

**OBSTETRIC ANAL SPHINCTER INJURIES
(OASIS) -
A PROSPECTIVE OBSERVATIONAL
LONGITUDINAL STUDY**

Dissertation submitted to

**THE TAMILNADU Dr.M.G.R MEDICAL
UNIVERSITY**

*In partial fulfillment of the requirement
for the award of*

**M.S.DEGREE – OBSTETRICS & GYNAECOLOGY
BRANCH - II**



**KILPAUK MEDICAL COLLEGE
KILPAUK, CHENNAI.**

APRIL 2017

BONAFIDE CERTIFICATE

This is to certify that the dissertation entitled “**OBSTETRIC ANAL SPHINCTER INJURIES (OASIS)- A PROSPECTIVE OBSERVATIONAL LONGITUDINAL STUDY**” is the bonafide original work of Dr. Anil kumar G.V. under the guidance of Prof. Dr. D. Tamilselvi M.D., D.G.O., Professor of Department of Obstetrics and Gynaecology, GKMCH, Chennai in partial fulfillment of the requirements for MS Obstetrics and Gynaecology branch II examination of the Tamilnadu Dr.MGR Medical university to be held in April 2017. The period of Postgraduate study and training from June 2014 to June 2017.

Prof. DR.D.TAMILSELVI
MD.,DGO,

Professor,

Department of Obstetrics and
Gynaecology,

Kilpauk Medical College.

Prof.Dr.T.K SHAANTHY GUNASINGH
MD.,DGO,

Professor and Head of the Department,

Department of Obstetrics and
Gynaecology,

Kilpauk Medical College.

Prof. Dr. R. NARAYANA BABU M.D, DCH.,

The Dean

Government Kilpauk Medical College,
Chennai – 600 010.

DECLARATION

I solemnly declare that this dissertation “**OBSTETRIC ANAL SPHINCTER INJURIES (OASIS)- A PROSPECTIVE OBSERVATIONAL LONGITUDINAL STUDY**” was prepared by me at Government Kilpauk Medical College and Hospital, Chennai, under the guidance of **Prof. Dr. D. Tamilselvi M.D., D.G.O.**, Department of Obstetrics and Gynaecology, Government Kilpauk Medical College and hospital, Chennai.

This dissertation is submitted to **The Tamil Nadu Dr.M.G.R. Medical University, Chennai** in partial fulfillment of the University regulations for the award of the degree of **M.S Obstetrics and Gynaecology.**

Place:

Date:

(Dr. ANIL KUMAR G.V.)

ACKNOWLEDGEMENT

I start this thesis in the name of Almighty God, the most beneficent and forgiving. I thank God that he has given me the privilege to learn from the able teachers in my department.

I express my sincere thanks to **Prof. Dr. R. NARAYANA BABU M.D., D.C.H.**, the Dean, Govt. Kilpauk Medical College, for allowing me to conduct the study using the available facilities.

I convey my heartfelt gratitude and sincere thanks to my guide **Prof. Dr. D. TAMILSELVI, M.D., D.G.O.**, Department of Obstetrics and Gynaecology, Govt. Kilpauk Medical College who with her exhaustive knowledge and Professional expertise has provided able guidance and constant encouragement throughout the Course of my study and in the preparation of this dissertation.

I express my sincere thanks to my professor **Prof. Dr. T. K. SHAANTHY GUNASINGH, M.D., D.G.O., F.I.C.O.G.**, Professor and Head of the department, Department of Obstetrics and Gynaecology and **Dr. SRIMATHY, M.D., D.G.O.**, Registrar, Department of Obstetrics and Gynaecology, Govt. Kilpauk Medical College, Kilpauk, Chennai, for their valuable help and encouragement.

I am grateful to my Assistant Professors, colleagues and my friends for their advice and suggestions.

My special thanks to my friend **DR. PRAVEEN B** for supporting me through my career in every possible way.

My heartfelt thanks to my parents, my family and friends, who have been a constant source of encouragement and immense help, for instilling in me a sense of commitment and for their belief in me.

Last but not least I thank all **my PATIENTS**, who formed the backbone of this study without them this study would not have been possible.

CONTENTS

SL.NO.	TITLE	PAGE NO
1	INTRODUCTION	1
2	AIMS AND OBJECTIVES	14
3	REVIEW OF LITERATURE	16
4	MATERIALS AND METHODS	31
5	OBSERVATION AND RESULTS	45
6	DISCUSSION	68
7	SUMMARY	77
8	CONCLUSION	79
9	LIMITATIONS	80
10	RECOMMENDATIONS	81
11	BIBLIOGRAPHY	83
12	ANNEXURES	
	A) STUDY PROFORMA	
	B) CONSENT FORM	
	C) MASTER CHART	

LIST OF ABBREVIATIONS

OASIS- OBSTETRIC ANAL SPHINCTER INJURIES

AST- ANAL SPHINCTER TRAUMA

EAS – EXTERNAL ANAL SPHINCTER

IAS – INTERNAL ANAL SPHINCTER

RCOG- ROYAL COLLEGE OF OBSTETRICS AND GYNECOLOGISTS

PP- POST PARTUM

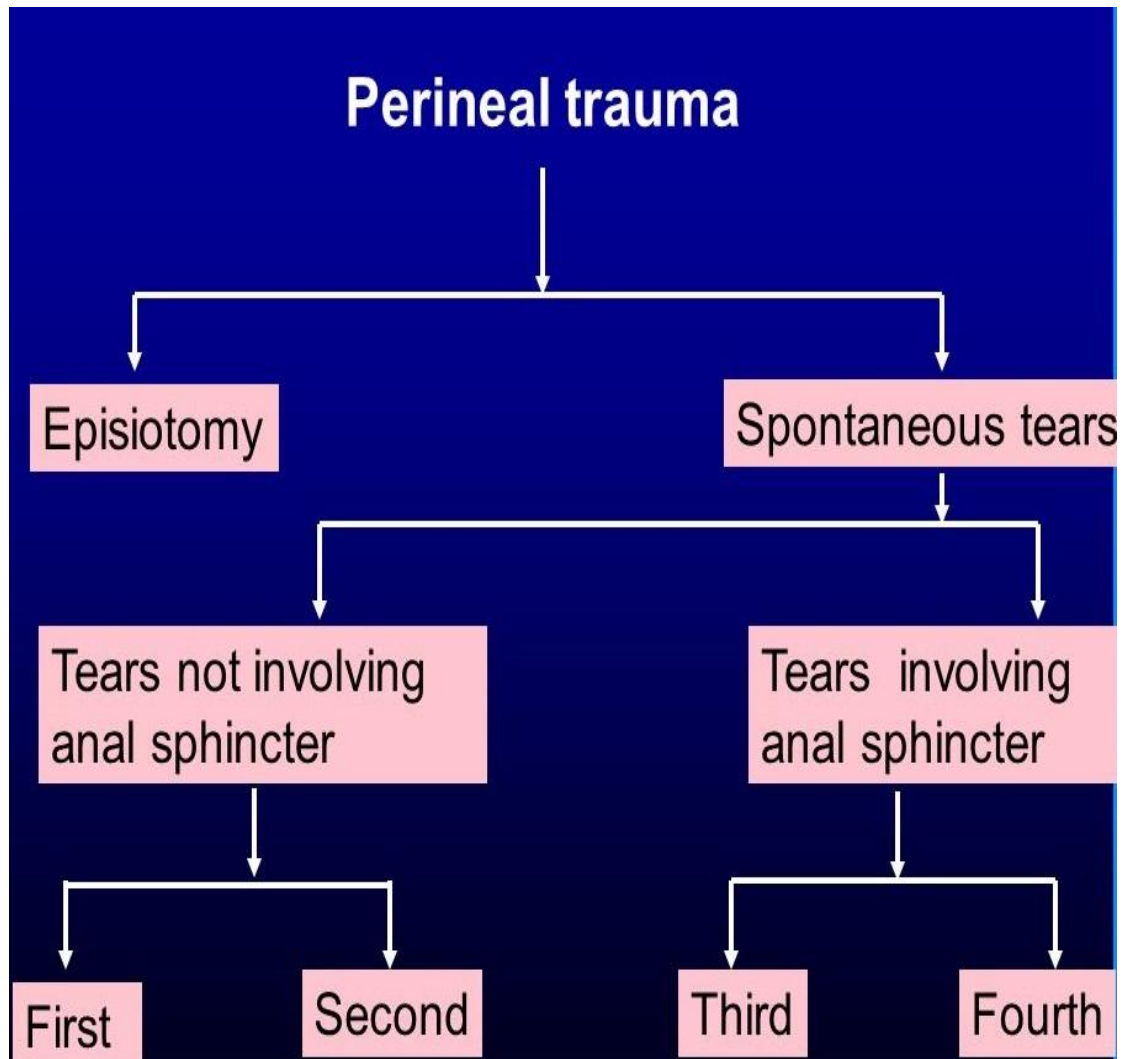
INTRODUCTION

INTRODUCTION

Perineal trauma is an adverse sequel to vaginal delivery. About 85% of women who have a vaginal birth sustain some form of perineal trauma¹. This can be either in form of intentional perineal incision (i.e.) episiotomy or unintentional perineal injury. However the incidence depends on difference in obstetric practice including rate of episiotomy which is different in various countries as well as various hospitals in same country also. In Netherland, England, USA and in East European countries rate of episiotomy is 8%, 14%, 50% and 99% respectively²⁻⁴.

The morbidity associated with perineal injury and its repair is a major health problem. In healthy women, anal sphincter tear at vaginal delivery is the most common precursor of fecal incontinence and may also be a marker for the development of subsequent pelvic dysfunction⁵⁻⁸.

Incidence of 3rd and 4th degree perineal tear are indicators of quality of care in many countries like UK, USA , Finland etc. and the organization for Economic Co-operation and Development routinely reports this indicator⁹⁻¹⁰.



Anatomy: Anal sphincter complex which is a neuromuscular complex consists of external sphincter(EAS) and internal anal sphincter(IAS) muscle and puborectalis muscle. Distal thickened 3 to 4 cms extension of large colon's circular muscle layer, 1.5 cm below dentate line, slightly above intersphincteric groove forms the internal anal sphincter which is a smooth muscle layer and is innervated by autonomic nervous system and is not under voluntary control.

IAS provides seventy to eighty percent resting pressure of anal canal and thus plays a major role in maintenance of continence at rest.

EAS has 2 portions, superficial and deep. Its subcutaneous portion attaches to perineal skin and it forms an encircling ring around lower most portion of anal canal and creates radially oriented fold in perianal skin.

EAS which is a striated muscle, innervated by inferior rectal branch of pudendal nerve and under voluntary control, is responsible for squeeze pressure of anal canal and helps in maintaining fecal incontinence when continence is threatened.

EAS provides twenty five percent resting anal canal pressure by being in constant contracting state. EAS relaxes during process of defecation and allows easy passage of stool. EAS appears pink like raw red meat and IAS appears white and pale like raw fish.

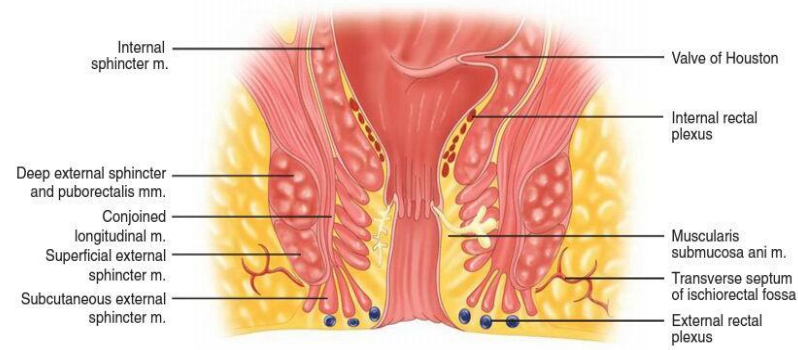


Diagram 1: Diagram of anal sphincter

Puborectalis muscle which is a part of levator ani muscle complex, maintains anorectal angle and prevents entry of rectal contents into anal canal. However its role in maintaining continence is a matter of controversy¹¹⁻¹².

Since 1949 to 2016 in various articles the incidence of overt perineal tear had been reported, ranging from 0% to 26.9%¹³⁻¹⁷. The possible reasons for this wide range are, many author had considered external anal sphincter tear as 2nd degree perineal tear¹⁸, under reported cases, type and rate of episiotomy and lack of uniform classification and inaccurate identification of major perineal tear involving external and/or internal sphincter.

The incidence of clinically detected anal sphincter tears at delivery most often is reported to be 2-19% in the United States ,where midline episiotomy is predominantly practiced¹⁹⁻²². But the centers where mediolateral episiotomy is practiced, overt sphincter damage due to third or fourth degree tear occurs in approximately 0.7- 1.7% of women undergoing vaginal delivery^{15,23,24}.

The most commonly used classification described by Sultan, has been adopted by International Consultation on Incontinence and the RCOG²⁵.

According to this classification, Obstetric anal sphincter injury includes both third and fourth degree perineal tears.

Third degree perineal tear: injury to perinium involving the anal sphincter complex

3a: less than 50% of EAS thickness torn

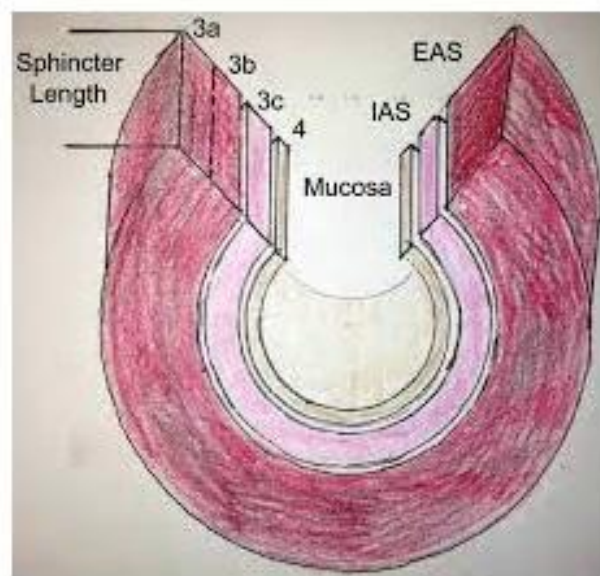
3b: more than 50% of EAS thickness torn

3c: both EAS and IAS torn

Fourth degree perineal tear: Injury to perineum involving the anal sphincter complex (EAS and IAS) and **anal epithelium**.

Rectal mucosal tear without involvement of anal sphincter (button hole) occurs very rarely and these tears are not included in the above classification²⁶.

In case of doubtful situations, clinician should consider higher classification. For example if confusion is there between 3b and 3c tear, it should be classified as 3c.



PICTURE SHOWING PERINEAL
TEARS.
EAS=EXTERNAL ANAL SPHINCTER;
IAS=INTERNAL ANAL SPHINCTER

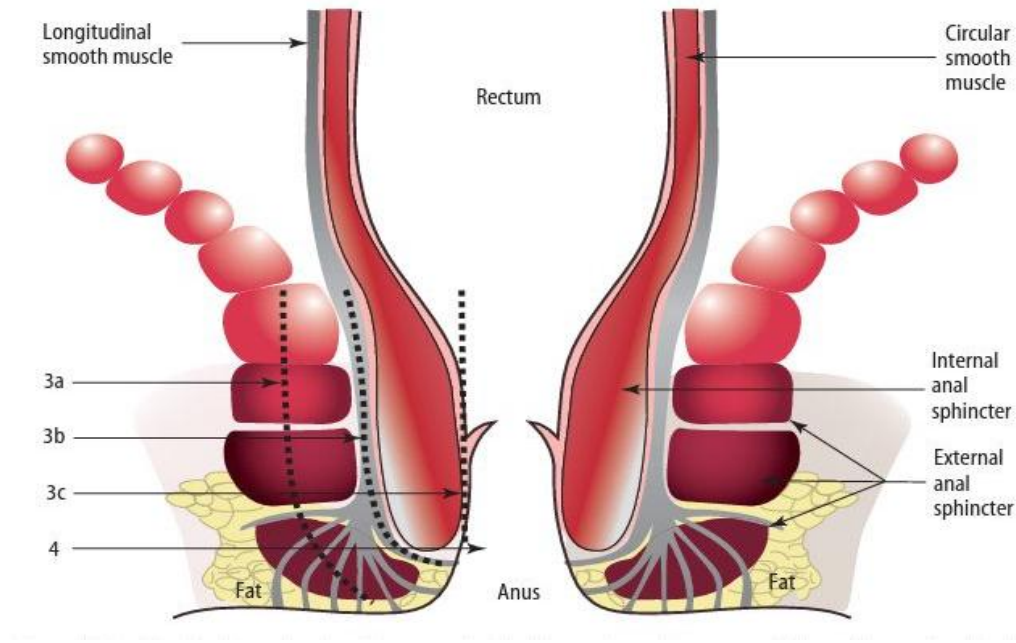


Diagram 2: Diagrammatic presentation perineal trauma classification

Anal sphincter tear incidence is highest among nulliparous women and those undergoing operative vaginal delivery. Among many other factors that may influence the risk of anal sphincter injuries, episiotomy is most controversial.

Midline episiotomies have been associated with highest incidence of sphincter tear when compared to either mediolateral episiotomy or with no episiotomy²⁷.

In our country we give mediolateral episiotomy instead of midline. But still mediolateral episiotomy is a risk factor or protective for perineal trauma is

matter of debate²⁸⁻³⁰.

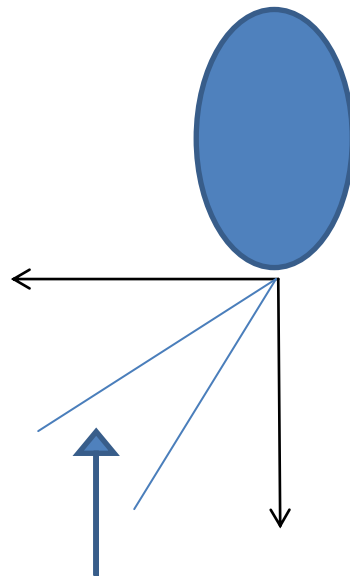
One of the probable cause is mediolateral episiotomy is not truly mediolateral but it is more midline. Episiotomy, in spite of being the commonest surgical procedure performed throughout the world, training in this procedure is not optimal.

Research studies shows that ideally an episiotomy should have a post-delivery angle of between 30-60 degree to midline to reduce the risk of sphincter injury.

The incidence of sphincter injury is 10% if the resultant episiotomy angle is <25 degrees and 0.5% if the angle is >45 degree³¹.

Episiotomy is given at the time of crowning when perineum is distended, ensuring that the angle is 60 degrees away from the midline with distended perineum, resulting in a post-delivery episiotomy angle of 44 degree.

Safe zone of 40- 60 degree post-delivery has been proposed.



A safe zone of 30 to 60 degree

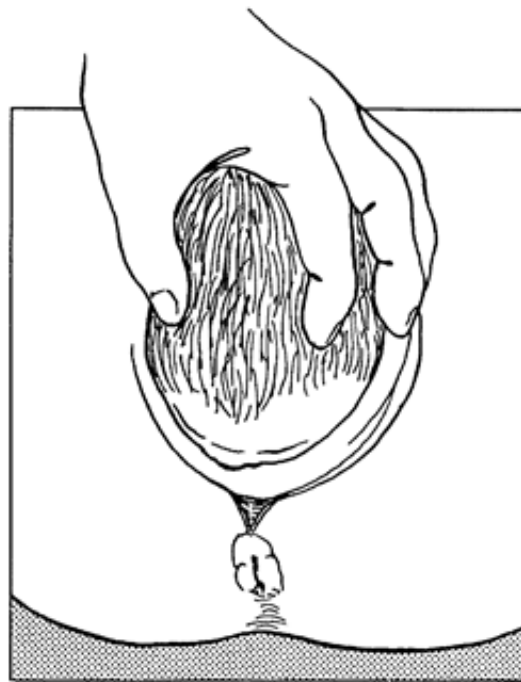
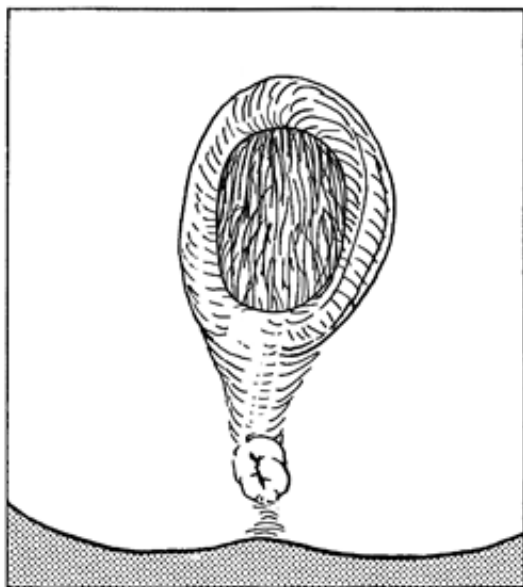
Other risk factors associated with an increased risk of sphincter tear are:

- Patient's age- elderly
- gestational age- post term
- malposition- persistence of occipitoposterior position
- pathological duration of 1st stage of labour
- pathological duration of 2nd stage of labour
- labour augmentation- oxytocin augmentation
- birth weight- macrosomia
- shoulder dystocia

- fundal pressure

Anal sphincter injuries are complication of childbirth with potentially debilitating long term consequences. As per International continence society ,anal incontinence is defined as the involuntary loss of stool and/or flatus.³² Anal incontinence after childbirth may be due to injury to the anal sphincter or its innervation or both³³⁻³⁵. Fourth degree tear may result in development of a rectovaginal fistula.

Recent studies have demonstrated a significant incidence of sphincter injuries after delivery, and majority of these injuries are occult and only detectable with endoanal sonography.



PICTURE SHOWING PERINEAL SUPPORT BY
MODIFIED RITGEN'S MANEUVER TO AVOID OASIS

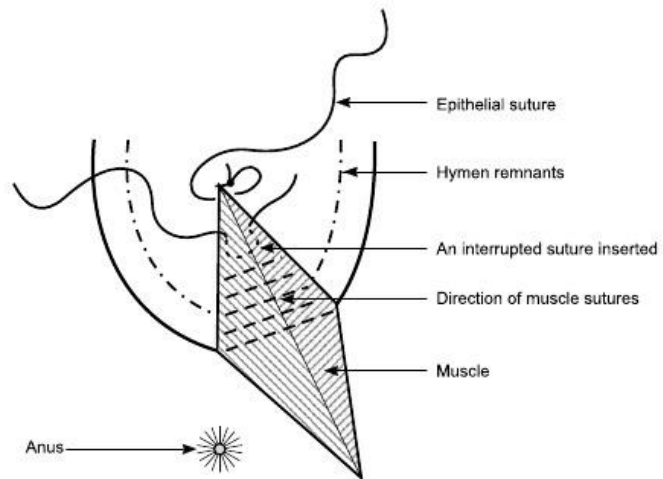
Additionally, anal incontinence is seldom spontaneously mentioned by patients, and therefore very often these problems remain undetected. Nearly half of women with anal sphincter tear experience persistent symptoms such as flatus incontinence and fecal incontinence.

Even when the repaired sphincter appears intact, symptoms of anorectal dysfunction can be present³⁵⁻³⁶. Indeed, it appears that anal sphincter function is never entirely restored by primary repair of anal sphincter tear at delivery, highlighting the importance of preventing the injury.

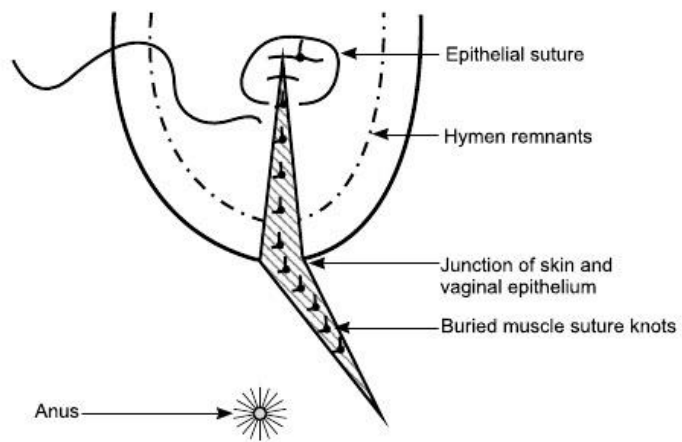
However without sphincter injury also ,symptoms of anal incontinence are increased after vaginal delivery which suggests some other factors also play a role in maintaining continence like pudendal nerve injury during vaginal delivery or the pregnancy by itself.

After joining the course I was posted in labour room for 3 months where I saw 4 patients of 3rd degree perineal tear and 1 patient with complete perineal tear which adversely affect patient's physical and social life in future and there is very limited data on perineal tear in Indian population so I decided to do study and find out the associated risk factors and symptomatic outcome of repair in our population.

The purpose of the present study is to assess incidence and various known risk factors associated with anal sphincter injuries during vaginal delivery and symptomatic outcome of its primary repair.



Suturing the muscles



The correct position of the skin and vaginal epithelium

AIMS & OBJECTIVES

The aim of this study is to determine incidence and risk factors of obstetric anal sphincter injuries during vaginal delivery and symptomatic outcome of primary repair.

The objectives:

- To determine the incidence of OASIS in KMC,Chennai
- To study the risk factors for obstetric anal sphincter injuries(OASIS) and to determine the significance of association
- To assess the symptomatic outcome of primary repair by subjective questionnaire regarding anal incontinence

REVIEW OF LITERATURE

REVIEW OF LITERATURE

- In 2006, **Vasanth Andrew et al**³⁷ conducted a prospective study with an objective of identifying risk factors for sphincter injuries and to measure dimensions of mediolateral episiotomies. 241 primi women were recruited who were expecting their first vaginal delivery and an experienced research fellow performed a perineal and rectal examination and classified tears according to the new international classification. Of the 241, 59 (25%) sustained sphincter injuries.

- In their study, Univariate analysis revealed that forceps delivery (OR 4.03), vacuum extraction (OR 2.64), gestation > 40 weeks (OR 3.18), and mediolateral episiotomy (OR 5.0) were associated with sphincter injuries. In addition, higher birth weight ($p<0.01$), larger head circumference ($p<0.01$), and longer second stage of labor ($p<0.01$) were associated more with sphincter injury than women who had no injuries. Higher birth weight and mediolateral episiotomy (OR 4.04) were independent risk factors.

- Episiotomies angled closer to the midline were significantly associated with such injuries (26 vs 37 degrees, $p=0.01$). They concluded that mediolateral episiotomy is an independent risk factor for anal sphincter injuries. Although a liberal policy of

mediolateral episiotomy does not appear to reduce the risk of such injuries, it may be related to inappropriate technique.

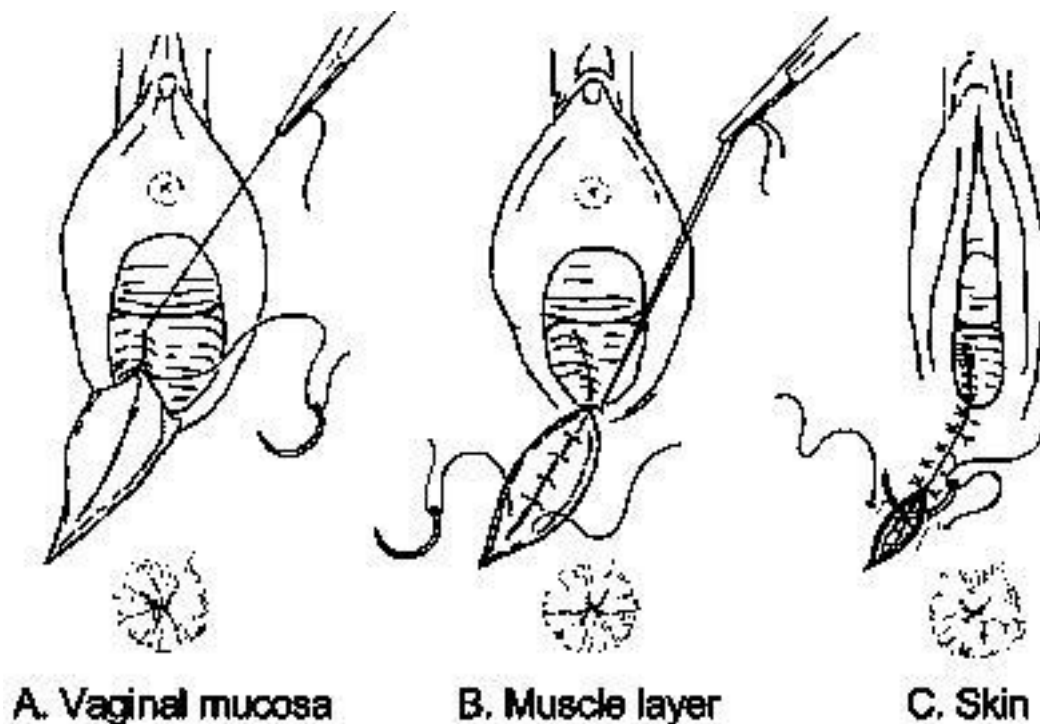
- **A.M . Roos et al³⁸** conducted a prospective study which included 531 women who had anal sphincter injuries and underwent primary sphincter repair and followed up for 9 weeks after delivery, between July 2002 to July2008. They assessed risk factors and outcomes of different grades of OASIS after primary repair.

- On follow up, defecatory symptoms and bowel related quality of life were evaluated and anal manometry and endoanal ultrasound were performed to assess outcome of OASIS. The development of defecatory symptoms and associated quality of life outcome were significantly poorer in major tear(3c/4) than minor tear(3a/3b). Women with major tears were more likely to have an endosonographic isolated IAS or combined IAS and EAS defects on follow up.

- Fecal incontinence and lower anal canal pressures were significantly higher with combined defects. Epidural analgesia was the only independent factor predicting major tear. They concluded that

identification of full extent of injury at the time of delivery and their proper repair, and in particular attention to IAS defects, is very important to prevent unfavorable outcome.

- **I Gurol Urganci et al³⁹** conducted a retrospective cohort study of singleton deliveries from a national administrative data base between April 2000 to March 2012 to describe time trends in England and measured the rate of third degree and fourth degree perineal tears in primiparous women who had singleton, cephalic, term, vaginal birth.



- They observed that the rate of 3rd or 4th degree perineal tears were tripled(from 1.8% to 5.9%) during the study period. Maternal age of more than 25 years, instrumental deliveries, especially without episiotomy, Asian ethnicity, a more affluent socioeconomic status, higher birth weight and shoulder dystocia were associated with higher risk of third or fourth degree perineal tears.

- They concluded that the observed increase in the rates of third or fourth degree tears were because of improved awareness and recognition of tears after implementation of a standardized classification of perineal trauma instead of a change in major risk factors.

- In Sweden, **Charlotte Jander et al**⁴⁰ conducted a retrospective case control study to identify significant predictable factors which leads to 3rd and 4th degree perineal tear.

- They recorded 214(3.7%) women with 3rd and 4th degree perineal tear after vaginal delivery from January 1995 to December 1996. Using a stepwise logistic regression model they found nulliparity, maternal age >35, baby birth weight >4000 gms, vacuum delivery, a squatting position while delivery, midline episiotomy, labour

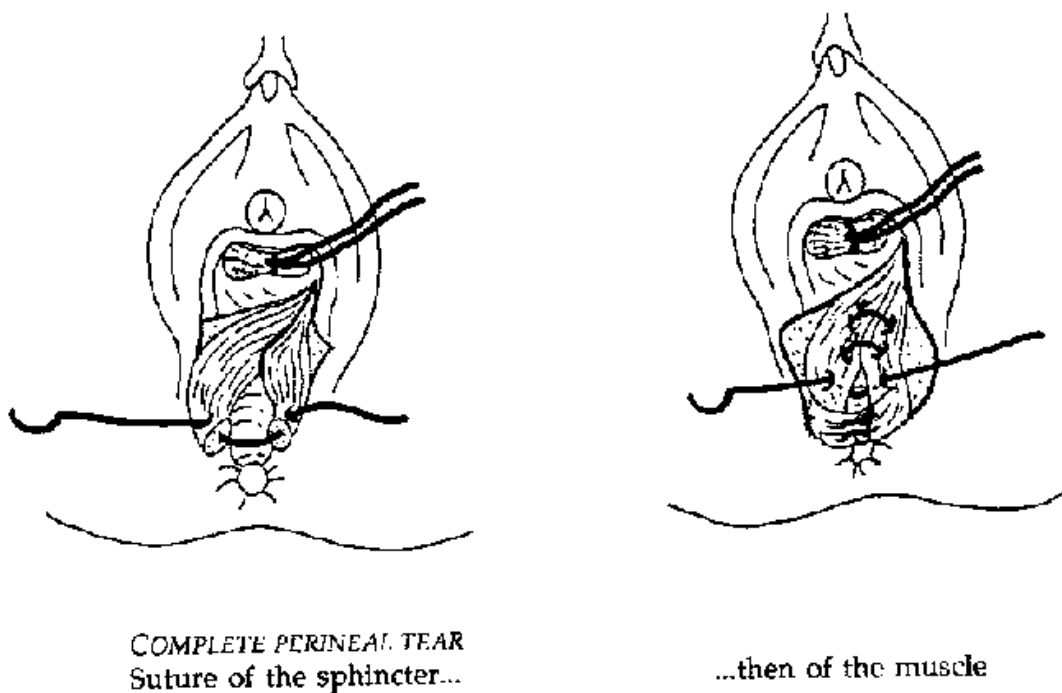
augmentation by oxytocin and those who give birth between 3 a.m. and 6 a.m. as significant independent risk factors for anal sphincter tear.

- They concluded that midline episiotomy should be avoided and cesarean section should be considered over vacuum delivery of macrosomic baby to prevent anal sphincter injuries.

- In 2007, **Gottvall et al**⁴¹ conducted observational cohort study to assess the role of various birth positions in occurrence of obstetric anal sphincter injuries during the study period April 2002 to December 2005.

- In their study anal sphincter injury occurred in 449(3.5%) women out of 12,782 women who were included in the study. Using stepwise logistic regression analysis, they found that anal sphincter injuries were more common in women who were in lithotomy position while giving birth followed by squatting position. Other risk factors of OASIS in their study were prolonged 2nd stage of labour (> 1 hour), primiparity, birth weight of infant (>4 kgs) and large infant head circumference (>35 cms).

- They concluded that even after control of other risk factors squatting and lithotomy birth position were significantly increased the risk of anal sphincter injury.



- **Nandini Gupta et al⁴²** have done a retrospective study to see risk factors which cause anal sphincter tear apart from nulliparity. In their study they took data of 52,916 deliveries during the period 1990-99.

- They found incidence of anal sphincter injuries was 0.8% in their study population. They found fetal macrosomia with induction of labour, postdates, doctor conducted deliveries and instrumental delivery to be significantly associated with anal sphincter injuries.

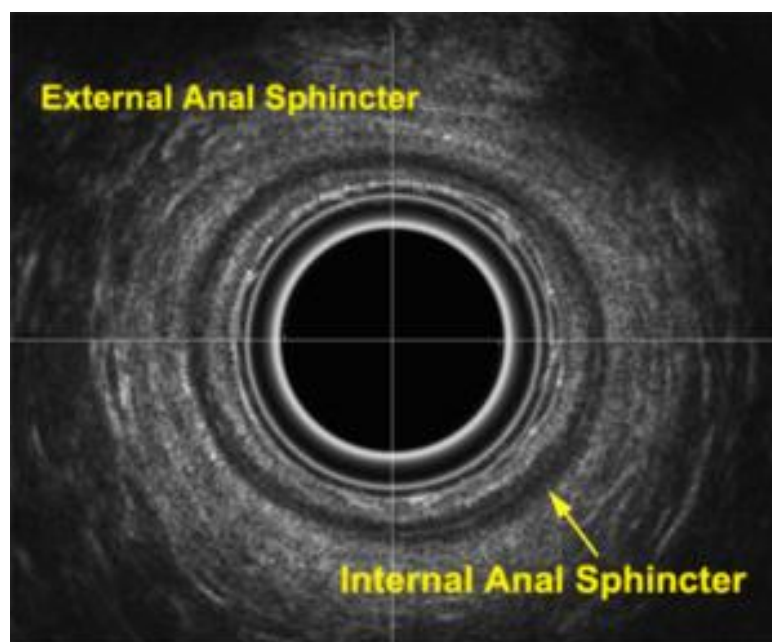
- Logistic regression showed fetal macrosomia and doctor conducted deliveries were independent risk factors for anal sphincter injury. They did not find any association between epidural analgesia and episiotomy to sphincter injuries.

- They concluded postdate primigravida with macrosomic baby with labour induction and if forceps to be used for prolonged 2nd stage significantly increase the risk of anal sphincter tear.

- **Williams et al⁴³** have done an audit of management of patient with anal sphincter injuries from 1997-99 with an aim to determine incidence, risk factors of anal sphincter tear and outcome of primary repair.

- They found 0.6% incidence of sphincter tears in their study. In their study mean age of patient with sphincter injuries was 27 years and mean birth weight was 3532 gms.

- In this case control study they found nulliparity, forceps delivery and mediolateral episiotomy as significant risk factors. They found epidural analgesia protective for sphincter injuries. 40% women were symptomatic and seventy five percent women had sphincter defect in endoanal ultrasound after primary repair of anal sphincter on follow up.



Picture: Endoanal
Ultrasound of anal sphincter

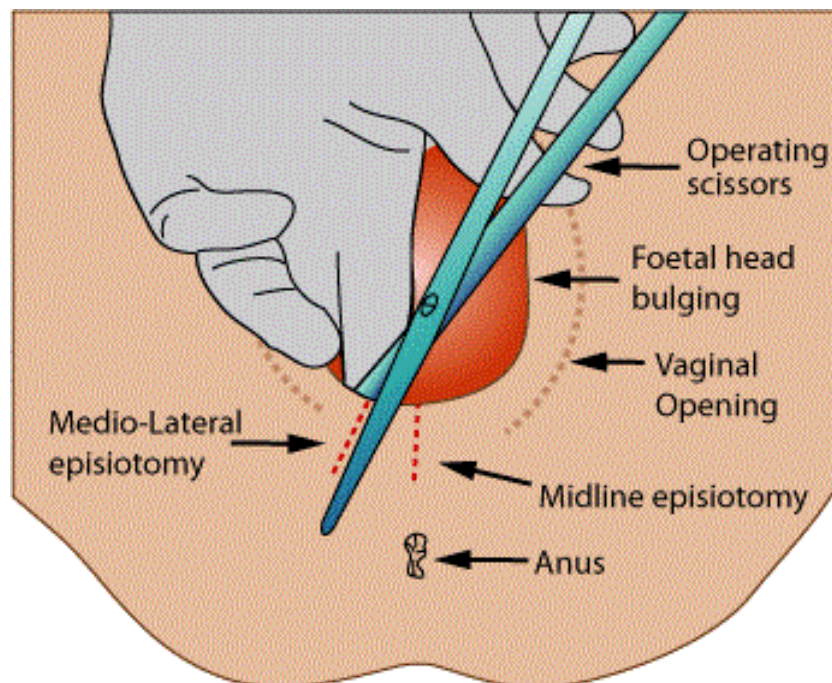


Picture: Endoanal ultrasound of anal sphincter tear

- In 2001, **J.W. Leeuw et al**⁴⁴ published a population based observational study with an objective of to determine risk factors for occurrence of third degree perineal tear during vaginal delivery. In their study they included 2,84,783 vaginal deliveries between 1994 & 1995.
- They found incidence of third degree tear was 1.94%. Using logistic regression analysis they found primiparity, prolonged duration of 2nd stage of labour, all type of assisted vaginal delivery specifically forceps delivery and high birth weight were associated risk factors of anal sphincter injury. They found mediolateral episiotomy was protective for anal sphincter injury.

- They concluded mediolateral episiotomy is protective for anal sphincter tear so it is effective as a primary prevention of fecal incontinence as well.

- In 2009, **Eskandar et al**⁴⁵ published a retrospective case control study with an aim to recognize various risk factors for occurrence of anal sphincter injury during vaginal delivery to identify high risk patient. In 2005 and 2006, 2278 patients were delivered vaginally in their study. They calculated incidence of 3rd and 4th degree perineal tear as 1.58%. They used SSPS version 15 for statistical analysis.



PICTURE: TYPES OF EPISIOTOMY

- They found primiparity, occipitoposterior position and instrumental delivery for OP position were statistically significant risk factors. Induction of labour, epidural analgesia, mediolateral episiotomy and instrumental delivery for occipitoanterior were protective factors against anal sphincter injury but they were not statistically significant.

- In 2015, **Allison La Cross et al**⁴⁶ conducted a systematic review and meta-analysis to see evidence for relationship between obstetric perineal tear (episiotomy and 3rd or 4th degree perineal tear) and anal incontinence in parous women. Of the 19 studies, seven examined 3rd- or 4th-degree perineal laceration, three examined episiotomy and nine studies examined both and risk factors for anal incontinence. 8 studies (n = 2929 women) examining the relationship between episiotomy and anal incontinence and twelve studies (n= 2288 women) examining the relationship between third- or fourth-degree perineal laceration and anal incontinence met criteria for inclusion in the meta-analyses.

- They demonstrated a significant association between perineal trauma both episiotomy [OR, 1.74; 95% confidence interval [CI], 1.28-2.38; Q = 8.9; P = .26; I = 21.4] and third- or fourth-degree perineal laceration (OR, 2.66; 95% CI, 1.77-3.98; Q = 27.9; P = .002; I = 64.1) with anal incontinence.

- They concluded that both episiotomy and third- or fourth-degree perineal laceration are significantly associated with anal incontinence after vaginal birth. It shows the importance of reducing perineal trauma during vaginal births to avoid anal incontinence in parous women.

- In Sweden, **Anna Palm et al**⁴⁷ conducted a retrospective case-control study in 2012 with an objective of comparing the prevalence of anal incontinence and dyspareunia in women with or without obstetric sphincter injury after standardizing the suture technique.

- They included 305 women with an obstetric sphincter injury and 297 women with spontaneous vaginal delivery in the study. To standardize and improve the repairing skills of sphincter injuries, collaboration between obstetricians and colorectal surgeons was done. Internal and external sphincters were repaired in two layers with continuous monofilament polydioxane sutures. The main outcome measured in terms of anal incontinence, dyspareunia and quality of life during follow up time of 15 months to 8 years.

- Incontinence of flatus and loose stool was significantly more in women in the sphincter injury group but there was no significant difference of incontinence of solid stool, soiling, or fecal urgency between the groups. There was no significant difference in quality of life between the groups. In the sphincter group, there was significantly more superficial coital pain compared to controls ($p = 0.02$). Compared to partial sphincter injury, complete sphincter injury had significant anal incontinence. They concluded that even though rate of anal incontinence and dyspareunia increased after anal sphincter rupture, statistically significant reduction in the woman's quality of life was not there.

- In 2004, **Sting Norderval et al**⁴⁸ published a study on anal sphincter injuries in Norway to assess the incidence of anal sphincter tear and outcome of its repair. In their study clinically detected sphincter tear incidence was 3.5% (180 out of 5123) out of them 58% patients were suffering from incontinence with a median follow up of was 25 months. They could not find any difference in outcome of partial and complete tear. They concluded anal incontinence was common after complete as well as partial obstetrics anal sphincter injuries.

- **Jan Zetterstrom et al⁴⁹** used multiple logistic regression to calculate the risk factors for obstetrics anal sphincter tears and to evaluate symptomatic outcome of repair. During their study period they recorded 6% of women had a clinically detected sphincter tear at delivery out of 845 women. In their study sphincter tear were associated with nulliparity, post maturity, fundal pressure and midline episiotomy. 54% of women with repaired sphincter tears suffered from gas and or fecal incontinence or both at 5 months and 41% at 9 months. They concluded that sphincter tear at vaginal delivery is a serious complication, and it is frequently associated with anal incontinence.

- **Mary P FitzGerald et al⁵⁰** have done prospective cohort study with an objective to identify risk factors associated with anal sphincter tear during vaginal delivery and to prevent this cause of fecal incontinence.

- In their study, out of 797 primiparous women 407 women had a recognizable anal sphincter tear. Based on univariate analysis, they found a woman with a sphincter tear was more likely to have longer gestation or prolonged second stage of labour, a larger infant or

an infant who was in occiput posterior position, or to have an episiotomy or operative delivery. Logistic regression found that forceps delivery and episiotomy were strongly associated with a sphincter tear.

- The combination of forceps and episiotomy was markedly associated with sphincter tear. The addition of epidural anesthesia to forceps and episiotomy increased the risk. They concluded forceps, fetal occiput posterior position, vacuum, prolonged second stage of labour, episiotomy and epidural anesthesia were modifiable risk factors that can be used in decision making to decrease anal sphincter tear.

MATERIAL AND METHODS

Study site:

Department of obstetrics and gynecology,

Government Kilpauk Medical College

Chennai.

Study population:

The study population comprised of antenatal patients delivering at KMC hospital, Chennai.

Study design:

Prospective observational longitudinal study

Sample size and sample technique:

The sample size was calculated based on the formula as below:

Anticipated prevalence: 12%

Precision needed 10 percentage points i.e., 2% to 12%

95% confidence interval (same as level of significance =5%)

n = Required Sample size

Z α = Confidence level at 95 % (Standard Value=1.96)

p = Estimated Prevalence (0.12)

q = (1-0.12) = 0.88

d = precision (0.10)

$$\begin{aligned}n &= \frac{z\alpha^2 * (pq)}{d^2} \\&= \frac{1.96^2 * (0.12 * 0.88)}{0.10^2} \\&= 40.69\end{aligned}$$

Sample size= 40.69

Time frame to address the study:

The study period is from July 2014 to May 2016

Criteria for selection of patient**Inclusion criteria:**

All patients who delivered vaginally with 3rd and 4th degree perineal tear

Exclusion criteria:

- All patients who delivered by caesarean section
- Patient with only 1st and 2nd degree perineal tear
- Patient with non cephalic presentation
- Multiple pregnancy
- Patient who delivered preterm (<37 weeks) (baby's birth weight will be less)
- Patient with previous anal sphincter injury
- Patient with repaired or unrepaired rectovaginal fistula

Source of Data

The source of data is the patients attending the obstetrics and gynecology department in KMC hospital, Chennai, which is a tertiary referral hospital. The study is conducted over a period of two years from July 2014 to May 2016 after obtaining ethics committee clearance and obtaining informed consent from patients.

METHODOLOGY:

All vaginal deliveries with OASIS are taken into study according to inclusion criteria and analyzed by taking factors into account:

Maternal:

Age

Parity

Gestational age(>40 weeks) (we are not allowing any patient to go beyond 41 weeks)

Fetal/Neonatal:

Birth weight

Occipitoanterior or occipitoposterior position

labour:

Duration of 1st stage

Duration of 2nd stage

Instrumental delivery- forceps

Shoulder dystocia- present/absent

(In our hospital, we do active management of labour which includes artificial rupture of membrane once patient enters active labour and

oxytocin augmentation if uterine contractions are inadequate. So almost all primigravida patients receive oxytocin augmentation. 3rd and 4th degree perineal tears were diagnosed by obstetrician by clinical examination.

PRIMARY REPAIR:

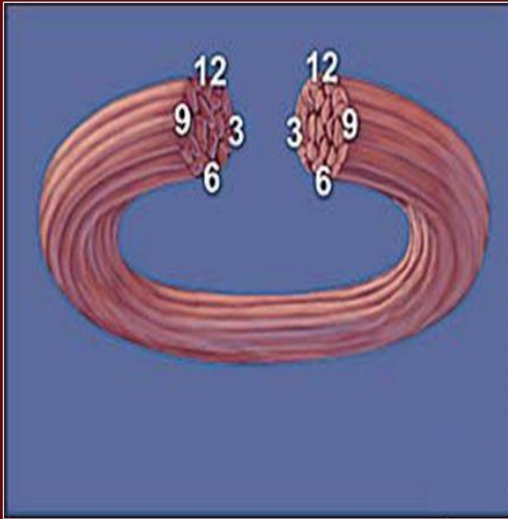
3rd and 4th degree tears should be repaired by trained expert under good lighting in operation theatre, under regional or general anaesthesia with adequate instruments.⁵²

Nowadays, figure of eight sutures are not used because these figure of eight sutures are haemostatic sutures and these sutures are more prone for tissue ischemia.

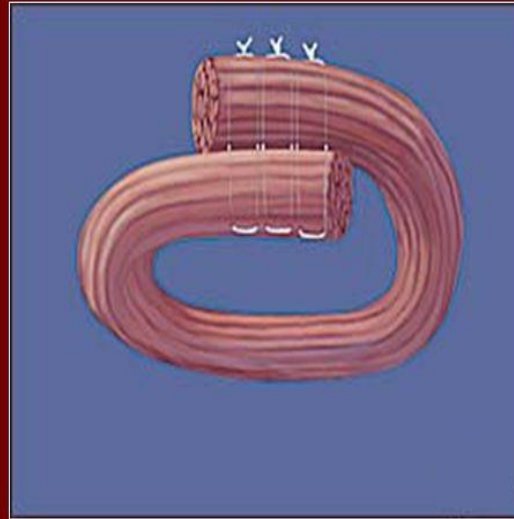
After repair of OASIS, per rectal examination is a must to verify whether sutures are through anorectal mucosa .If sutures are taken through anorectal mucosa, if they should be removed.

Anorectal mucosa tear should be repaired either with continuous interrupted technique.⁵³

End-to-end (approximation) method



Overlap technique



For repair of internal anal sphincter , it is better to repair with interrupted or mattress sutures without using the overlapping technique.^{38,55-}

57

For repair of external anal sphincter i.e. for full thickness tear either an overlapping or an end to end method is used. ^{58,59}

For partial thickness tear, (all 3a and some 3b) end to end method is recommended.

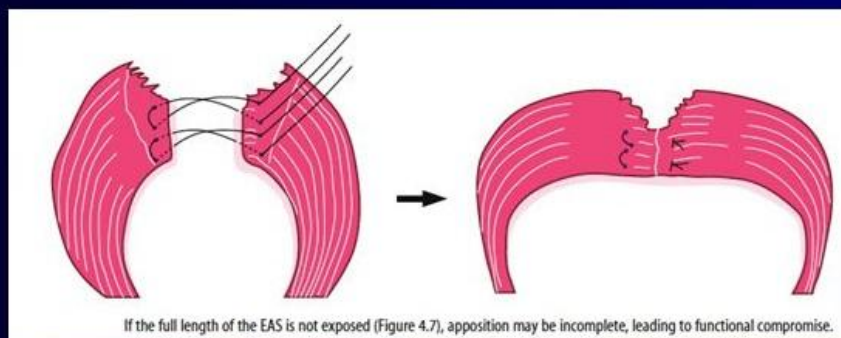
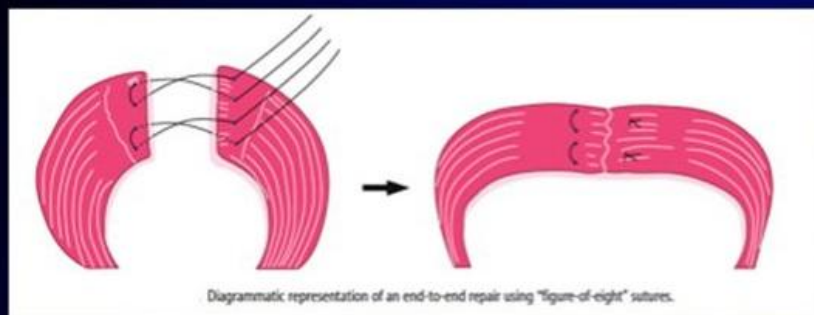
Suture material for repair:

For repair of anorectal mucosa, it is better to use 3-0 polyglactin instead of using polydioxanone (PDS) because 3-0 polyglactin causes less chance of irritation or discomfort.^{53,54}

For repair of EAS and/ or IAS muscle, either 3-0 polydioxanone or 2-0 polyglactin is recommended. Both of them have equal outcomes.⁵⁴

Repair of third and fourth degree tears

End– to – end Or overlap repair?



During repair of OASIS, it is recommended to bury the surgical knots beneath the superficial perineal muscles in order to reduce the risk of knot and suture migration.

Post-operative management of OASIS:

Prophylactic intravenous antibiotics is recommended following OASIS repair in order to reduce the perineal wound infection.⁶⁰

Following OASIS, patients are more prone to postpartum urinary retention, so bladder catheterisation is recommended.

Laxatives are used following repair of OASIS because these laxatives causes painless bowel movements following repair.^{58,65}

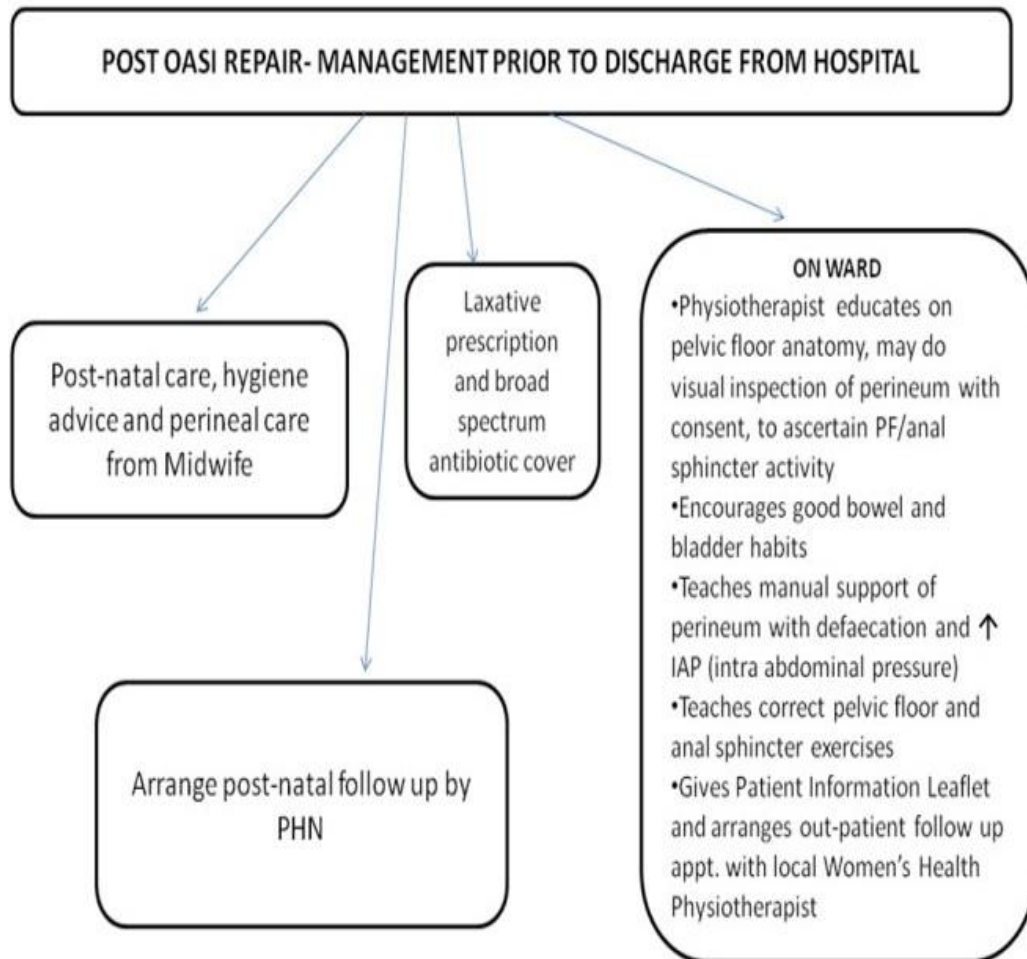
Constipating and bulking agents are not advised with laxatives.⁶⁶

Non-Steroidal Anti Inflammatory Drugs or Paracetamol are the first line of drugs for post-operative management.

Women with OASIS repair are advised for regular physiotherapy for strengthening of perineal muscles.⁶⁷

Women with OASIS repair are advised to have regular follow-up at a convenient period (usually 6-12 weeks postpartum period).⁶⁸

During her follow-up, if symptoms of incontinence are present, patients are referred to specialised gynaecologists attached to perineal clinics supported with endo-anal ultrasonography and anal manometry.^{69,70}



Flow chart: Post operative management of perineal tear.

Advice about future deliveries:

All mothers who had OASIS repair in a previous pregnancy should be advised about the mode of delivery and properly documented in the Discharge notes.

Proper documentation of anatomical structure repaired, method of repair and choice of suture material used should be done. ^{24,70-74}

Women should be advised about regular follow-up with proper previous pregnancy records and information. ^{24,70-74}

Anal sphincter injuries can be prevented by the following ways

- Liberal episiotomy during instrumental deliveries i.e. mediolateral episiotomy is preferred.^{39,51} i.e. 60° away from the midline when the perineum distends.^{31,61-63}
- Perineal support during crowning i.e. Modified Ritgen maneuver.^{62,64}
- To give warm compresses during second stage of labour.

All patients are informed and taught to do perineal floor and anal sphincter muscle exercise once they feel comfortable and pain resolves.

After delivery, all patients were given 3 questionnaires- 1st before discharge from hospital, 2nd after 1 month and 3rd after 3 months

1st questionnaire - symptoms existing before discharge regarding flatus or fecal incontinence (liquid and/or solid)

2nd questionnaire and 3rd questionnaires – same symptoms at 1month and 3 months respectively.

STATISTICAL ANALYSIS

The data was analyzed using SPSS (Statistical Package for Social Science) Ver 16.01. The data collected was scored and analyzed. Continuous variables were presented as means with Standard deviation (sd) and categorical variables were presented as frequency and percentages. Chi-square test was used to compare proportions. All the Statistical results were considered significant at P value ≤ 0.05 .

OBSERVATION & RESULTS

OBSERVATION AND RESULTS

A total of 40 patients diagnosed to have OASIS over a period of 2 years.

The following observations were made in the present study.

TABLE-1 Patient's mean age and OASIS

AGE GROUP	NUMBER	PERCENTAGE
≤ 25 Years	8	20.00
26 – 30 Years	26	65.00
31 – 35 Years	6	15.00
TOTAL	40	100
Minimum	23	
Maximum	35	
Mean	27.73	
Standard Deviation (SD)	2.77	

Table 1 shows the mean age of patients having OASIS is 27.73 years.

TABLE-2 Age and type of Perineal Tear

AGE GROUP (IN YEARS)	TYPE OF PERINEAL TEAR								TOTAL	
	3A		3B		3C		4		N	%
	N	%	N	%	N	%	N	%		
≤ 25	5	16.67	2	33.33	0	0.00	1	50.00	8	20.00
26 – 30	21	70.00	4	66.67	0	0.00	1	50.00	26	65.00
31 – 35	4	13.33	0	0	2	100	0	0.00	6	15.00
TOTAL	30	100	6	100	2	100	2	100	40	100
Chi square	14.38									
p-value	0.03									
Significant	Significant									

Table 2 shows the percentage of patients in age groups, <25, 26-30, 32-35 are 20%, 65% and 15% respectively

AGE OF STUDY SUBJECTS

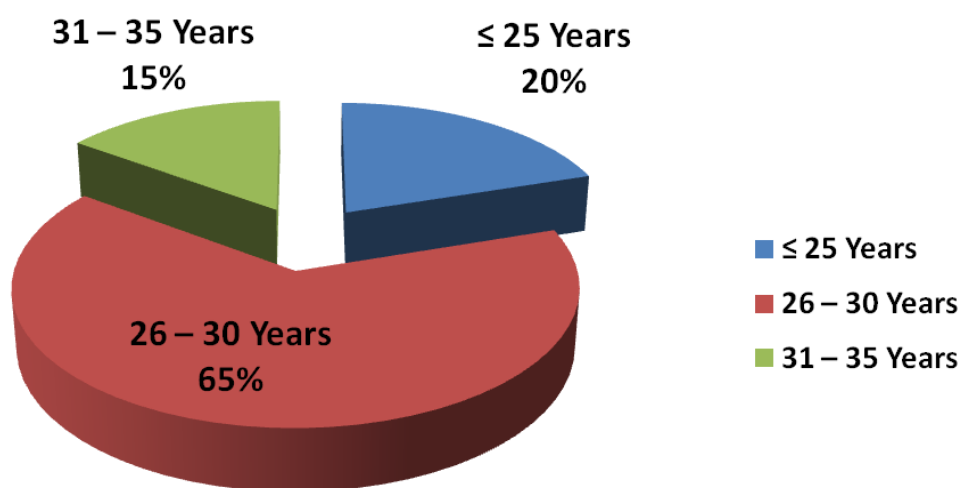


CHART NO. 1 age of study subjects

AGE & TYPE OF PERINEAL TEAR

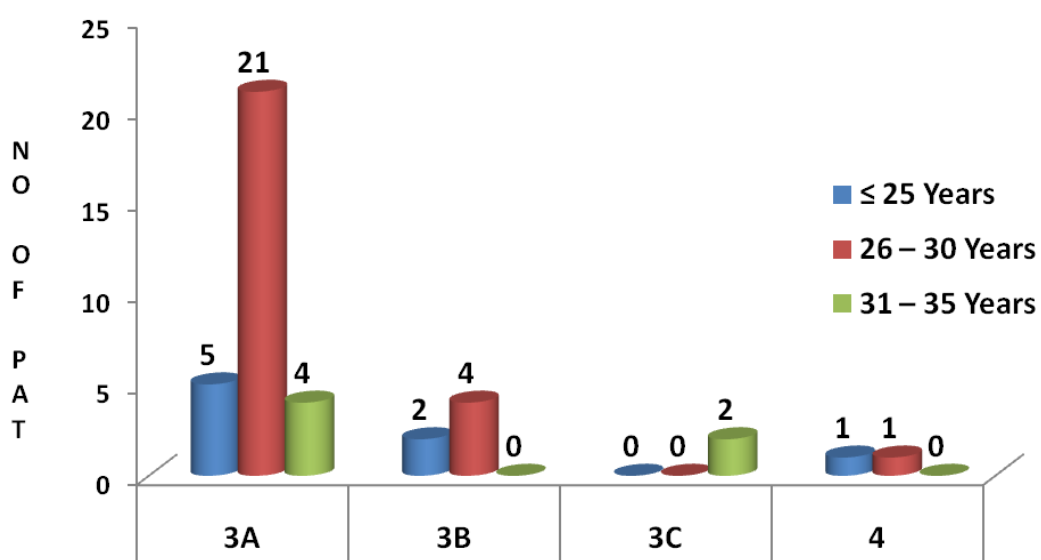


TABLE-3 GRAVIDA WITH TYPE OF PERINEAL TEAR

GRAVIDA	TYPE OF PERINEAL TEAR								TOTAL	
	3A		3B		3C		4			
	N	%	N	%	N	%	N	%	N	%
PRIMI	25	83.33	4	66.67	0	0.00	2	100	31	77.50
MULTI	5	16.67	2	33.33	2	100	0	0.00	9	22.50
TOTAL	30	100	6	100	2	100	2	100	40	100
Chi square	8.46									
p-value	0.04									
Significant	Significant									

Table 3 shows 77.50% patients who had OASIS were primigravida whereas 22.50% patients were multigravida and there is a significant association between primigravida and perineal tear

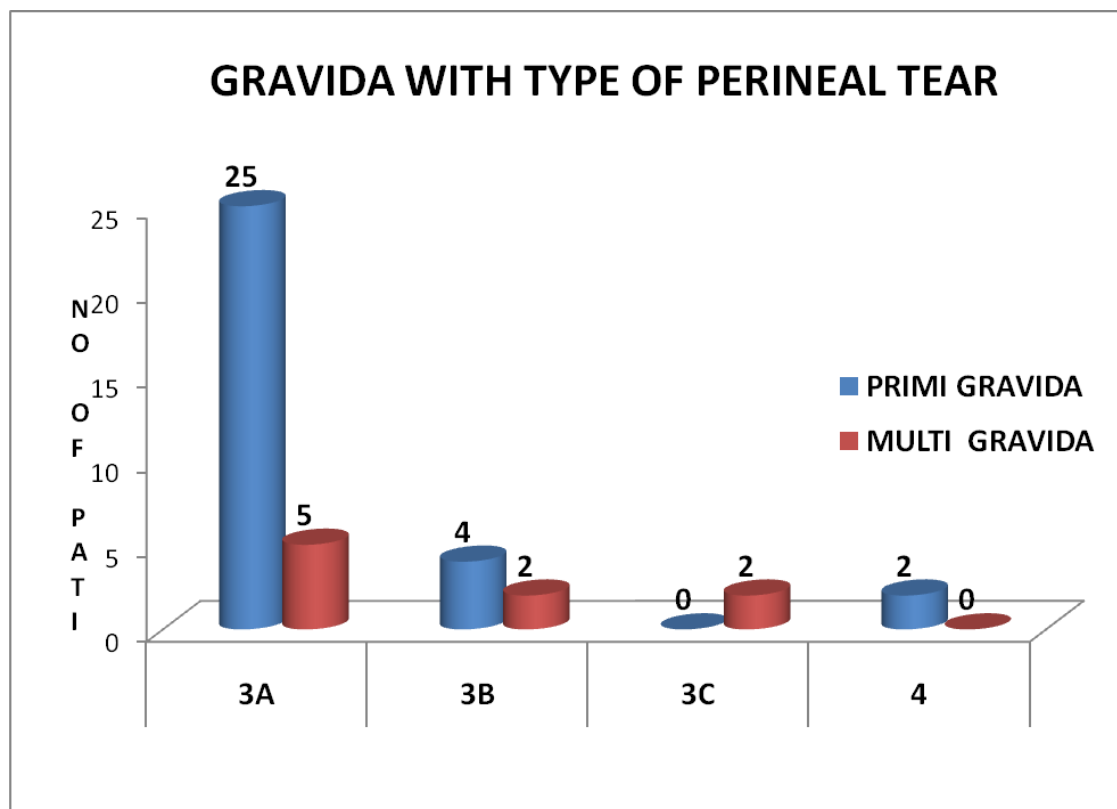


CHART NO.2 GRAVIDA WITH TYPE OF PERINEAL TEAR

TABLE-4 GESTATIONAL AGE WITH TYPE OF PERINEAL TEAR

Gestational Age	TYPE OF PERINEAL TEAR								TOTAL	
	3A		3B		3C		4			
	N	%	N	%	N	%	N	%	N	%
< 40 Weeks	17	56.67	3	50.00	1	50.00	1	50.00	22	55.00
≥ 40 Weeks	13	43.33	3	50.00	1	50.00	1	50.00	18	45.00
TOTAL	30	100	6	100	2	100	2	100	40	100
Chi square	0.14									
p-value	0.99									
Significant	Not Significant									

Table 4 shows 55% and 45% of the patient were < 40 weeks and ≥40 weeks respectively of the period of gestational age.

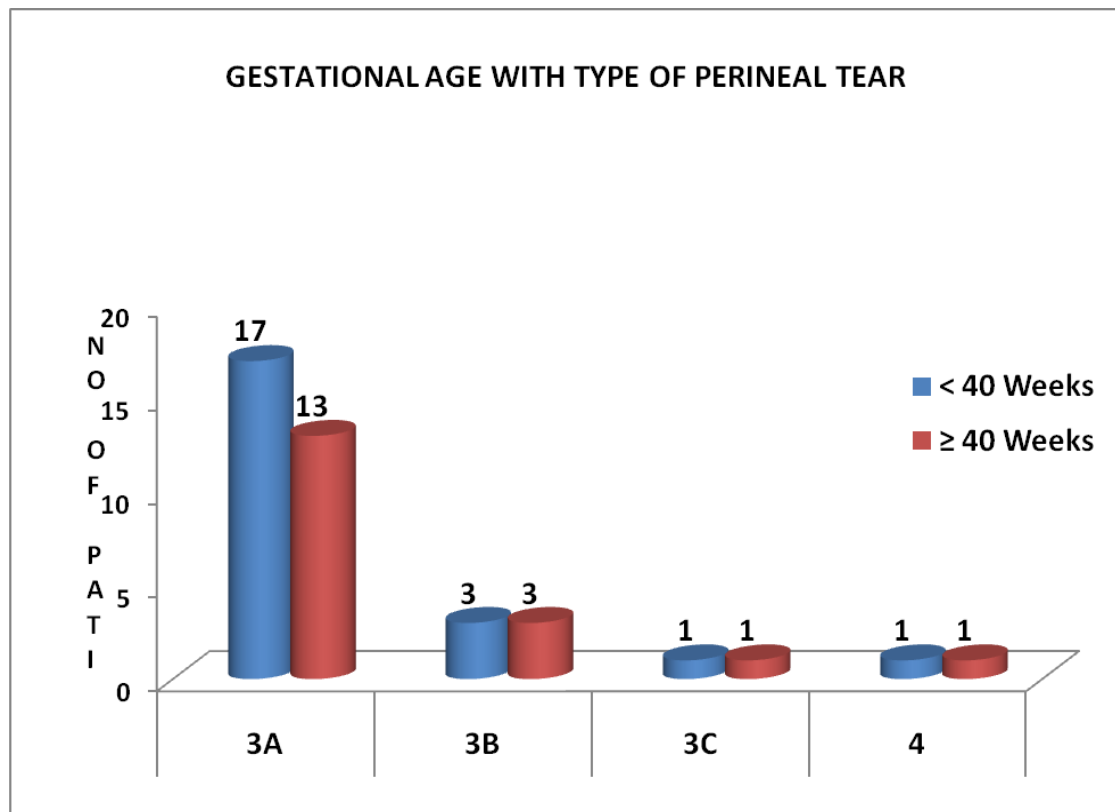


CHART NO. 3 GESTATIONAL AGE WITH TYPE OF PERINEAL TEAR

TABLE-5 BIRTH WEIGHT WITH TYPE OF PERINEAL TEAR

Birth Weight	TYPE OF PERINEAL TEAR								TOTAL	
	3A		3B		3C		4			
	N	%	N	%	N	%	N	%	N	%
< 3.5 Kg	19	63.33	3	50.00	0	0	0	0.00	22	55.00
≥ 3.5 Kg	11	36.67	3	50.00	2	100	2	100	18	45.00
TOTAL	30	100	6	100	2	100	2	100	40	100
Chi square	5.79									
p-value	0.12									
Significant	Not Significant									

Table 5 shows 22 patients (55%) and 18 patients(45%) have their babies birth weight <3.5 kg and ≥3.5 kg respectively.

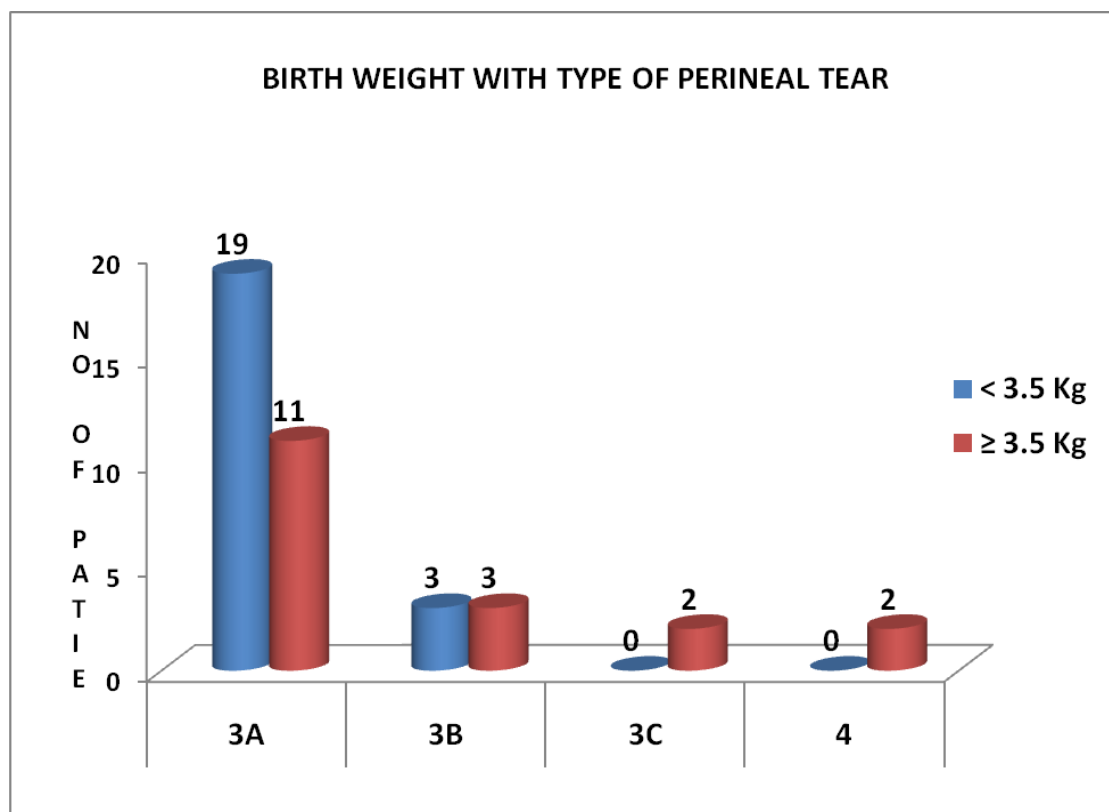


CHART NO. 4 BIRTH WEIGHT WITH TYPE OF PERINEAL TEAR

Table;6 OCCIPITO POSTERIOR POSTION WITH TYPE OF PERINEAL TEAR

OCCIPITO POSTERIOR POSITION	TYPE OF PERINEAL TEAR								TOTAL	
	3A		3B		3C		4			
	N	%	N	%	N	%	N	%	N	%
YES	6	20.00	2	33.33	2	100	2	100	12	30.00
NO	24	80.00	4	66.67	0	0.00	0	0.00	28	70.00
TOTAL	30	100	6	100	2	100	2	100	40	100
Chi square	10.80									
p-value	0.01									
Significant	Significant									

Table 6 shows 30% patients with perineal tear had persistent occipito posterior position and 70% patients did not have occipito posterior position.

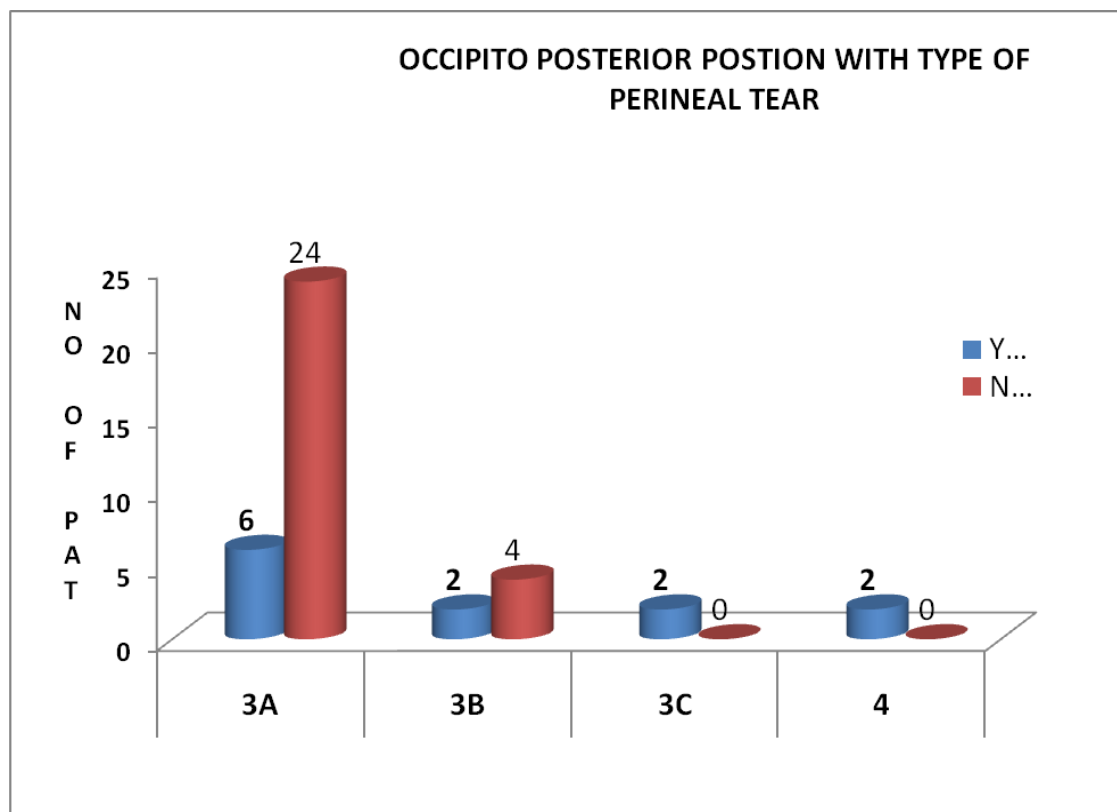


TABLE-7**Duration of 1st Stage WITH TYPE OF PERINEAL TEAR**

Duration of 1 st Stage in hrs	TYPE OF PERINEAL TEAR								TOTAL	
	3A		3B		3C		4			
	N	%	N	%	N	%	N	%	N	%
5 – 7	1	3.33	0	0.00	0	0.00	0	0.00	1	2.50
7 – 9	10	33.33	2	33.33	0	0.00	0	0.00	12	30.00
9 – 11	10	33.33	3	50.00	1	50.00	0	0.00	14	35.00
11 – 13	6	20.00	1	16.67	0	0.00	2	100	9	22.50
13 – 15	3	10.00	0	0.00	1	50.00	0	0.00	4	10.00
TOTAL	30	100	6	100	2	100	2	100	40	100
Chi square	12.87									
p-value	0.38									
Significant	Not Significant									

Table 7 shows 2.50%, 30%, 35%, 22.50%, 10.00% patients have duration of 1st stage of labour 5-<7, 7-<9, 9-<11, 11-<13, 13-<15 hours respectively which is statistically not significant.

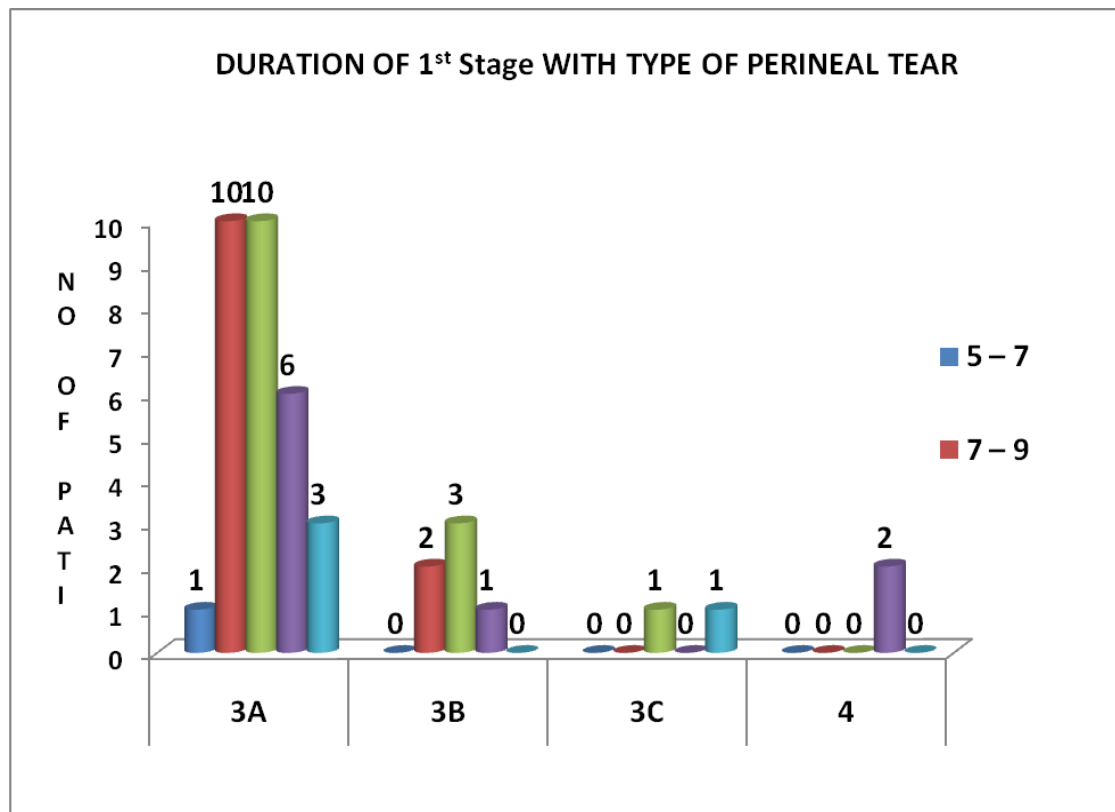


CHART NO.5 DURATION OF 1st STAGE OF LABOUR AND TYPE OF PERINEAL TEAR

TABLE-8**DURATION OF 2nd Stage WITH TYPE OF PERINEAL TEAR**

Duration of 2nd Stage	TYPE OF PERINEAL TEAR								TOTAL	
	3A		3B		3C		4			
	N	%	N	%	N	%	N	%	N	%
< 30 Mints	1	33.33	0	0.00	0	0.00	0	0.00	1	2.50
45 – 59 Minutes	1	33.00	0	0.00	0	0.00	1	50.00	2	5.00
60 – 74 Minutes	15	50.00	2	33.33	0	0.00	0	0.00	17	42.50
75 – 89 Minutes	9	30.00	3	50.00	0	0.00	1	50.00	13	32.50
≥90 Minutes	4	13.33	1	16.67	2	100	0	0.00	7	17.50
TOTAL	30	100	6	100	2	100	2	100	40	100
Chi square	21.11									
p-value	0.05									
Significant	Significant									

Table 8 shows 1%, 2% ,17%, 13% and 7% patients have duration of 2nd stage of labour <30 mins, 45 -59 mins, 60 – 74 mins, 75 – 89 mins and ≥90 mins respectively which is statistically significant.

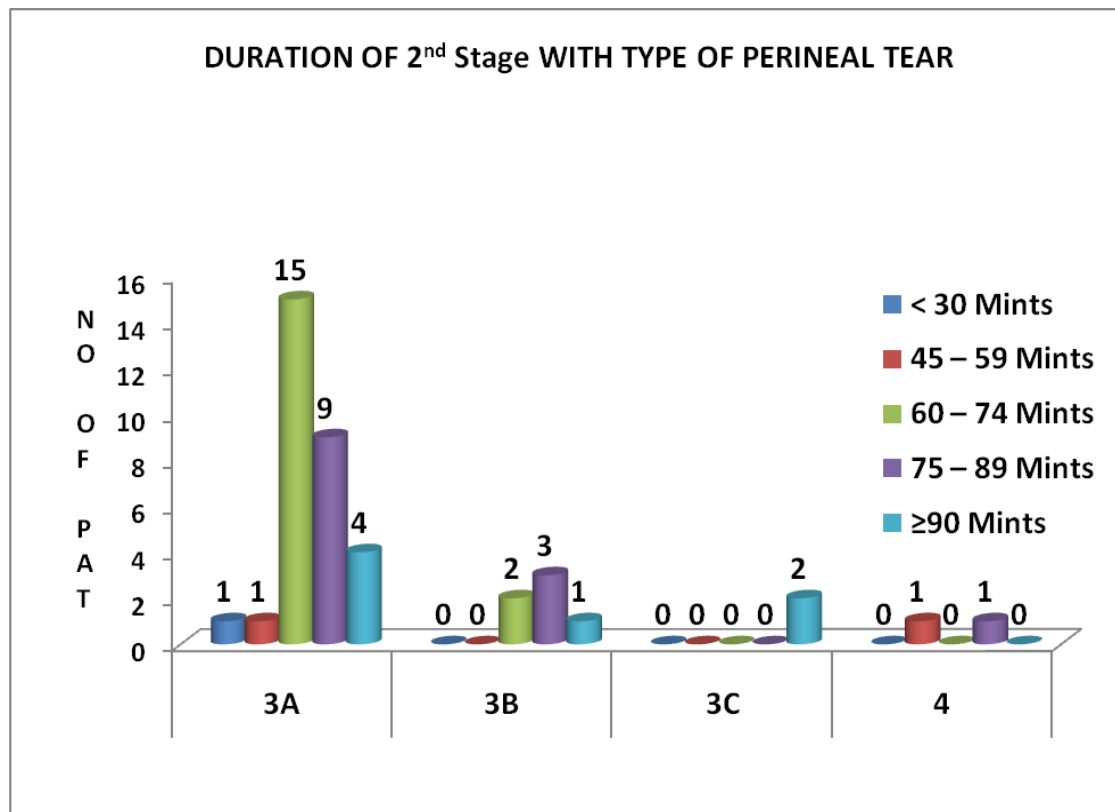


CHART NO.6 duration of 2nd stage of labour with type of perineal tear

TABLE-9**FORCEPS WITH PERINEAL TEAR**

FORCEPS	TYPE OF PERINEAL TEAR								TOTAL	
	3A		3B		3C		4			
	N	%	N	%	N	%	N	%	N	%
NORMAL VAGINAL DELIVERY	26	86.67	4	66.67	0	0.00	1	50.00	31	77.50
FORCEPS DELIVERY	4	13.33	2	33.33	2	100	1	50.00	9	22.50
TOTAL	30	100	6	100	2	100	2	100	40	100
Chi square	9.00									
p-value	0.02									
Significant	Significant									

Table 9 shows 77.50% and 22.50% patient with perineal tear were delivered by normal vaginal delivery and forceps delivery respectively and there is significant association between forceps delivery and perineal tear.

chart no 7: Forceps delivery with type of perineal tear.....

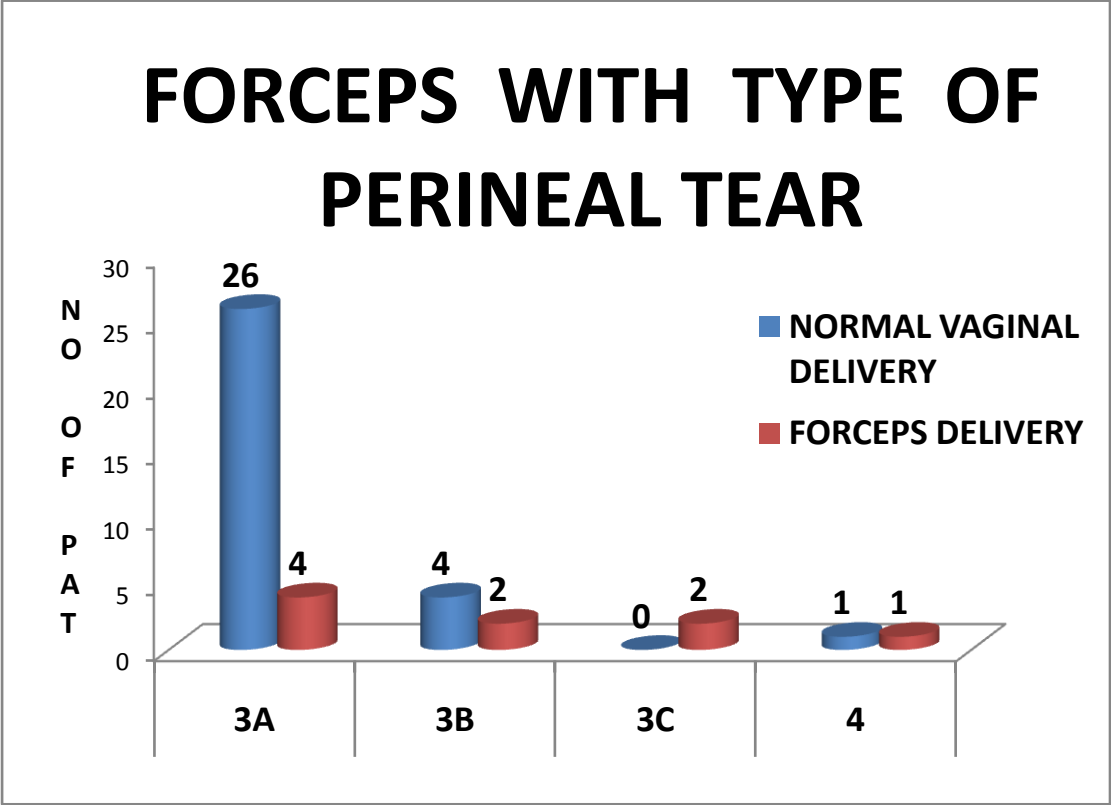


Table 10: Mode of Delivery at KMC Hospital

Mode of Delivery	Number (N)	Percentage (%)
Normal Vaginal Delivery	5599	95.8%
Forceps Delivery	241	4.1%
Total	5840	100%

Table 10 shows at KMC hospital, out of 5840 patients, 5599 patients (95.8%) delivered normal vaginally and 241 patients (4.1%) by forceps.

Table- 11 : Mode of Delivery and Incidence of Tears

Mode of Delivery	TOTAL Number (N)	No of Tears	Incidence Rate
Normal Vaginal Delivery	5599	31	0.5%
Forceps Delivery	241	9	3.73%
Total			

Table 11 shows incidence of perineal tear in normal vaginal delivery, and forceps delivery were 0.5% and 3.73% respectively.

TABLE-12 Shoulder Dystocia with perineal tear

Shoulder Dystocia	TYPE OF PERINEAL TEAR								TOTAL	
	3A		3B		3C		4			
	N	%	N	%	N	%	N	%	N	%
Yes	2	6.67	2	33.33	2	100	0	0.00	6	15.00
No	28	93.33	4	66.67	0	0.00	2	100	34	85.00
TOTAL	30	100	6	100	2	100	2	100	40	100
Chi square	14.92									
p-value	0.002									
Significant	Significant									

Table 12 shows those who have perineal tear.15% patients had shoulder dystocia whereas 85% patient did not have shoulder dystocia.

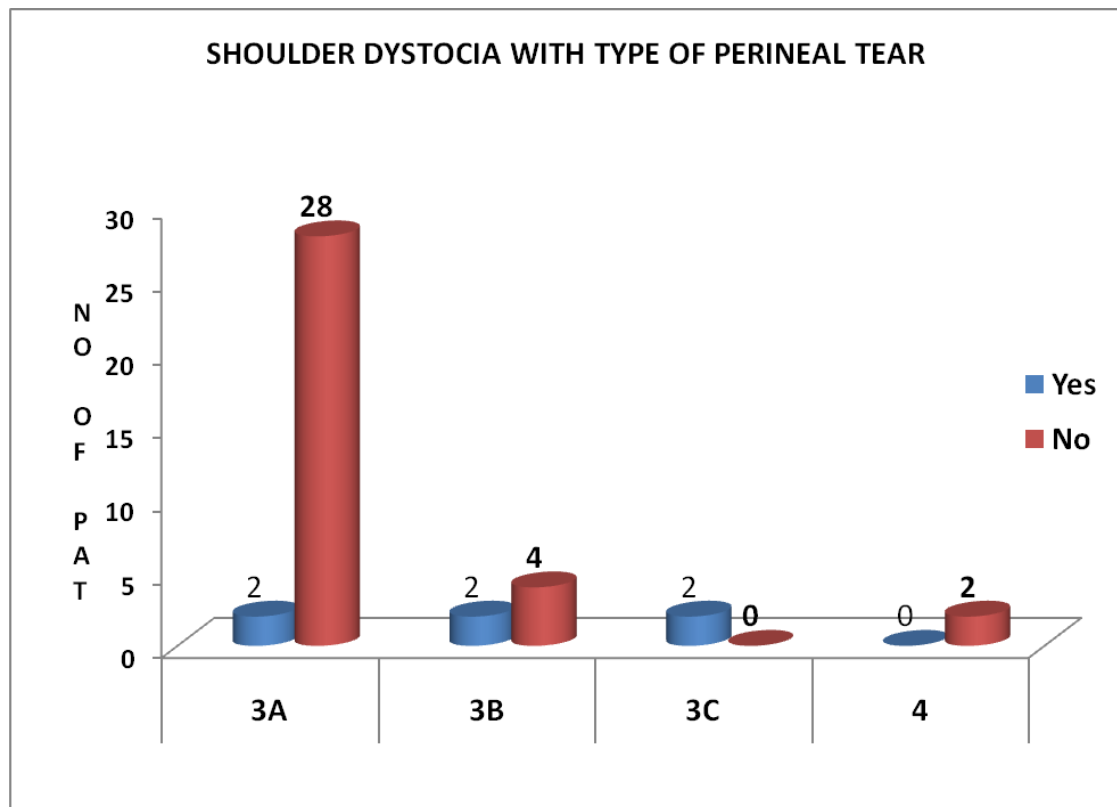


TABLE-13**OUT COME (ANAL INCONTINEUCE) WITH PERINEAL TEAR**

OUT COME	TYPE OF PERINEAL TEAR								TOTAL	
	3A		3B		3C		4			
	N	%	N	%	N	%	N	%	N	%
NO	30	100	6	100	0	0.00	2	100	38	95.00
GAS	0	0.00	0	0.00	2	100	0	0	2	5.00
TOTAL	30	100	6	100	2	100	2	100	40	100
Chi square	40.00									
p-value	0.0001									
Significant	Significant									

Out of 40 patients at 1st month postpartum follow up 2(5.25%)patients had complaints of flatus incontinence and 1(2.63%) patient had liquid incontinence and none of the patient had solid incontinence.

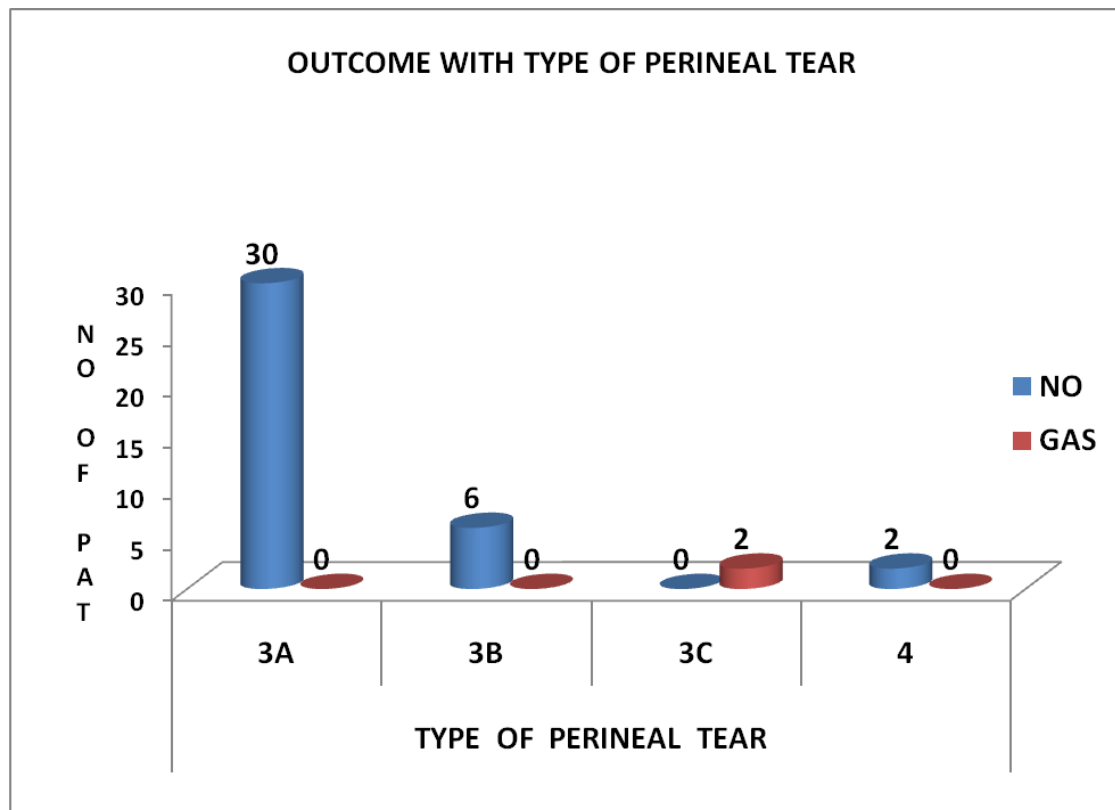


Chart NO. 8 out come with type of perineal tear with anal incontinence
(one= no incontinence, two= flatus incontinence, three= liquid incontinence)

At 3 months postpartum follow up, 2 (2.5%) patients had flatus incontinence and 38 patients were asymptomatic.

DISCUSSION

DISCUSSION

Obstetric anal sphincter injuries (OASIS) which is a major risk factor for anal incontinence, adversely affects woman's physical and social life. OASIS is grossly underreported because of lack of awareness and knowledge. Because of that, there is a huge variation in incidence of OASIS reported in different countries.

The present study is prospective observational study to assess incidence and various known risk factors associated with OASIS and symptomatic outcome of its primary repair in terms of anal incontinence.

During the study period of 2 years from July 2014 to May 2016 a total of 5840 patients delivered vaginally at KMC hospital, Chennai.

Out of 5840 patients, 40 patients were diagnosed clinically as 3rd and 4th degree perineal tear (38 as 3rd degree and 2 patients as 4th degree).

So, overall incidence of OASIS in present study is 0.68%.

In a study done by Vasanth Andrews et al³⁷, Charlotte Jander et al⁴⁰, Gottvall et al⁴¹, Nandini Gupta et al⁴² and Williams et al⁴³ the incidence of OASIS were 25%, 3.7%, 3.5%, 0.8% and 0.6% respectively.

Study	Incidence
Vasanth Andrews et al ³⁷	25%
Charlotte Jander et al ⁴⁰	3.7%
Gottvall et al ⁴¹	3.5%
Nandini Gupta et al ⁴²	0.8%
Williams et al ⁴³	0.6%
Current study	2.59%

In our study mean age of patient is 27.73 years.

In the study conducted by Williams et al,⁴³ mean age of patient was 27 year.

In our study there are significantly more number of patients (65%) in 26-30 years group than <25 Years (20%) and 31-35 Years (15%). It may be because in Indian population (and in KMC hospital, Chennai) maximum number of the woman get pregnant during this age (25 -30 years).

Older age is considered as a risk factor because ageing leads to decreased elasticity of perineum. In Urganci et al³⁹ study, a maternal age >25

years was a significant risk factor. In the study by Charlotte Jander et al⁴⁰ maternal age >35 years (OR 4.97) was a significant independent risk factor.

Probable explanation is that in European countries women give birth at older age than compared to Indian women. In Nandini Gupta et al⁴², study there was no association between age and anal sphincter injury.

In our study, out of 40 patients with OASIS, 31(77.50%) patients are primigravida and 9 patients(22.50%) are multigravida with p value=0.04, which shows primigravida were significantly associated with OASIS.

Primigravida is considered as a risk factor for OASIS because of the relatively inelasticity of perineum in primigravida compared to multigravida.

In Charlotte Jander et al⁴⁰ study primigravida was an independent risk factor (OR: 7.55, 95% CI: 3.72-15.29). In a study by De Leeuw et al,⁴⁴ primigravida was a highly associated risk factor (OR: 2.39, 95% CI: 2.24-2.56). In the study conducted by Gottvall et al,⁴¹ primigravida was major risk factor (OR:2.12, 95%CI: 2.55-4.25).

In current study, 22(55%) patients' gestational age is between 40 weeks to 40weeks+6 days. Some studies have mentioned >42 weeks of gestational age as a risk factor.

In a study by Nandini Gupta et al⁴² mean gestational age of patient was 40.2 weeks \pm 1.3(SD) and advanced gestational age (OR 1.3, 95%CI: 1.0-1.6) and postdates were significant risk factors (OR: 1.8, 95% CI: 1.3-2.6). In a study by Vasanth Andrews et al³⁷ for gestational >40 weeks p value was 0.026 and was statistically significant. In a study by Eskandar et al⁴⁵ mean gestational age of patient was 39.7 weeks.

In the present study number of patients with birth weight <3.5 kg and \geq 3.5 kg groups are 22(55%) and 18(45%) respectively.

In a study by Vasanth Andrews et al³⁷ higher birth weight was a significant risk factor for perineal tear. In Charlotte Jander et al⁴⁰ study, birth weight >4kg was a significant risk factor (OR:3.98, 95% CI: 2.12 – 7.47). In a study conducted by Gottvall et al⁴¹ also birth weight >4kg was a significant risk factor for perineal tear (OR: 2.12, 95% CI: 1.64 -2.72).

>95th percentile growth of fetus is considered as macrosomic baby. In the west it is > 4kg but based on our ethnicity, in Indian population mean birth weight is lower than western population. So instead of 4 kg we took 3.5 kg as a risk factor.

In our study 12 patients (21.05%) who have OASIS had persistent occipitoposterior position and 28 patients (78.95%) did not have occipitoposterior position.

In Gottvall et al⁴¹ study there was no association between non occipitoanterior and perineal tear (OR: 0.75, 95% CI: 0.87-2.32). However in a study by Eskandar et al⁴⁵ occipitoposterior was significantly associated with perineal tear ($p < 0.0001$).

In our hospital set up, once patient enters into active stage of labour, labour augmentation is done by artificial rupture of membranes and oxytocin augmentation

In our study we could not find any association between duration of 1st stage and perineal tear.

Nandini Gupta et al⁴² also took prolonged 1st stage of labour but could not find any significance between prolonged 1st stage of labour and perineal tear.

In the present study, there is a significant association between 2nd stage of labour and perineal tear. Stretching of perineum for a longer period of time may lead to ischemia, which may increase the risk of perineal rupture.

Similar results were also shown in Vasanth Andrews et al³⁷, Gottvall et al⁴¹, Nandini Gupta et al⁴² and J.W. Leeuw et al⁴⁴ studies.

Role of episiotomy is controversial in causing anal sphincter tear. In our hospital we give routine episiotomy for all term primigravida patient and select multigravida patient.

In our study, for all patients with anal sphincter tear we have given right/left mediolateral episiotomy, however the angle of episiotomy was not controlled for 30 to 60 degree but it was done on assumption.

Vasanth Andrews et al³⁷ said mediolateral episiotomy is a risk factor but it may be the inappropriate technique. I Gurol Urganci et al³⁹ found episiotomy as a protective for anal sphincter tear.

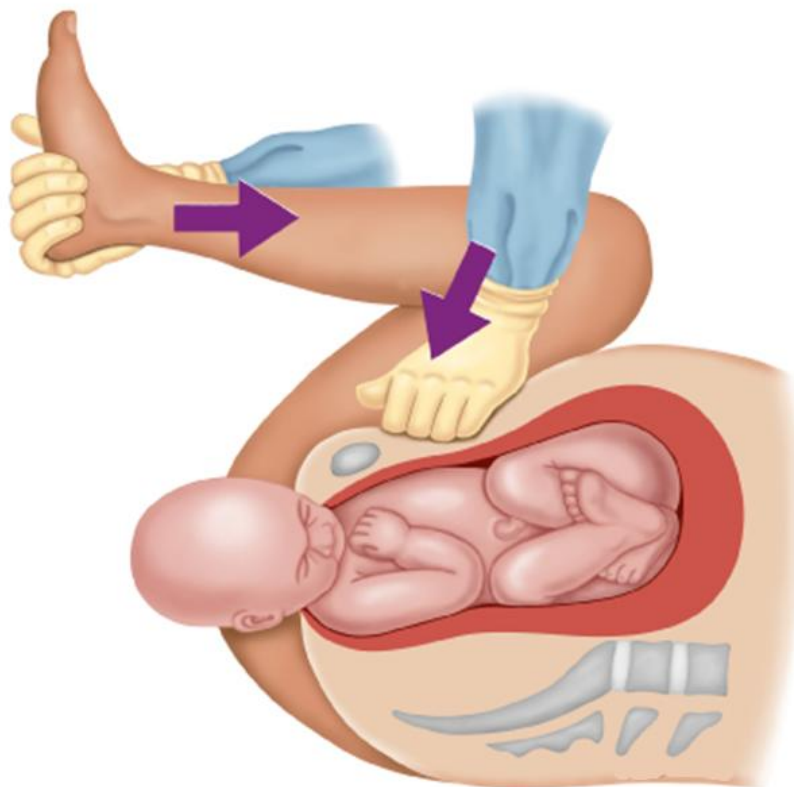
Similarly J.W. Leeuw et al⁴⁴ also found mediolateral episiotomy was strongly protective for anal sphincter tear. Whereas Williams et al⁴³ found mediolateral episiotomy was significantly associated with anal sphincter tear.

In the current study, out of 40 patients, 31 (77.50%) patients were delivered vaginally and 9 patients were delivered with forceps with $p=0.02$.. So our results show, that forceps has 3.73% chances of having anal sphincter tear and normal vaginal delivery has 0.5% chances of perineal tear.

So from the above results we can say that forceps has got the highest risk for anal sphincter tear compared to normal vaginal delivery

Almost all studies like Vasanth Andrews et al³⁷, I Gurol Urganci et al³⁹, J.W. Leeuw et al⁴⁴, Charlotte Jander et al⁴⁰ etc. have found instrumental delivery as a significant risk factor for anal sphincter tear.

According to our hospital's norm, if we anticipate shoulder dystocia, we follow MacRobert's maneuver which has 95% success rate. In case of failed Mc Robert's maneuver we deliver baby by delivery of posterior shoulder.



PICTURE: MC ROBERT'S MANEUVER

In the current study, 6(15%) patients with OASIS had shoulder dystocia for whom we followed McRobert's maneuver. A.M . Roos et al³⁸ and Charlotte Jander et al⁴⁰ were not able to find association between shoulder dystocia and perineal tear.

Vasanth Andrews et al³⁷ and I Gurol Urganci et al³⁹ found shoulder dystocia as a risk factor for perineal tear.

After repair of OASIS, we followed up the patient and asked the woman to fill up the questionnaire at 1 month postpartum and at 3 months postpartum.

Out of the 40 patients, 2(5.25%) patients had complaint of flatus incontinence and 1(2.63%) patient had liquid incontinence.

But at 3 month postpartum 2(2.5%) patients had flatus incontinence and 38 patients (97.5%) were asymptomatic. Because muscle healing takes time almost 2 to 3 months, could be the reason behind good outcome at 3 month compared to 1 month.

A.M . Roos et al³⁸ found (at mean 9 weeks postpartum) patient with major perineal tear (3c/4) had significant poor outcome in term of defecatory symptoms, quality of life and anal manometry.

They found more chances of endoanal sonographic defect after major perineal tear compared to minor (3a/3b) which was a probable cause of poor outcome of repair.

In a meta-analysis by Allison La Cross et al⁴⁶ found both episiotomy and third/ fourth degree perineal laceration were significantly associated with anal incontinence. Anna Palm et al⁴⁷ found patient with anal sphincter tear were significantly associated with anal incontinence (during follow up 15 month to 8 years).

Sting Norderval et al⁴⁸ for whom median follow up was 25 months also found patients had significant anal incontinence if they had anal sphincter tear.

SUMMARY

This is a prospective observation study conducted in Kilpauk Medical College & Hospital, Chennai. The aim of this study is to determine incidence and risk factors of obstetric anal sphincter injuries during vaginal delivery and symptomatic outcome of primary repair. 40 patients with obstetrics anal sphincter injury are included in this study

The following observations are made in the study:

1. Incidence of patient with obstetric anal sphincter injury is 0.67%.
2. Mean age of patient with OASIS is 27.73 years and more number of patients are in age group 26 to 30 year.
3. Primigravida are more (77.5%) compared to multigravida (22.5%) which is statistically significant.
4. Patients with perineal tear are almost equally distributed (22 vs 18) between <40 weeks and ≥ 40 weeks
5. Patients are almost equally distributed (22 vs 18) between <3.5 kg and ≥ 3.5 kg babies.
6. 12 patients had occipitoposterior position and 28 patients had occipitoanterior position.
7. Longer duration of 1st stage of labour is not significantly associated with perineal tear.

8. Longer duration of 2nd stage of labour is significantly associated with perineal tear.
9. In our study all patients got mediolateral episiotomy (angle of episiotomy was not controlled between 30 to 60 degree to midline)
10. Forceps delivery has the highest chances of perineal tear(3.73%), compared to normal vaginal delivery(0.5%).
11. In the current study, 6 patients (13.16%) had shoulder dystocia during delivery and all 6 patients were managed by McRobert's maneuver.
12. In the present study after primary repair of OASIS at 1 month follow up only 5.25% patients had flatus incontinence and only 2.63% patients had liquid incontinence and at 3 months postpartum follow up 97.74% patients were asymptomatic and only 2.63% patient had flatus incontinence.

CONCLUSION

This study concluded that incidence of OASIS in KMC hospital, Chennai is 0.67%. We found primigravida, prolonged 2nd stage of labour and instrumental delivery (axis traction forceps) are significantly associated with OASIS. Correct identification of perineal layers and its proper repair gives encouraging results in terms of anal incontinence.

LIMITATIONS

- 1) A small sample size of the patients and a low power of study
- 2) Angle of episiotomy is not controlled between 30 to 60 degree which is considered as a safe zone
- 3) A short term study and no data on symptomatic outcome on long follow up
- 4) Head circumference of new born baby could have taken as a risk factor for OASIS
- 5) Symptomatic outcome measured subjectively and endoanal ultrasound could have been used to assess the objective outcome

RECOMMENDATIONS

1. Episiotomy angle should be decided possibly with a marker pan during delivery before perineum distends at an angle between 40 and 60 degrees to prevent post-delivery medialisation of episiotomy angle
2. Studies on large number of patients with long term follow up are require and preferably to be assessed objectively with endoanal sonography if feasible
3. There should be a dedicated perineal clinic which deals with various perineal problems
4. We should pay attention to providing perineal support during the delivery of head and shoulder which could be protective for perineal tear
5. Training of midwives and resident doctors in proper identification and repair of OASIS is very important to prevent long term consequences of OASIS
6. Regular audit on OASIS to be conducted

BIBLIOGRAPHY

BIBLIOGRAPHY

1. McCandlish R, Bowler U, Asten H, Berridge G, Winter C, Sames L, Garcia J, Renfrew M, Elbourne D. A randomised controlled trial of care of the perineum during second stage of normal labour. *BJOG: an international journal of obstetrics & gynaecology*. 1998 Dec 1;105(12):1262-72.
2. Wagner M. Pursuing the birth machine: the search for appropriate birth technology. Ace Graphics; 1994.
3. Statistical Bulletin – NHS Maternity Services. London: Department of Health, 2003.
4. Graves EJ, Kozak LJ. National hospital discharge survey: annual summary, 1996. Vital and health statistics. Series 13, Data from the National Health Survey. 1999 Jan(140):i-v.
5. Bols EM, Hendriks EJ, Berghmans BC, Baeten CG, Nijhuis JG, De Bie RA. A systematic review of etiological factors for postpartum fecal incontinence. *Acta obstetrica et gynecologica Scandinavica*. 2010 Mar 1;89(3):302-14.
6. Zetterström J, López A, Holmström B, Nilsson BY, Tisell Å, Anzén B, Mellgren A. Obstetric sphincter tears and anal incontinence: an observational follow-up study. *Acta obstetrica et gynecologica Scandinavica*. 2003 Oct 1;82(10):921-8.

7. Sultan AH, Kamm MA, Hudson CN, Thomas JM, Bartram CI. Anal-sphincter disruption during vaginal delivery. *New England Journal of Medicine*. 1993 Dec 23;329(26):1905-11.
8. Zetterström J, Lopez A, Anzen BO, Norman M, Holmström B, Mellgren A. Anal sphincter tears at vaginal delivery: risk factors and clinical outcome of primary repair. *Obstetrics & Gynecology*. 1999 Jul 1;94(1):21-8.
9. Blondel B, Alexander S, Bjarnadóttir RI, Gissler M, Langhoff-Roos J, Novak-Antolič Ž, Prunet C, Zhang WH, Hindori-Mohangoo AD, Zeitlin J. Variations in rates of severe perineal tears and episiotomies in 20 European countries: a study based on routine national data in Euro-Peristat Project. *Acta obstetrica et gynecologica Scandinavica*. 2016 Apr 1.
10. Pyykönen A, Gissler M, Jakobsson M, Lehtonen L, Tapper AM. The rate of obstetric anal sphincter injuries in Finnish obstetric units as a patient safety indicator. *European Journal of Obstetrics & Gynecology and Reproductive Biology*. 2013 Jul 31;169(1):33-8.
11. Schorge J, Schaffer J, Halvorson L, Hoffman B, Bradshaw K, Cunningham F. *Williams gynecology*.
12. Dunn D, Beilman G, Brunicardi FC. in *Schwartz's Principles of Surgery*.

13. Ingraham HA, Gardner MM, Heus EG. A report on 159 third degree lacerations. *American journal of obstetrics and gynecology*. 1949 Apr;57(4):730.
14. Roberts PL, Collier JA, Schoetz Jr DJ, Veidenheimer MC. Manometric assessment of patients with obstetric injuries and fecal incontinence. *Diseases of the Colon & Rectum*. 1990 Jan 1;33(1):16-20.
15. Haadem K, Ohrlander S, Lingman G. Long-term ailments due to anal sphincter rupture caused by delivery—a hidden problem. *European Journal of Obstetrics & Gynecology and Reproductive Biology*. 1988 Jan 31;27(1):27-32.
16. Oberwalder M, Connor J, Wexner SD. Meta-analysis to determine the incidence of obstetric anal sphincter damage. *British journal of surgery*. 2003 Nov 1;90(11):1333-7.
17. Thacker SB, Banta HD. Benefits and risks of episiotomy: an interpretative review of the English language literature, 1860-1980. *Obstetrical & gynecological survey*. 1983 Jun 1;38(6):322-38.
18. Fernando RJ, Sultan AH, Radley S, Jones PW, Johanson RB. Management of obstetric anal sphincter injury: a systematic review & national practice survey. *BMC Health Services Research*. 2002 May 13;2(1):1.
19. Angioli R, Gómez-Marín O, Cantuaria G, O'Sullivan MJ. Severe perineal lacerations during vaginal delivery: the University of Miami

- experience. American journal of obstetrics and gynecology. 2000 May 31;182(5):1083-5.
20. Fenner DE, Genberg B, Brahma P, Marek L, DeLancey JO. Fecal and urinary incontinence after vaginal delivery with anal sphincter disruption in an obstetrics unit in the United States. American journal of obstetrics and gynecology. 2003 Dec 31;189(6):1543-9.
 21. Handa VL, Pannu HK, Siddique S, Gutman R, VanRooyen J, Cundiff G. Architectural differences in the bony pelvis of women with and without pelvic floor disorders. Obstetrics & Gynecology. 2003 Dec 1;102(6):1283-90.
 22. Coats PM, Chan KK, Wilkins M, Beard RJ. A comparison between midline and mediolateral episiotomies. BJOG: An International Journal of Obstetrics & Gynaecology. 1980 May 1;87(5):408-12.
 23. Sultan AH, Kamm MA, Bartram CI, Hudson CN. 3rd degree Tear-incidence, risk factors and poor clinical outcome after primary sphincter repair. In Gut 1992 Jan 1 (Vol. 33, No. 2, pp. S29-S29). BRITISH MED ASSOC HOUSE, TAVISTOCK SQUARE, LONDON, ENGLAND WC1H 9JR: BRITISH MED JOURNAL PUBL GROUP.
 24. Harkin R, Fitzpatrick M, O'Connell PR, O'Herlihy C. Anal sphincter disruption at vaginal delivery: is recurrence predictable?. European Journal of Obstetrics & Gynecology and Reproductive Biology. 2003 Aug 15;109(2):149-52.

25. No GT. 29 “The Management of third and fourth degree perineal tears”.
London: Royal College of Obstetricians & Gynaecologists. 2007.
26. Sultan AH. Primary repair of obstetric anal sphincter injury. Textbook
of female urology and urogynaecology. London: ISIS Medical Media.
2006.
27. Green JR, Soohoo SL. Factors associated with rectal injury in
spontaneous deliveries. *Obstetrics & Gynecology*. 1989 May
1;73(5):732-8.
28. Poen AC, Felt-Bersma RJ, Dekker GA, Deville W, Cuesta MA,
Meuwissen SG. Third degree obstetric perineal tears: risk factors and
the preventive role of mediolateral episiotomy. *BJOG: An International
Journal of Obstetrics & Gynaecology*. 1997 May 1;104(5):563-6.
29. Anthony S, Buitendijk SE, Zondervan KT, Rijssel EV, Verkerk PH.
Episiotomies and the occurrence of severe perineal lacerations. *BJOG:
An International Journal of Obstetrics & Gynaecology*. 1994 Dec
1;101(12):1064-7.
30. Sartore A, De Seta F, Maso G, Pregazzi R, Grimaldi E, Guaschino S.
The effects of mediolateral episiotomy on pelvic floor function after
vaginal delivery. *Obstetrics & Gynecology*. 2004 Apr 1;103(4):669-73.
31. Eogan M, Daly L, O'Connell PR, O'Herlihy C. Does the angle of
episiotomy affect the incidence of anal sphincter injury?*. *BJOG: An
International Journal of Obstetrics & Gynaecology*. 2006 Feb
1;113(2):190-4.

32. Haylen BT, De Ridder D, Freeman RM, Swift SE, Berghmans B, Lee J, Monga A, Petri E, Rizk DE, Sand PK, Schaer GN. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. *International urogynecology journal*. 2010 Jan 1;21(1):5-26.
33. Snooks SJ, Henry MM, Swash M. Faecal incontinence due to external anal sphincter division in childbirth is associated with damage to the innervation of the pelvic floor musculature: a double pathology. *BJOG: An International Journal of Obstetrics & Gynaecology*. 1985 Aug 1;92(8):824-8.
34. Sandridge DA, Thorp Jr JM, Roddenberry P, Kuller J, Wild J. Vaginal delivery is associated with occult disruption of the anal sphincter mechanism. *American journal of perinatology*. 1997 Oct;14(9):527-33.
35. Sultan AH, Kamm MA, Hudson CN, Thomas JM, Bartram CI. Anal-sphincter disruption during vaginal delivery. *New England Journal of Medicine*. 1993 Dec 23;329(26):1905-11.
36. Belmonte-Montes C, Hagerman G, Vega-Yepez PA, Hernández-de-Anda E, Fonseca-Morales V. Anal sphincter injury after vaginal delivery in primiparous females. *Diseases of the colon & rectum*. 2001 Sep 1;44(9):1244-8.

37. Andrews V, Sultan AH, Thakar R, Jones PW. Risk factors for obstetric anal sphincter injury: a prospective study. *Birth*. 2006 Jun 1;33(2):117-22.
38. Roos AM, Thakar R, Sultan AH. Outcome of primary repair of obstetric anal sphincter injuries (OASIS): does the grade of tear matter?. *Ultrasound in obstetrics & gynecology*. 2010 Sep 1;36(3):368-74.
39. Gurol-Urganci I, Cromwell DA, Edozien LC, Mahmood TA, Adams EJ, Richmond DH, Templeton A, Meulen JH. Third-and fourth-degree perineal tears among primiparous women in England between 2000 and 2012: time trends and risk factors. *BJOG: An International Journal of Obstetrics & Gynaecology*. 2013 Nov 1;120(12):1516-25.
40. Jandér C, Lyrenäs S. Third and fourth degree perineal tears. *Acta obstetricia et gynecologica Scandinavica*. 2001 Mar 1;80(3):229-34.
41. Gottvall K, Allebeck P, Ekeus C. Risk factors for anal sphincter tears: the importance of maternal position at birth. *BJOG: An International Journal of Obstetrics & Gynaecology*. 2007 Oct 1;114(10):1266-72.
42. Gupta N, Usha Kiran T, Mulik V, Bethel J, Bhal K. The incidence, risk factors and obstetric outcome in primigravid women sustaining anal sphincter tears. *Acta obstetricia et gynecologica Scandinavica*. 2003 Aug 1;82(8):736-43.
43. Williams A. Third-degree perineal tears: risk factors and outcome after primary repair. *Journal of Obstetrics and Gynaecology*. 2003 Nov 1;23(6):611-4.

44. de Leeuw JW, Struijk PC, Vierhout ME, Wallenburg HC. Risk factors for third degree perineal ruptures during delivery. *British Journal of Obstetrics and Gynaecology*. 2001 Apr 30;108(4):383-7.
45. Eskandar O, Shet D. Risk factors for 3rd and 4th degree perineal tear. *Journal of Obstetrics and Gynaecology*. 2009 Jan 1;29(2):119-22.
46. LaCross A, Groff M, Smaldone A. Obstetric Anal Sphincter Injury and Anal Incontinence Following Vaginal Birth: A Systematic Review and Meta-Analysis. *Journal of Midwifery & Women's Health*. 2015 Jan 1;60(1):37-47.
47. Palm A, Israelsson L, Bolin M, Danielsson I. Symptoms after obstetric sphincter injuries have little effect on quality of life. *Acta obstetrica et gynecologica Scandinavica*. 2013 Jan 1;92(1):109-15.
48. Norderval S, Nsubuga D, Bjelke C, Frasurek J, Myklebust I, Vonen B. Anal incontinence after obstetric sphincter tears: incidence in a Norwegian county. *Acta obstetrica et gynecologica Scandinavica*. 2004 Oct 1;83(10):989-94.
49. Zetterström J, López A, Anzén B, Norman M, Holmström B, Mellgren A. Anal sphincter tears at vaginal delivery: risk factors and clinical outcome of primary repair-A prospective study in women with sphincter rupture and controls. *Obstetrics & Gynecology*. 1999;1(94):21-8.
50. FitzGerald MP, Weber AM, Howden N, Cundiff GW, Brown MB, Pelvic Floor Disorders Network. Risk factors for anal sphincter tear

during vaginal delivery. *Obstetrics & Gynecology*. 2007 Jan 1;109(1):29-34.

51. De Leeuw JW, Vierhout ME, Struijk PC, Hop WC, Wallenburg HC.

Anal sphincter damage after vaginal delivery: functional outcome and risk factors for fecal incontinence. *Acta Obstet Gynecol Scand* 2001;80:830–4.

52. .Sultan AH, Kettle C. Diagnosis of Perineal Trauma. In: Sultan AH,

Thakar R, Fenner DE, editors. *Perineal and anal sphincter trauma*.

London: Springer; 2007. p. 13–9.

53. Sultan AH, Thakar R. Lower genital tract and anal sphincter trauma.

Best Pract Res Clin Obstet Gynaecol 2002;16:99–115.

54. Williams A, Adams EJ, Tincello DG, Alfirevic Z, Walkinshaw SA,

Richmond DH. How to repair an anal sphincter injury after vaginal delivery: results of a randomised controlled trial. *BJOG* 2006;113:201–7.

55. De Leeuw JW, Vierhout ME, Struijk PC, Hop WC, Wallenburg HC.

Anal sphincter damage after vaginal delivery: functional outcome and risk factors for fecal incontinence. *Acta Obstet Gynecol Scand* 2001;80:830–4.

56. Mahony R, Behan M, Daly L, Kirwan C, O’Herlihy C, O’Connell PR.

Internal anal sphincter defect influences continence outcome following

- obstetric anal sphincter injury. *Am J Obstet Gynecol* 2007;196:217.e1–5.
57. Visscher AP, Lam TJ, Hart N, Felt-Bersma RJ. Fecal incontinence, sexual complaints, and anorectal function after third-degree obstetric anal sphincter injury (OASI): 5-year follow-up. *Int Urogynecol J* 2014;25:607–13.
58. Sultan AH, Monga AK, Kumar D, Stanton SL. Primary repair of obstetric anal sphincter rupture using the overlap technique. *Br J Obstet Gynaecol* 1999;106:318–23.
59. Fernando RJ, Sultan AH, Kettle C, Thakar R. Methods of repair for obstetric anal sphincter injury. *Cochrane Database Syst Rev* 2013;(12):CD002866
60. Buppasiri P, Lumbiganon P, Thinkhamrop J, Thinkhamrop B. Antibiotic prophylaxis for third- and fourth-degree perineal tear during vaginal birth. *Cochrane Database Syst Rev* 2010;(11):CD005125.
61. Stedenfeldt M, Pirhonen J, Blix E, Wilsgaard T, Vonen B, Øian P. Episiotomy characteristics and risks for obstetric anal sphincter injuries: a case-control study. *BJOG* 2012;119:724–30.
62. National Institute for Health and Clinical Excellence. Intrapartum care: Care of healthy women and their babies during childbirth. NICE clinical guideline 55. Manchester: NICE; 2007.

63. Kalis V, Landsmanova J, Bednarova B, Karbanova J, Laine K, Rokyta Z. Evaluation of the incision angle of mediolateral episiotomy at 60 degrees. *Int J Gynaecol Obstet* 2011;112:220–4.
64. Jönsson ER, Elfaghi I, Rydhström H, Herbst A. Modified Ritgen’s maneuver for anal sphincter injury at delivery: a randomized controlled trial. *Obstet Gynecol* 2008;112:212–7.
65. Mahony R, Behan M, O’Herlihy C, O’Connell PR. Randomized, clinical trial of bowel confinement vs. laxative use after primary repair of a third-degree obstetric anal sphincter tear. *Dis Colon Rectum* 2004;47:12–7.
66. Eogan M, Daly L, Behan M, O’Connell PR, O’Herlihy C. Randomised clinical trial of a laxative alone versus a laxative and a bulking agent after primary repair of obstetric anal sphincter injury. *BJOG* 2007;114:736–40.
67. Peirce C, Murphy C, Fitzpatrick M, Cassidy M, Daly L, O’Connell PR, et al. Randomised controlled trial comparing early home biofeedback physiotherapy with pelvic floor exercises for the treatment of third-degree tears (EBAPT Trial). *BJOG* 2013;120:1240–7.
68. Royal College of Obstetricians and Gynaecologists. A third- or fourth-degree tear during birth: Information for you. London: RCOG; 2015.

69. Fowler G, Williams A, Murphy G, Taylor K, Wood C, Adams E. How to set up a perineal clinic. *The Obstetrician & Gynaecologist* 2009;11:129–32.
70. Scheer I, Thakar R, Sultan AH. Mode of delivery after previous obstetric anal sphincter injuries (OASIS)—a reappraisal? *Int Urogynecol J Pelvic Floor Dysfunct* 2009;20:1095–101.
71. Poen AC, Felt-Bersma RJ, Strijers RL, Dekker GA, Cuesta MA, Meuwissen SG. Third-degree obstetric perineal tear: long-term clinical and functional results after primary repair. *Br J Surg* 1998;85:1433–8.
72. Goffeng AR, Andersch B, Andersson M, Berndtsson I, Hulten L, Öresland T. Objective methods cannot predict anal incontinence after primary repair of extensive anal tears. *Acta Obstet Gynecol Scand* 1998;77:439–43.
73. Bek KM, Laurberg S. Risks of anal incontinence from subsequent vaginal delivery after a complete obstetric anal sphincter tear. *Br J Obstet Gynaecol* 1992;99:724–6.
74. Fynes M, Donnelly VS, O’Connell PR, O’Herlihy C. Cesarean delivery and anal sphincter injury. *Obstet Gynecol* 1998;92:496–500.

ANNEXURES

ANNEXURE :A

STUDY PROFORMA

Name:

Age:

IP NO:

Date of admission:

Date of delivery:

Date of discharge:

Address:

Phone number:

Menstrual history:

L.M.P:

E.D.D:

Gestational age:

Obstetrics history:

Gravida	Para	Abortion	Live
---------	------	----------	------

Antepartum comorbidity:

Intra partum:

Spontaneous labour/ induced labour?

Duration of 1st stage of labour:

Duration of 2nd stage of labour:

Episiotomy given? 1) Yes 2) No

If yes, which type?

Mode of delivery:

1) Normal delivery

2) forceps delivery

Position of baby at crowning:

Baby detail: date/time:

Sex:

Birth weight:

Height:

Apgar score:

Type of perineal tear:

Method of Repair of perineal tear:

Questionnaires regarding symptoms to patient:

At postpartum day 1

- 1) Did you have involuntary leakage of intestinal gas before pregnancy? If
yes, then frequency?

- 2) Did you have involuntary leakage of stool before pregnancy? If yes,
then frequency?

At 1 month postpartum

- 1) Do you have involuntary leakage of intestinal gas? If yes, frequency?

- 2) Do you have involuntary leakage of stool? if yes, frequency?

At 3 month postpartum

- 1) Do you have involuntary leakage of intestinal gas? If yes, frequency?

- 2) Do you have involuntary leakage of stool? if yes, frequency?

ANNEXURE :B - PATIENT CONSENT FORM

Name of the participant :

Name of the principal investigator : Dr. Anil kumar G.V

Name of the institution : KMC Hospital ,KilpaukChennai

Name and address of the funding

Agency

Documentation of the informed consent

I.....have read the information in this form(or it has been read to me).I was free to ask any questions and they have been answered. I am over 18 years of age and exercising my free power of choice, hereby give my consent to be included as participant in “**OBSTETRIC ANAL SPHINCTER INJURIES (OASIS) – A PROSPECTIVE OBSERVATIONAL LONGITUDINAL STUDY**” in KMC hospital, Chennai.

1. I have read and understood this consent form and information provided to me.
2. I have had consent document explained to me.
3. I have been explained about the nature of study.
4. My rights and responsibilities have been explained to me by investigator.
5. I have been advised about the risk associated with my participation in the study.

6. I have informed the investigator of all the treatments I am taking or have taken in the past 6 months including any alternative treatments.
7. I agree to cooperate with the investigator and inform him/her immediately if I suffer unusual symptoms.
8. I have not participated in any research study within the past 6 months.
9. I have not donated any blood in past 6 months.
10. I am aware of the fact that I can opt out of the study at any time without having to give any reason and this will not affect my future treatment in the hospital.
11. I am also aware that the investigators may terminate my participation in the study at any time, for any reason, without my consent.
12. I hereby give permission to the investigators to realize the information obtained from me as result of participation in this study to the sponsors, regulatory authorities, government agencies and ethics committee. I understand that they may inspect my original records.
13. My identity will be kept confidential if my data are publicly presented.
14. If, despite following the instructions, I am physically harmed because of any substance or any site the sponsor will bear all the expenses, if they are not covered by my insurance agency or by a Government program or any third party.
15. I have had my questions answered to my satisfaction.
16. I have decided to be in the research study.

Participant's Initials: _____

I am aware, that if I have any questions during this study, I should contact investigator. By signing this consent form, I attest that the information given in this document and the HIV consent form has been clearly explained to me and apparently understood by me. I will be given a copy of this consent document.

Signature :

Name :

(Impartial witness)

.....

Address & Contact Number: Sign/Thumb Impression of impartial
witness

.....

.....

(Name of the Participant) Date:

Place :

Dr. ANIL KUMAR G.V

(Investigator)

Date:

Place:

Investigator certificate:

I certify that all the elements including the nature, purpose and possible risk of the above study as described in the consent documents have been fully explained to the subject. In my judgment, the participant possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.

Sign

Dr.ANIL KUMAR G.V

சுயஒப்புதல் படிவம்

ஆய்வுசெய்யப்படும் தலைப்பு : மகப்பேறியில் குதசுறுக்குதசை
காயங்கள் பற்றிய ஆராய்ச்சி.

இடம் : மகப்பேறியில் மருத்துவத்துவ துறை ,
அரசு கீழ்பாக்கம் மருத்துவ கல்லூரி

மருத்துவமனை , சென்னை

பங்குபெறுபவரின் பெயர் :

பங்குபெறுபவரின் வயது : பங்குபெறுபவரின் எண் :

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு
விளக்கப்பட்டது . நான் இவ்வாய்வில் தன்னிச்சையாக பங்கேற்கிறேன் .
எந்த காரணத்தினாலோ எந்த சட்டசிக்கலுக்கும் உட்படாமல் நான்
இவ்வாய்வில் இருந்து விலகிக்கொள்ளல்லாம் என்றும் அறிந்து
கொண்டேன் .

இந்த ஆய்வு சம்பந்தமாகவோ , இதை சார்ந்து மேலும் ஆய்வு
மேற்கொள்ளும்போதும் இந்த ஆய்வில்பங்கு பெறும் மருத்துவர்
என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என் அனுமதி
தேவையில்லை என அறிந்து கொள்கிறேன் . இந்த ஆய்வின் மூலம்
கிடைக்கும் தகவலையோ , முடிவையோ பயன்படுத்திக்கொள்ள மறுக்க
மாட்டேன் .

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன் . இந்த
ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன்
என்றும் உறுதியளிக்கிறேன் .

பங்கேற்பவரின் கையொப்பம்

ஆய்வாளரின் கையொப்பம்

இடம் :

தேதி :

INSTITUTIONAL ETHICAL COMMITTEE
GOVT.KILPAUK MEDICAL COLLEGE,

CHENNAI-10

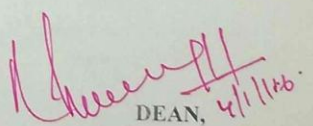
Protocol ID. No. 08/2015 Dt: 02.11.2015

CERTIFICATE OF APPROVAL

The Institutional Ethical Committee of Govt. Kilpauk Medical College, Chennai reviewed and discussed the application for approval "Incidence, risk factors of obstetric anal sphincter injuries during vaginal delivery and symptomatic outcome of primary repair in Tertiary care Hospital". - For Project Work submitted by Dr. Anil Kumar.G.V 2nd Year M.S. Post Graduate in Obstetrics and Gynaecology, Govt. Kilpauk Medical College, Chennai.

The Proposal is APPROVED.

The Institutional Ethical Committee expects to be informed about the progress of the study any Adverse Drug Reaction Occurring in the Course of the study any change in the protocol and patient information /informed consent and asks to be provided a copy of the final report.


DEAN, 4/1/11/10
Govt.Kilpauk Medical College,
Chennai - 10.

Turnitin Document Viewer - Google Chrome

https://www.turnitin.com/dv?is=1800=708040724&u=1055596316&student_user=1&lang=en_us&...
The Tamil Nadu Dr.M.G.R.Medical ... 2015-2015 plagiarism - DUE 07-Nov-201...

turnitin 21% SIMILAR OUT OF 0

OASIS BY ANIL KUMAR

Match Overview

Rank	Source	Similarity
1	onlinelibrary.wiley.com Internet source	2%
2	lib.bionio.pl Internet source	2%
3	Panis, Y., J. D. Zeitoun... Publication	2%
4	www.greenjournal.org Internet source	1%
5	teintitli.globalgold.co.uk Internet source	1%
6	www.slideshare.net Internet source	1%
7	Mary P. Fitzgerald. "RL..." Publication	1%
8	www.epostersonline.com Internet source	1%

Originality GradeMark PeerMark

OBSTETRIC ANAL SPHINCTER INJURIES (OASIS)-
A PROSPECTIVE OBSERVATIONAL LONGITUDINAL
STUDY

Disertation submitted to

THE TAMILNADU Dr.M.G.R MEDICAL
UNIVERSITY

In partial fulfillment of the requirement
for the award of

M.S.DEGREE - OBSTETRICS & GYNAECOLOGY
BRANCH - II

THE TAMILNADU Dr.M.G.R MEDICAL UNIVERSITY

Page 1 of 79

Print Only Report

NAME	AGE	PER TEA R	GR A VID A	G A	B.W T	OCCIPIT O POSTERI OR POSITIO N	DURATI ON OF 1 ST STAGE	SECO ND STAGE	FORCE PS	SHOULD ER DYSTOCI A	OUTCOME (ANAL INCONTINE NCE)
MANJULA	24	2.0	1	2	1	1	4	4	2	2	1
AARTHI	31	1.0	2	1	1	2	2	1	1	2	1
INDIRANI	26	1.0	1	1	1	2	3	4	1	2	1
AMULYA	26	2.0	2	2	1	2	3	6	2	2	1
JANSI	26	1.0	1	1	1	1	3	5	1	2	1
DEVANAYA GI	28	1.0	1	1	1	2	4	4	2	2	1
PADMA	27	4.0	1	1	2	2	5	3	1	2	1
NILOFER	24	2.0	1	1	2	2	5	4	1	1	1
SUSEELA	28	1.0	1	2	2	2	4	4	1	2	1
SIVAMMA	25	4.0	1	2	2	2	5	5	2	2	1
ROOPA	29	1.0	1	2	1	1	6	4	2	2	1
AISHWARY A	28	1.0	1	1	2	2	5	4	1	2	1
PREMA	32	1.0	2	1	1	1	4	6	1	2	1
PUSHPA	28	1.0	1	2	1	2	5	5	1	2	1
SHAILA	29	1.0	1	2	2	1	6	4	2	1	1
RATHNA	30	1.0	1	1	1	2	4	6	1	2	1
GEETHA	30	1.0	1	2	2	2	3	4	2	2	1

SORNA	27	1.0	1	1	1	2	4	3	1	2	1
SUMANGA LA	29	1.0	1	2	2	2	3	4	1	2	1
KAYAKAM MA	34	1.0	1	1	1	2	5	4	1	2	1
THENMOZ HI	28	1.0	1	1	1	2	4	4	1	2	1
RAJINI	26	2.0	1	1	2	2	4	5	1	1	1
VANITHA	31	3.0	1	2	2	1	6	6	2	2	2
SUNITHA	25	1.0	1	2	1	2	6	4	1	2	1
SHILPA	27	1.0	1	1	1	2	4	4	1	2	1
GOWRI	30	1.0	2	2	2	2	3	6	1	2	1
ZONILA	29	1.0	1	2	2	2	5	4	1	2	1
EVANZI	35	1.0	1	1	1	2	4	5	1	2	1
FATHIMA	27	1.0	1	2	1	2	4	5	1	2	1
SUJATHA	23	1.0	1	2	2	1	3	4	1	2	1
MALARVIZ HI	26	1.0	1	1	1	2	3	5	1	1	1
INDRANI	29	2.0	1	2	2	2	3	5	1	2	1
SUSHEELA	23	1.0	1	2	1	2	4	6	1	2	1
AVALI	26	1.0	1	1	2	2	3	5	1	2	1
SUSAN	28	1.0	2	1	1	2	3	4	1	2	1
LALITHA	31	3.0	1	1	2	1	4	6	2	1	2

TAMILSELV I	25	1.0	1	2	2	2	5	5	1	2	1
PRIYA	29	1.0	1	1	2	2	3	5	1	2	1
MAHALAKS HMI	24	1.0	1	1	1	1	5	5	1	2	1
LATHA	26	2.0	1	1	1	1	4	5	1	2	1

MASTER CHART CODING

TYPE OF PERINEAL TEAR	GRAVIDA	GA (WKS)	B.W T (KG)	OCCIPITOPOSTERIOR POSITION	DURATION OF FIRST STAGE OF LABOUR (HRS)	SECOND STAGE (MINUTES)	FORCEPS	SHOULDER DYSTOCIA	OUTCOME (ANAL INCONTINENCE)
1-3A	1-PRIMI	1-<40	1-<3.5	1-YES	1-<5	1-<30	1-normal vaginal delivery	1-YES	1-NO
2-3B	2-MULTI	2->40	2->3.5	2-NO	2-5 TO 7	2-30 TO 40	2-forceps delivery	2-NO	2-GAS
C-3C					3-7 TO 9	3-45 TO 59			3-LIQUID
4-4					4-9 TO 11	4-60 TO 74			4-SOLID
					5-11 TO 13	5-75 TO 89			
					6-13 TO 15	6->90			
					7->15				