

**A 5-YEAR REVIEW OF RECURRENT PELVIC
ORGAN PROLAPSE FOLLOWING PELVIC
RECONSTRUCTIVE SURGERIES IN HOSPITAL
SULTANAH NUR ZAHIRAH**

DR SUKAINAH BINTI SULAIMAN

**Dissertation Submitted in Partial Fulfilment of the
Requirement for Degree of Master of Medicine
(Obstetrics and Gynaecology)**



UNIVERSITI SAINS MALAYSIA

2020

1.0 PRELIMINARIES

1.1 Acknowledgements

“In The Name of Allah, Most Gracious, Most Merciful”

First of all, I am grateful to The Almighty God for the wisdom He bestowed upon me, the strength, peace of mind and good health in order to complete this research.

This thesis becomes a reality with the kind support and help of many individuals. I would like to extend my sincere thanks to all of them.

I would like to express my gratitude towards my family for the encouragement which helped me in completion of this research. My beloved and supportive husband, Ahmad Tarmizi bin Yusof for his continuous support either morally and financially and my lovable children who served as my inspiration to pursue this undertaking on time. Not to forget my mother and mother-in-law for their support and prayers.

I would like to express my special gratitude to my supervisors, Associate Professor Dr Mohd Pazudin bin Ismail, Dr Mohd Zulkifli bin Mohd Kasim and Dr Faridah Mohd Yusof for their guidance and for imparting their knowledge and expertise in this study. A big thank you to Mr Khairuldin, an HIS officer at HSNZ for providing the data needed.

I also appreciate HREC, NIH and MREC Ethics Review Board members for their considerate endorsement.

My thanks and appreciations also go to all my professors, lecturers, consultants, specialists, friends and staffs in Obstetrics and Gynaecology Department of Hospital Universiti Sains Malaysia and Hospital Sultanah Nur zahirah.

Sukainah binti Sulaiman

1.2 Table of Contents

1.0 Preliminaries	ii
<i>1.1 Acknowledgements</i>	ii
<i>1.2 Table of Contents</i>	iii
<i>1.3 Abbreviations</i>	v
<i>1.4 List of Table</i>	vii
<i>1.5 List of Figure</i>	viii
<i>1.6 Abstrak</i>	ix
<i>1.7 Abstract</i>	xi
2.0 Introduction	1
3.0 Literature Review	3
<i>3.1 Definition of Recurrent Pelvic Organ Prolapse</i>	3
<i>3.2 Prevalence of Recurrent Pelvic Organ Prolapse</i>	3
<i>3.3 Risk Factors Associated with Recurrent Pelvic Organ Prolapse</i>	4
<i>3.4 Compartment Re-Prolapse</i>	5
<i>3.5 Management of Recurrent Pelvic Organ Prolapse</i>	5
4.0 Rationale of The Study	6
5.0 Research Questions	7
6.0 Objective	8
7.0 Research Methodology	9
<i>7.1 Study Design, Study Venue and Study Duration</i>	9
<i>7.2 Reference and Source Population</i>	9

<i>7.3 Sampling Frame, Sampling Unit, Study Sample</i>	10
<i>7.4 Sampling Methods</i>	11
<i>7.5 Determination of Sample Size</i>	12
<i>7.6. Definition of Operational Terms</i>	14
<i>7.7 Flow Chart</i>	16
<i>7.8 Data Analysis</i>	17
<i>7.9 Ethical Issues</i>	18
8.0 Manuscript	19
9.0 Appendices	46
<i>9.1 Result</i>	46
<i>9.2 Ethical Committee Approval Letter</i>	54
<i>9.3 Medical Journal Of Malaysia (MJM) Format</i>	61
<i>9.4 Raw data</i>	73

1.3 List of Abbreviations

APFR	Anterior Pelvic Floor Repair
BMI	Body Mass Index
HRT	Hormonal Replacement Therapy
HSNZ	Hospital Sultanah Nur Zahirah
Kg	Kilograms
LAVH	Laparoscopic Assisted Vaginal Hysterectomy
m	Meter
MREC	Medical Research and Ethics Committee
NIH	National Institutes of Health
PPFR	Posterior Pelvic Floor Repair
POP	Pelvic Organ Prolapse
PRS	Pelvic Reconstructive Surgery
POP-Q	Pelvic Organ Prolapse Quantification System
IUGA	International Urogynaecology Association
SPSS	Statistical Package for the Social Sciences
SSF	Sacrospinous Fixation
TAH	Total Abdominal Hysterectomy

USM

Universiti Sains Malaysia

VH

Vaginal Hysterectomy

1.4 List of Table

Description	Pages
Table 1: Number of operations according to type of procedure	29
Table 2: Patient characteristics	31
Table 3: Recurrent prolapse severity according to site involved	34
Table 4: Nature of recurrent POP according to site	34
Table 5: Management following recurrence of prolapse	34
Table 6: Risk factor associated with recurrent POP	35

1.5 List of Figure

	Description	Pages
Figure 1:	Number of operation according to surgeon specialty	30
Figure 2:	Prevalence of recurrence	33

1.6 Abstrak

Objektif: Kejadian organ peranakan jatuh semula selepas pembedahan rekonstruksi kali pertama adalah biasa berlaku dengan kadar pengulangan 29-34%. Kajian ini dijalankan untuk menentukan kelaziman kejadian organ peranakan jatuh semula selepas pembedahan rekonstruksi kali pertama dan untuk menentukan faktor-faktor yang mempengaruhinya dalam masyarakat setempat.

Kaedah Kajian: Kajian retrospektif ini dijalankan di Hospital Sultanah Nur Zahirah, Kuala Terengganu dan melibatkan semua pesakit yang menjalani pembedahan rekonstruksi kali pertama dari 1 Januari 2011 hingga 31 Disember 2015. Data sosiodemografi dan rawatan susulan pesakit telah dilihat dan dianalisa. Pesakit yang telah menjalani pembedahan rekonstruksi kali pertama dalam tempoh kajian dan mengalami masalah organ peranakan jatuh semula pada tahap dua atau lebih mengikut sistem 'Baden-Walker' dalam masa dua tahun pembedahan dijalankan adalah termasuk dalam kajian ini.

Keputusan: Seramai 125 pesakit terlibat dalam kajian ini. Peratusan untuk berlakunya kejadian organ peranakan jatuh semula selepas pembedahan rekonstruksi kali pertama adalah 24.8%. Faktor-faktor yang mempengaruhi kadar kejadian organ peranakan jatuh semula dianalisa tetapi tiada faktor yang dikesan dapat mempengaruhi kadar kejadian organ peranakan jatuh semula dengan signifikan.

Kesimpulan: Peratusan kejadian organ peranakan jatuh semula selepas pembedahan rekonstruksi kali pertama di HSNZ adalah 24.8% dalam masa dua tahun pembedahan dijalankan. Tiada signifikan faktor yang mempengaruhi kejadian organ peranakan jatuh semula dikenalpasti dalam kajian ini. Walaubagaimanapun, usia dilihat sebagai faktor yang paling hampir mempengaruhi kejadian organ peranakan jatuh semula.

1.7 Abstract

Objective: Recurrent pelvic organ prolapse after primary pelvic reconstructive surgery is common with recurrence rate 29-34%. The study was carried out to determine the local prevalence of recurrent pelvic organ prolapse (POP) and to determine the associated factors for its recurrence following primary pelvic reconstructive surgery (PRS).

Methodology: It was a retrospective observational study which was carried out at Hospital Sultanah Nur Zahirah, Kuala Terengganu involving all patient who underwent PRS between 1st January 2011 and 31st December 2015. Case notes were review and patients who had recurrent POP more or equal to grade 2 Baden-Walker System within two years of the operation were included.

Result: A total of 125 patients were involved. The prevalence of recurrent POP following primary PRS in studied population was 24.8%. The association between each related variable towards recurrent POP was examined. However, no variables were found to be significant at the end.

Conclusion: The prevalence of recurrent pelvic organ prolapse in HSNZ was 24.8% within two years interval between primary operation and recurrence. There were no significant risk factors identified to be associated with the recurrence in the studied population. However, the age was the nearest factor that influence recurrence of POP.

2.0 INTRODUCTION

Pelvic organ prolapse (POP) affecting almost 30-50% of parous women (1-3). Conservative treatment using such as pessaries had been used to treat prolapse. However, women in the present days had longer life expectancy and together with complication associated with the use of pessaries, they were reluctant to use them in long term. Pelvic Reconstructive Surgeries (PRS) was the definitive treatment for prolapse. It has been estimated that 11.1% of women age less than 80 years old will undergone a PRS at some point in their lives (4).

The most challenging problems in managing women with prolapse was recurrence following surgery. Recurrence rate of the prolapse after primary PRS was reported to be ranging from 29-34% (4-6).

Identifying risk factors associated with recurrence of POP will help in reducing its incidence and in counselling of patients prior to the surgery. Many studies were done to identify the factors associated with failure of surgical correction or recurrent. Probably, the factors that associated with occurrence of pelvic organ prolapse in the first place were also the factors that associated with its recurrence (7).

Among the risk factors for pelvic organ prolapse that have been identified and described in previous studies were aging, obesity, family history of prolapse, and collagen weakness (8-12). Vakili *et al.* said diminished in the strength of *levator ani* muscles and a widened genital hiatus led to an increase in incidence of recurrence especially in early

postoperative period (5). Other risk factor including ages, parity, menopausal status of women and obesity were also observed.

The recurrence of POP in individual compartments of the vagina was not well understood. The anterior vagina was commonly regarded as the site that was more prone to get recurrent pelvic organ prolapse (7). However, in the study done by Price *et al.*, posterior repair appeared to be just as prone as anterior repair at failing. They also reported that recurrence POP can occur at different compartment compared with initial operation. From 142 patients who underwent re-operation in their study, only 38.5% had repeated surgery done on the same compartment (13).

The reported rate of re-operation ranging from 10-30% (4, 13). Studies looking into rate of recurrence based on re-operation rate may underestimate the true incidence of recurrent POP since many women did not seek repair of recurrence incident. Study by Diez-Itza *et al.* demonstrated that only one third or less of those with recurrence were symptomatic (14). Being asymptomatic could be the reason why many women choose conservative treatment rather than re-operation.

3.0 LITERATURE REVIEW

3.1 Definition of Recurrent Pelvic Organ Prolapse

Vakili *et al.* defined recurrence as descent of any vaginal compartment below the normal anatomic position (POP-Q stage greater than 0 or Baden-Walker Halfway systems grade greater than 0). Whiteside *et al.* and Costa *et al.* on the other hand, defined recurrent prolapse as descent equal to stage II or greater by POP-Q, while Fialkow *et al.* defined recurrence as prolapse equal to grade 1 or more according to the classification system for clinical descriptors developed by Olsen *et al.* (5, 6, 15, 16). A committee from International Urogynecological Association (IUGA) Research after reviewing all literatures concluded there is no agreed definition for recurrent POP. The committee also agreed that there is an urgent need for standardization of recurrent prolapse definition and further research into all aspects of recurrence (17).

3.2 Prevalence of Recurrent Pelvic Organ Prolapse

Fialkow *et al.* reported an incidence rate of recurrence of 3.7 per 100 woman-years (95% confidence interval: 2.6-5.1 per 100 woman-years) almost similar with recurrence rate reported by Vakili *et al.* (34.6%) (5, 16). Recurrence rate reported by studies varies depends on the definition of recurrent POP defined by the researchers.

Some researchers also differentiate between functional recurrence and anatomical recurrence of POP. According to Costa *et al.* subjective recurrences (16%) was half that of objective recurrence (32.76%). They stressed more on subjective recurrence since patients only seek medical treatment and some requiring re-operation only when they

were symptomatic (6). Miedel *et al.* confirmed this by reporting an anatomical recurrence rate of 41.1% with less than one half of cases were symptomatic (18).

3.3 Risk Factors Associated with Recurrent Pelvic Organ Prolapse

Risk factors associated with recurrent POP following primary PRS are not well understood. Most researchers agreed that age, vaginal parity, menopausal status, body weight, chronic diseases such as diabetes, chronic cough and chronic straining, advance stage of prolapse at the time of primary repair are among the possible risk factors.

Increasing age is a well-established risk factor for advancing prolapse. Interestingly, there was a study which reported a contradict result. Whiteside *et al.* reported that women less than 60 years old were associated with greater risk for recurrent POP at one year. This probably due to bias in the surgeon's choice of procedure who had tendency to preserve sexual function with a less aggressive repair which were more functional but not as durable (15). Fialkow *et al.* otherwise reported differently in which age has no relation with recurrence of POP (16).

Fialkow *et al.* also reported that women who had two or fewer vaginal deliveries appeared to be at increased risk of recurrence (HR = 1.6;95% CI = 0.81-3.3) compared with women with three and more vaginal deliveries. This result also contradicts the known fact that increasing parity will increase risk to developed pelvic organ prolapse (16).

Salvatore *et al.* reported the presence of preoperative vaginal compartment descent stage III and more was the only significant risk factor for recurrence (1). This result consistent with what previously reported by Whiteside *et al.* and concluded by systematic review by Tineke *et al.* (15, 19). Those studies were done in the developed European countries with the only significant risk factor for recurrence was the preoperative stage. The risk factors for recurrence POP may be differ in our population since we are still developing countries owing to early childbearing age, high parity, and low birth spacing.

3.4 Compartment Re-Prolapse

Recurrence of the prolapse occurs either in the same compartment or in the different compartment. The anterior vagina is commonly regarded as the site that is more prone to recurrent prolapse (4, 16) however Price *et al.* concluded that there is no difference in rate of prolapse between anterior and posterior compartment (13).

3.5 Management of Recurrent Pelvic Organ Prolapse

Recurrent pelvic organ prolapse can be managed either conservatively, surgically or expectantly. Fialkow *et al.* cohorted 142 women who underwent PRS and identified 36 recurrent cases. From those recurrent cases, only 17% underwent repeat surgery, 38.9% had conservative management and another 44.1% had no additional management (16). From this value, we can say that almost half of the patients with recurrent POP opted for expectant management.

4.0 RATIONALE OF THE STUDY

In Hospital Sultanah Nur Zahirah (HSNZ), PRS were done since 2005, however to date, there is no study conducted to estimate the prevalence of recurrent POP. Recurrence is one of the most worrying problems in PRS since majority of the patients were elderly with some of them having co-morbidities. Further management in case of recurrence could be difficult. Going for another PRS would carry operative and anaesthetic risks. Therefore, determining our own population prevalence and the associated risks factor would help to predict which patients will have the potential to develop recurrence of POP and hence optimal surgical plan and pre-operative counselling could be provided. Knowing the type and grade of prolapse that recur most will help us to plan the optimal operation for the patients in the future.

5.0 RESEARCH QUESTIONS

1. What are the prevalence of recurrent POP after PRS in HSNZ?
2. What are the associated risk contributing to recurrent POP in HSNZ patients?
3. What are the commonest compartment that prolapse in case of recurrence?
4. What are the commonest treatment received by patient after recurrence?

6.0 OBJECTIVE

General objectives

To study the recurrent Pelvic Organ Prolapse (POP) following primary Pelvic Reconstructive Surgery (PRS) and its associated risk factors in HSNZ.

Specific objectives

1. To determine the prevalence of recurrent POP in HSNZ.
2. To determine the associated factors for recurrent POP in HSNZ.

7.0 RESEARCH METHODOLOGY

7.1 Study Design, Study Venue and Study Duration

The present work is a retrospective observational study. It was carried out at Hospital Sultanah Nur Zahirah, Kuala Terengganu, which was the only referral centre for the state of Terengganu. The research was done from January 2018 to November 2019 including preparation of proposal and getting the approval, data collection, data analysis, and write up.

7.2 Reference and Source Population

The reference population is all women who attending Urogynaecology Clinic, HSNZ.

From this reference, all patients who underwent PRS between 1st January 2011 and 31st December 2015 were included in this study.

7.3 Sampling Frame, Sampling Unit, Study Sample:

From all patients who underwent for the PRS from 1st January 2011 until 31st December 2015, patients who fulfil the inclusion criteria were included, whereas those with incomplete data and underwent repeat PRS in this time frame were excluded.

Inclusion criteria:

- all patients who had recurrent POP more or equal to grade 2 Baden-Walker System within two years following the operation

Exclusion criteria:

- repeat PRS
- all patients with incomplete data

7.4 Sampling Methods

The method of sampling was a case notes review. A list of patients who had undergone PRS from 1st of January 2011 until 31st of December 2015 was obtained from computerised database after getting the permission from the Hospital Director. Case notes of each of the patient from the list was reviewed through the computerized hospital system (HIS system) including the clerking sheet, operative record and follow up notes after the operation. Any recurrent of the POP identified within two years (48months) of PRS either same site or different site were recorded. The associated factors for recurrent POP were identified and analysed.

7.5 Determination of Sample Size

The sample size was determined using those calculations based on the objective.

For specific objective number 1 in which we need to determine the prevalence, we followed this simple formula described by Daniel (1999):

$$n = \frac{z^2 P(1 - p)}{e^2}$$

n = sample size

Z = statistic for a level of confidence

P = expected prevalence or proportion

e = precision

Values used for this study:

$Z = 1.96$ (For the confidence level of 95%, which is conventional, Z value is 1.96)

$P = 34\%$ (0.34) – according to Vakili *et al.* (5)

$e = 5\%$ (0.05)

Thus estimated sample size (ss) = 344 patients

Since the source population was small, so adjustment for finite population was calculated according to formula described by Thrusfield M (2005):

$$ss = n$$

$$N = \frac{n}{1 + \frac{n-1}{POP}}$$

$$N = \frac{344}{1 + \frac{344 - 1}{125}}$$

= 92 + correction for missing data 20%

= 111 patients

The sample size was also calculated based on specific objective number II which are determination of associated risk factors. Since preoperative stage is the only confirmed risk factor, sample size recalculated for preoperative stage using sample size calculator in www.surveysystem.com. It was calculated according to Whiteside et al.(15) POP-Q stage III or IV had 64.5% recurrence (95% CI, 1.3-5.3, P = 0.005). From the calculation, sample size = 104 + correction for missing data 20%

= 125 patients.

146 operative records for patient who underwent urogynaecology operation from 1st of January 2011 until 31st of December 2015 were reviewed. 125 patients who underwent primary PRS and fulfilled the inclusion criteria were included in this study.