

A 10-YEAR REVIEW ON THE OUTCOME OF PRIMARY REPAIR OF OBSTETRIC ANAL SPHINCTER INJURY IN HOSPITAL UNIVERSITI SAINS MALAYSIA

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Dissertation Submitted In Partial Fulfilment Of The
Requirement for the Degree Of Master Of Medicine
(Obstetrics And Gynaecology)



UNIVERSITI SAINS MALAYSIA

2022

1.0 PRELIMINARIES

1.1 ACKNOWLEDGEMENT

“In the name of Allah, Most Gracious, Most Merciful”

All praises to Allah S.W.T, the Almighty for His blessing and generosity. Thank you Allah for the strength, courage, and wisdom bestowed upon me throughout the completion of this research.

First and foremost, I owe my heartiest gratitude to my supervisor, Dr. Ahmad Amir bin Ismail, Urogynaecologist / Senior Lecturer / Consultant Obstetrics and Gynaecologist of Department of Obstetrics and Gynaecology, Universiti Sains Malaysia, for his kind assistance, great support, and guidance.

Many thanks to Assoc. Prof Dr Mohd Pazudin Ismail, Head of Department of Obstetrics and Gynaecology, Universiti Sains Malaysia, and to all lecturers in the department who has tirelessly contributed during my masters’ journey.

Most importantly, my parents, my late father Ar. Abdul Haiyee Hasshim whom I lost during the training and my beloved mother Mardiah Lokman. I am particularly indebted to them for their constant encouragement, understanding, patience, and prayer. Not to forget, Dr. Fatimah Zakiah who has kindly assisted, supported and contributed a lot during this journey.

Last but not least, thank you to all patients who have made the completion of this study possible.

Syafnaz Abdul Haiyee

1.2 Table of Contents	<i>Page</i>
1.1 Acknowledgement	ii
1.2 Table of contents	iii
1.3 List of abbreviations	v
1.4 Abstrak	vii
1.5 Abstract	ix
2.0 Introduction	1
2.1 Literature Review	2
2.1.2 Risk Factors of OASIS	3
2.1.3 Management of OASIS	4
2.1.4 Anal Incontinence	5
2.1.5 Outcomes Of OASIS And Risk Factors For Anal Incontinence	7
3.0 Study Justification	9
4.0 Research Questions	9
5.0 Objectives	
5.1 General Objectives	10
5.2 Specific Objectives	10
6.0 Research methodology	
6.1 Study design, study venue and study duration	10
6.2 Study Population, Reference and source population, the study sample	10
6.3 Sampling frame, sampling unit,	11
6.4 Sample size calculation	11
6.5 Ethical consideration	14

6.6 Sampling methods	14
6.7 Statistical analysis	15
6.8 Definition of operational terms	16
6.9 Study flow chart	18
7.0 The manuscript	19
8.0 References	41
9.0 Appendices	
10.1 List of Tables	46
10.2 Ethical approval letter from USM Human Research Ethical Committee(JEPeM)	52
10.2 Ethical approval letter from Hospital USM Director	53
10.3The Medical Journal of Malaysia Manuscript submission guideline	55

1.3 List of Abbreviations

Abbreviation	
AI	Anal Incontinence
BMI	Body Mass Index
CI	Confidence Interval
EAS	External Anal Sphincter
EAUS	Endoanal Ultrasound
GDM	Gestational Diabetes Mellitus
Hospital USM	Hospital Universiti Sains Malaysia
IAS	Internal Anal Sphincter
ICS	International Continence Society
OASIS	Obstetric Anal Sphincter Injury(s)
O&G	Obstetrics & Gynaecology
PDS	Polydioxanone Suture
RCOG	Royal College of Obstetricians and Gynaecologists
RCT	Randomized Controlled Trial

SD	Standard Deviation
SVD	Spontaneous Vertex delivery

1.4 ABSTRAK

Latar Belakang Kecederaan obstetrik sfinkter anus (OASIS) adalah faktor utama penyumbang kepada keadaan inkontinen najis dan boleh memberi impak yang besar terhadap wanita baik dari segi emosi dan fizikal. Ia merupakan suatu komplikasi yang serius kerana ianya mampu memberi kesan terhadap kualiti hidup dan kandungan seterusnya. Pembedahan pembaikan yang berjaya adalah sangat penting untuk mengelakkan terjadinya inkontinen najis.

Objektif Di dalam kajian ini, kami akan mengenal pasti bilangan kes yang mengalami inkontinen najis hasil selepas pembedahan membaik pulih primer dibuat pada gred kecederaan yang berbeza-beza di Hospital Universiti Sains Malaysia dalam jangka masa 10 tahun.

Kaedah Kajian Ini adalah kajian retrospektif yang melibatkan semua wanita yang menjalani pembedahan membaik pulih primer selepas mengalami kecederaan obstetric sfinkter anus (OASIS). Secara keseluruhan terdapat 271 kes OASIS telah dijumpai dan maklumbalas selepas 6 bulan pembedahan pembaikan dilakukan telah dianalisa.

Pesakit telah di analisa mengenai symptoms inkontinen najis dan faktor-faktor yang boleh menyumbang terhadap kejadian tersebut. Darjah kecederaan koyakan perineum dan lain-lain maklumat telah didapati melalui fail pesakit. Analisis statistik dilakukan dengan versi SPSS 27.0. Data telah dianalisis menggunakan analisis univariasi untuk melihat kaitan di antara faktor risiko dan hasil selepas pembedahan pembaikan dijalankan. Kajian ini telah diluluskan oleh Jawatankuasa Etika Penyelidikan Manusia USM (JEPeM-USM) (rujuk Lampiran 8)

Hasil Kajian

Dalam kajian ini setelah meneliti 271 kes kecederaan obstetrik sfinkter anus , kadar inkontinens najis selepas pembedahan membaik pulih primer dijalankan hanya 1.8% (5 kes). Terdapat hubungkait signifikan di antara gred koyakan perineum dan kejadian inkontinens najis pada analisis deskriptif.

Daripada jumlah keseluruhan OASIS, terdapat 80 wanita (29.6%) mempunyai luka perineum tahap 3a, 127 wanita(47%) mempunyai luka perineum tahap 3b, 32 pesakit (11.9%) mempunyai luka perineum tahap 3c dan 32 pesakit (11.9%) mempunyai luka perineum tahap 4.

Walaubagaimanapun tiada hubungkait dapat ditunjukkan pada 'multiple logistic regression'.

Juga tiada hubungkait dapat dijelaskan di antara faktor risiko dan inkontinens najis.

Keputusan

Kajian ini menunjukkan kadar inkontinen najis adalah kecil iaitu sebanyak 1.8% (5 kes) daripada keseluruhan 271 kes Kecederaan Obstetrik Sfinkter Anus (OASIS) dalam tempoh 10 tahun kajian. Dalam kajian ini, telah didapati bahawa tiada hubungan signifikan di antara inkontinens najis dengan faktor-faktor risiko yang telah dikaji.

1.5 ABSTRACT

Background Obstetric anal sphincter injuries (OASIS) are a major factor in the development of anal incontinence and can have a devastating effect on the physical and emotional well-being of affected women. It is a grave complication as it can affect the quality of life as well as it can give an impact on subsequent pregnancies. Sound operative repair is essential, yet between 14 and 61% patients with obstetric anal sphincter injuries report incontinence symptoms.

Objective To determine the proportion of anal incontinence following primary repair and to identify the risk factor associated with anal incontinence after six months post-primary repair in Hospital USM from 1st December 2010 until 31st November 2020.

Methodology:

This was a retrospective observational study involving all women who underwent primary repair following obstetrics anal sphincter injury in Hospital Universiti Sains Malaysia, Kubang Kerian, Kelantan. A total of 271 cases of OASIS were encountered and at six months its repair outcome was analyzed. Patients were assessed regarding the anal incontinence symptoms and the risk factors contributing to OASIS were also analyzed. The degree of perineal injury and other related information were retrieved from the case notes. Data were analysed using univariate analysis to look for the association between risk factors and the outcome of primary repair.

Results

In this research, there were 271 cases of OASIS during the 10 years study period. Only 5 cases (1.8%) of anal incontinence cases were encountered. There was a significant association between grading of OASIS and the occurrence of anal incontinence on descriptive statistics.

80 women sustained a Grade 3a tear (29.6%), 127 women had a Grade 3b tear (47%), 32 women had a Grade 3c (11.9%) and 31 women had a fourth-degree tear (11.5%)

However, this association was not significant on multiple logistic regression. There was no association noted between other variables and anal incontinence.

Conclusion :

Anal incontinence complicates 1.8% (5 cases) of OASIS during the 10 year study period. There was no significant association between anal incontinence and risk factors.

2.0 INTRODUCTION

Obstetric anal sphincter injuries (OASIS) are a major factor in the development of anal incontinence and it can have a devastating effect on the physical and emotional well-being of affected women ¹. It constitutes a heterogeneous group with the involvement of the anal sphincter ranging from a few superficial external anal sphincter (EAS) muscle fibers to involvement of the internal anal sphincter (IAS) and anorectal epithelium ².

Sultan's ³ descriptive classification of perineal tears divide perineal tears into four grades, two of which include OASIS and depend on the degree of sphincter damage. Obstetric anal sphincter injury (OASIS) is one of the most severe obstetrical complications. Although risk factors for OASIS have been identified, little is known about various parameters that can influence symptoms' severity.

It is the major cause of anal incontinence in young women and also a cause of major morbidity post-partum, both in the short and long term, with a positive correlation with bladder, bowel, and sexual dysfunction. Despite primary repair, up to 60% of mothers can develop symptoms of faecal incontinence following anal sphincter injury ^{2,4}. Correct diagnosis and repair of the injury are of utmost importance since the persistence of a sphincter defect can predict anorectal symptoms in the long term ⁵.

Besides anal incontinence, perineal pain and dyspareunia may occur and persist chronically. Several risk factors such as forceps delivery, high birth weight, nulliparity, episiotomy, induced labour, and abnormal fetal presentation have been reported. This study aimed to determine the outcome of primary repair of obstetric anal sphincter injury and to identify the risk factors that may contribute to it.

2.1 LITERATURE REVIEW

Obstetric anal sphincter injury (OASIS) is a 3rd and 4th-degree perineal injury that occurs during delivery. The reported incidence of OASIS varies from 0.1% to 11% worldwide ⁶. The prevalence of OASIS in Nordic countries was reported to be 0.6-4.2% while the rate in Europe was reported between 0.1-4.9% ⁷.

In another study by Tung⁸ et al in 2015 on the Chinese women population, the percentage of OASIS from 2011 to 2014 was 0.3% to 0.38% which showed an increasing trend throughout the years, but still lower from the reported figure in literature.

Local data in Hospital Universiti Sains Malaysia reported the prevalence of OASIS was 0.16%. However, recent study data from 2007 to 2016 showed an increasing trend of OASIS from 0.16% to 0.25%.

The classification used for grading of perineal injury has been adopted from Sultan³ et al, by the International Consultation on Incontinence and the RCOG and has been classified into 4 groups.

1. First-degree tear is an injury to perineal skin and/or vaginal mucosa
2. Second-degree tear is an injury to the perineum involving perineal muscles but not involving the anal sphincter.
3. Third-degree tear is an injury to the perineum involving the anal sphincter complex; which can be subclassified into;
 - i. Grade 3a tear; less than 50% of external anal sphincter (EAS) thickness torn.
 - ii. Grade 3b tear; More than 50% of EAS thickness torn
 - iii. Grade 3c tear; Both EAS and internal anal sphincter (IAS) torn
4. Fourth-degree tear; Injury to the perineum involving the anal sphincter complex (EAS & IAS) and anorectal mucosa.

2.1.2 Risk Factors Of OASIS

Severe perineal tears can have considerable and essentially long-term repercussions on the quality of life in affected women ⁹. Risk factors for OASIS can be grouped into maternal, intrapartum and neonatal characteristics. A study conducted by Sultan² AH, found that 3rd degree occurs in about 0.6% of vaginal delivery. Although 3rd-degree tears are an uncommon complication of childbirth, it carries a huge impact on a woman's future continence ².

Based on the literature, known risk factors of OASIS are high fetal birth weight, long duration of the second stage of delivery, operative delivery, primiparity, and midline episiotomy¹³. A study by Mahgoub¹⁰ S et

al (2019) also found that the risk factors for OASIS were nulliparity, birth weight of more than 3500gm, and assisted delivery. However, in addition to that, previous Caesarean section, a uterine fundal height greater than 32cm, gestational or pre-pregnancy diabetes, and use of a second instrument or obstetric maneuver also increased the risk for OASIS ¹¹.

Sultan AH ² in 1994 described that vacuum extraction is associated with fewer third-degree tears than forceps delivery. In addition, they found that an episiotomy does not always prevent a third-degree tear. Their findings revealed that primary repair is inadequate in most women who sustain third-degree tears, most having residual sphincter defects and about half experiencing anal incontinence, which is caused by persistent mechanical sphincter disruption rather than pudendal nerve damage. There was no significant association between the use of antibiotics, occurrence of wound infection, form of anaesthesia for repair, or the type of suture material used and the outcome in terms of the later development of symptoms, or the development of sphincter defects.

2.1.3 Management Of OASIS

According to the Royal College of Obstetrics and Gynecology (RCOG) guideline, the repair of 3rd and 4th-degree tear should be conducted by an appropriately trained clinician or by a trainee under supervision. Repair should take place in an operating theatre and under regional or general anaesthesia with good lighting and with appropriate instruments.

For the repair of a full-thickness of the external anal printer, either an overlapping or end-to-end approximation method can be used with equivalent outcomes. For partial thickness (3a and 3b) tears, an end-to-end technique must be used. However, a Cochrane review demonstrated no difference in outcomes between an end-to-end and an overlap repair and therefore the end-to-end technique can be used for all external sphincter tears. The torn anorectal mucosa should be repaired with sutures using either the continuous or interrupted technique.

3-0 polyglactin suture should be used to repair the anorectal mucosa as it may cause less irritation and discomfort than Polydioxanone (PDS) suture. When repair of the EAS and/or IAS muscle is being performed, either monofilament sutures such as 3-0 PDS or modern braided sutures such as 2-0 polyglactin can be used with equivalent outcomes. The use of PDS sutures for repair of the anorectal should be avoided as they take longer to dissolve and may cause discomfort in the anal canal.

Women who have undergone obstetric anal sphincter repair should be reviewed at a convenient time usually (6 to 12 weeks postpartum). Where possible, the review should be by clinicians with a special interest in OASIS. Physiotherapy following repair of OASIS could be beneficial.

2.1.4 Anal Incontinence

It is defined as the complaint of involuntary loss of flatus and/or feces affecting the quality of life ¹². The IAS plays a role in the maintenance of continence. In a prospective study involving followup of 531 women after OASIS, those with a grade 3C/4 tear had a significantly poorer outcome ($p < 0.05$) compared with women with a grade 3A/3B tear concerning the development of defecatory symptoms, anal manometry results, and the associated quality of life ¹. Another prospective follow-up study of 125 women who had OASIS reported a significantly increased incidence of anal incontinence ($p < 0.001$) in women who had 3B and fourth-degree compared with 3A tears ¹³.

A third prospective study of 500 women followed up at 3 months showed that IAS defect thickness (partial thickness defect greater than one quadrant or full-thickness IAS defect) was predictive of severe incontinence (OR 5.1, 95% CI 1.5–22.9)¹⁴. A retrospective, descriptive cross-sectional study of 66 women who were followed up for a mean of 5 years showed that women with combined IAS and EAS

injury (n=6) had worse fecal incontinence ($p<0.05$) and lower anal pressures ($p=0.04$) than women with isolated EAS injury (n=10)¹⁵.

Inclusion of the IAS in the classification above would allow differentiation between future incontinence related to IAS injury and that related to EAS injury alone. It is recognized that identification of the IAS may be difficult in acute obstetric trauma, but every attempt should nonetheless be made to exclude and document injury to the IAS. Recording the degree of EAS damage (more or less than 50%) should be possible in all cases. If one is unsure whether it is more than 50% then it should be classified as 3B to avoid underestimation

2.1.5 Outcomes Of OASIS And Risk Factors For Anal Incontinence

The outcomes following primary repair include anal incontinence, fecal urgency, sonographic anal sphincter defects, anal incontinence with coitus. Anal incontinence is defined as the complaint of involuntary loss of flatus and/or feces affecting the quality of life.

In a study by Thakar R ¹⁶, anal incontinence constitutes about 39% of outcomes following repair. In a retrospective study by K. Kuismanen⁵ et al, at 6 months post-primary repair, a total of 28% of women experienced mild anal incontinence while 9% experienced similar symptoms.

The extent of sphincter damage, operative vaginal delivery, older age, and high body mass index (BMI) are associated with the risk of fecal incontinence after primary repair ¹³. A study conducted by K. Kuismanen⁵ et al in 2018, revealed that following a primary repair, 27% of women had mild anal incontinence, while 8.7% experienced severe symptoms. Persistent symptoms were associated with instrumental vaginal delivery, the severity of the injury, and increased maternal age. However, they found no statistical difference in the results between the two techniques used, or the stage of specialization of the operating physician.

Roos AM, Thakar R, Sultan AH ¹ also reported in 2010, that women with a major grade of perineal tear (Grade 3c/4) had a significantly poorer outcome compared with women with minor tears. A study in 2017 by Hanna Jango et al found that following a second delivery, women with a history of 4th degree OASIS have a higher risk of long-term anal incontinence than women with a 3rd-degree sphincter injury. They have found that the risk of anal incontinence in 4th-degree tear is 58.8% while the risk of anal incontinence in a 3rd degree tear was 41%.

The risk of fecal incontinence is also lower in women with a 3rd degree tear, which was 14.6% in comparison to 4th degree tear which was 30.6%. They also found that elective Caesarean delivery has a protective effect.

Meanwhile, Jaan Kirss¹⁷ et al. (2016) found that the primary repair failed in 31.7% of the tears. These included more tears repaired by less experienced personnel and more repairs performed during on-call hours than

in the successful primary repair group. The author suggested that delaying the repair until the next morning is recommended if experienced personnel are unavailable during on-call hours. Significantly more pain medication was used in the failed group, and the use of antibiotics and laxatives after the repair was more common in the successful group. Sphincter injuries were repaired using the overlapping suture technique in 95.1% of the repairs in the successful group compared with 47.4% in the failed group.

In the other study, Joris F¹⁸ et al. (2019) reported more symptomatic women were significantly older and had a significantly lower body mass index. Even though there was no difference in the overall rate of vacuum/forceps assisted delivery, they have found that the use of forceps was significantly higher in the symptomatic group (9.7% vs. 1.8%). There were statistically significant differences in regards to the birth weight, use of episiotomy, nulliparity at delivery, duration of the second stage, and use of oxytocin during the second stage of labour.

3.0 STUDY JUSTIFICATION

Despite the establishment of the Urogynaecology Unit in Hospital USM, the prevalence and management of obstetrical anal sphincter injury remain about the same. A cut point of 6 months post assessment is taken given complete wound healing may occur in 6 months.

The current study looking into OASIS complications particularly anal incontinence and factors associated with it is limited in this country. Therefore, studying these factors would contribute to new knowledge and would help in better management of the patients

By having an objective view of the problem and the associated factors, management and progress of the involved patients could be addressed, thus a better management plan could be planned.

4.0 RESEARCH QUESTIONS

1. What are the outcomes of primary repair of obstetric anal sphincter injury in Hospital Universiti Sains Malaysia from 1st December 2010 until 31st November 2020.
2. What is the proportion of anal incontinence following primary repair?
3. What are the risk factors associated with anal incontinence after 6 months post-primary repair?

5.0 OBJECTIVES

5.1 General Objective

To study the outcomes of primary repair of obstetric anal sphincter injury in Hospital USM from 1st December 2010 until 31st November 2020 (10 years).

5.2 Specific Objectives

1. To determine the proportion of anal incontinence following primary repair in 6 months follow-up
2. To identify the risk factor associated with anal incontinence after 6 months post-primary repair

6.0 RESEARCH METHODOLOGY

6.1 Study Design, study venue and duration

6.1.1 Study design

This study is an observational (retrospective) study conducted in Obstetrics and Gynaecology Department Hospital Universiti Sains Malaysia.

6.1.2 Study period

All patients that undergone primary repair of obstetric anal sphincter injury in Hospital USM from 1st December 2010 until 30th November 2020

6.2 Study Population

6.2.1 Reference population:

All patients delivered in Hospital USM

6.2.2 Source population:

All patients delivered in Hospital USM who sustained OASIS

6.2.3 Study sample

All patients that undergone primary repair of obstetric anal sphincter injury in HUSM

6.2.4 Inclusion and Exclusion criteria

Inclusion criteria

Women who sustained OASIS & underwent primary surgical repair and followed up under Urogynaecology clinic in Hospital USM 6 months post repair.

Exclusion criteria

Women with recurrent anal sphincter injury.

6.3 Sampling Frame

All patients that undergone primary repair of obstetric anal sphincter injury in Hospital USM from 1st December 2010 until 30th November 2020.

6.4 Sample Size Calculation

The sample size for each objective was calculated according to the formula and references as stated. We used the single proportion formula to calculate the first objective and the comparison of two proportion formulas for the second objective.

Objective 1 - To determine the proportion of anal incontinence following primary repair in 6 months follow-up

Single proportion formula.

$$n = \frac{Z^2 \cdot p(1-p)}{\Delta^2}$$

Δ

Z value based on 95% CI = 1.96

$\Delta = 0.05$ (5%)

P = 0.2 based on a prevalence of anal incontinence following primary repair (Dickinson, Pickersgill and Anwar, 2013)

Estimate sample size calculated = 246 + 10% drop-out rate

Total sample size = **271**

Objective 2: To identify the risk factor associated with anal incontinence after 6 months post-primary repair

PS software - 2 proportion formula

P₀ = proportion of factors among women without anal incontinence following primary OASIS repair.

P₁ = estimated proportion of factors among women with anal incontinence following primary OASIS repair.

m = ratio between women with anal incontinence and women without anal incontinence following primary OASIS repair

$\alpha = 0.05$

Power = 80%

Variables	P0	P1	m	n	n + 10% non-response rate	2n	Reference
Maternal age (>30)	0.53	0.35	3	86	95	190	(Kuismanen K et al., 2018)
Grading (3b/c/4)	0.65	0.5	4	43	47	94	(Kuismanen K et al., 2018)

Instrumental delivery	0.5	0.3	4	65	71	142	(Kuismanen K et al., 2018)
Birth weight (> 3.5kg)	0.36	0.15	4	49	54	108	(Levin et al., 2020)
Suturing method	0.52	0.3	4	55	61	122	(Kuismanen K et al., 2018)
Suture types	0.3	0.15	4	87	96	192	(Williams et al., 2006)
Surgeon's factor (specialist)	0.15	0.05	4	107	118	236	(Kuismanen K et al., 2018)

The biggest estimated sample size calculated

= 236 + 10% drop-out rate

= 260

- In summary,

Sample size for objective 1= **271**

Sample size for objective 2= 260 (from the biggest number calculated)

- In view of the sample size of specific objective number (1) being the largest, a total of 271 patients need to be recruited to meet 80% of statistical power. 271 patients were reviewed.

6.5 Ethical Consideration

The conduct of this study was approved by the Universiti Sains Malaysia Human Medical Research and Ethics Committee Research and Ethics Committee of the School of Medical Sciences, USM (JEPeM-USM), with assigned study protocol code USM/JEPeM/21010032 (Refer Appendix) prior to retrieving of medical data and collection from record office Hospital USM, Kubang Kerian.

6.6 Sampling Method/Data collection

A purposive sampling method was used. Based on the list of patients provided by the record unit Hospital Universiti Sains Malaysia, all patients who underwent primary repair of OASIS in Hospital USM from 1st December 2010 until 31st November 2020 and fulfilled the inclusion criteria and exclusion were included in the study. Consent from the Director of Hospital Universiti Sains Malaysia was obtained to get access to the case notes.

Data of women who delivered in Hospital Universiti Sains Malaysia (HUSM) and sustained Obstetric Anal Sphincter Injury from December 2010 until November 2020 traced through hospital birth registry book, Patient Assessment Centre (PAC) record, antenatal ward and Urogynaecology clinic patient's attendance record and reviewed to identify patients for the study.

The patient's record was traced from the record office, and their information was documented in the patient's clinical form. The grading of the injuries and the associated factors which may lead to the complications analysed. A proforma was used to collect data in the following areas such as demographics and pregnancy outcomes including antenatal problems, pregnancy, and fetal outcomes.

6.7 Statistical analysis