) is defined as the descent of one or more of the anterior, posterior, or apical vagina with up to 50% of women having prolapse on examination in their lifetimes.[1] POP can have a significant impact on a patient's quality of life secondary to symptoms of pelvic pressure, vaginal bulge, urinary and bowel dysfunction, or sexual dysfunction.[2]

In patients with asymptomatic POP, observation is typically used. Vaginal pessary use is the preferred first-line management choice for vaginal prolapse in most older women.[3] The cumulative probability of continued ring pessary use was 84.1%, 64.4%, 49.3%, and 33.5%, at 1, 3, 5, and 10 years, respectively. Most common reason for discontinuation was frequent expulsion (21.6%), followed by vaginal erosion (16.5%), no prolapse improvement (12.4%), inability or inconvenience to do self-care (9.3%) and improvement of prolapse (9.3%).[4] Roughly 13% of women underwent surgery for prolapse in their lifetime.[2] A 2022 systematic review and meta-analysis concludes that abdominal and vaginal reconstructive surgery, and the use of pessary for POP increased patient quality of life.[5]

The main pessaries used are the ring and cube types in French practice[6], and the ring and doughnut in American practice[7]. The most commonly used pessaries are made from polyvinyl-chloride, polythene, silicone or latex.[8] Ring pessaries can be removed or left in place for intercourse.[9] In our practice the polyvinyl-chloride ring pessary is the first line pessary for POP management.

Women with POP who attended the outpatient clinic for pessary cleaning having used a pessary continuously report mean NRS pain score during pessary removal of 4.3 (± 2.7), with 25% of women scoring a 7 or higher and mean NRS during reinsertion of 1.8 (± 2.0).[10] In another

study, 58.2% reported that pessary removal was more painful than insertion, 30.5% reported equal pain, and 10.8% reported that insertion was more painful than removal. Ring pessaries were significantly less painful to both remove and insert than shelf and Gellhorn pessaries. Smaller pessaries were more painful to both remove and insert.[11]

A 2020 Cochrane systematic review and meta-analysis on 'Pessaries (mechanical devices) for managing pelvic organ prolapse in women' included only four studies involving a total of 478 women and meta-analysis could not be performed because each of the trials addressed a different comparison.[8] Trial data on removal or insertion technique is lacking.

Typically, the introital opening is widest anterior to posterior in the vertical plane whilst the vaginal canal is widest side to side in the horizontal plane. The ring pessary diameter used in the management of POP is often larger than the introital opening making removal as well as fitting a tight process. It is hypothesized that after first grasping with the index-middle fingers the infra symphysis pubis portion of indwelling ring pessary. 1) rotating to vertical the ring pessary in the downward and outward traction to remove compared to 2) standard removal by downward then outward traction with the ring pessary in the horizontal plane to remove, will reduce the patient's pessary removal pain score by taking theoretical advantage of the anatomy.

2.0 OBJECTIVE OF THE STUDY

2.1 PRIMARY OUTCOMES

1. Pain score (0-10 Numerical Rating Score [NRS])
    A. immediately and
    B. at 5 minutes

after pessary removal

2.2 SECONDARY OUTCOMES

1. Ease of removal by clinician using the allocated insertion technique (0-10 NRS)
2. Recommendation to a friend of allocated removal technique
3. Vulva-vaginal bleeding
4. Vaginal laceration at speculum examination
5. Vulvar laceration on visual inspection
6. Pain score (0-10 NRS) after standard pessary reinsertion
    A. immediately and
    B. at 5 minutes

3.0 RESEARCH HYPOTHESIS

It is hypothesized after first grasping with the index-middle fingers the infra symphysis pubis portion of indwelling ring pessary, 1) rotating to vertical the ring pessary in the downward and outward traction to remove compared to 2) standard removal by downward then outward traction with the ring pessary in the horizontal plane to remove will reduce the patient's pain score.

4.0 MATERIALS AND METHODOLOGY

4.1 STUDY DESIGN

This is a parallel group randomized controlled trial

4.2 PLACE OF STUDY

Gynaecology Clinic, University Malaya Medical Centre (UMMC)

4.3 STUDY POPULATION

Women attending the Gynaecology Clinic with Stage 1-2 POP on ring pessary management.

4.4 ETHICAL CONSIDERATION

This proposal will be submitted to the Medical Research and Ethics Committee (MREC) of University of Malaya Medical Centre, the local institutional review board for approval. Written informed consent will be obtained from all participants. This study will also be registered with ISRCTN.

4.5 INCLUSION CRITERIA

1. Attending clinic for ring pessary change or review.
2. Stage 1, Stage 2 or Stage 3 POP (defined as descending not more than 1cm below hymen using the POP-Q technique)
3. POP managed using PVC ring pessary (most common in our centre)

4.6 EXCLUSION CRITERIA

1. First-time insertion of vaginal pessary

2. Existing vaginal or vulvar lacerations
3. Vaginal infection
4. Previous vaginal surgery (not including childbirth related perineal repair)
5. Postmenopausal bleeding in the last 6 months (if not investigated)
6. Abnormal cervical cytology / histology (if not investigated)

4.7 METHODOLOGY

Patient recruitment will take place in the Gynaecology Clinic of UMMC. Prior to approaching these women, we will assess for suitability of recruitment into the trial through their Electronic Medical Records (EMR) and the use of the eligibility assessment form (EAF), based on the inclusion and exclusion criteria mentioned above.

Eligible women will be approached and provided with the Patient Information Sheet (PIS) and counselled with regards to trial participation (as described below). Queries about the study are invited and will be answered by the recruiting investigator. Written informed consent will be obtained. Participants' characteristics as per the Case Report Form (CRF) and data will be transcribed thereof.

Participants will be informed that their existing ring pessary will be removed and checked for the need to replace with a new ring pessary, or it could be reused after cleaning as standard practice.

Interventions

They will then be randomised to

(1) Intervention group: after first grasping with the index-middle fingers the infra symphysis pubis portion of indwelling ring pessary, rotating to vertical the ring pessary in the downward and outward traction to remove.

(2) Control group: after first grasping with the index-middle fingers the infra symphysis pubis portion of indwelling ring pessary, standard removal by downward then outward traction with the ring pessary in the horizontal plane to remove.

Randomisation

Randomisation sequence will be generated online using https://www.sealedenvelope.com/simple-randomiser/v1/lists, in blocks of 4 or 8, following a 1 to 1 ratio, by a co-investigator who will not be involved in the recruitment process. Allocation will be sealed within a numbered opaque envelope. Randomisation will be implemented using strict sequential opening of the lowest-numbered remaining sealed envelopes to the latest recruit.

Outcomes

After pessary removal, the vulva will be inspected for bleeding and laceration. A speculum examination will be performed to check the vaginal for ulceration, new laceration, and bleeding. Prolapse will be graded using the POP-Q system. Participants will be asked to rate their pain scores during the ring pessary removal on a 11-point Numerical Rating Scale (NRS), 0 as no pain to 10 as the worst pain imaginable, 1) immediately after removal and 2) 5 minutes after removal. The care provider who inserted the ring pessary will be asked to rate the ease of insertion, also

using the 11-point NRS with 0 as the easiest insertion imaginable to 10 as being the worst insertion imaginable. Participants will also be asked using a 5-grade Likert scale response if they would recommend their allocated removal technique to a friend. We will review participants' medical records to check for the need to reinsert or readjust the ring pessary within 4 weeks.

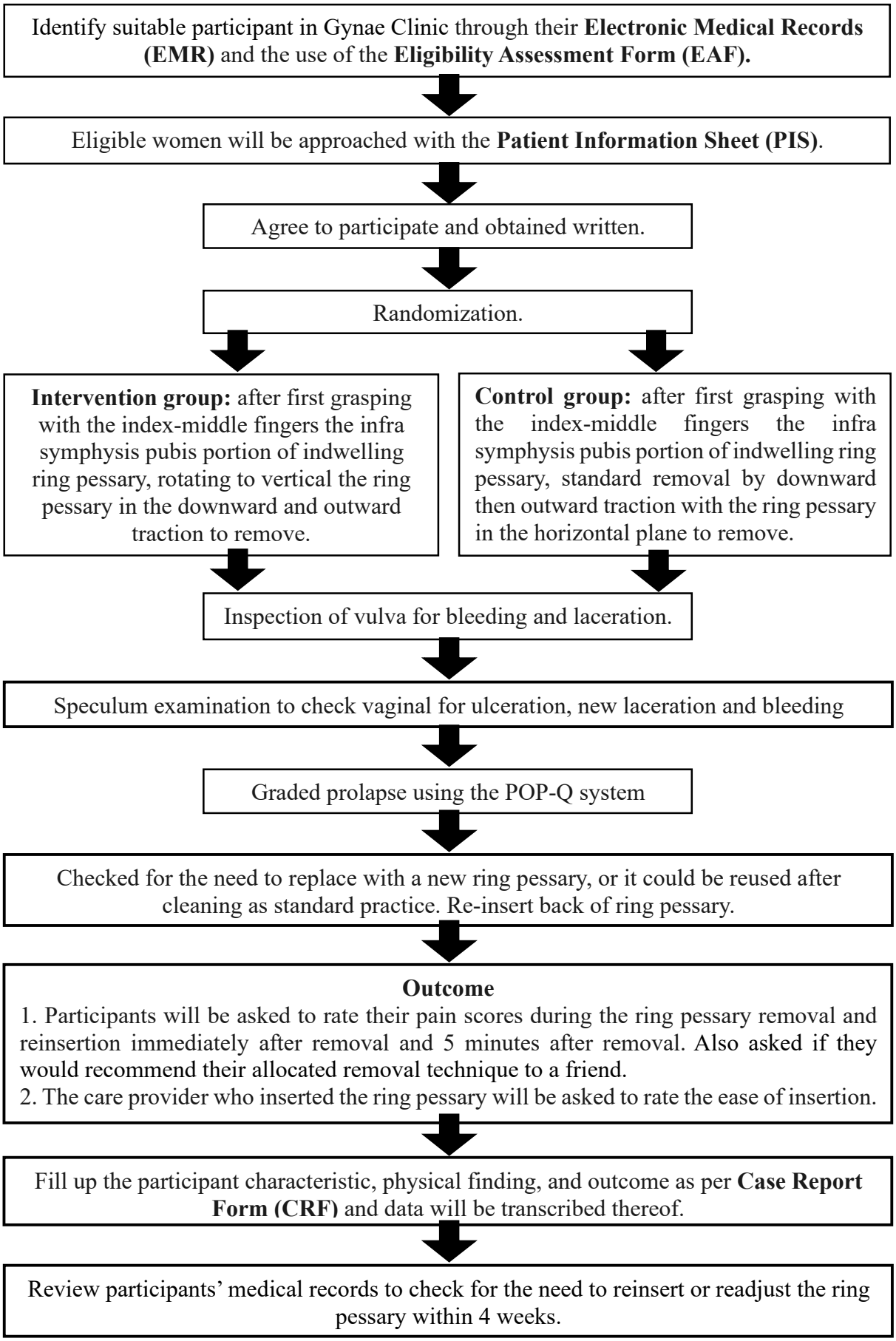
4.8 SAMPLE SIZE CALCULATION

It is assumed that a 1-point difference to be clinically relevant in the pain 11-point 0-10 NRS and the standard deviation is 2 in the pain score distribution for both arms. Using PS Power and Sample Size Program[12], applying the t test, alpha 0.025 (Bonferroni correction for 2 primary outcomes). 80% power, 1 to 1 ratio, 77 women are required per arm. Factoring in the Mann-Whitney U test application as the score is ordinal, we increase sample size by 15% and assuming a 10% dropout, 98.4 (= [77 x 1.15]/0.9) women in each arm. We planned to recruit a total of 200 women (100 each arm) for a powered study.

4.9 STATISTICAL ANALYSIS

Data will be entered into a statistical software package SPSS (Version 26, IBM, SPSS Statistic). Normality of distribution of continuous data will be assessed with the Kolmogorov-Smirnov test. The Student t-test will used to analyze continuous data with normal data distribution, the Mann-Whitney U test for non-normally distributed data or ordinal data and Chi-square test for categorical data (Fisher exact test if ≥20% of cells had cell number <5). Two-sided P values will be reported. $P < 0.025$ will be regarded as significant for the 2 primary outcomes. $P < 0.05$ will be regarded as significant for other analyses. Analysis will be on intention-to-treat basis.

Schematic diagram/ Flowchart



5.0 GANTT CHART

Research Activity	**2023**			**2024**											
	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
Literature Review															
Proposal Defence Presentation															
Approval from Ethics Committees															
Participants Recruitment and Data Collection															
Data Analysis / Interpretation															
Thesis Defence Presentation															
Thesis Submission															

6.0 REFERENCES

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Please state whether you have submitted this research proposal for funding, now or before

- ☐ Yes: If Yes, which grant? _____
- ✓
- ☐ No

This proposal will be kept strictly private and confidential. It will not be shared with anyone without your prior approval.

Name of Researcher (CAPITAL): FAHAZRINIZAM BIN MAT DESA

Signature of Researcher:

…….

Date: ……20/2/2024…….